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Overview of the food chain system and the European regulatory framework in the fields of food safety and nutrition

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Table of Contents

List of Tables	8
List of Figures	9
Abstract	12
1. Introduction.....	13
The food chain and the associated food safety and nutrition legislation.....	13
Methodology	14
2. Food chain overarching legislation	16
2.1. Background information	16
2.1.1. Treaty of the Functioning of the European Union	16
2.1.2. White Paper on food safety	16
2.2. General food law	18
2.2.1. Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety	18
2.3. Official controls	21
2.3.1. Regulation (EC) No 882/2004 on official controls performed to ensure compliance with feed and food law, animal health and animal welfare rules.....	21
3. Legislation related to the inputs to food chain system	26
3.1. Fertilisers	26
3.1.1. Synthetic fertilisers – Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers	26
3.1.2. Organic fertilisers – Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption.....	28
3.2. Pesticides and plant protection products.....	31
3.2.1. Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 91/414/EEC and 79/117/EEC	31
3.2.2. Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides..	33
3.2.3. Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin	34
3.3. Radioactive contamination of food and feed	38
3.3.1. Council Regulation (Euratom) 3954/87 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency	38
3.3.2. Council Regulation (Euratom) 944/89 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency	38

3.3.3.	Council Regulation (EURATOM) 770/90 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency	38
4.	Legislation related to primary production	40
4.1.	Genetically modified organisms	40
4.1.1.	Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms	40
4.1.2.	Regulation (EC) No 1829/2003 on genetically modified food and feed 43	
4.1.3.	Regulation (EC) No 1830/2003 on the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC	44
4.1.4.	Cartagena Protocol on Biosafety	45
4.2.	Veterinary drug residues	48
4.2.1.	Directive 2001/82/EC on the Community code relating to veterinary medicinal products	48
4.2.2.	Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (repealing Regulation (EEC) No 2377/90)	50
4.2.3.	Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.....	52
4.2.4.	Council Directive 96/22/EC concerning the prohibition on the use in stock-farming of certain active substances having a hormonal or thyrostatic action and of beta-agonists.....	55
5.	Legislation related to the harvesting / slaughtering / fishing step of the food chain	58
5.1.	Legislation on the hygiene of foodstuffs	58
5.1.1.	Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs	58
5.1.2.	Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin.....	60
5.1.3.	Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption	62
5.2.	Animal health rules for the production, processing, distribution and introduction of products of animal origin for human consumption	65
5.2.1.	Council Directive 2002/99/EC – products of animal origin	65
5.3.	Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs	66
5.4.	Regulation (EC) No 2160/2003 on the control of Salmonella and other specified food-borne zoonotic agents	69
5.5.	Directive 2003/99/EC of the European Parliament and of the Council on the monitoring of zoonoses and zoonotic agents	71
6.	Legislation related to the manufacturing step of the food chain	74
6.1.	Food improvement agents	74

6.1.1.	Regulation (EC) No 1331/2008 on a common authorisation procedure for food additives, enzymes and flavourings.....	74
6.1.2.	Regulation (EC) No 1333/2008 on food additives.....	74
6.1.3.	Regulation (EC) No 1332/2008 on food enzymes.....	76
6.1.4.	Regulation (EC) No 1334/2008 on food flavourings.....	76
6.1.5.	Regulation (EC) No 2065/2003 on smoke flavourings.....	79
6.1.6.	Directive 2009/32/EC on extraction solvents used in the production of foods and food ingredients.....	80
6.2.	Contaminants.....	82
6.2.1.	Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food.....	82
6.2.2.	Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs.....	83
6.3.	Food and food ingredients treated with ionising radiation.....	86
6.3.1.	Directive 1999/2/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation	86
6.4.	Novel foods and novel food ingredients.....	88
6.4.1.	Regulation (EC) No 258/97 concerning novel foods and novel food ingredients.....	88
7.	Legislation related to the packaging step of the food chain.....	90
7.1.	Packaging materials and materials in contact with food.....	90
7.1.1.	Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.....	90
7.1.2.	Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.....	91
8.	Legislation related to placing foods on the market.....	94
8.1.	Food Information to Consumers.....	94
8.1.1.	Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs.....	94
8.1.2.	The New Framework Regulation: Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers.....	95
8.1.3.	Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs.....	98
8.2.	Nutrition and Health Claims.....	99
8.2.1.	Regulation (EC) No 1924/2006 on nutrition and health claims made on food.....	99
8.3.	Food for specific groups (FSG).....	101
8.3.1.	Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses ...	101

8.4.	Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control	103
8.5.	Further relevant nutrition policies.....	105
8.5.1.	EU Platform on Diet, Physical Activity and Health.....	105
8.5.2.	White Paper on "A strategy for Europe on Nutrition, Overweight and Obesity Related Health Issues".....	105
8.5.3.	High Level Group on Nutrition and Physical Activity.....	107
8.5.4.	School Fruit and Milk Schemes	107
8.5.5.	3 rd EU health programme (2014-2020).....	108
8.5.6.	EU Action Plan on Childhood Obesity	109
8.5.7.	Dietary Reference Values (DRVs).....	109
9.	Implementation of EU legislation in the Member States	111
9.1.	Responsibilities	111
9.2.	Competent authorities and official food control.....	112
9.3.	International and EU level organisations.....	113
10.	Other food policies.....	114
10.1.	Global food safety and nutrition governance	114
10.2.	EU food safety information exchange networks and early warning systems ⁹⁹	118
10.3.	Better Training for Safer Food.....	119
10.4.	Resource efficiency and food waste	120
10.5.	EU agricultural quality product policy – Single CMO and Green Paper... 121	
10.5.1.	Single CMO and Green Paper.....	121
10.5.2.	EU agricultural quality product policy – Quality scheme	121
10.5.3.	EU agricultural quality product policy – Organic farming and products 122	
10.5.4.	EU agricultural quality product policy – Food Quality Certification schemes	123
10.6.	Common Agricultural Policy (CAP)	124
10.7.	Common Fisheries Policy (CFP)	127
10.8.	Audio-visual Media Services.....	128
10.9.	Transatlantic Trade and Investment Partnership (TTIP).....	129
Annex I:	Additional implementing measures for selected Articles of Regulation 178/2002 and their respective requirements	131
Annex II:	Additional implementing measures for selected Articles of Regulation 882/2004 and their respective requirements	137
Annex III:	Additional implementing measures for selected Articles of Regulation 2003/2003 and their respective requirements	145
Annex IV:	Additional implementing measures for selected Articles of Regulation 1069/2009 and their respective requirements	147
Annex V:	Additional implementing measures for selected Articles of Regulation 1107/2009 and their respective requirements	149
Annex VI:	Additional implementing measures for selected Articles of Regulation 396/2005 and their respective requirements	153

Annex VII: Additional implementing measures for selected Articles of Regulation 3954/87 and their respective requirements.....	155
Annex VIII: Additional implementing measures for selected Articles of Directive 2001/18/EC and their respective requirements.....	156
Annex IX: Additional implementing measures for selected Articles of Regulation 1829/2003 and their respective requirements	163
Annex X: Additional implementing measures for selected Articles of Regulation 1830/2003 and their respective requirements	170
Annex XI: Additional implementing measures for selected Articles of Directive 2001/82/EC and their respective requirements.....	171
Annex XII: Additional implementing measures for selected Articles of Regulation 470/2009 and their respective requirements	176
Annex XIII: Additional implementing measures for selected Articles of Directive 96/23/EC and their respective requirements	178
Annex XIV: Additional implementing measures for selected Articles of Directive 96/22/EC and their respective requirements	183
Annex XV: Additional implementing measures for selected Articles of Regulation 852/2004 and their respective requirements.....	185
Annex XVI: Additional implementing measures for selected Articles of Regulation 853/2004 and their respective requirements.....	189
Annex XVII: Additional implementing measures for selected Articles of Regulation 854/2004 and their respective requirements.....	197
Annex XVIII: Legislation implemented under Directive 2002/99/EC and in particular Articles 8 and 9 on lists of approved third countries, special import conditions and certification documents	201
Annex XIX: Additional implementing measures for selected Articles of Regulation 2073/2005 and their respective requirements	203
Annex XX: Additional implementing measures for selected Articles of Regulation 2160/2003 and their respective requirements	205
Annex XXI: Additional implementing measures for selected Articles of Directive 2003/99/EC and their respective requirements.....	208
Annex XXII: Additional implementing measures for selected Articles of Regulation 1333/2008 and their respective requirements	211
Annex XXIII: Additional implementing measures for selected Articles of Regulation 1332/2008 and their respective requirements	214
Annex XXIV: Additional implementing measures for selected Articles of Regulation 1334/2008 and their respective requirements	216
Annex XXV: Additional implementing measures for selected Articles of Regulation 2065/2003 and their respective requirements	218
Annex XXVI: Additional implementing measures for selected Articles of Regulations 315/93 and 1881/2006 and their respective requirements.....	219
Part I: Regulation 315/93.....	219
Part II: Regulation 1881/2006	219
Annex XXVII: Additional implementing measures for selected Articles of Directive 1999/2/EC and their respective requirements	222

Annex XXVIII: Additional implementing measures for selected Articles of Regulation (EC) No 258/97 and their respective requirements.....	223
Annex XXIX: Additional implementing measures for selected Articles of Regulation 1935/2004 and their respective requirements	224
Annex XXX: Additional implementing measures for selected Articles of Directive 82/711/EEC and their respective requirements.....	229
Annex XXXI: Additional implementing measures for selected Articles of Directive 2000/13/EC and their respective requirements.....	230
Annex XXXII: Additional implementing measures for selected Articles of Regulation (EU) No 1169/2011 and their respective requirements	240
Annex XXXIII: Additional implementing measures for selected Articles of Directive 90/496/EEC and their respective requirements.....	242
Annex XXXIV: Additional implementing measures for selected Articles of Regulation (EC) No 1924/2006 and their respective requirements	244
Annex XXXV: Additional legislation related to selected Articles of Directive 2009/39/EC and respective requirements	246

List of Tables

Table 1: Implementing Regulations and Implementing Decisions establishing emergency measures for the import of products from third countries under Article 53 of Reg (EC) No 178/2002	134
Table 2: examples of Commission Decisions implementing provisions for protection measures or for emergency vaccination against certain diseases in the different Member States.....	175

List of Figures

Figure 1: Overview of the food chain with the major food safety and nutrition legislation fields	15
Figure 2: Main provisions of the general food law (Regulation (EC) No 178/2002)	19
Figure 3: Overview of certain provisions of the general food law (Reg. (EC) No 178/2002) and cross-links with additional implementing documents	20
Figure 4: Summary of the provisions of Regulation (EC) No 882/2004 on official controls for verification of compliance with food and feed law, animal health and animal welfare.	22
Figure 5: Summary of the most important legal documents in the field of official controls for verification of compliance with food and feed law, animal health and animal welfare.	25
Figure 6: Main requirements of Regulation (EC) No 2003/2003	27
Figure 7: Legislative acts in the field of fertilisers	28
Figure 8: Main requirements of Regulation (EC) No 1069/2009	29
Figure 9: Legislative acts in the field of organic fertilisers	30
Figure 10: Summary of the main requirements of Regulation (EC) No 1107/2009	32
Figure 11: Summary of the main provisions of Directive 2009/128/EC	34
Figure 12: Summary of the main provisions of Regulation (EC) No 396/2005.....	36
Figure 13: Summary of the legal acts related to the placement of plant protection products on the market and the establishment of maximum residue levels of pesticides in food	37
Figure 14: Summary of legislation in the field of radioactive contamination of food and feed	39
Figure 15: Main requirements of Directive 2001/18/EC	42
Figure 16: Main requirements of Regulation (EC) No 1829/2003	44
Figure 17: Main requirements of Regulation (EC) No 1830/2003	45
Figure 18: Main legal documents in the field of GMOs, their deliberate release, traceability and labelling in food and feed.....	47
Figure 19: Main provisions of Directive 2001/82/EC.....	50
Figure 20: Main provisions of Regulation (EC) No 470/2009.....	52
Figure 21: Main provisions of Directive 96/23/EC	54
Figure 22: Main provisions of Directive 96/22/EC	56
Figure 23: Summary of legislation on veterinary medicinal products, their residues and prohibition of use of certain substances in stock farming	57
Figure 24: Main legislation related to the hygiene of foodstuffs	58
Figure 25: Summary of the requirements of Regulation 852/2004 on the hygiene of foodstuffs.....	59
Figure 26: Summary of the requirements of Regulation (EC) No 853/2004 on the hygiene of food of animal origin	61
Figure 27: Summary of the requirements of Regulation (EC) No 854/2004 on the official controls for products of animal origin.....	63
Figure 28: Summary of the legal documents in the field of food hygiene with additional implementation legislation and their relationships	64
Figure 29: Summary of the provisions of Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs	68
Figure 30: Summary of the provisions of Regulation (EC) No 2160/2003 on the control of Salmonella and other food-borne zoonotic agents	70

Figure 31: Summary of the requirements of Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents.....	72
Figure 32: Summary of the most important legal documents in the field of microbiological criteria for foodstuffs, control of food-borne zoonotic agents and of monitoring of zoonoses, zoonotic agents and antimicrobial resistance and cross-links between this documents	73
Figure 33: Summary of the requirements of Regulation (EC) No 1333/2008 on food additives	75
Figure 34: Summary of the provisions of Regulation (EC) No 1332/2008 on food enzymes	76
Figure 35: Summary of the provisions of Regulation (EC) No 1334/2008 on flavourings and food ingredients with flavouring properties	78
Figure 36: Summary of the provisions of Regulation (EC) No 2065/2003 on smoke flavourings used or intended to be used in or on food	79
Figure 37: Summary of the provisions of Directive 2009/32/EC on extraction solvents for the production of food and food ingredients.....	80
Figure 38: Summary of the most important legal documents in the field of food additives, food enzymes and food flavourings	81
Figure 39: Summary of the requirements of Regulation (EEC) No 315/93 on Community procedures for contaminants in food	82
Figure 40: Summary of the requirements of Regulation 1881/2006 on maximum levels for certain contaminants in foodstuffs	84
Figure 41: Summary of the most important legal documents in the field of contaminants in foodstuffs.	85
Figure 42: Summary of legislative acts in the field of treatment of food and food ingredients with ionising radiation	87
Figure 43: Summary of the legislation on novel foods and cross interaction with other legal acts. Red arrows correspond to legislation referring and /or adding to the main novel foods legislation. Blue arrows correspond to legislation referred in the Novel Foods legislation	89
Figure 44: Main provisions of Regulation (EC) No 1935/2004.....	91
Figure 45: Main provisions of Directive 82/711/EEC.....	92
Figure 46: Summary of the legal documents in the field of materials and articles intended to come into contact with food.....	93
Figure 47: Summary of the legislation on labelling, presentation and advertising of foodstuffs and cross interaction with other legal acts.	95
Figure 48 (a and b): Summary of the legislation on Food Information to Consumers (FIC) and cross interaction with other legal acts. Red arrows correspond to legislation referring and /or adding to the FIC legislation. Blue arrows correspond to legislation referred in the FIC legislation.	97
Figure 49: Summary of the legislation on Nutrition and health claims and cross interaction with other legal acts. Red arrows correspond to legislation referring and /or adding to the Nutrition and Health Claims legislation. Blue arrows correspond to legislation referred in the Nutrition and Health Claims legislation.....	100
Figure 50: Summary of the legislation on Food for Specific Groups (FSG) and cross interaction with other legal acts. Red arrows correspond to legislation referring and /or adding to the FSG legislation. Blue arrows correspond to legislation referred in the FSG legislation.	104
Figure 51: An overview of actors at global, EU and national level	111
Figure 52: An overview of actors at global, EU and national level	112

Abbreviations

ALARA: as low as reasonably achievable

AMR: antimicrobial resistance

BSE: Bovine Spongiform Encephalopathy

CEC: Commission of the European Communities

Dec.: Decision

EAFRD: European Agricultural Fund for Rural Development

EAGGF: European Agricultural Guidance and Guarantee Fund

EC: European Commission

EMA: European Medicines Agency

FIC: Food Information to Consumers

FSG: Food for Specific Groups

FVO: Food and Veterinary Office

GAP: Good Agricultural Practice

GM: Genetically Modified

GPPP: Good Plant Protection Practice

HACCP: Hazard Analysis and Critical Control Points

MRL: Maximum Residue Level

M.S.: Member States

MSM: mechanically separated meat

RASSF: Rapid Alert System for Food and Feed

Reg.: Regulation

SCFCAH: Standing Committee on Food Chain and Animal Health

UHT: Ultra High Temperature

UK: United Kingdom

Abstract

To ensure the highest standards of food safety in the European Union and avoid barriers to internal trade, harmonised food legislation is implemented across all steps of the food and feed chain. However, recent crises have revealed certain vulnerabilities that can compromise these high food safety standards. At the same time, public health measures must address malnutrition to protect the health and wellbeing of EU citizens from chronic diseases such as diabetes, cardiovascular disease or cancer. To preserve the functioning of the food system towards the production of safe and nutritious food for healthy populations also in the future, policy must be able to respond to unforeseen disruptive developments. This may only be achieved through preparedness and through proactive rather than reactive policy-making initiatives.

The aim of this report is to provide an overview of the current food safety and nutrition regulatory and policy framework in Europe up to 2014, identifying all the documents that are necessary for the implementation of food legislation. The legal acts are presented in this report following the flow of raw materials and food products through a model of the food chain. The main legal text(s) in each step of this chain were identified and briefly summarised. All legislation that is directly related to these main texts and provides additional implementation information was also identified and linked to the main texts in legislation maps. A detailed description of these legal acts in each field is included in the Annexes to the report.

1. Introduction

The food chain and the associated food safety and nutrition legislation

The food system is complex and broad. The food chain itself is often defined as "from farm to table" or "from farm to fork", yet it encompasses much more than that. The food system is a dynamic system constantly influenced and shaped by several factors such as the environment and the climate, the global political and socio-economic situation, the scientific and technological developments and the consumer who shapes it through his demands and preferences. The consumer is highly influenced by the food system, food supply and food access. Food and dietary choices in turn are the basis of human nutrition, a key element in individual and population health.

Food is essential to life and a prime channel for health. Hence, ensuring the highest standards of food safety is a key policy priority in the European Union (EU) as indicated in the White Paper on food safety¹. This is based on an integrated and comprehensive approach and achieved through the implementation of food legislation across all the steps of the food and feed chain. Indeed, the European approach to food safety covers all sectors: primary production, food processing, packaging, storage, transport and placing on the market. This legislation is harmonised in the European Union in order to not pose barriers to internal trade within the Community. Despite the regulatory framework already in place in Europe, recent crises have brought to the surface vulnerabilities that can compromise these high standards of food safety. Transparency at all levels of food safety policy and the interactions of different stakeholders is identified as a fundamental principle for ensuring the highest level of food safety and for enhancing consumer confidence. Food safety and the development of food policies are also strongly related to environmental policies. Also, new technological developments at different steps in the food chain may require new policy responses².

The provision of safe food, however, is not sufficient to ensure that food consumption is conducive of good health. Indeed, Europe arguably has one of the safest food chains in the world but it struggles with one of the highest mortality rates caused by chronic diseases such as diabetes, cardiovascular disease or cancer. These are intimately linked to poor nutrition and physical activity habits. Malnutrition is unfortunately a reality on our continent and public health measures must address this as well – not only to protect health and wellbeing of our citizens but also because the financial pressure of such diseases on our healthcare systems is unsustainable.

The food and drink sector (including agriculture) is also of great importance to the European economy. It employs approximately 1/5 of the European workforce and the EU is the biggest exporter and importer of food and drink worldwide.

In order to be able to preserve the functioning of the food system towards the production of safe and quality food for healthy populations within a flourishing economy, policy must be able to respond to any developments, either slow and gradual or urgent and fast-changing. This may only be achieved through preparedness and through proactive rather than reactive policy-making initiatives.

The aim of this report is to provide an overview of the current food safety and nutrition regulatory and policy framework in Europe in 2014. The report is set around a model of the food chain as described in Figure 1 (modified from³). The food chain is considered here for simplification purposes as a sequence of steps starting from raw materials,

¹ White paper on food safety COM(1999) 719 final

² Eurostat, 2011. Food: from farm to fork statistics (Pocketbook)

³ Commission SWD (2013) 516 final, 'A fitness check of the food chain: State of play and next steps

moving onto the manufacturing stage and ending with the placement of finished food products on the market and their consumption. This food chain can apply to all different food categories, however simple or complex. Figure 1 also captures the major food safety and nutrition legislation areas depicted along the food chain and placed immediately prior to the step where they are perceived of more direct relevance.

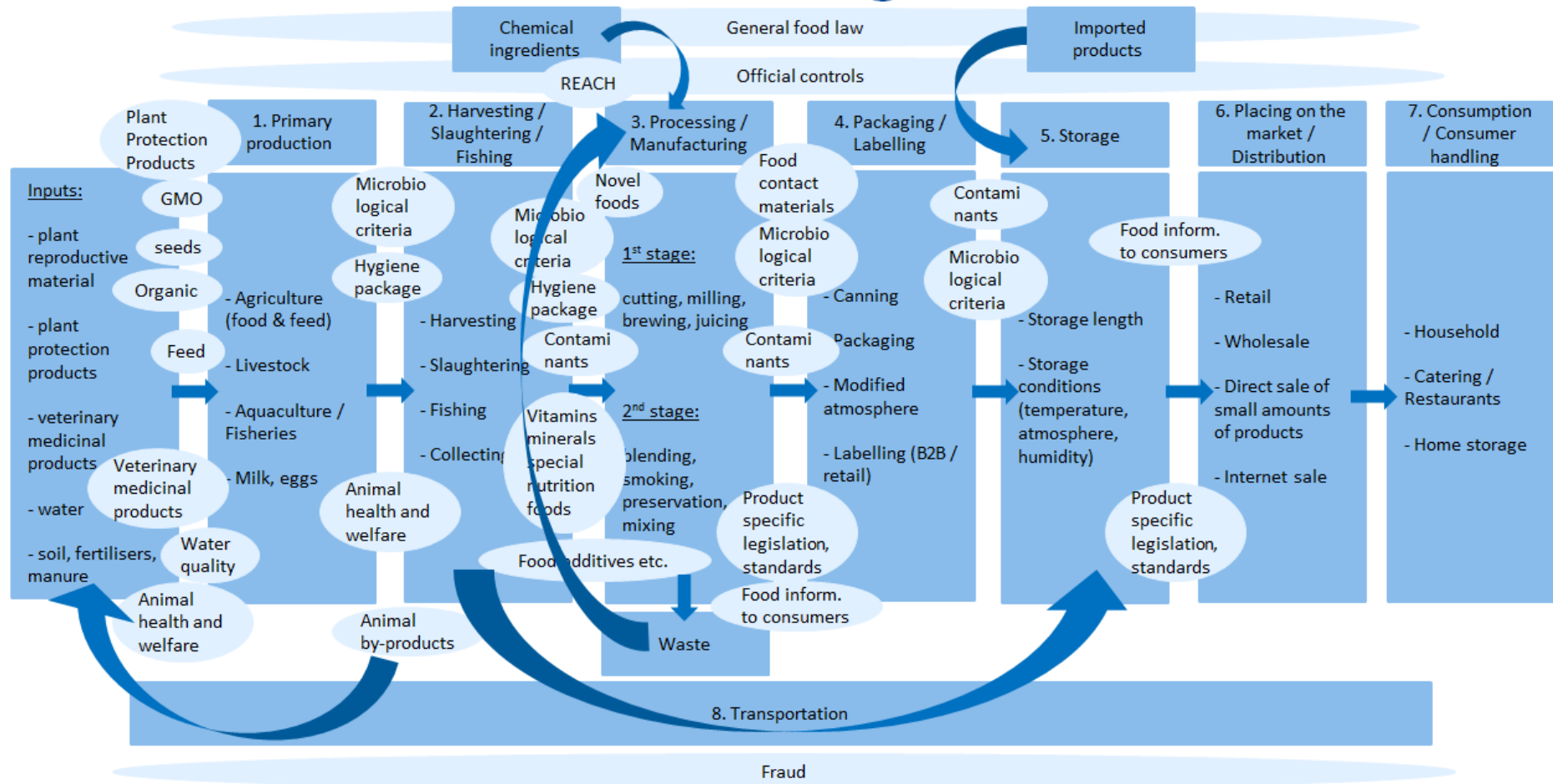
The order by which the legal acts are referred to in this report also follows the flow of raw materials and food products through the food chain as represented in Figure 1. The legislative framework is preceded by background information on the development and aim of food legislation in Europe and by a description of the general food law and the legislation on official controls, as these apply to all steps of the food chain. For legislation applicable to more than one steps in the food chain, this is described in the step where it is considered more relevant. The report also presents some additional food-related policies and some brief information on the implementation of food legislation in the EU Member States.

Methodology

Even though the main legislative texts can be easily identified through different websites, for the complete implementation of food legislation across the food chain it is necessary to identify all related legislative texts that add information to the main document. The methodology followed is as follows: The main legal text(s) in each field were identified and briefly summarised. The most recent consolidated form that includes all amendments to the main text was used for this purpose. In instances, a repealed legislation document is being described because the one replacing it is so recent that the surrounding legislation has not been updated to reflect the transposition. In many cases, summary maps outlining the content of this main legal text were also prepared. Subsequently the EUR-LEX⁴ website was screened for all legislation that was directly related to these main texts. The documents identified were linked to the main texts to which they provide additional information by preparing legislation maps. Due to the complexity of the results, only the legislation maps are presented in the main report and for readers that need further detail in specific regulatory areas, the detailed description of all related legislation in each field is included in the Annexes to the report. Also any links between different legislative texts were identified and presented, as appropriate, in the above maps. The overall aim of this work was to identify the majority of documents relevant to each area of legislation that are necessary for its implementation.

⁴ <http://eur-lex.europa.eu/homepage.html>

The food chain and legislation overview



Modified from: Commission SWD (2013) 516 final 'A fitness check of the food chain: State of play and next steps'

Figure 1: Overview of the food chain with the major food safety and nutrition legislation fields

2. Food chain overarching legislation

2.1. Background information

2.1.1. Treaty of the Functioning of the European Union

The Treaty of the Functioning of the European Union organises the functioning of the Union and determines the areas and arrangements for the Union to exercise its competences and the limitations.

Article 43 of the Treaty of the Functioning of the European Union (or ex Article 37 of the Treaty of the European Communities) refers to the implementation of a common agricultural policy and a common fisheries policy.

Article 114 of the Treaty (or ex Article 95) refers to the approximation of laws of the Member States concerning health, safety and environmental and consumer protection. A high level of protection is sought taking into account new developments based on scientific facts.

Article 168 (or ex Article 152) refers to public health. The Treaty provides for a high level of human health protection in the implementation of all Union policies and activities. The European Parliament and the Council can adopt, in the interest of safety, veterinary and phytosanitary measures.

Article 191 refers to the precautionary principle. It aims at ensuring a high level of environmental protection through preventative decision-taking in the case of risk. However, in practice, the scope of this principle is far wider and also covers EU legislation concerning food, animal and plant health.

Article 207 (or ex Article 133) refers to the common commercial policy based on uniform principles.

2.1.2. White Paper on food safety

In the last decades significant technological developments have been observed in primary food production methods, food processing and novel technologies. At the same time the world's population is increasing and so is the importance of the food industry in both feeding this population but also in the economical context. Food safety is of primary importance and the increasing consumer awareness and their preferences also implement additional criteria. To ensure the highest level of food safety, food legislation must be up to date in all the above aspects. The legislative system in Europe was reviewed in the Commission Green Paper on the "General principles of food law in the European Union" and the need for improvement was expressed.

The White Paper on food safety reflects the key policy priority of ensuring the highest standards of food safety in Europe. In order to ensure these standards of food safety and health protection and also in order to restore and maintain consumer confidence, an independent European independent Food Authority (EFSA) was established, entrusted with the following tasks:

- to provide independent scientific advice relating to food safety,
- to operate the rapid alert systems,

- to communicate food safety and health issues to the consumers,
- to network with national authorities and scientific organisations,
- and to provide scientific analysis to the Commission.

In the White Paper it is emphasised that food safety is a shared responsibility between different stakeholders in the food chain but similarly in the feed chain as well. The primary responsibility lies with food operators and food manufacturers. The authorities are responsible for monitoring and enforcing food safety through the national control systems, while the Commission is responsible for evaluating the performance of the different competent authorities. However, even consumers are responsible for food safety, from the moment they purchase food, through to its storage, handling and cooking until consumption.

Traceability is another important aspect highlighted in the White Paper towards ensuring food safety. Procedures must allow the traceability of raw materials and ingredients to their source as well as the withdrawal of products from the market in case of a food safety risk.

Food policy must be based on the foundations of Risk Analysis and its three components, risk assessment, risk management and risk communication. By using the highest quality of scientific advice in the analysis of information for risk assessment and by employing the precautionary principle in risk management, but also through independence, excellence and transparency, the Food Authority can build consumer confidence. Important information for the purposes of risk analysis can be gathered from controls, surveillance, laboratory analytical results and epidemiological studies and must be provided in a timely and reliable manner to allow for decision making. Continuous monitoring and management of this information will allow the early identification of potential hazards and therefore allow the Commission to pro-actively respond and act in preventing crisis.

Last but not least, the White Paper makes reference to other factors that should be considered in decision making to ensure consumer health protection. These include animal welfare, sustainability, product quality, consumer expectations and consumer information with regards to product characteristics and their production methods.

It is clarified that even though a European Food Safety Authority shall be established, the Commission, the Parliament and the Council shall still be the bodies responsible for the drafting and making of legislation.

2.2. General food law

2.2.1. Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Regulation (EC) No 178/2002⁵ establishes that food legislation must be based on risk analysis. Risk management must be based on the advice provided by independent, objective and transparent risk assessment also taking into account the precautionary principle. Consumer protection is established as the main aim of food legislation. Food law must be subject to open consultation and consumers must be informed of risks. It also establishes the obligations of the food business operators with regards to food safety requirements and traceability and the actions that should be taken in case a risk is identified.

Regulation (EC) No 178/2002 establishes EFSA and its aims and obligations. It provides the details on how the Authority should be organised, on the preparation of its opinions and also on procedures to be followed in case different bodies have different opinions. The Regulation specifies that the Authority is responsible for identifying emerging risks and indicating how these should be communicated to the European Parliament, the Commission and the Member States. The Regulation also established the Rapid Alert System for Food and Feed (RASFF) and tasked EFSA with monitoring the system in order to provide the Commission and the Member States with information for the purposes of risk analysis. Procedures are specified for emergency measures as well as for crisis management and for the setting-up of a crisis unit when an emergency health risk is identified in the food chain. The principles of independence, transparency, confidentiality and communication in the functions of the Authority are highlighted.

In order to assist in the interpretation and implementation of Regulation 178/2002, the Commission has encouraged discussions with all interested parties and held a meeting in 2004. The Standing Committee on the Food Chain and Animal Health approved the conclusions of this meeting, which were made available to the public through a guidance document that was published and reviewed again in 2010⁶. Guidance is provided on the following topics: food safety requirements, responsibilities of the different stakeholders in the food/ chains, traceability, withdrawal from the market, product recalls and notifications as well as on import and export requirements.

Figure 2 provides a graphical representation of the main provisions of Regulation (EC) No 178/2002. However for the complete implementation of the requirements of the general food law the above text is not sufficient. Additional requirements are laid down by implementing Regulations or other legal instruments that must be followed in combination with the above main text. This can be better illustrated by the following graph, while details on the specific requirements introduced by the different Articles of Regulation (EC) No 178/2002 which are fulfilled by the connected documents can be found in Annex I.

Figure 3 provides a graphic representation of certain of the provisions of Regulation (EC) No 178/2002 and the legislative acts that add information for the implementation of their requirements.

⁵ Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (2002). Official Journal of the European Union (OJ) L 31

⁶ Conclusions of the Standing Committee on the Food Chain and Animal Health, 2010. Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on general food law

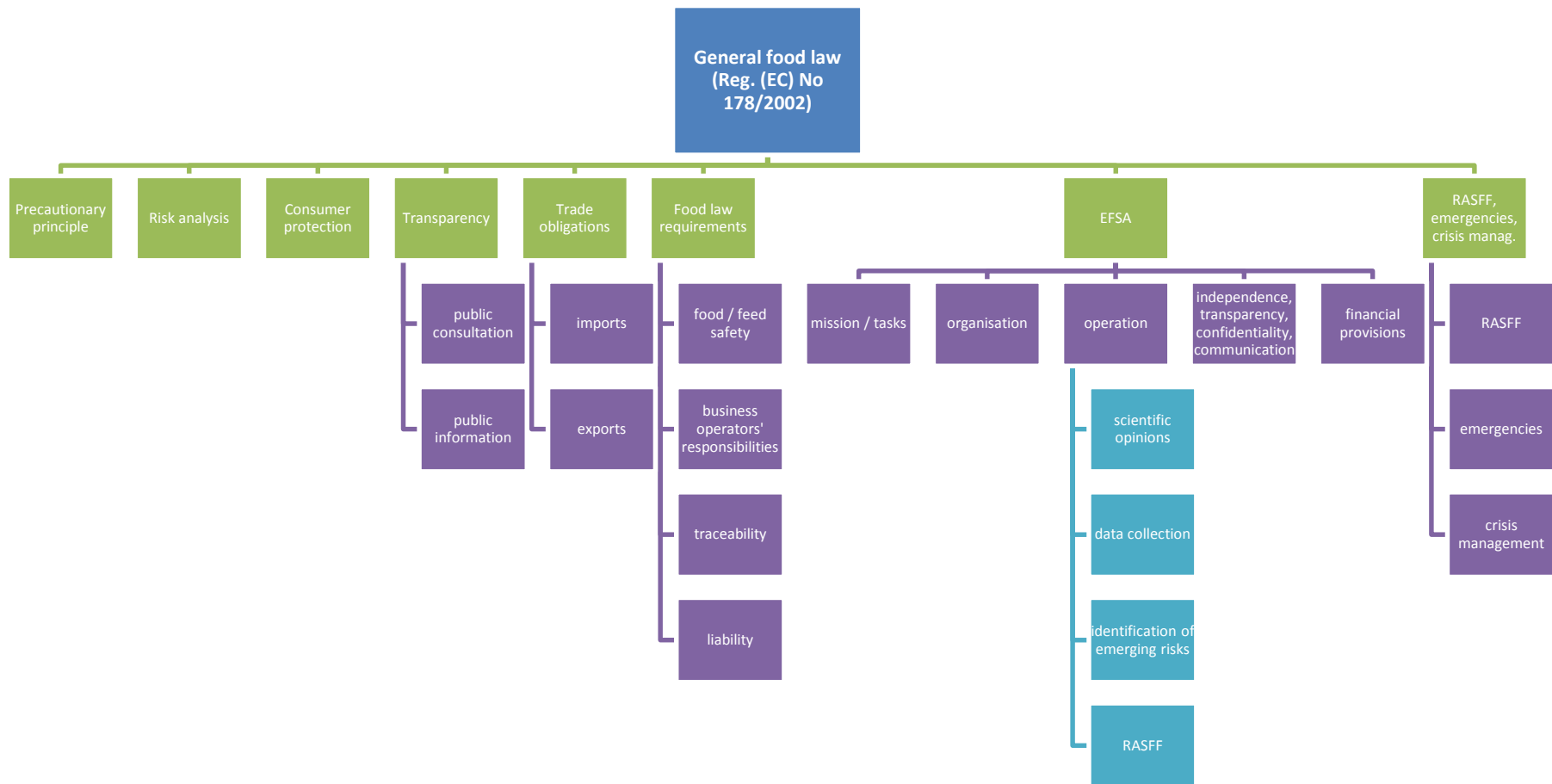


Figure 2: Main provisions of the general food law (Regulation (EC) No 178/2002)

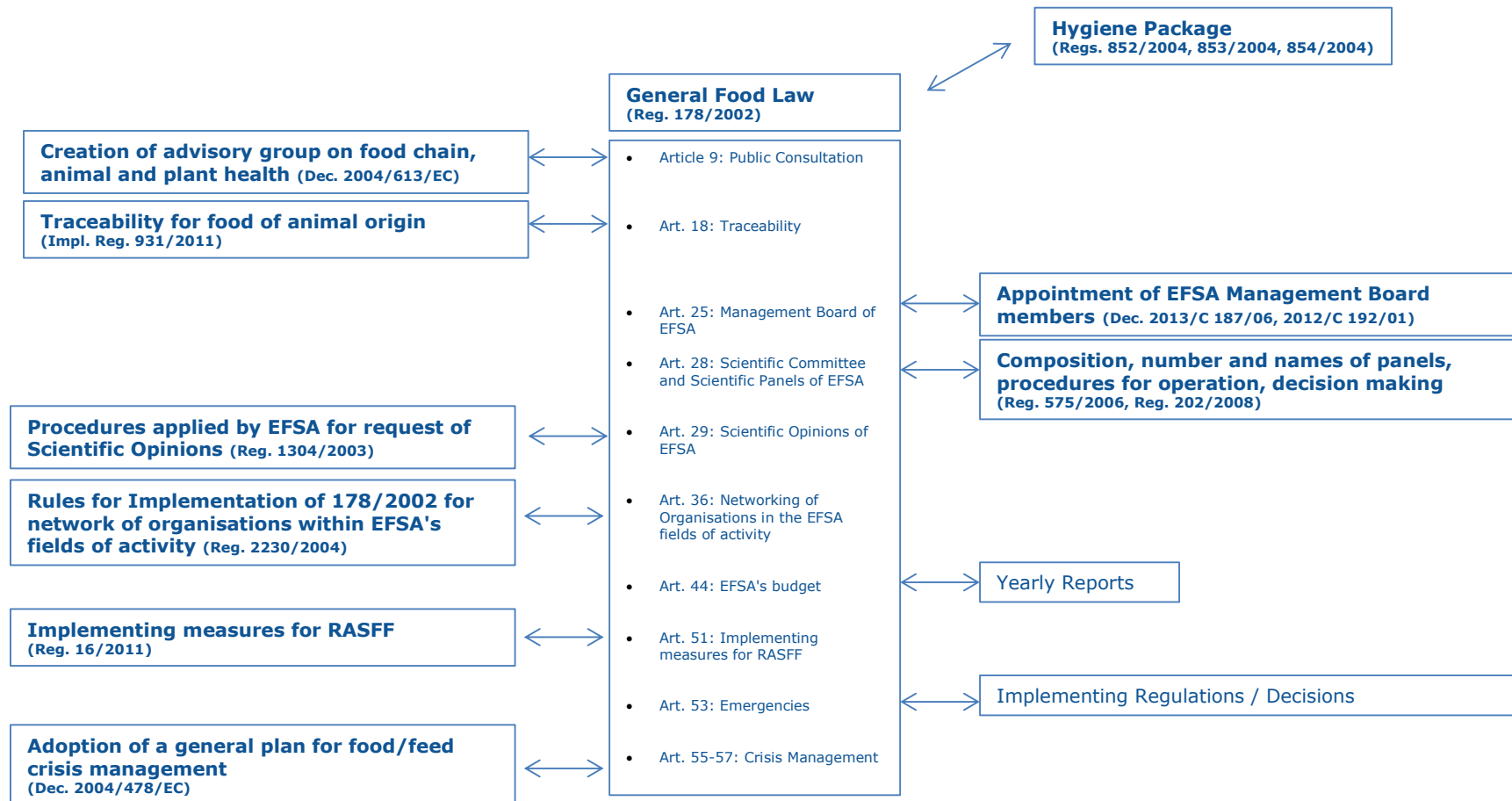


Figure 3: Overview of certain provisions of the general food law (Reg. (EC) No 178/2002) and cross-links with additional implementing documents

2.3. Official controls

2.3.1. Regulation (EC) No 882/2004 on official controls performed to ensure compliance with feed and food law, animal health and animal welfare rules

Regulation (EC) No 882/2004⁷ lays down general rules for the performance of official controls in order to verify compliance with EU legislation aiming at different aspects of food and feed safety and ensure consumer protection.

Figure 4 provides a graphical representation of the main content and requirements of Regulation (EC) No 882/2004 while details on the implementation of specific requirements introduced by the different Articles of the Regulation can be found in Annex II.

This Regulation emphasises the legal responsibility of the food business operator to ensure food safety. It lays down the general obligations of the Member States with regard to official controls, their basis and their frequency. Generally official controls must be carried out without prior warning unless an audit is required, or on an ad hoc basis and they should also cover products intended for export, not only for Community use. Regulation (EC) No 882/2004 lays down provisions for the designation of competent authorities in the different Member States, their duties and operational criteria but also some principles to be followed to ensure efficiency and effectiveness. The Regulation provides for "control bodies" delegated to carry out specific tasks and establishes conditions for the fulfilment of their role. Control bodies must be accredited and must conform to requirements established by standards. If they fail in fulfilling their role, they may be withdrawn from delegation. Certain provisions are laid down with regard to the role of staff performing official controls and specific mention is made to the principles of transparency and confidentiality and to the fact that information should be publicly available as established by Regulation (EC) No 178/2002.

Official controls must be carried out according to specified procedures which must be documented in order to ensure their effectiveness and that corrective action is taken. Commission guidelines must be established in particular with regard to the implementation of Hazard Analysis Critical and Control Points (HACCP) and the operation of management systems in order to ensure microbiological, physical and chemical safety of food and feed.

The competent authorities of the Member States must compile reports on the results of the official controls which must include their purpose, methods applied, results obtained and action that may need to be taken by the food business operator. Official controls must be carried out using appropriate methodology and including specific tasks detailed within the Regulation. Details are provided with regard to the methods for sampling and analysis that must follow internationally recognised protocols or methods developed in accordance with such protocols while the Regulation also provides specific criteria that such methods must fulfil. Also it allows the food business operator under official control to apply for a supplementary expert opinion and lays down relevant procedures. The analysis of samples taken for official controls must be carried out in official laboratories which must be accredited to specific internationally accepted standards.

Regulation (EC) No 882/2004 requires Member States to draw up operational contingency plans for crisis management and specifies their set up and responsibilities.

⁷ Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure compliance with feed and food law, animal health and animal welfare rules. OJ L 165

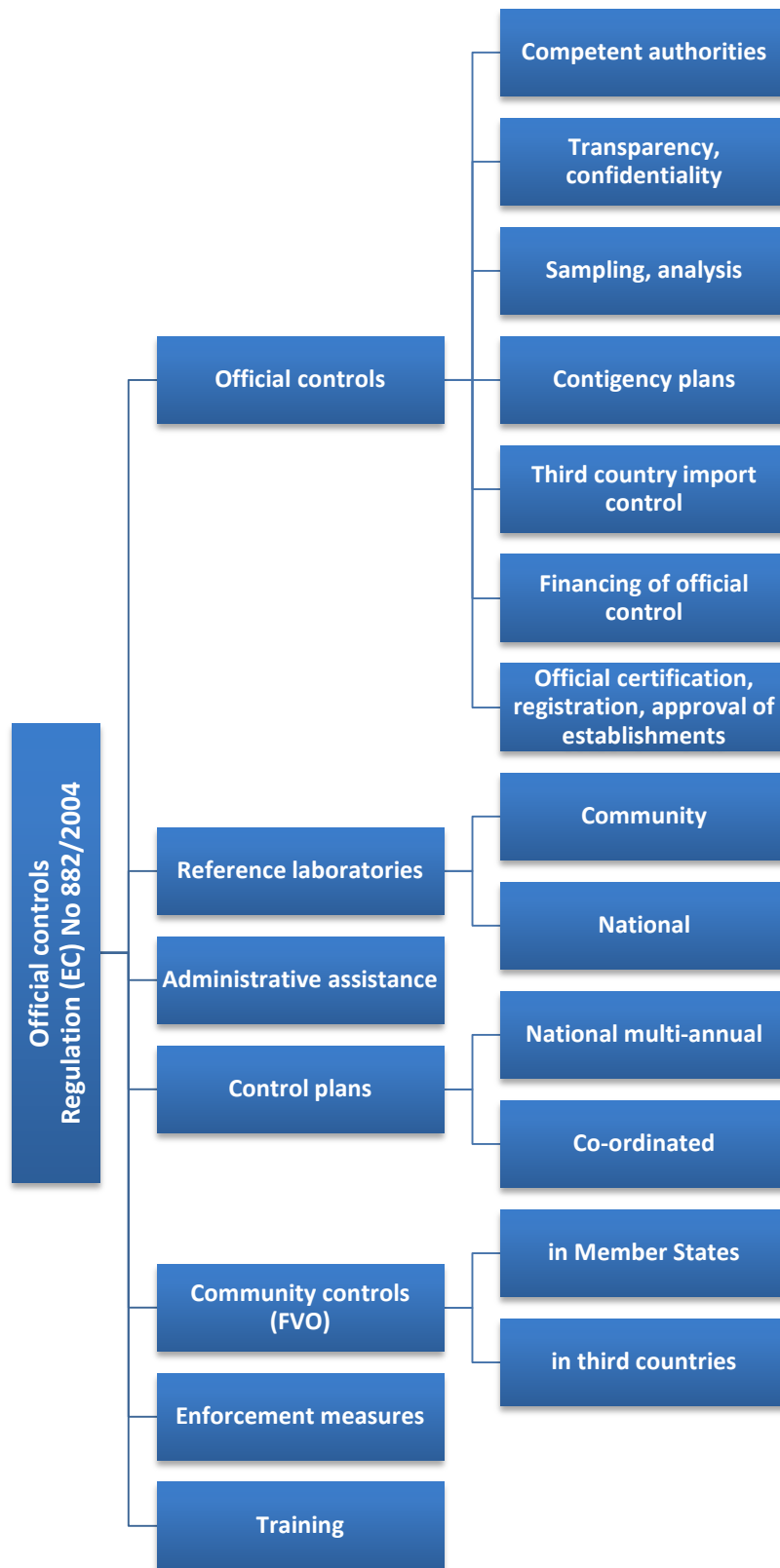


Figure 4: Summary of the provisions of Regulation (EC) No 882/2004 on official controls for verification of compliance with food and feed law, animal health and animal welfare.

For carrying out controls on products of non-animal origin imported from third countries, Regulation (EC) No 882/2004 provides detailed rules related to the checks that need to be performed and the follow-up action. Costs associated with re-dispatching non-compliant products or their special treatment is the responsibility of the food business operator. Details are also provided for pre-export checks of food that may be carried out in certain countries. If a significant non-compliance is detected, the RASFF procedures of Regulation (EC) No 178/2002 must immediately be followed.

The importance of cooperation between competent authorities and customs for the purposes of Regulation (EC) No 882/2004 is emphasised. The Regulation lays down provisions for the financing of official controls in the Member States and for the establishment of relevant specific fees. It also highlights the responsibility of food business operators to cover for additional expenses in case of non-compliance.

Regulation (EC) No 882/2004 indicates that the competent authorities must establish procedures for the registration or approval of establishments in accordance with Regulation (EC) No 852/2004 and also indicates when the withdrawal of such approvals must be initiated.

Provisions are laid down with regards to the Community Reference Laboratories, the requirements they must fulfil and their financing. Also one or more national reference laboratories in each Member State must be designated for each Community reference laboratory and for their role provisions are included.

Member States are required to provide administrative assistance to the Commission in relation to the outcomes of official controls and the relevant procedures are provided. Also the Regulation requires the establishment of "liaison bodies" and indicates their role in assisting and coordinating the communication between authorities with regards to requests for assistance. Further details are laid down for providing assistance under different circumstances, in relation to third countries or on request for coordinated assistance in special cases.

Regulation (EC) No 882/2004 also lays down requirements for the implementation of multi-annual control plans in the different Member States and the principles and the content of such plans as well as the need for Commission guidelines for their preparation. The Regulation also requires that one year after the implementation of the multi-annual national control plans Member States must submit a report to the Commission on their progress and effectiveness and specific instructions are provided for the reparation of the report and timelines for its delivery. The Commission must also compile an annual report on the overall operation of official controls in the Member States, including recommendations on possible improvements, specific actions or the requirement for coordinated plans for issues of particular interest.

Regulation (EC) No 882/2004 also lays down requirements for Community controls and specific audits and inspections in the Member States, but also for Community controls in third countries, their aims, frequency and determination of risks.

Specific requirements are also provided on the information required for imports from third countries, additional conditions not covered by the hygiene Regulation (EC) No 853/2004 and on the establishment of lists of third countries from where products may be imported and the conditions for granting the status of equivalence of third countries' controls to the Commission ones. Finally, measures are implemented for providing assistance to developing countries in order to meet the requirements of the Regulation.

Regulation (EC) No 882/2004 lays down provisions for the training of staff performing official controls in the competent authorities of the Member States. Also provisions are established for the performance of other Community activities such as coordinated control plans.

Procedures are established for enforcement measures on national level in case of non-compliance and for relevant sanctions. In case of serious non-conformances, emergency measure must be taken according to the provisions of Article 53 of Regulation (EC) No 178/2002.

Finally, Regulation (EC) No 882/2004 requires the Commission to submit a report to the Parliament and the Council on the experience gained from its application, specifically focusing on whether need exists for the review of specific provisions also taking into consideration the implementation of the hygiene package Regulations.

Figure 5 provides a graphic representation of the main content of Regulation (EC) No 882/2004 and the legislative acts that add information for the implementation of its requirements.

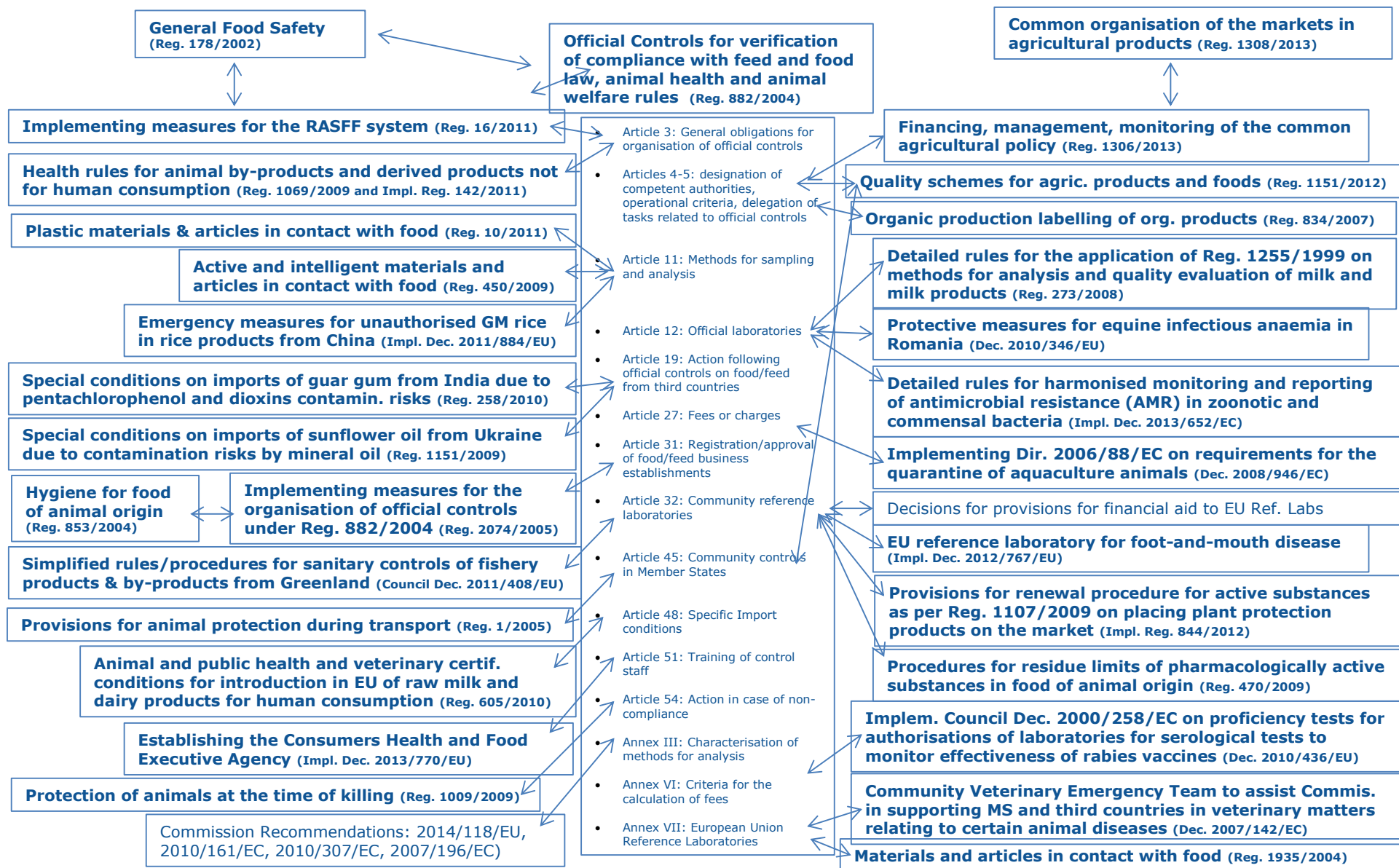


Figure 5: Summary of the most important legal documents in the field of official controls for verification of compliance with food and feed law, animal health and animal welfare.

3. Legislation related to the inputs to food chain system

3.1. Fertilisers

3.1.1. Synthetic fertilisers – Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers

Regulation (EC) No 2003/2003⁸ applies to products placed on the Community market as fertilisers. Any fertiliser belonging to the types of products listed in Annex I of the Regulation and meeting its requirements may be designated "EC fertiliser". Manufacturers of "EC fertilisers" must be established within the Community. Products bearing this designation may circulate freely in the EU market.

The Regulation lays down requirements and formats for indicating the nitrogen, phosphorous and potassium content of the fertilisers as well as the calcium, magnesium, sodium and sulphur content of primary and secondary nutrient fertilisers. Details are also provided on the declaration of the content of micro-nutrients depending on their quantities and on whether there are water-soluble or chemically linked with other organic molecules. EC fertilisers must bear an identification marking which must appear on the packaging or label for pre-packed products or on the accompanying documents for bulk products. Details are also provided on the compulsory and optional information that must appear on the label/packaging or accompanying documents which must also be indelible and clearly legible. Compulsory and optional information must be clearly separated between them and from any other information appearing on the label. For fluid fertilisers, instructions on storage temperature and accident prevention must also be provided. If the packaging contains a seal, this must bear the name and mark of the packager. Information must appear in at least the official languages of the Member States where the product is marketed. The packaging of EC fertilisers must be such that once they are opened their seal is irreversibly damaged.

The manufacturer must maintain records of the origin of the fertilisers in order to ensure traceability. The Regulation also lays down tolerances for the nutrient content of EC fertilisers which allow for deviations in manufacture, sampling and analysis; these however do not apply to the minimum and maximum contents of Annex I to the Regulation. The Regulation allows for safeguard measures and the procedure to be followed.

Regulation (EC) No 2003/2003 also lays down provisions for specific types of fertilisers such as inorganic primary nutrient fertilisers, inorganic secondary nutrient fertilisers, inorganic micro-nutrient fertilisers and ammonium nitrate fertilisers of high nitrogen content.

EC fertilisers must be subject to official controls to ensure compliance with the requirements of Regulation (EC) No 2003/2003, according to the methods of sampling and analysis provided in Annexes III and IV to the Regulation. The Regulation also requires the establishment of lists of Member States' laboratories that meet certain standards laid down in Annex V to the Regulation and may assist in checking the compliance of EC fertilisers to its requirements. New types of fertilisers may be added to Annex I of Regulation (EC) No 2003/2003 if required, provided the manufacturer provides the relevant technical information required. Finally Member States must establish penalties for infringements of the provisions of the Regulation.

⁸ Regulation (EC) No 2003/2003 of the European Parliament and of the Council relating to fertilisers (2003). OJ L 304/1

Figure 6 provides a graphical representation of the main content and requirements of Regulation (EC) No 2003/2003. More details on legislation adding information for the implementation of this Regulation can be found in Annex III. Also Figure 7 below summarises the legislative acts in the field of fertilisers.

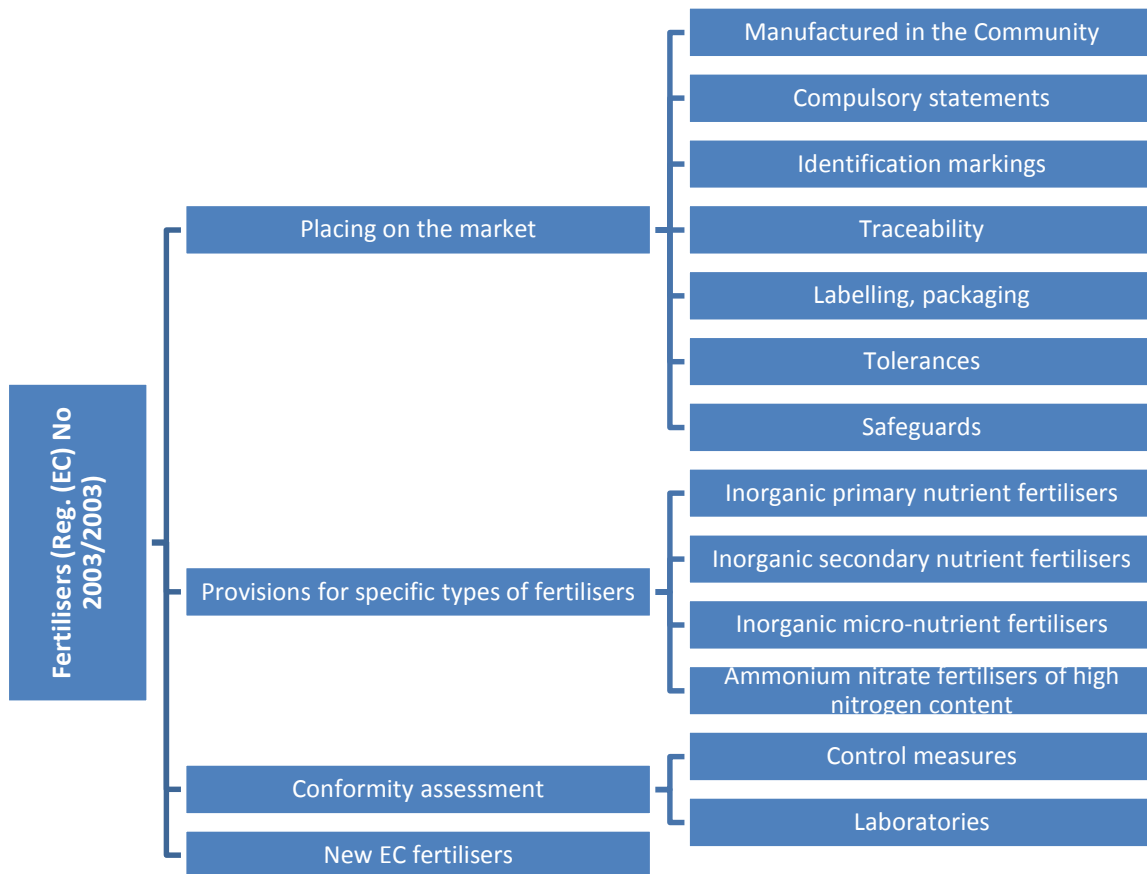


Figure 6: Main requirements of Regulation (EC) No 2003/2003

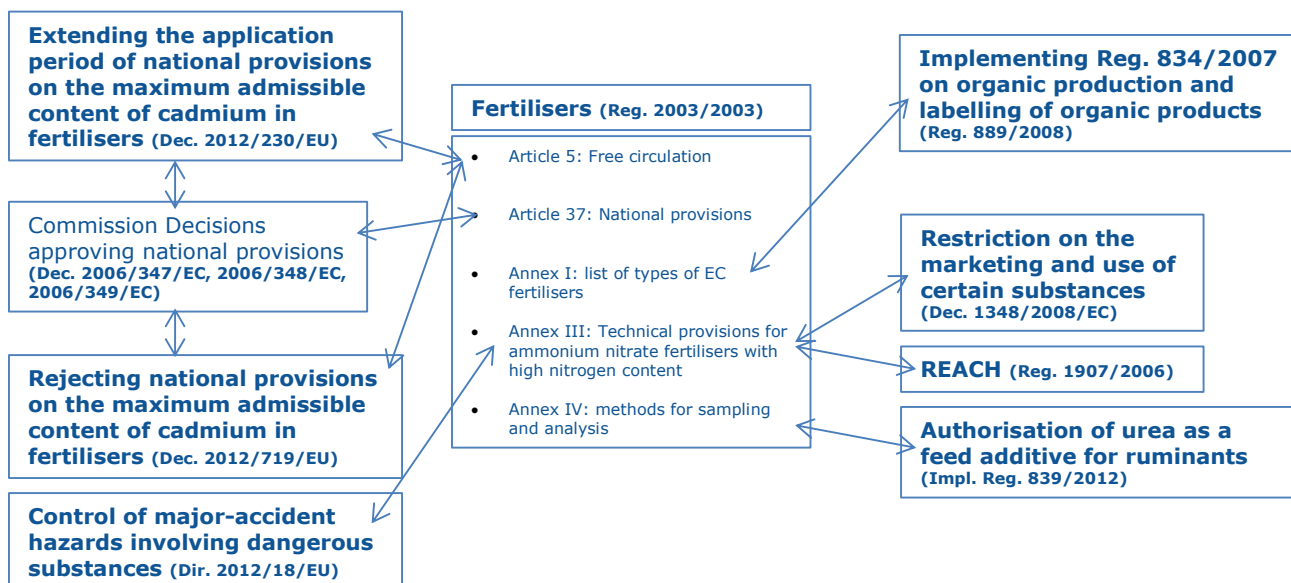


Figure 7: Legislative acts in the field of fertilisers

3.1.2. Organic fertilisers – Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption⁹

Regulation (EC) No 1069/2009 lays down rules for animal by-products and derived products with the aim to minimise the risk to public and animal health and reduce the safety risks to the food and feed chains. Amongst the other provisions of the Regulation, certain provisions refer to the use of animal by-products as organic fertilisers. Certain restrictions are laid down with regard to the feeding of animals on herbage from land where organic fertilisers and soil improvers have been applied and certain waiting periods are implemented. Category 2 material can be used for the manufacture of organic fertilisers and soil improvers following specified treatments while category 3 material may also be used under specific conditions. Establishments and plants where organic fertilisers and soil improvers are produced or derived products intended to be used for the above purposes are stored must be authorised by the competent authorities. The Regulation also lays down certain provisions for the placing on the market and use of organic fertilisers and soil improvers. Member States may still adopt relevant national provisions on the use of such products if there are concerns for the protection of public and animal health.

Figure 8 provides a graphical representation of the main content and requirements of Regulation (EC) No 1069/2009. More details on legislation adding information for the implementation of this Regulation can be found Annex IV.

⁹ Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (2009) OJ L 300/1

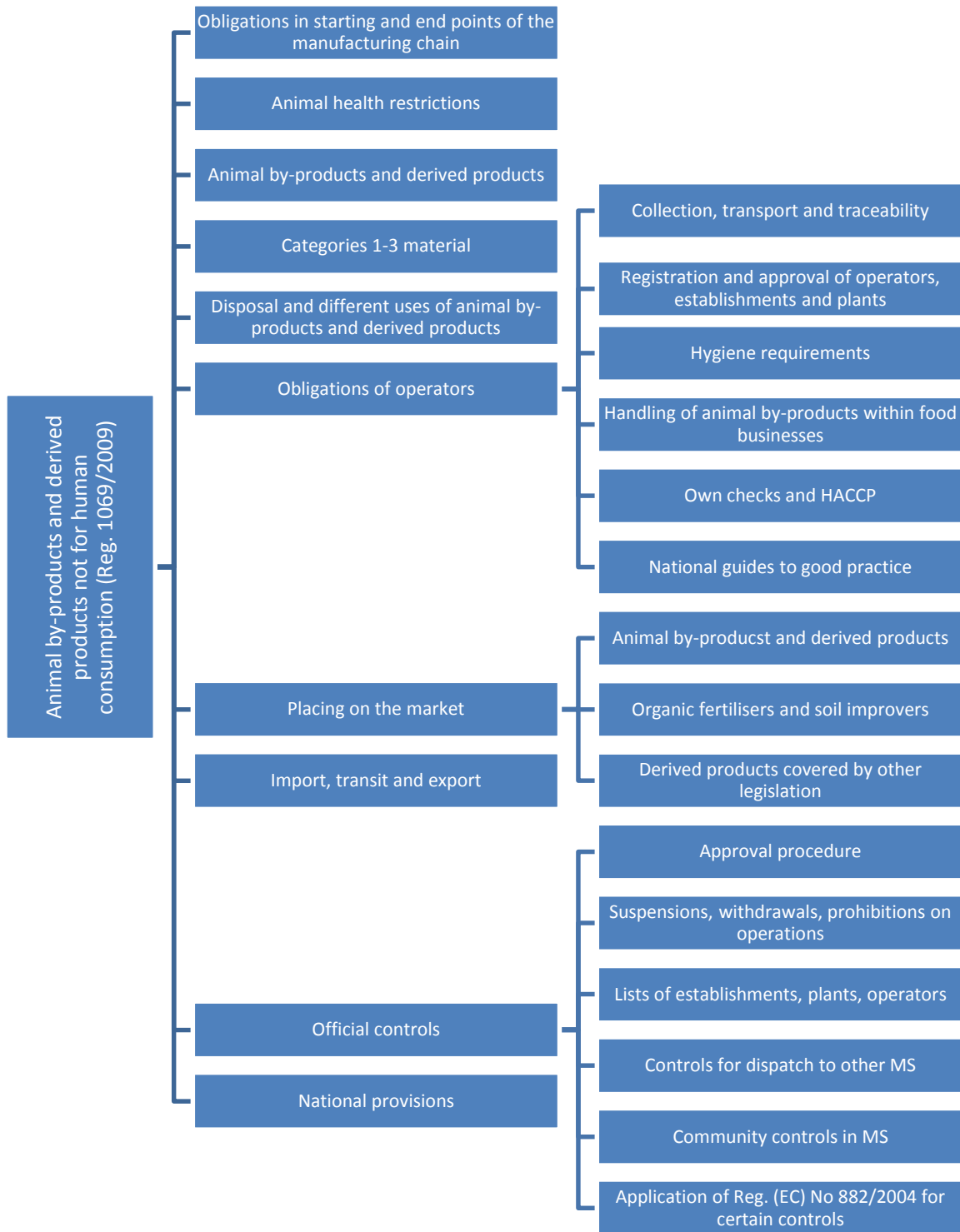


Figure 8: Main requirements of Regulation (EC) No 1069/2009

Figure 9 below summarises the legislative acts in the field of organic fertilisers.

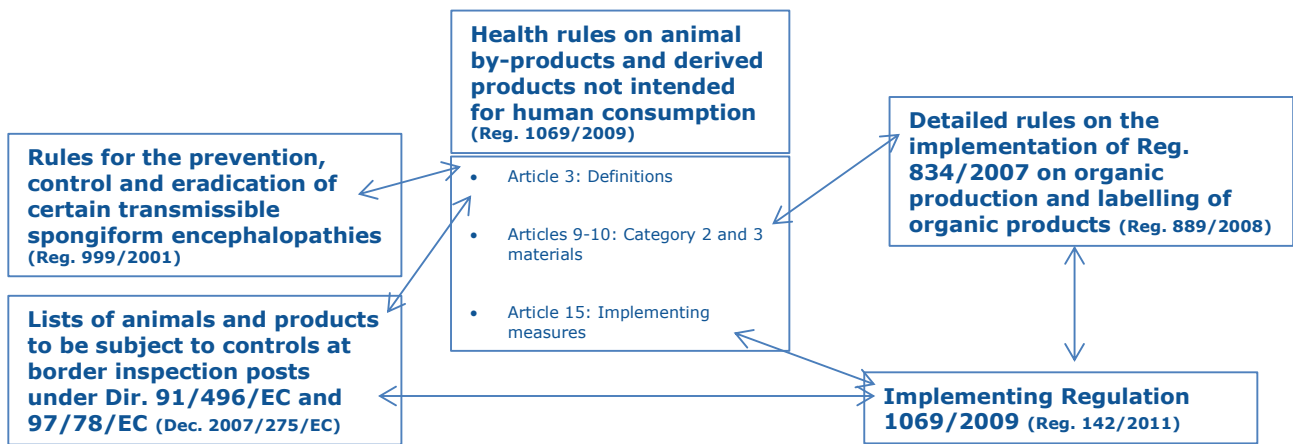


Figure 9: Legislative acts in the field of organic fertilisers

3.2. Pesticides and plant protection products

3.2.1. Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 91/414/EEC and 79/117/EEC

Regulation (EC) No 1107/2009¹⁰ lays down rules for the authorisation, placement on the market, use and control of plant protection products. It also provides for the approval of active substances, safeners, synergists, adjuvants and co-formulants contained in plant protection products. Its aim is to ensure a high level of protection of human and animal health and the environment while improving agricultural production. Member States are encouraged to still apply the precautionary principle during the authorisation of plant protection products in case of uncertainty related to risks from the use of a certain product.

The Regulation applies to products in the form supplied to the users and intended for protecting plants or plant products, for hygiene reasons, for influencing certain life processes of plants, preserving plant products or destroying/preventing the growth of undesired plants, unless they are applied to water or soil. It also applies to active substances that have a general or specific action against harmful organisms or plants and plant products. Finally, it also applies to safeners, synergists, co-formulants and adjuvants.

The Regulation lays down the criteria (in a specified order) for a substance to be approved as active substance. These must be satisfied for one or more representative uses and for at least one plant protection product containing the active substance. Approved active substances must be included in the list of active substances that must be electronically available to the public.

Plant protection products containing an active substance not yet approved may be placed on the market under certain conditions. Detailed information is laid down on the content of authorisations for plant protection products, their duration, the procedure for applications and the documents that need to be submitted for the evaluation. Also details are provided on how Member States should examine the applications. Provisions are also laid down for the authorisation of authorised plant protection products for the same use and under comparable conditions in another Member State under the mutual recognition principle.

The Regulation lays down provisions for placing on the market low-risk plant protection products and the conditions they must meet. Reference is made to authorisations of plant protection products containing a genetically modified organism. Also requirements are laid down for placing on the market seeds treated with plant protection products and the information that must appear on their labels and the accompanying documentation.

Regulation (EC) No 1107/2009 lays down requirements for placing plant protection products authorised in one Member State on the market of another, under a parallel trade permit. Details are provided on the requirements for products to be considered as identical and also on the application procedure.

Under emergency situations and where there is a danger that cannot be controlled by other means, a Member State may authorise the limited and controlled use of a plant protection product for a short period of time, also informing the other Member States and the Commission, unless the product contains GM material. Also unauthorised plant

¹⁰ Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 91/414/EEC and 79/117/EE (2009). OJ L 309/1

protection products may be released into the environment for research and development purposes.

If there is information that a plant protection product or its ingredients may have harmful effects or may no longer be compliant or efficient, the Regulation requires the authorisation holder to notify the Member State that granted the authorisation. For each approved substance, Member States must maintain a list of tests and study reports. The Regulation also requires the control of plant protection products and specifically the maintenance of records by producers and professional users regarding the use, timing and dosage of the products. Information on post-authorisation monitoring and on the sales volume of such products is also required. Official controls and audits must also be carried out in the Member States to confirm compliance with the requirements of the Regulation.

Regulation (EC) No 1107/2009 establishes procedures for the adoption of emergency measures in case of serious risk to human or animal health or the environment in relation to a plant protection product or its components where there is need to restrict or prohibit its use.

Figure 10 provides a graphical representation of the main content and requirements of Regulation (EC) No 1107/2009. More detailed information on certain of the Articles of this Regulation and additional legislation establishing relevant implementing measures can be found in Annex V.

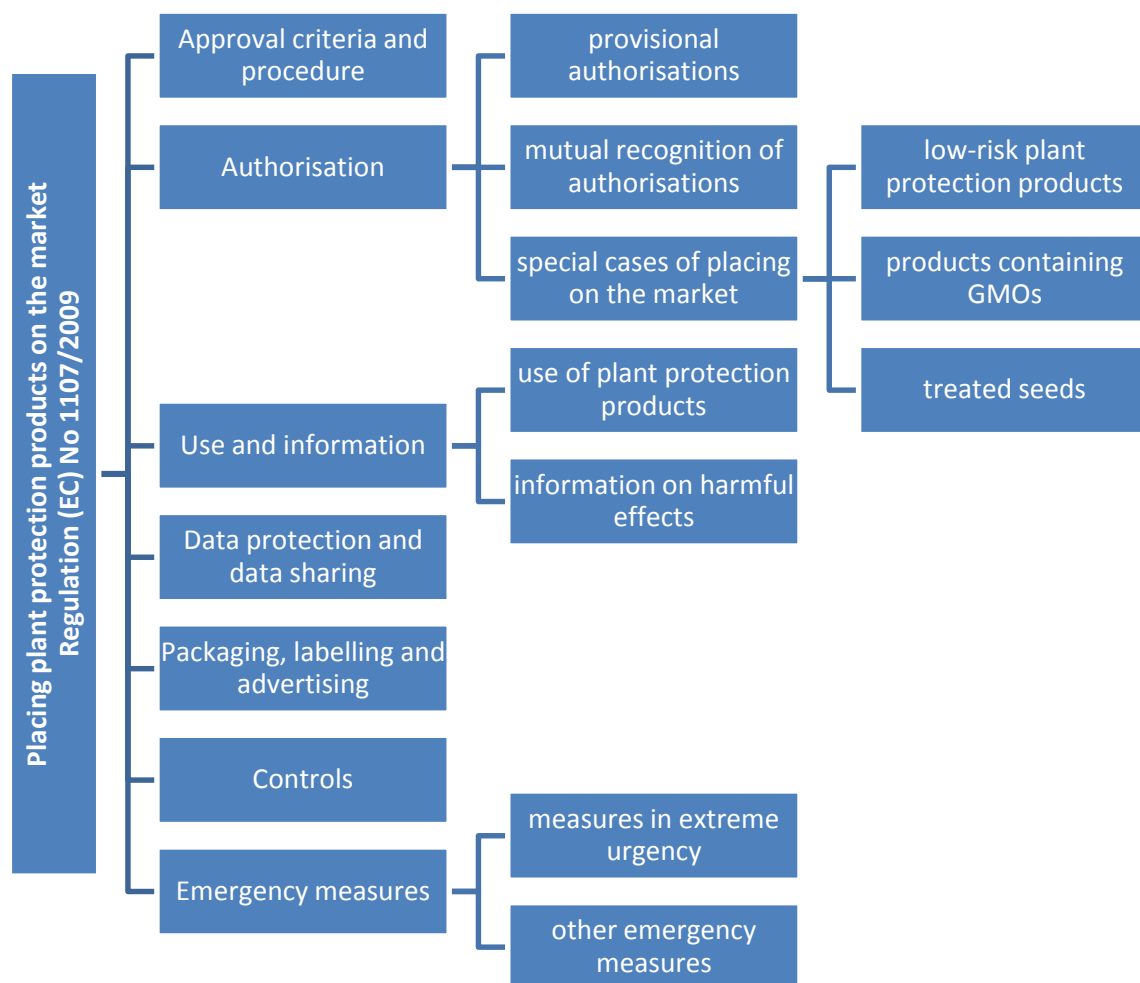


Figure 10: Summary of the main requirements of Regulation (EC) No 1107/2009

3.2.2. Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides

Directive 2009/128/EC¹¹ requires Member States to adopt National Action Plans within a framework for achieving sustainable use of pesticides and set their objectives and timeframes for moving towards integrated pest management, reduction of use of pesticides and introduction of alternative approaches thus reducing risks to human and animal health and the environment. Attention needs to be paid to plant protection products containing active substances of concern. The Directive also implements requirements for the training and certification of professional pesticide users, staffing requirements, requirements for the sale of such products and for public information and awareness-raising on the risks associated with the use of pesticides and on alternatives. The requirement for a system for the monitoring of pesticide-related incidents or of effects on groups of people more exposed to pesticides is also expressed.

The Directive lays down provisions for the inspection, calibration and checking of pesticide application equipment. It requires the prohibition of aerial spraying in the Member States, unless under very special conditions in which case the procedure is detailed. Measures are also laid down for the protection of the aquatic environment and drinking water and for the reduction of use of pesticides in specified areas. Member States are required to adopt measures to prevent risks to human health and the environment from the storage and handling of pesticides. Use of low-risk substances, integrated pest management and organic practices is promoted. The National Action Plans must include details of the implementation of integrated pest management by professional users, while the Member States must provide incentives and guidelines. Information is given on how Member States and at Community level the Commission, may calculate risk indicators and identify trends in the use of certain substances and priorities and on the assessment of the efficiency of Community policies. The exchange of information and best practice is encouraged.

Figure 11 provides a graphical representation of the main content and requirements of Directive 2009/128/EC.

¹¹ Directive 2009/128/EC of the European Parliament and of the Council establishing a framework for Community action to achieve the sustainable use of pesticides (2009). OJ L 309/71

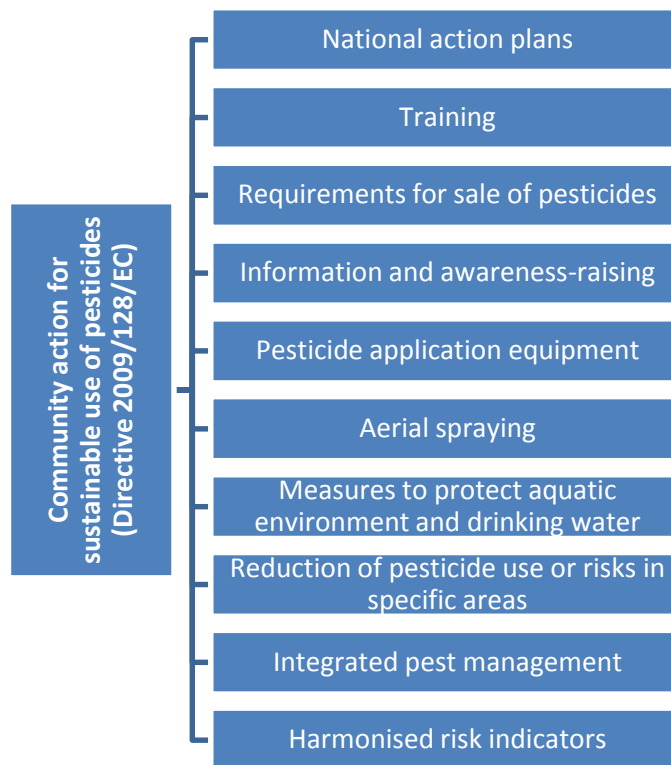


Figure 11: Summary of the main provisions of Directive 2009/128/EC

3.2.3. Regulation (EC) No 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin

Regulation (EC) No 396/2005¹² lays down maximum levels for pesticide residues in food and feed of plant or animal origin aimed at ensuring the highest level of consumer protection. It applies to fresh, processed and/or composite food/feed, while certain exempt products are mentioned. Annex I of Regulation (EC) No 396/2005 lists all products for which harmonised MRLs have been established and those for which MRLs must be established. The Regulation lays down the procedure, required particulars and documents for the submission of an application for the setting, modification or deletion of an MRL for an active substance. Details and timeframes on carrying out the evaluation of the application (by EFSA) are provided. A reasoned opinion must be reached that must be made publicly available. The result and the inclusion of the new or modified MRL in the appropriate Annex to the Regulation are published in the form of a Regulation. Details are also provided for setting temporary MRLs to be included in Annex III of Regulation (EC) No 396/2005, provided there are no unacceptable risks to consumers or animals following monitoring data and risk assessment by the Authority. Reference is also made to the revocation of authorisation of a plant protection product in which case the relevant MRLs must be deleted.

Products of plant or animal origin must not exceed the MRLs laid down in Annex I of Reg. (EC) No 396/2005, or the default values set. Specific derogations are authorised for products that may exceed the limits established further to post-harvest treatment with a fumigant, provided the Commission and the other Member States have been informed. Such products may be authorised for placement on the market in a Member State under

¹² Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin (2005). OJ, L 70/1

exceptional circumstances and provided they do not constitute an unacceptable risk. This must be notified to the MS, the Commission and the Authority and must be accompanied by a risk assessment with a view to setting temporary MRLs.

The Regulation prohibits the mixing or dilution of non-compliant products for placement on the market as food or feed. When there are no MRLs for processed or composite products, the product MRLs apply taking into account changes due to processing or mixing. Specific concentration or dilution factors must be established for certain processes.

The Regulation lays down the requirement for official controls to be carried out in the Member States to enforce compliance. These should involve sampling and analysis for identification and quantification of the residues present. Details are also provided on sampling and methods of analysis.

The Commission must prepare a coordinated multiannual control programme in order to be able to assess consumer exposure to plant protection product residues but also assess the enforcement of the legislation. National control programmes must be established in the Member States which must cover certain details specified in the Regulation. Every year the Member States must forward specific information to the Commission, the Authority and the other Member States in order to allow the compilation by the Commission of an Annual Report on pesticide residues.

In case pesticide residues or MRLs may pose risks to health, emergency measures may be established under Articles 53 and 54 of Regulation (EC) No 178/2002. The Regulation also lays down the requirement for establishment of harmonised MRLs at Community level and of support measures to this effect, while the Community must contribute financially for the related costs. Member States must designate national authorities for the purposes of this Regulation and certain tasks as detailed therein. One of these tasks is the development and maintenance of a database containing all relevant information for the purposes of establishing MRLs.

Figure 12 provides a graphical overview of the main content and requirements of Regulation (EC) No 396/2005. More detailed information and legislation establishing additional implementing measures for certain of the requirements of the Regulation can be found in Annex VI.

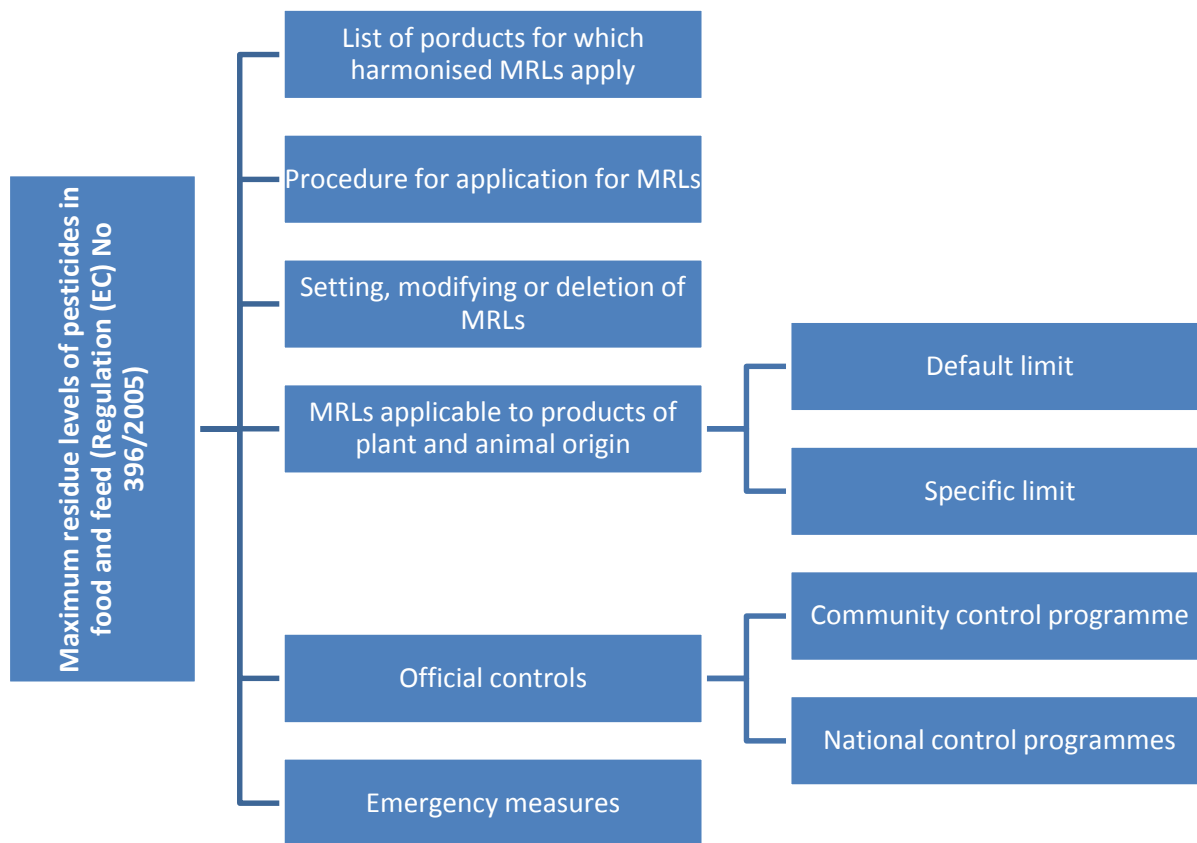


Figure 12: Summary of the main provisions of Regulation (EC) No 396/2005

Figure 13 provides a summary of the legal acts related to the placement of plant protection products (ppps) on the market and the establishment of maximum residue levels of pesticides in food and their interactions.

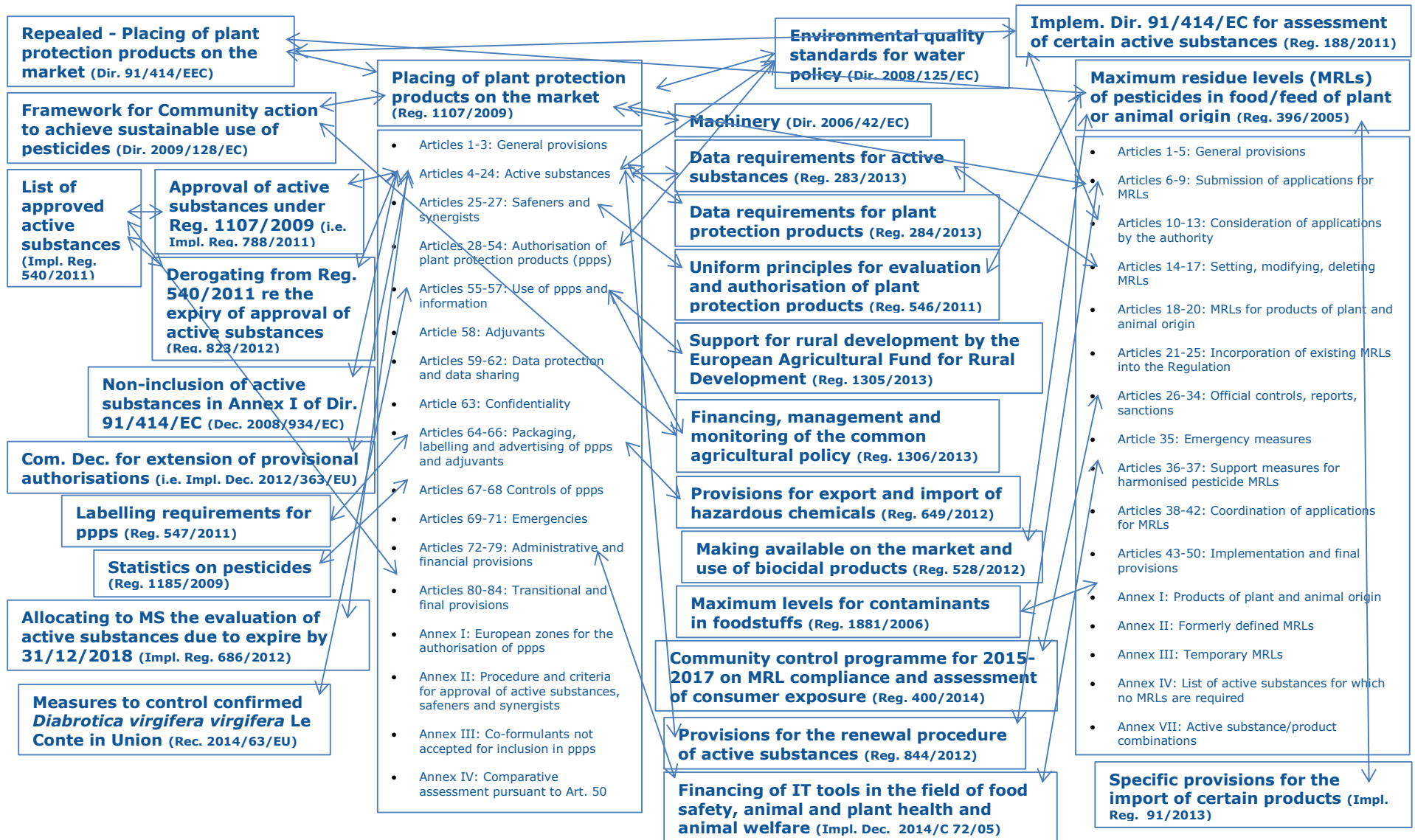


Figure 13: Summary of the legal acts related to the placement of plant protection products on the market and the establishment of maximum residue levels of pesticides in food

3.3. Radioactive contamination of food and feed

3.3.1. Council Regulation (Euratom) 3954/87 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency

Regulation 3954/87¹³ lays down the procedure for determining maximum levels of radioactive contamination in food or feed following a nuclear accident or other radiological emergency. In such cases of emergency and if the maximum levels laid down in the Annex to the Regulation are likely to be reached, a Regulation must be adopted enforcing those maximum permissible levels in order to protect consumer health. Provisions are also laid down with regard to the length of validity of these maximum levels. Non-compliant food and feed must not be placed on the market. More detail and additional legislation relevant for its implementation are provided in Annex VII.

3.3.2. Council Regulation (Euratom) 944/89 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency

The Annex to Commission Regulation (Euratom) 944/89¹⁴ lays down a list of minor foodstuffs under the requirement of Article 7 of Reg. 3954/87. The maximum permitted levels for radioactive contamination for these foodstuffs is established at ten times the one established for other foodstuffs by Reg. 3954/87.

3.3.3. Council Regulation (EURATOM) 770/90 laying down maximum permitted levels of radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency

The Annex to Commission Regulation (Euratom) 770/90¹⁵ lays down maximum permitted levels for radioactive contamination in feedingstuffs under the requirement of Article 7 of Reg. 3954/87. Specifically it lays down maximum levels for the sum of caesium-134 and caesium-137 in feed. Commission Implementing Regulation (EU) No 322/2014¹⁶ imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station, lays down maximum levels for the above radioactive materials in feed originating or

¹³ Council Regulation (Euratom) No 3954/87 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feedingstuffs following a nuclear accident or any other case of radiological emergency (1987). Official Journal L 371

¹⁴ Council Regulation (Euratom) No 944/89 laying down maximum permitted levels of radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency (1987). Official Journal L 101

¹⁵ Council Regulation (Euratom) No 770/90 laying down maximum permitted levels of radioactive contamination in feedingstuffs following a nuclear accident or any other case of radiological emergency (1987). Official Journal L 083

¹⁶ Commission Implementing Regulation (EU) No 322/2014 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station. Official Journal of the European Union, L 95/1

consigned from Japan, which replace the ones established by Reg. 3954/87 on a provisional basis.

Figure 14 summarises the legislative acts in the field of radioactive contamination of food and feed following a nuclear accident or other radiological emergency.

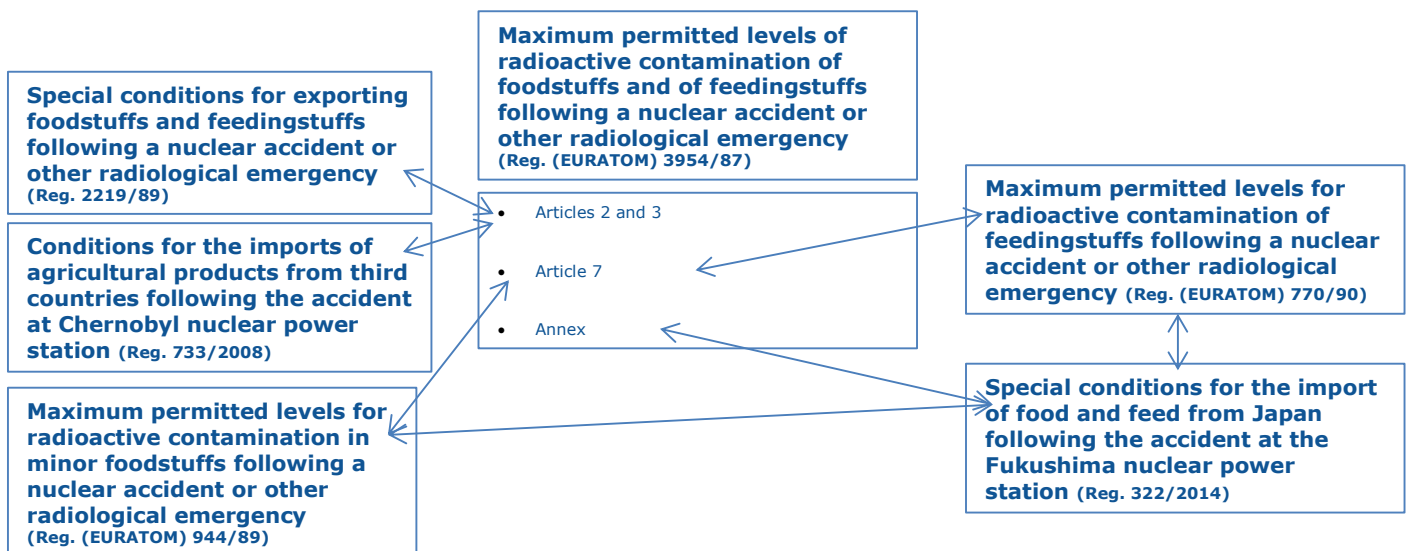


Figure 14: Summary of legislation in the field of radioactive contamination of food and feed

4. Legislation related to primary production

4.1. Genetically modified organisms

4.1.1. Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms

Directive 2001/18/EC¹⁷, in accordance with the precautionary principle, aims at protecting human health and the environment during the deliberate release of genetically modified organisms into the environment for the purposes of placing on the market or other. Member States must take all appropriate measures to achieve the above aim. The Directive does not apply to certain organisms produced by the techniques specified in its Annex I B, nor to the carriage of GMOs. GMOs may only be deliberately released or placed on the market in accordance with Parts B and C of the Directive. Before submitting a notification for the deliberate release of GMOs in the environment, an environmental risk assessment must be carried out in accordance with its Annex III. Member States must designate competent authorities for the purposes of this Regulation and for organising inspections and controls.

Part B of Directive 2001/18/EC lays down the procedure for authorisation of the deliberate release of GMOs in the environment for purposes other than placing on the market. It also lays down a differentiated procedure for the release of certain GMOs in certain ecosystems for which sufficient experience of releases has been obtained. Material derived from GMOs deliberately released in accordance with Part B may not be placed on the market unless in accordance with Part C. Provisions are also established for the action to be taken by the notifier in the event of unintended modification or new information that may give rise to risks to human health or the environment. The Directive requires the set-up of a system of exchange of information related to notifications. Member States must submit to the Commission a yearly list of all GMO releases as well as a list of rejected notifications, which must be distributed to the competent authorities of the other Member States.

Part C of Directive 2001/18/EC lays down the procedure for the placement on the market of GMOs or GMOs in products, which is subject to prior notification to the competent authority of the Member State where it will be placed on the market for the first time. The details that must be included in the notification and timelines for the assessment procedure are also described. The competent authority must send an assessment report to the Commission, indicating whether the GMO may be placed on the market or not and under what conditions. Specific criteria and information for the placement on the market of specified GMOs are also established.

The detailed procedure for the renewal of authorisations and the relevant information required is also laid down. Procedures are established in case an objection is raised and maintained by a competent authority or the Commission, in which case a decision has to be adopted. When a written consent has been given for a GMO to be placed on the market, this product may be used without further notification throughout the Community, provided the specific conditions of use and any environmental restrictions are followed.

The Directive defines as the responsibility of the notifier to monitor and report on a GMO placed on the market and to submit a report to the competent authorities of the Member States and the Commission. Based on this information, the monitoring plan may be amended after the first monitoring period. Also, in light of new information relevant to

¹⁷ Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (2001). Official Journal L 106

the risks posed by a GMO, the notified must take measures to protect human health and the environment and also notify the competent authority. GMOs and GM products must be labelled as specified in the written consent at all stages of placing on the market. Minimum thresholds for the adventitious or technically unavoidable presence of traces of authorised GMOs must be established. Member States must not inhibit the placing on the market of GMOs that comply with the requirements of this Directive. Safeguard measures are established in case a notified GMO or product poses risks to human health or the environment. The Directive requires that all relevant information is made publicly available. Final provisions include confidentiality, the labelling of GMOs for which stringent containment measures must be used, measures to avoid the unintended presence of GMOs in other products and the development of relevant guidelines.

The Directive indicates that in cases of objection with regards to the risks from GMOs, the Commission may consult the relevant Scientific Committees. Also the Commission must consult groups such as the European Group on Ethics in Science and New Technologies on ethical issues or ethical implications of biotechnology. Public registers must be established that record the locations of release of GMOs. Member States and the Commission must publish reports on their experience with the placement on the market of GMOs. Member States must determine the penalties applicable for breach of the national provisions of relevance to this Directive. The Directive finally requires the Commission to take action in order to implement the provisions of the Cartagena Protocol on Biosafety.

The following figure shows the main requirements of Directive 2001/18/EC. More detail on these requirements and additional legislation required for the implementation of this Directive are provided in Annex VIII.

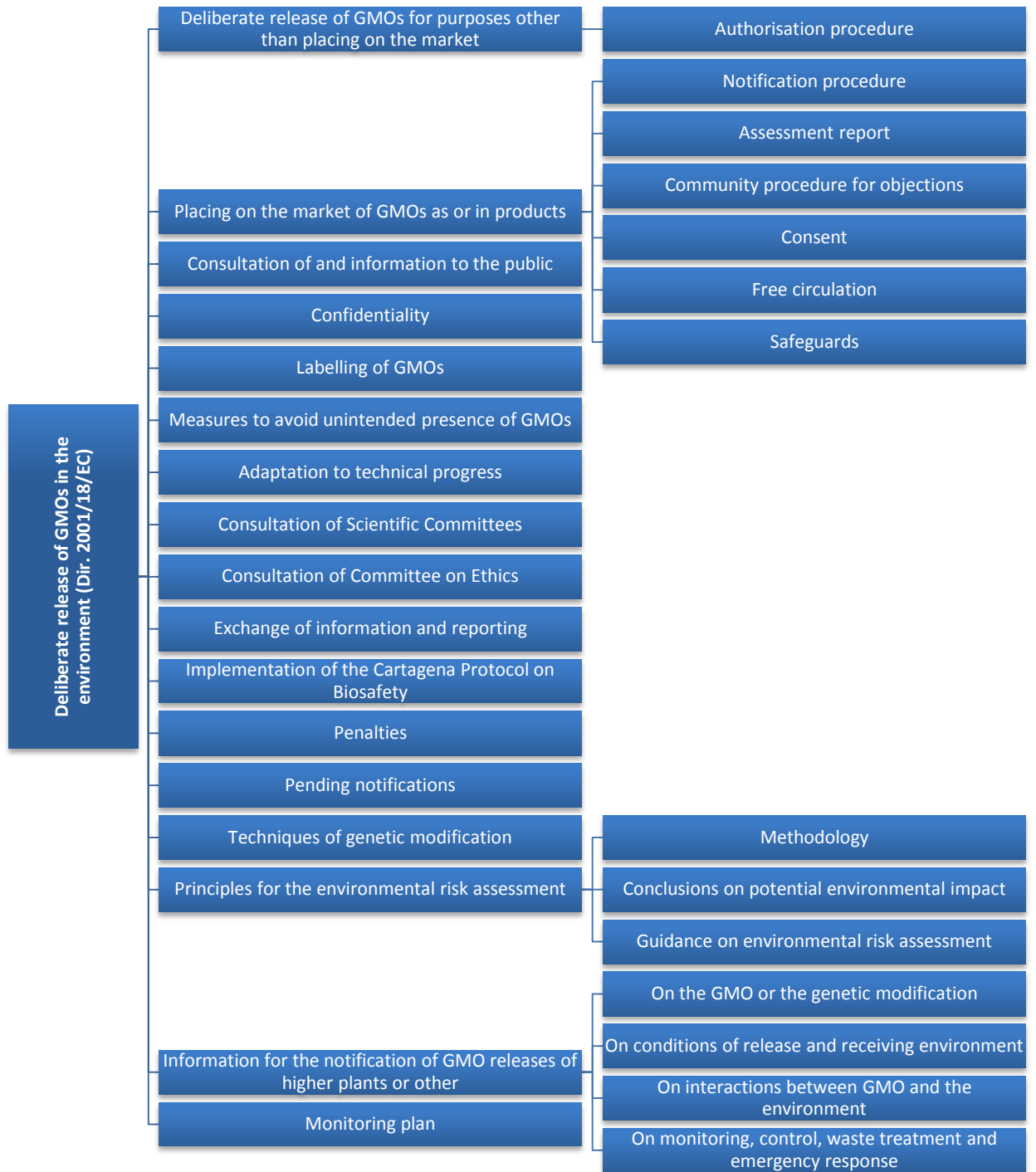


Figure 15: Main requirements of Directive 2001/18/EC

4.1.2. Regulation (EC) No 1829/2003 on genetically modified food and feed

Regulation (EC) No 1829/2003¹⁸ lays down more specific procedures for the authorisation, supervision and labelling of GM food and feed and the foundations for the highest level of human and animal health and welfare protection, protection of the environment and of consumer interests in relation to GM food and feed, while ensuring the uninterrupted functioning of the internal market. It applies to GMOs for food use, to food containing or consisting of GMOs and to food produced from or containing ingredients produced from GMOs. The above food products must have no adverse effects to human or animal health or the environment, they must not mislead the consumer and they must not differ nutritionally from the food they are intended to replace. Applications for authorisation of GM foods are sent to the national competent authority of a Member State and details are provided in the Regulation on the information that needs to be submitted and the procedure to be followed.

The Regulation also lays down rules for the labelling of foods intended for the final consumer or the mass caterer that contain GM material or are produced from or contain GM material, excluding however food that contains <0.9% GM material due to adventitious or unavoidable contamination. Specific labelling requirements are included to indicate any differences of the GM food from its conventional counterpart. The Regulation also lays down requirements for GM feed, for the authorisation and for the labelling of such products. Information is provided on the status of existing GM food and feed products that were authorised prior to the entrance in force of Regulation (EC) No 1829/2003. Also details are provided for the supervision of authorised food and feed products once they are placed on the market and of any applicable conditions or restrictions. For products that are likely to be used both as food and feed a single application for authorisation must be submitted requiring a single Authority opinion and a single Commission decision. Also the Regulation requires the establishment and maintenance of a Community register of approved GM food and feed materials which must be publicly available. Provisions apply for data protection and confidentiality of information.

Regulation (EC) No 1829/2003 provides for a Community Reference Laboratory for GM products and its tasks are outlined. National reference laboratories may also be established. The cost of GM product authorisations and of the operation of the Reference laboratories must be supported by the applicants. With reference to ethical issues the Commission may consult the European Group on Ethics in Science and New Technologies and make such opinions public. In case of risks to human or animal health or the environment, emergency measures may be established in accordance with the relevant procedures of Reg. (EC) No 178/2002. Any authorisation decision reached in accordance with Reg. (EC) No 1829/2003 must also be notified to the Parties to the Cartagena Protocol. Finally, the Regulation lays down rules for penalties to be implemented in case of infringement of its requirements.

Figure 16 shows the main requirements of Regulation (EC) No 1829/2003. More detail on these requirements and additional legislation required for the implementation of this Directive are provided in Annex IX.

¹⁸ Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (2003). Official Journal L 268

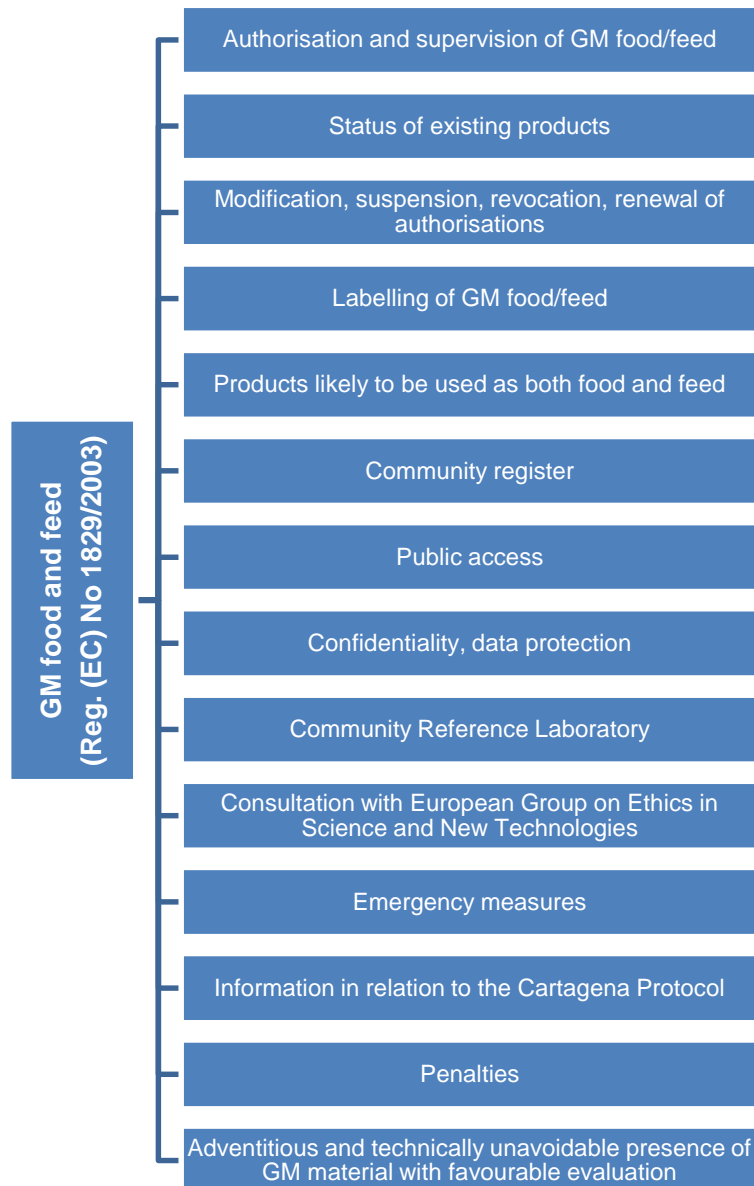


Figure 16: Main requirements of Regulation (EC) No 1829/2003

4.1.3. Regulation (EC) No 1830/2003 on the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC

Regulation (EC) No 1830/2003¹⁹ lays down the framework for traceability of products consisting of or containing GM material and food/feed produced from GMOs. Its objective is to facilitate the accurate labelling, the monitoring of GMOs' effects on health and the environment and the implementation of relevant risk management and applies to all steps of placing GM products on the market. It also specifies the responsibilities of the food business operator with regard to the traceability and labelling at the different steps.

¹⁹ Regulation (EC) No 1830/2003 of the European Parliament and of the Council on the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC (2003). Official Journal L 268

The Regulation requires the Commission to establish a system for the development and assignment of unique identifiers for GMOs. Information is provided on inspection and control measures related to the marketing of GMOs and the requirement for the development and publication of guidance by the Commission is expressed. A central register with all GMO sequencing information and reference materials must be established. Finally Member States must establish penalties for non-compliance and measures for their implementation.

Figure 17 shows the main requirements of Regulation (EC) No 1830/2003. More detail and additional legislation relevant for its implementation are provided in Annex X.

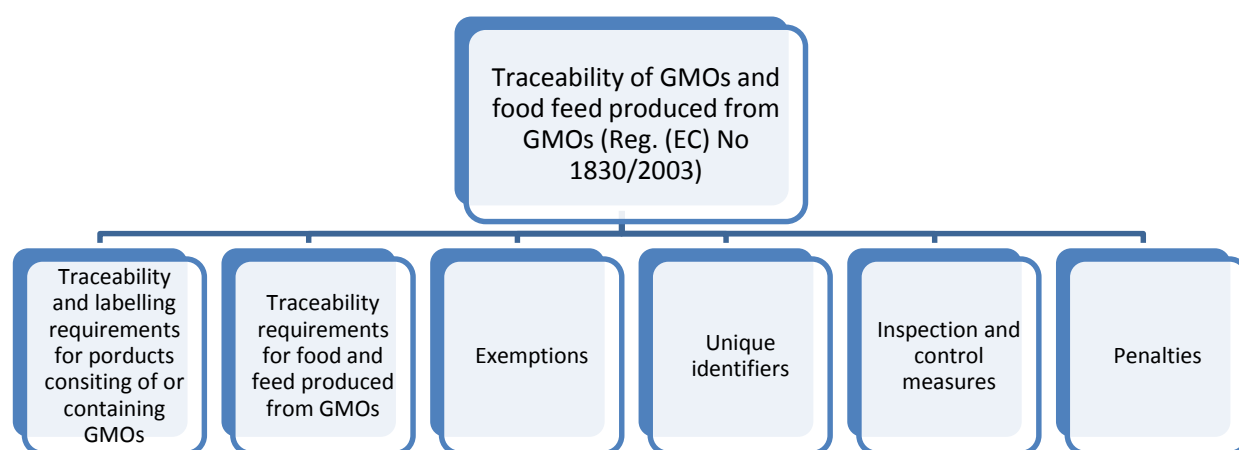


Figure 17: Main requirements of Regulation (EC) No 1830/2003

4.1.4. Cartagena Protocol on Biosafety

The Cartagena Protocol on Biosafety was approved in the European Community by Council Decision 2002/628/EC²⁰. The aim of this Protocol is, based on the precautionary principle, to contribute to ensuring protection in the trans-boundary movements (transfer, handling and use) of living modified organisms resulting from modern biotechnology that may have adverse effects on conservation and sustainable use of biological diversity, also considering risks to human health. It lays down the procedure for the first intentional trans-boundary movement of living modified organisms for intentional introduction into the environment of the Party of import (excluding for use as food or feed or for processing), for the notification process and the decision procedure. A procedure is also described for the trans-boundary movement of living modified organisms intended for direct use as food, feed or for further processing. Provisions are laid down for bilateral, regional and multilateral agreements between Parties and also for the procedures for risk assessment and risk management to be carried out under the requirements of this Protocol. The Protocol also indicates the need for the establishment of measures for the unintentional trans-boundary movement of organisms and for emergency measures.

²⁰ Council Decision 2002/628/EC concerning the conclusion, on behalf of the European Community, on the Cartagena Protocol on Biosafety (2002). Official Journal of the European Communities, L 201/48

The establishment of the Biosafety Clearing-House and its role is included in the Protocol. Further information is provided on the handling of confidential information, public awareness, illegal actions and liability, financial points of relevance, organisational aspects but also monitoring, reporting and review of the effectiveness of the Protocol.

Figure 18 summarises the legal documents in the field of genetically modified organisms, their deliberate release and their traceability and labelling in food and feed produced from such organisms.

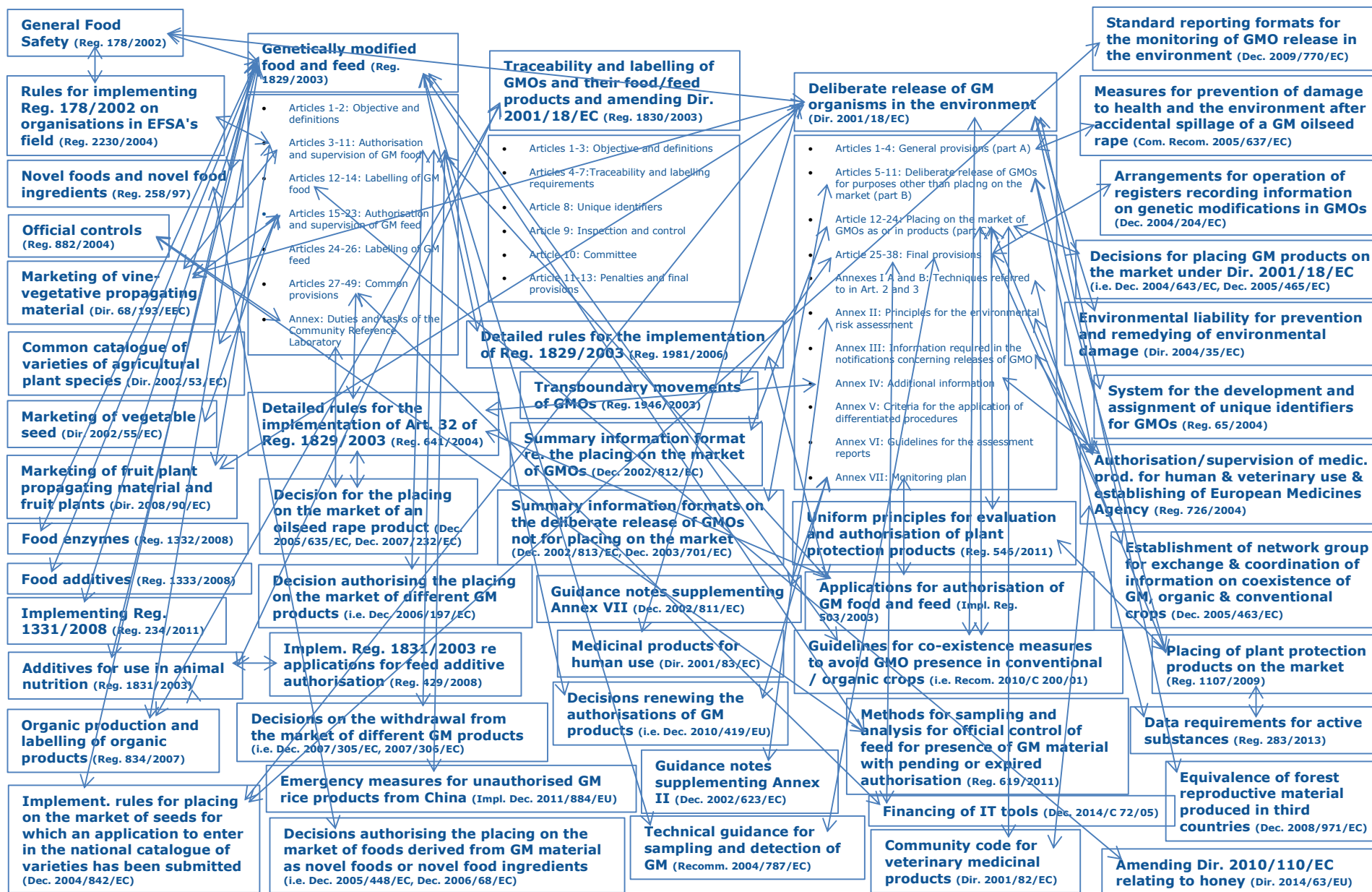


Figure 18: Main legal documents in the field of GMOs, their deliberate release, traceability and labelling in food and feed

4.2. Veterinary drug residues

4.2.1. Directive 2001/82/EC on the Community code relating to veterinary medicinal products

Directive 2001/82/EC²¹ laying down Community provisions on veterinary medicinal products applies to industrially prepared veterinary medicinal products including pre-mixes for medicated feedingstuffs, active substances used as starting materials and substances with anabolic, anti-infectious, anti-parasitic, anti-inflammatory, hormonal or psychotropic properties, for placement in the Community market. Such products may only be placed on the market if they have been granted an authorisation by the competent authority of a Member State. Additional species, strengths, pharmaceutical forms, administration routes, presentations, variations or extensions must also be granted a marketing authorisation or be included in the initial marketing authorisation. The marketing of such products is the responsibility of the authorisation holder. Only specified veterinary medicinal products may be authorised for administering to food-producing species. In case of serious epizootic diseases and in the absence of suitable medicinal products, Member States can provisionally allow the use of immunological veterinary medicinal products without marketing authorisation after informing the Commission on the conditions of use. Such use may also be authorised in animals imported or exported to third countries, under certain conditions. Veterinary medicinal products may only be administered to animals once the marketing authorisation has been issued. Detailed rules are also laid down for the administration of veterinary medicinal products to non-food producing animals in a Member State where authorised such products are not available. Similarly, rules are provided in case there is no authorised product for treating specific conditions in food-producing animal species.

Directive 2001/82/EC also lays down the procedure for obtaining marketing authorisation for a veterinary medicinal product, when the pharmacologically active substance has not yet been approved. Marketing authorisations may only be granted to applicants established in the Community. The Directive also lays down provisions on homeopathic veterinary medicinal products and conditions for their registration or authorisation.

The authorisation holder may be requested by the competent authorities to provide sufficient quantities of a substance to enable controls on the presence of residues or technical expertise in the implementation of an analytical method for the detection of residues in products of animal origin in accordance with the requirements of Directive 96/23/EC. The holder must also inform the competent authorities of the authorising Member State of the actual dates when the products are placed on the market or cease to be placed on the market, temporarily or permanently.

The Directive lays down procedures for granting marketing authorisations in more than one Member States. In case of divergent decisions, the matter can be referred to the Committee for Medicinal Products for Veterinary Use. The Directive also lays down provisions in case a marketing authorisation needs to be amended by the holder. The Agency must publish an annual report on these procedures while the Commission must prepare a report on the experience gained at least once every ten years; both reports must be forwarded to the Parliament and the Council.

Directive 2001/82/EC also lays down rules, timeframes and obligations for the manufacture of veterinary medicinal products that are subject to an authorisation even if intended for export and covers whole or partial manufacture as well as import of such products from third countries. The Commission must implement good manufacturing

²¹ Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products (2001). Official Journal of the European Communities, L311/1

practices and provide guidance. The manufacturing authorisation holder must permanently employ a qualified person whose qualifications and duties are laid down in detail. For imported products, the Community must ensure that they have been manufactured under at least equivalent good manufacturing practices and controls.

The information that must appear on the immediate and outer packaging of veterinary medicinal products is detailed in the Directive and must be approved by the competent authorities. If it can all be placed on this packaging, the inclusion of a leaflet inside is not compulsory. The information must appear in the languages of all Member States where the product is marketed and must be identical in all the languages. In breach of these provisions, Member States may revoke the authorisation. Details are also provided on the labelling information of homeopathic veterinary medicinal products.

Wholesale of veterinary medicinal products is subject to an authorisation and the requirements for obtaining this are laid down in the Directive. Retail supply of such products is subject to national legislation at Member State level. For dispensing veterinary medicinal products to the public, a veterinary prescription is required. Such products may only be in the possession of persons empowered by the national legislation, while records of the details of all manufacturers and dealers must be maintained. Owners of food producing animals must be able to provide evidence of purchase, possession and administration of veterinary medicinal products to their animals even after they have been slaughtered.

The Directive implements the establishment of a pharmacovigilance system by the Member States in order to collect information on adverse reactions to veterinary medicinal products in animals and humans and to be able to evaluate this information scientifically. This information must be communicated to the other Member States and the Agency and must be recorded in a database. Information related to lack of expected efficacy, off-label uses, deviations in the reported withdrawal times, environmental issues etc. may also be maintained in this system. Marketing authorisation holders must employ a person tasked with maintaining the pharmacovigilance related information.

Competent authorities of the Member State must conduct inspections and where appropriate analysis of samples by an Official Medicines Control laboratory to confirm compliance with the above legal requirements. Inspections may also be carried out on starting materials. Provisions are laid down on how Member State competent authorities can suspend, revoke or withdraw market authorisations or prohibit a product from placement on the market. Also it is possible to suspend or withdraw the manufacturing authorisation of a preparation. It is prohibited to advertise to the general public veterinary medicinal products that may be administered only with a veterinary prescription or which contain substances with narcotic or psychotropic properties.

The principle of communication between the Member States and the competent authorities concerned is highlighted for the purposes of this Directive.

Figure 19 provides a graphical overview of the main content and requirements of Directive 2001/82/EC. More detail on some of these requirements as well as additional information on related implementing measures is provided in Annex XI.

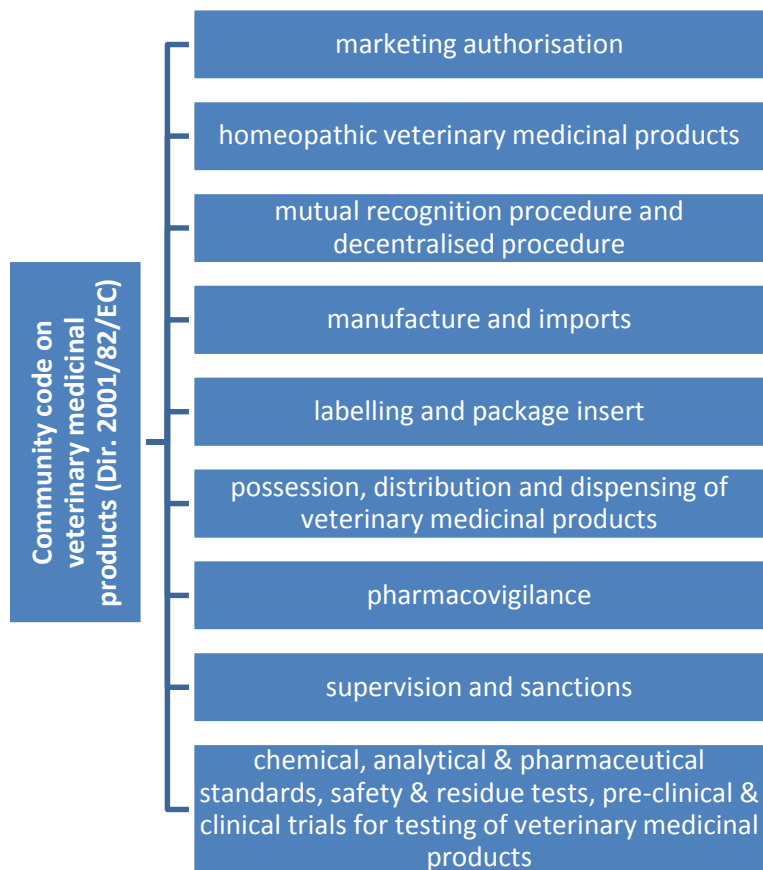


Figure 19: Main provisions of Directive 2001/82/EC

4.2.2. Regulation (EC) No 470/2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (repealing Regulation (EEC) No 2377/90)

Regulation (EC) No 470/2009²² lays down rules and procedures for establishing maximum residue limits of pharmacologically active substances in foodstuffs of animal origin or, in case maximum residue limits have not been established, it lays down levels of residues of substances for control purposes.

Pharmacologically active substances for use in veterinary medicinal products to be administered to food producing animals in the Community, must be subject to an opinion by the European Medicines Agency (EMA) on the maximum residue limit, formulated by the Committee for Medicinal Products for Veterinary Use, unless the Codex Alimentarius procedure applies. The opinion of the Agency must consist of a scientific risk assessment and of risk management recommendations and must be based on ensuring the highest level of human health protection, animal health and animal welfare. It must not be negatively affected by the lack of availability of appropriate veterinary medicinal products. The opinion must also take into consideration any relevant scientific findings of

²² Regulation (EC) No 470/2009 of the European Parliament and of the Council laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin (repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation 726/2004 of the European Parliament and of the Council (2009). Official Journal of the European Union, L152/11

EFSA. The Regulation also indicates that maximum residue limits established for one pharmacologically active substance in one foodstuff may be used to extrapolate for other foodstuffs derived from the same species or even from one species to another. Detailed instructions are provided on carrying out the risk assessment and on the factors to be considered. Also based on the scientific risk assessment, recommendations are provided on considerations for the risk management decisions.

Detailed provisions are laid down with regard to the procedure and timelines for application for an opinion of the Agency on the use of a pharmacologically active substance, either requested by an individual, the Commission or by a Member State. Also details are provided on the establishment of maximum residue levels for pharmacologically active substances contained in biocidal products used in animal husbandry. A specific budget is provided by the agency to cover the costs of substance evaluations. In case a review of an already published opinion is necessary, a request for a new opinion may be submitted to the Agency accompanied by an explanation. The above provisions also apply for the establishment of maximum residue levels in certain foods or species. Agency opinions must be made public, but any confidential information must be deleted. The Commission, for setting maximum limits in other species/foods, must adopt measures based on the opinions issued on the use of maximum residue limits in one food or species.

The Commission is required to classify pharmacologically active substances establishing a list of these and the therapeutic classes to which they belong and for each substance the maximum residue limits, or provisional limits for a defined period of time, or the need to establish such limits or the prohibition of use of the substance. Maximum residue limits must be established where necessary according to an opinion of the Agency or of Codex Alimentarius Commission, unless it is not considered necessary. If the presence of residues of a substance may constitute risk to human health or uncertainty persists, the administration of the substance must be prohibited. Pharmacologically active substances may be administered to food-producing animals only if maximum residue limits or provisional limits are established, or they are considered unnecessary. Special conditions or restriction of use may be included in the classification of substances if it is necessary for the protection of human health. In case of an urgent requirement for authorisation of a veterinary medicinal product or biocidal product, in order to ensure the protection of public health or animal health and welfare, an accelerated procedure for the establishment of maximum residue limits can be followed and the procedure is laid down.

The Regulation allows for the implementation of reference points for action for pharmacologically active principles not subject to classification, in order to ensure the functioning of controls of food of animal origin. These must be based on the content of an analyte in a sample which can be detected and confirmed by official control laboratories. A request may be submitted to EFSA for assessing the risk of whether reference points for action can ensure consumer health protection. The Community reference laboratories must be consulted on methods for the analysis of residues and such information must be forwarded to Community and national reference laboratories. Depending on the analytical tests results, competent authorities may carry out investigations in accordance with Directive 96/23/EC to check for illegal administration of non-authorised active substances and take further action. The Commission must be assisted by the Standing Committee on Veterinary Medicinal Products and by the Standing Committee on the Food Chain and Animal Health. Finally, the Regulation lays down the requirement for adoption by the Commission of a Regulation incorporating the pharmacologically active substances and their classification regarding the maximum residue levels as established under Reg. (EEC) No 2377/90.

Figure 20 provides a graphical representation of the main content and requirements of Regulation (EC) No 470/2009. More detail on some of these requirements as well as additional information on related implementing measures is provided in Annex XII.

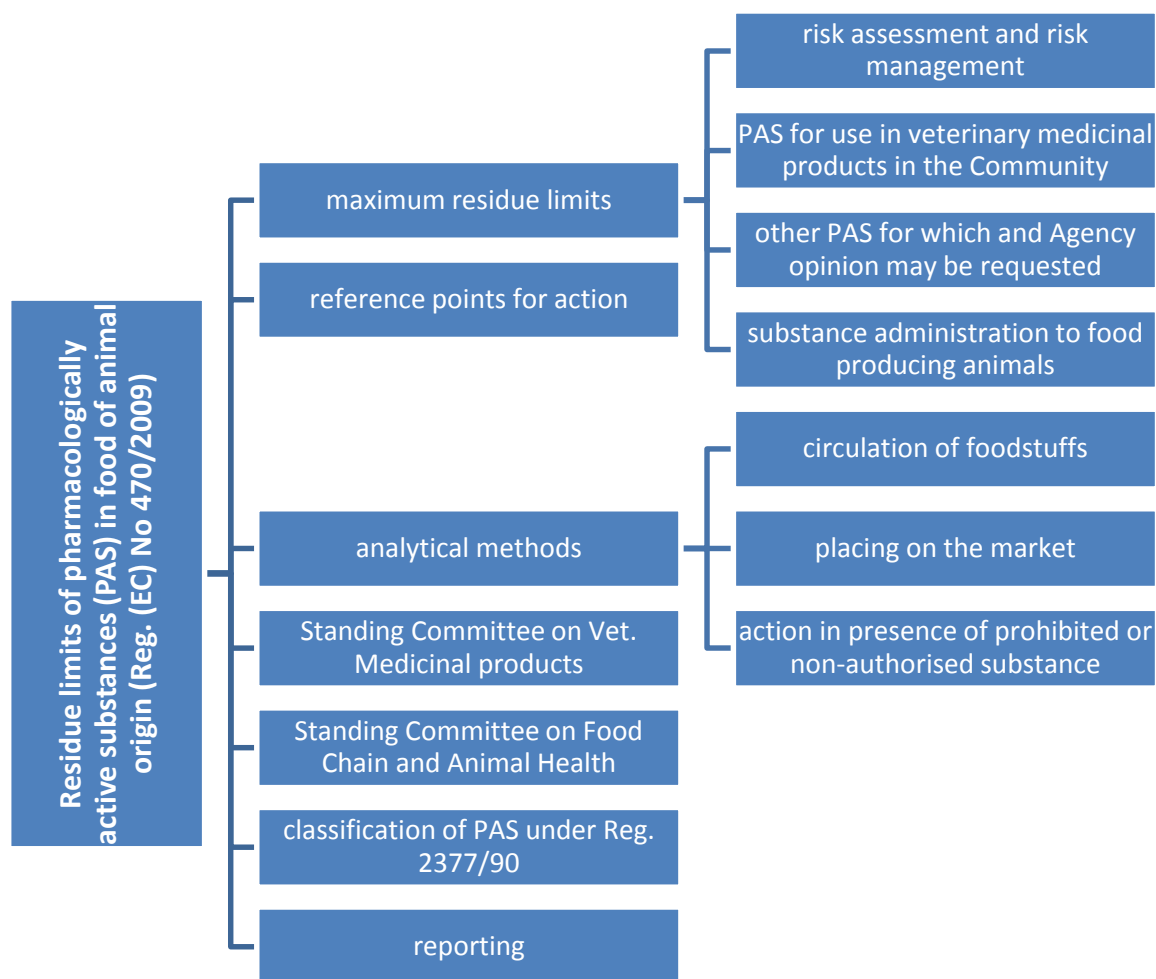


Figure 20: Main provisions of Regulation (EC) No 470/2009

4.2.3. Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products

Directive 96/23/EC²³ lays down measures for the monitoring of certain substances and their residues in animals and animal products during the production process in different tissues, body fluids, animal products, feed and drinking water. The Directive requires Member States to assign to a central public department or body the implementation of inspections: plan organisation, coordination of related activities, data collection to evaluate the results obtained and sending these to the Commission together with the results of any surveys undertaken. The plan must provide for the detection of groups of

²³ Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC (1996). Official Journal of the European Communities, L125/10

residues according to the type of animal and for substances and/or their residues in certain products and must comply with the rules for sampling, sampling frequencies and maximum levels laid down in the Annexes to the Directive. The initial plans must take into account the existing situation in each Member State in relation to legislation, controls, infrastructure, methods of analysis, official sampling schemes and national tolerances and the presence of national laboratories. These plans are then examined for approval by the Commission. The results of Member States' plans and control measures must also be forwarded to the Commission and must be made public.

Directive 96/23/EC establishes the responsibility of Member States to ensure that farm operators and legal persons placing animals on the market are registered beforehand with the Authorities. Owners of establishments of initial processing of animal products must take all necessary steps to ensure they only accept animals that do not contain illegal substances or residues of substances higher than the maximum permitted levels. Member States must also ensure that the requirement for quality monitoring of the production chain is established in the legislation and that any self-monitoring measures are included in the specifications. The responsibilities and terms of reference for veterinarians monitoring farms are also laid down and specifically the requirement for a register of any treatment administered, the animals treated and any withdrawal periods to be kept in the farm. Record keeping is also required and records must be available if requested by the competent authorities. The Directive allows the Authorities to carry out random official checks without prior notice for the possession or presence of prohibited substances at any stage of the substance or animal production chain or where fraud is suspected. For these purposes, the Authorities may perform sampling and checks as required. Each Member State must designate at least one national reference laboratory for the purposes of this Directive, while the Community reference laboratories should be those referred in Reg. 882/2004. Official samples must be taken as described in the Directive and according to Commission rules. Also the procedure for authorisation of a veterinary medicinal product to be administered to a species intended for human consumption is laid down. Procedures are established for action in case test results prove positive, as well as for the restriction of animals from which samples were taken for analysis to leave the farm before the results have been obtained. Investigation must be carried out to determine the reason for non-compliance and measures must be implemented for the protection of public health. Any associated costs are the responsibility of the person in charge of these animals. In case of suspicion that a Member State does not carry out the controls required above, the Commission must be immediately notified.

The Directive also establishes measures for the unauthorised possession of unauthorised substances and the tasks of the official veterinarian. Where the use or manufacture of unauthorised substances is detected in a holding, its authorisation or official approval must be suspended or in case of repeated offence withdrawn.

In order for a country to be included in the list of approved countries for the import of animals and animal products a plan must be submitted, showing the guarantees for monitoring substances and their residues. Compliance must be verified through checks and if they reveal unauthorised use of substances or products, the Commission and the Member States must be informed and carry out checks in accordance with Reg. 882/2004. If non-compliance is confirmed, the authorisation of the third country must be suspended. The Commission must be assisted by the Standing Committee on the Food Chain and Animal Health. Finally, the details of the Annexes to the Directive may be amended after risk assessment relevant to the toxicity and likelihood of residues in food of animal origin.

Figure 21 shows the main requirements of Directive 96/23/EC. More detail on some of these requirements as well as additional information on related implementing measures is provided in Annex XIII.

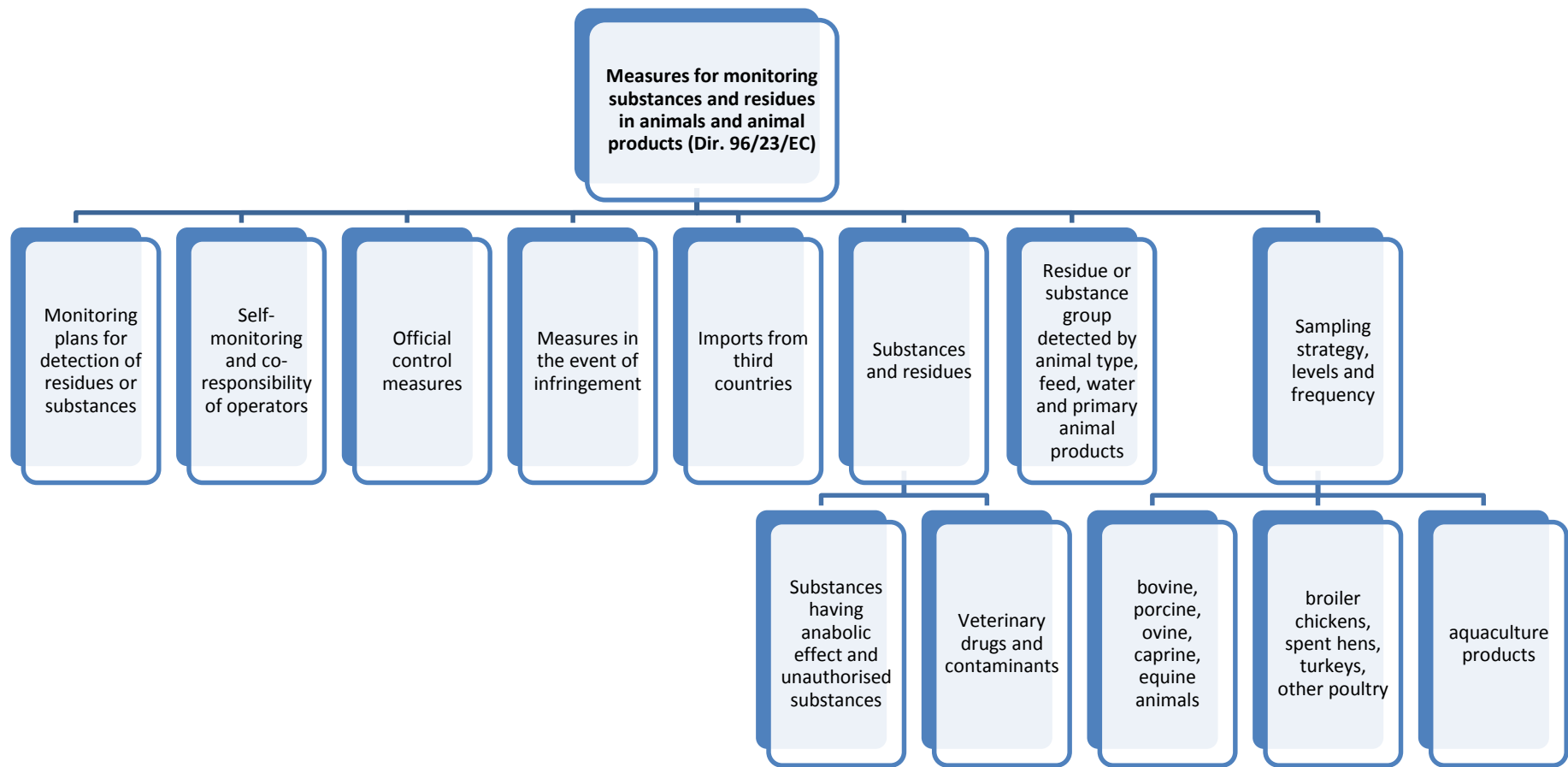


Figure 21: Main provisions of Directive 96/23/EC

4.2.4. Council Directive 96/22/EC concerning the prohibition on the use in stock-farming of certain active substances having a hormonal or thyrostatic action and of beta-agonists

Directive 96/22/EC²⁴ implements the prohibition or provisional prohibition of administration of certain substances in animals intended for human consumption as well as the prohibition of placing on the market animals treated with the above substances. The administration of substances such as progesterone or testosterone to farm animals for therapeutic purposes is permitted, provided it is performed by a veterinarian or for authorised veterinary medicinal products by a person under his responsibility and provided the information is registered in a register. Provisions are also laid down for the administration of substances to farm animals for zootechnical purposes or to aquaculture animals for the purpose of sex inversion. Specific prohibitions are established for the administration of hormonal products and the placement on the market of breeding and trade animals subjected to treatments.

The Directive also implements provisions for the import, storage, sale and use of chemical substances that fall within its scope. Specific prohibitions are also laid down for the import of farm and aquaculture animals as well as of meat and meat products from third countries where the use of certain substances is legally permitted. Finally the Directive requires the Commission to monitor and review the use of the substances of its Annex III and indicates that the use of oestradiol 17 β in animals intended for human consumption should be banned in Europe.

Figure 22 shows the main provisions of Directive 96/22/EC. More detail on some of these requirements as well as additional information on related implementing measures is provided in Annex XIV.

Figure 23 summarises the legal acts in the field of veterinary medicinal products and their residues in animals and foodstuffs of animal origin and on the prohibition of use in stock-farming of substances with certain effects.

²⁴ Council Directive 96/22/EC concerning the prohibition on the use in stock-farming of certain active substances having a hormonal or thyrostatic action and of beta-agonists and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (1996). Official Journal of the European Communities, L125/3

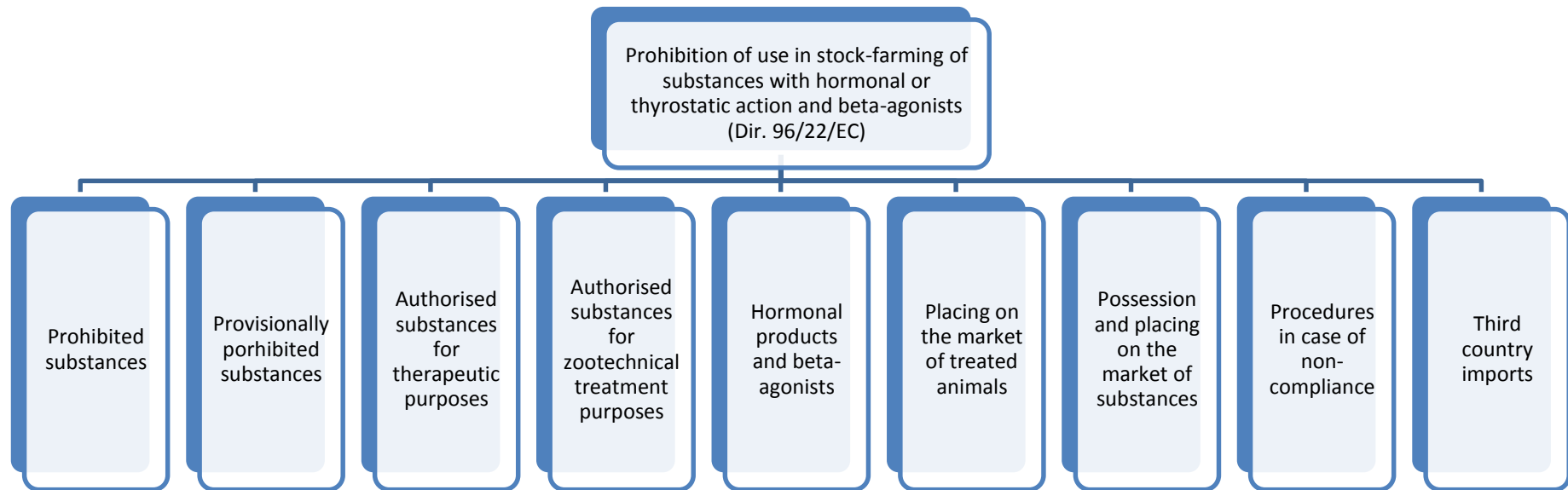


Figure 22: Main provisions of Directive 96/22/EC

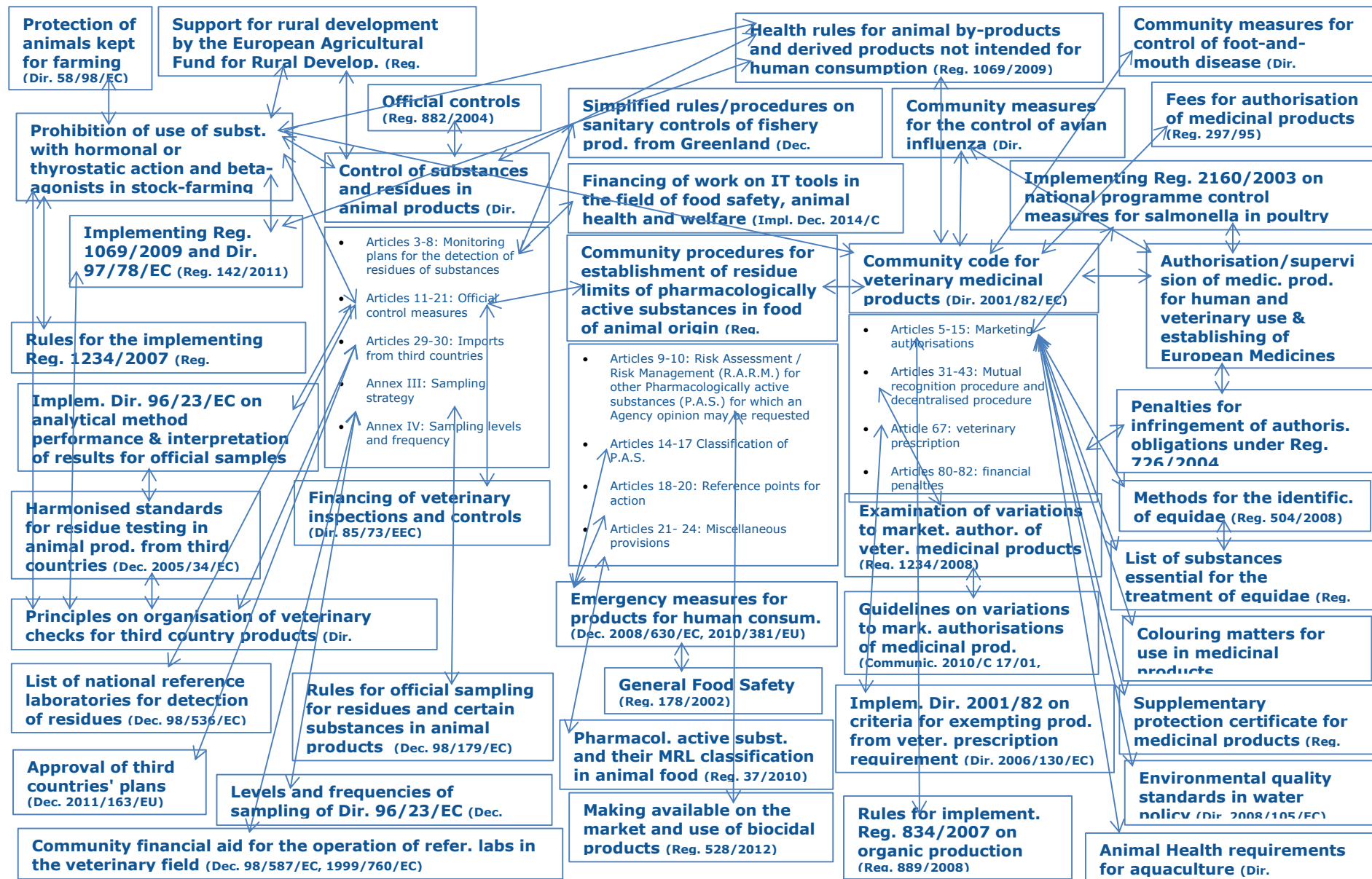


Figure 23: Summary of legislation on veterinary medicinal products, their residues and prohibition of use of certain substances in stock farming

5. Legislation related to the harvesting / slaughtering / fishing step of the food chain

5.1. Legislation on the hygiene of foodstuffs

The hygiene of foodstuffs is regulated by three main legal texts, known as the hygiene package. These are Regulations (EC) No 852/2004, 853/2004 and 854/2004 laying down requirements for the hygiene of foodstuffs, specific hygiene requirement for food of animal origin and rules for official controls on products of animal origin for human consumption respectively. These are summarised in Figure 24.

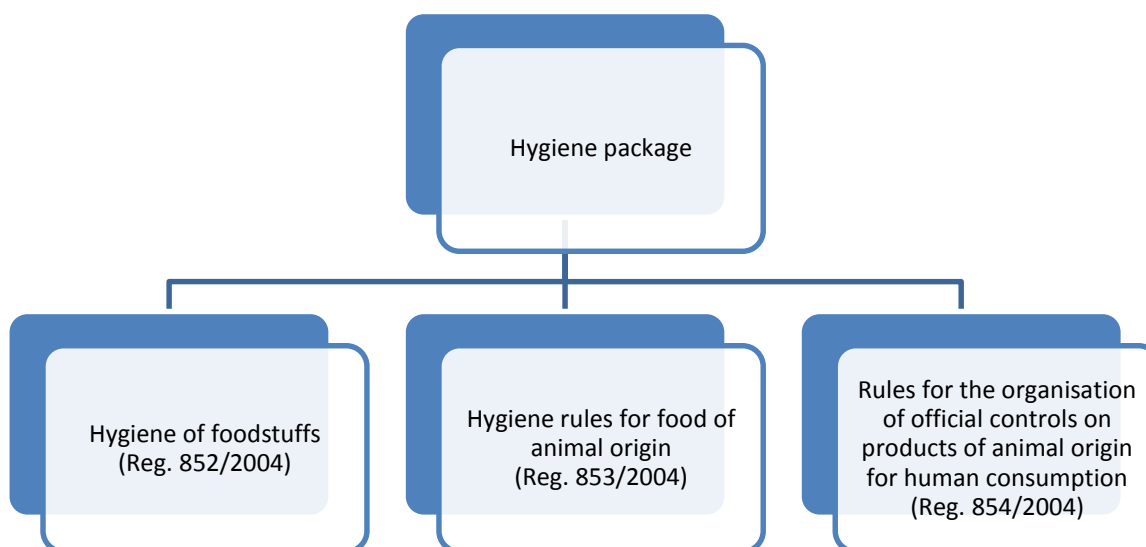


Figure 24: Main legislation related to the hygiene of foodstuffs

5.1.1. Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs

Regulation (EC) No 852/2004²⁵ lays down the general provisions on the hygiene of foodstuffs for the food business operators who are responsible for ensuring food safety at all stages of the food chain under Regulation (EC) No 178/2002. Regulation (EC) No 852/2004 applies to all stages in the food chain as well as to exports of foodstuffs, but excludes primary production for private use, or food prepared for domestic production or for limited supply directly to the consumer or local retail establishments. Figure 25 provides a graphical representation of the main content and requirements of Regulation (EC) No 852/2004.

²⁵ Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs (2004). Official Journal of the European Union, L204/26

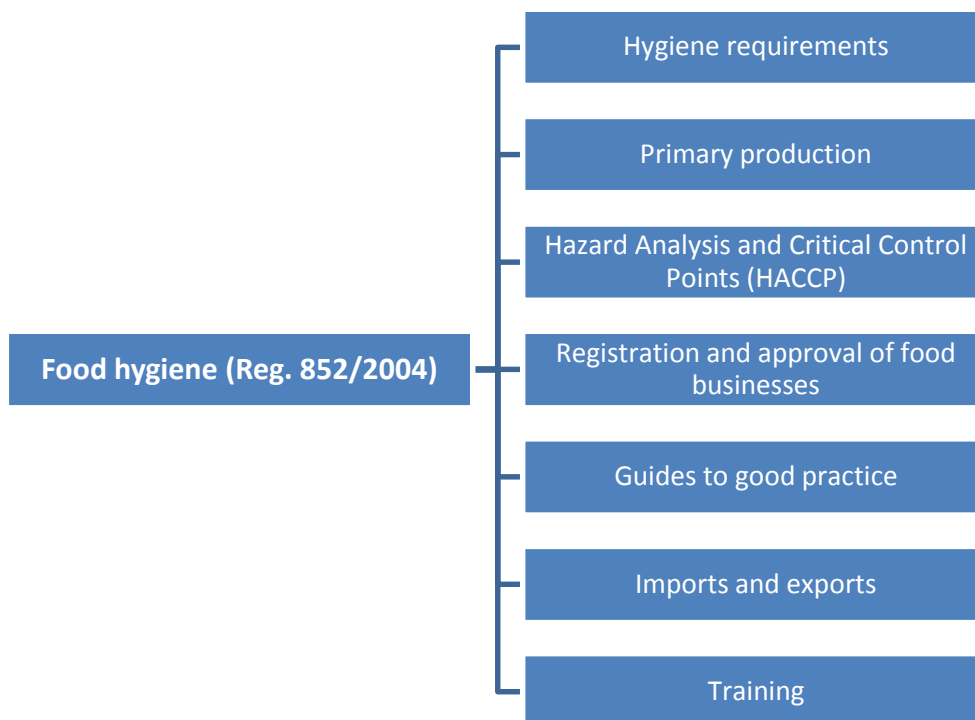


Figure 25: Summary of the requirements of Regulation 852/2004 on the hygiene of foodstuffs

According to Regulation (EC) No 852/2004 the specific hygiene measures for all food business operators are: the compliance with microbiological criteria, the establishment of procedures in order to meet the food hygiene requirements, the compliance with temperature control requirements, the maintenance of the cold chain and the requirement for sampling and analysis. Specific criteria, requirements and targets for these parameters as well as methods for the sampling and analysis for control purposes are established via other Regulations.

Regulation (EC) No 852/2004 requires food business operators to implement and maintain their procedures according to the principles of HACCP which are listed within the text of the Regulation. These procedures must be modified if there are modifications to the manufacturing process. It is also required that the food business operators provide evidence of implementation of the HACCP principles and that they maintain records of these procedures and any modifications, as these may be requested by the Authorities. Food business operators must notify their establishments to the Authorities which must be registered and approved.

Additional measures are established depending on the sector of operation. Food businesses operating in primary production must ensure the protection of primary products from contamination through the implementation of adequate control measures while different requirements are specified for the operators in primary production of plant or animal products. The maintenance of appropriate records for the control of different hazards is a requirement and they should be made available to the authorities upon inspection.

Similarly measures are also provided for food businesses that operate in the production, processing and distribution of food, which include requirements for the food premises, such as their layout, airflow, ventilation etc., as well as the actual rooms where food is

prepared with regards to their design and all their surfaces, but also for the utensils and equipment used. Requirements are also laid down for movable and temporary premises and vending machines, for conveyances and containers used for the transport of foodstuffs and for the equipment used in order to ensure it is free from contamination. Also provisions are established for the handling of food waste and for the supply and use of water depending on the application where it is used, as well as for steam, ice or treated water. The hygiene of personnel working in food-handling areas is also considered. Lastly provisions are laid down for the condition of raw materials and their storage, but also for the maintenance of the cold chain, the thawing of frozen products, the heat treatments and the packaging materials to be used and their storage. The training on food hygiene of the personnel working in food production is also established as a responsibility of the food business operator. Reference is also made to the cleaning and disinfection products and their storage in a food production environment.

The Regulation also lays down provisions for the preparation of guidance documents for practices that can be used to control hygiene hazards on national or European level. These are to be prepared according to specified guidelines and can be used on a voluntary basis. Community guides may also be prepared. An important requirement is that any guides should be practicable and take account of technological and scientific developments.

Regulation (EC) No 178/2002 on food law and food safety requires that food imported in the Community must meet the food law requirements of the Community, while similar requirements apply to food to be exported to third countries, unless otherwise required by the importing country. With regards to the hygiene of imported and exported food all the above requirements of Regulation (EC) No 852/2004 apply.

Finally, Regulation (EC) No 852/2004 allows for amendments to the hygiene requirements established if considered necessary due to technological and scientific developments, but also allows for the adoption of national measures under special conditions. Details on the procedure to be followed for notification of those national measures to the Commission and the other Member States are included.

More details on certain of the requirements of Regulation (EC) No 852/2004 and any related implementing measures can be found in Annex XV.

5.1.2. Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin

Regulation (EC) No 853/2004²⁶ lays down specific provisions on the hygiene of processed and unprocessed food of animal origin for food business operators, supplementing the rules of Regulation (EC) No 852/2004. It is intended to apply for wholesale activities rather than retail.

Regulation (EC) No 853/2004 prescribes that only potable water (or clean water) can be used to remove surface contamination from products of animal origin, unless otherwise provided by European legislation. Provisions are established for the registration and approval of establishments manufacturing animal products. In order to place products of animal origin on the market they must bear a health or identification mark which can only be applied for products that have been manufactured in accordance with the provisions of Regulations (EC) No 853/2004 and 854/2004. Products of animal origin

²⁶ Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene rules for food of animal origin (2004). Official Journal of the European Union, L139/55

may only be imported from third countries if they fully meet the requirements of Regulations (EC) No 852/2004, 853/2004 and 854/2004 and any additional Community legislation that may be in place for the import controls of such products. Food products that contain products of both plant and animal origin must also satisfy the above requirements for the animal product ingredients and the food business operators must be able to demonstrate compliance. Some special hygiene requirements for specific products originating from specific countries are also laid down.

The Regulation contains some final provisions for adaptation or amendments of the requirements for products of plant origin or other more specific requirements, in light of future needs. EFSA should be consulted for matters related to this Regulation that could have a significant impact on public health.

The following figure provides a graphical representation of the main content and requirements of Regulation (EC) No 853/2004 while details on these requirements and any related implementing measures can be found in Annex XVI.

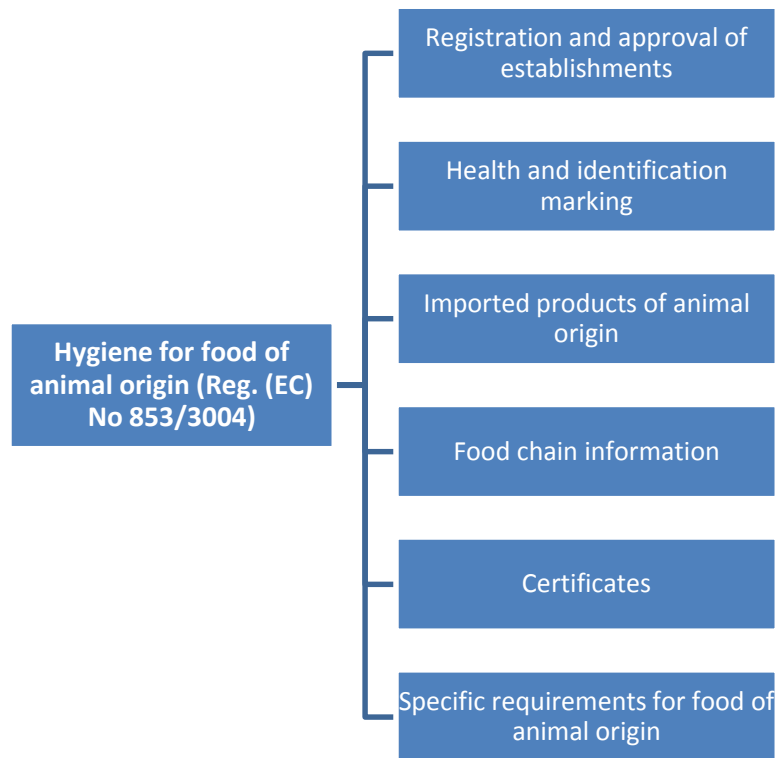


Figure 26: Summary of the requirements of Regulation (EC) No 853/2004 on the hygiene of food of animal origin

5.1.3. Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

Regulation (EC) No 854/2004²⁷ lays down specific provisions for the organisation of official controls on products of animal origin intended for human consumption and applies only to persons and activities to which Regulation (EC) No 853/2004 also applies. According to Reg. (EC) No 854/2004 establishments must be approved by the competent authorities and must be provided with an approval number. This applies for all establishments, either operating before the date of application of the Regulation or afterwards. Official controls must verify food business operators comply with the requirements of Regulations (EC) Nos: 852/2004, 853/2004 and 1774/2002 (repealed by Regulation (EC) No 1069/2009). For official control purposes, audits must be conducted to verify food business operators comply with the hygiene requirements and enforce HACCP-based procedures, but also with regards to the health mark application, traceability requirements and record-keeping. The Regulation also requires the development of lists of third countries approved for the import of certain animal products and of lists of approved establishments. All consignments of animal products imported in the Community must be accompanied by a certificate satisfying the requirements of Regulations (EC) No 852/2004, 853/2004 and 882/2004 and any other relevant Community legislation. The above provisions do not apply to fishery products that originate from fishing vessels from third countries, for which special provisions are established. Finally the Regulation lays down some transitional measures and allows for amendments and adaptations based on scientific progress. It also allows for certain exemptions as well as for the implementation of additional measures on national level by the Member States. For the fulfilment of the requirements of this Regulation, the Commission should be assisted by the Standing Committee on the Food Chain and Animal Health and when necessary consult EFSA. Finally the Regulation requires the Commission to submit a report on the experience gained from the application of this Regulation within 5 years of its enforcement.

Figure 27 provides a graphical representation of the main content and requirements of Regulation (EC) No 854/2004 while details for the implementation and additional requirements introduced by related legislative documents can be found in Annex XVII.

Figure 28 summarises the most important legal documents in the field of food hygiene and includes any legislation adding information to the main documents or assisting in the implementation of their requirements and their relationships.

²⁷ Regulation (EC) No 854/2004 of the European Parliament and of the Council on specific rules for the organisation of official controls on products of animal origin intended for human consumption (2004). Official Journal of the European Union, L204/26

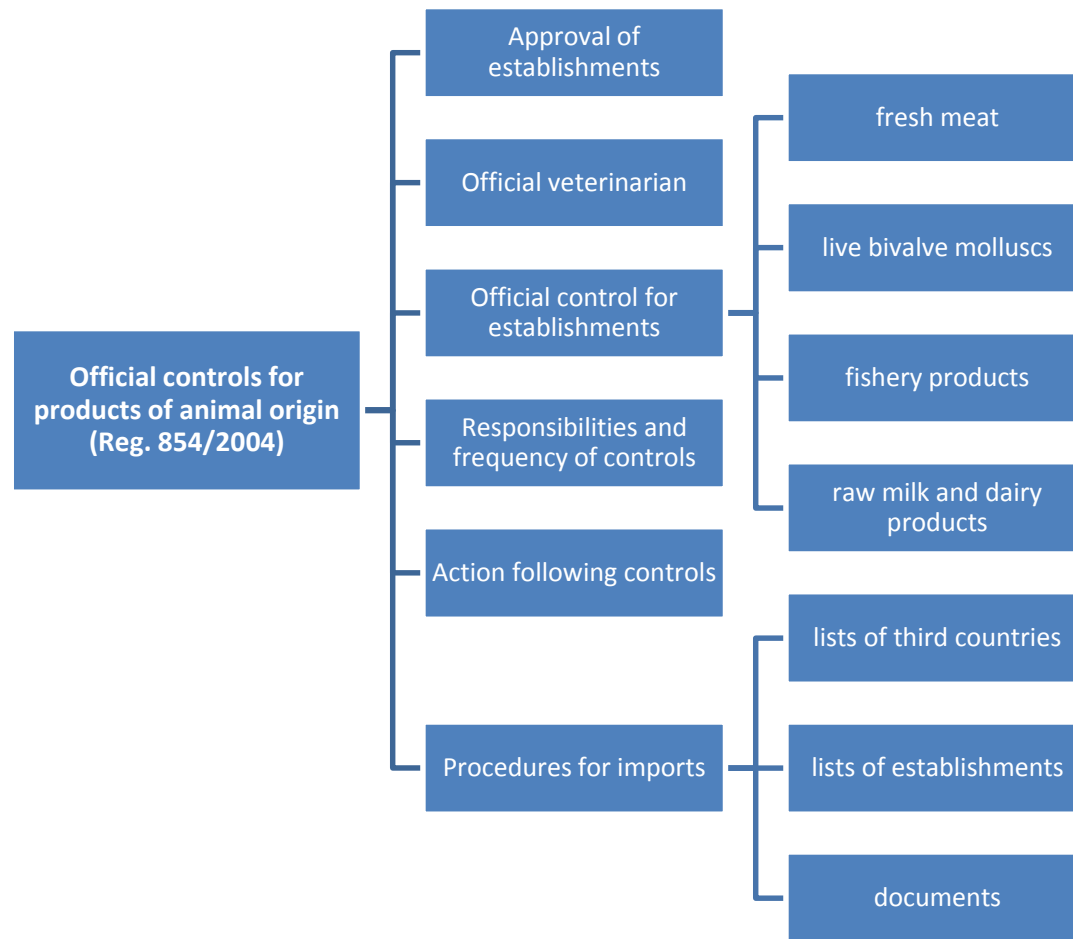


Figure 27: Summary of the requirements of Regulation (EC) No 854/2004 on the official controls for products of animal origin

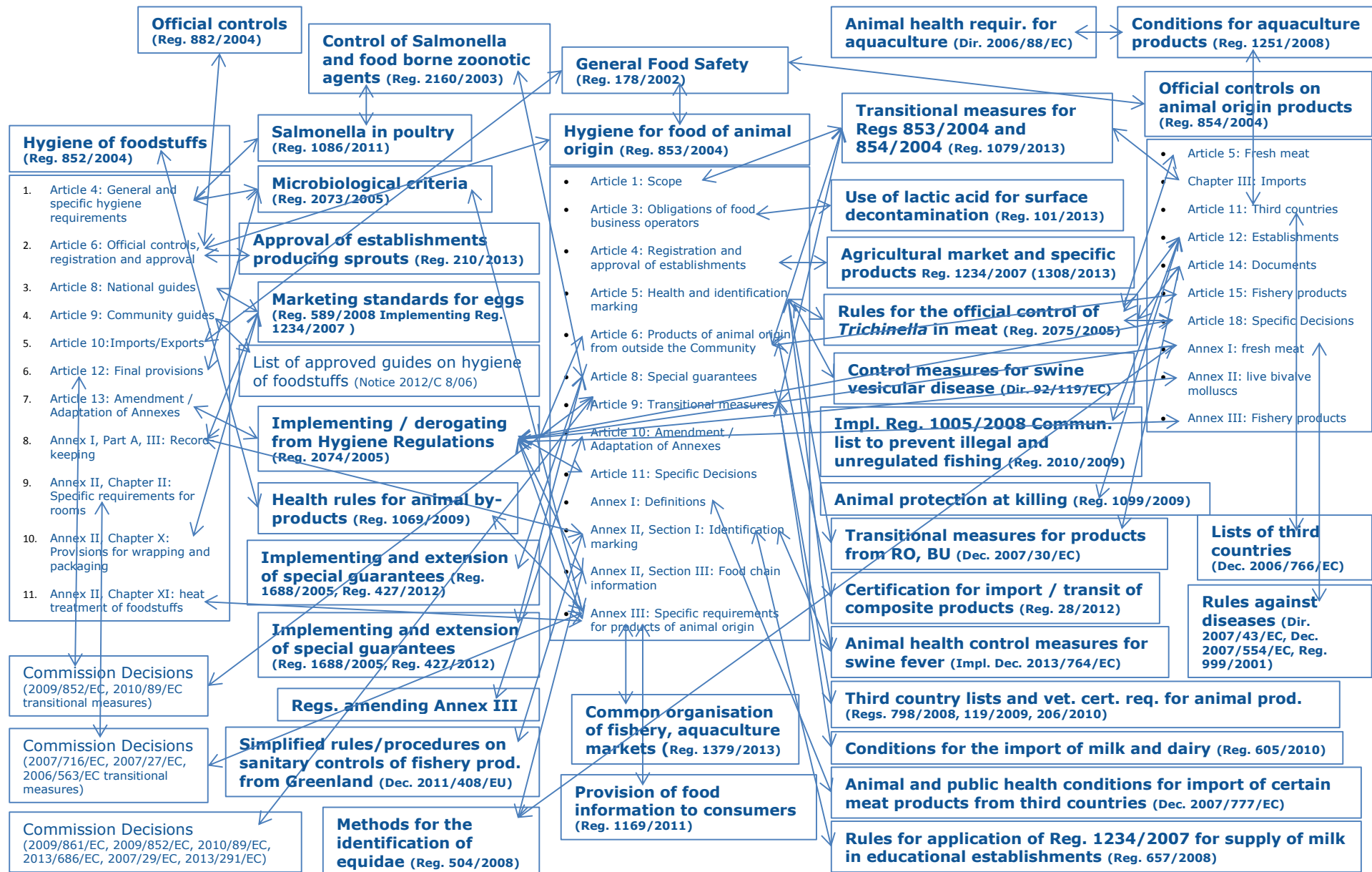


Figure 28: Summary of the legal documents in the field of food hygiene with additional implementation legislation and their relationships

5.2. Animal health rules for the production, processing, distribution and introduction of products of animal origin for human consumption

5.2.1. Council Directive 2002/99/EC – products of animal origin

Directive 2002/99/EC²⁸ establishes the general rules for animal health for the production, processing and distribution of products of animal origin in the Community, but also for their introduction from third countries. It must be ensured that food business operators prevent the spread of animal diseases. All products of animal origin must originate from establishments free from any animal diseases or animal health restrictions. Products from a territory where animal health restrictions apply may be authorised by Member States, provided they are not from an infected or suspected establishment, they have been handled, stored and transported separately from products that fully meet the animal health conditions and where conditions for the transport of restricted products are approved by the competent authority. These products need to undergo treatment to eliminate health risks related to meat and milk, they need to be clearly identified as products intended to be treated and the treatment must be in an establishment approved for that purpose. The Directive also provides for veterinary certificates for products intended for human consumption and for official controls to be carried out. Products may be imported from third countries only if they meet the above requirements. In order to ensure compliance, the Directive provides for the establishment of lists of third countries and of the products that may be imported from those. It also lays down the criteria to draw these lists. Products entering the Community market must be accompanied by a veterinary certificate. The Community may carry out inspections or audits in third countries during any of the stages covered by the above provisions.

A series of legal texts have been subsequently implemented under Directive 2002/99/EC and in particular Articles 8 and 9 on lists of approved third countries, special import conditions and certification documents. They are also directly related to the transitional measures established in the hygiene Regulations 852/2004, 853/2004 and 854/2004. More details can be found in Annex XVIII.

²⁸ Council Directive 2002/99/EC laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption (2002). Official Journal of the European Communities, L 18/11

5.3. Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

Regulation (EC) No 2073/2005²⁹ lays down microbiological criteria for foodstuffs and implementing rules for the food business operators. Compliance with the requirements of the Regulation must be verified by the competent authority according to the provisions of Regulation (EC) No 882/2004 on official controls.

Microbiological criteria are harmonised safety criteria for certain pathogenic micro-organisms and they give guidance on the acceptability of foodstuffs and their manufacturing, handling and distribution processes. Their use should be an integral part of HACCP-based procedures and hygiene control measures and could be used for the verification and validation of these procedures and measures. Food business operators must comply with the microbiological criteria through the control of raw materials, hygiene, temperature and shelf-life of their products and they must test and analyse samples according to the values established for the criteria and implement corrective action accordingly. For many foodstuffs there are not yet international guidelines for microbiological criteria established. The Commission has followed the Codex Alimentarius guideline "Principles for the establishment and application of microbiological criteria for foods CAC/GL 21 – 1997" as well as advice provided by the Scientific Committee on Veterinary Measures relating to Public Health and also the Scientific Committee on Foodstuffs.

Annex I of Regulation (EC) No 2073/2005 lays down the microbiological criteria to be met by the food business operators throughout the shelf-life of their products. These are categorised as food safety criteria and process hygiene criteria while rules are also established for sampling and preparation of the tests samples. Food business operators must perform testing against these criteria and they may decide the appropriate sampling frequencies according to the size of their business, unless it is established in the Annex in which case the one provided must be followed. Annex I of Regulation (EC) No 2073/2005 also provides analytical methods and sampling plans and methods which must be used as reference methods. Other sampling and testing procedures may be used as far as the food business operator can demonstrate to the competent authorities that they are at least equivalent to the ones provided. Alternative methods must also be validated against the reference method of Annex I and according to international standards and protocols and must be approved by the competent authority.

When the results of testing against the food safety microbiological criteria are unsatisfactory, the products concerned must be withdrawn or recalled according to the provisions of Reg. (EC) No 178/2002. In certain cases and if the products have not yet reached the market, they may be submitted for further processing in order to eliminate the hazard concerned, provided such procedures are already established in the HACCP plan and authorised.

Finally, the Regulation requires the food business operators to conduct studies in order to investigate the compliance of their products with the microbiological criteria established throughout the shelf-life of the products, in particular in the case of ready-to-eat foods that may support the growth of *Listeria monocytogenes* and may pose a risk to public health.

Figure 29 provides a graphical representation of the main content and provisions of Regulation (EC) No 2073/2005. Details on the implementation of the specific

²⁹ Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs (2005). Official Journal of the European Union, L 283/62

requirements introduced by the different Articles of the Regulation and any additional legislative acts adding information for these requirements can be found in Annex XIX.

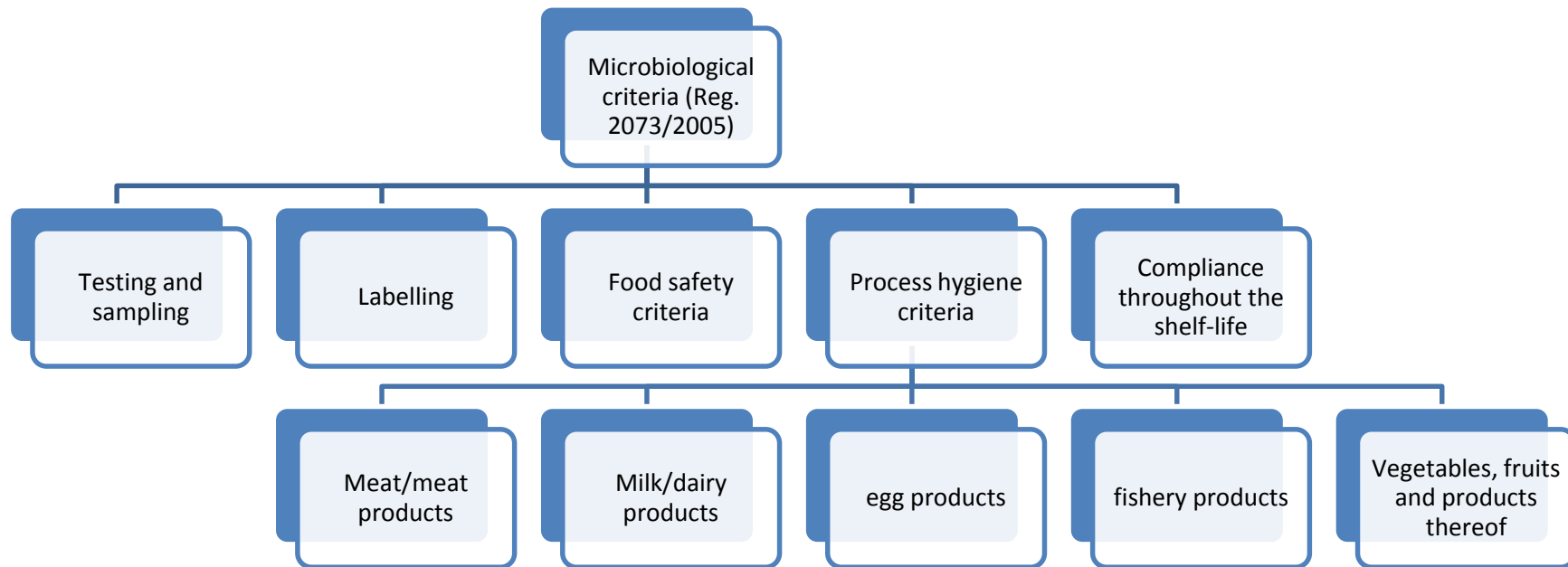


Figure 29: Summary of the provisions of Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs

5.4. Regulation (EC) No 2160/2003 on the control of Salmonella and other specified food-borne zoonotic agents

Regulation (EC) No 2160/2003³⁰ aims at ensuring that effective measures are in place for the detection and control of Salmonella and other zoonotic agents at all stages of production, processing and distribution, at primary production level and for feed in order to ensure adequate protection of public health. It covers the adoption of targets for the reduction of the prevalence of specific zoonoses in animals, the approval of specific control programmes in different Member States and by food business operators and the adoption of specific rules for control methods as well as for intra-Community trade and imports from third countries. The Regulation does not apply to private domestic use or to the direct supply of small quantities of primary products to the consumer, which is controlled at national level.

The Regulation requires the Member States to designate the competent authority for its purposes and to inform the Commission thereof and lays down the responsibilities of this authority. Detailed rules are provided on the procedure for the establishment of Community targets for the reduction of the prevalence of zoonoses and zoonotic agents and their specifications, taking into account the experience gained from national measures and also information provided by EFSA gained from existing Community measures. Also procedures are established for the timing of implementation of Community targets and for any amendments or modifications to those.

The Regulation also requires Member States to establish national control programmes for each zoonosis and zoonotic agent providing details for these control programmes and their content and to provide testing methods for the assessment of their results. Annex II provides the requirements and minimum sampling rules for the control programmes. Provisions are also laid down for the approval of national control programmes but also for control programmes established by food business operators who wish them to form part of national control programmes.

The Regulation also allows for the application of specific control methods for the reduction of zoonoses or zoonotic agents at primary production of animals or at other stages. Also provisions are laid down for the testing of flocks and herds of certain species for zoonoses and zoonotic agents for intra-Community trade as well as for imports from third countries. The Commission shall be assisted by the Food and Veterinary Office (FVO) for the verification of equivalence of the controls programmes in place in third countries resulting in the admission and retention of these countries in the lists of approved countries. The Regulation requires the Commission to designate appropriate reference laboratories for the testing and analysis for specific zoonoses and zoonotic agents and lay down their responsibilities and tasks. These laboratories must apply quality assurance schemes according to the requirements of the current EN/ISO standards and must participate in collaborative testing. The Commission shall be assisted by the Standing Committee for the Food Chain and Animal Health and shall consult EFSA.

The following figure provides a graphical representation of the main content and requirements of Regulation (EC) No 2160/2003. More detailed information on the basic requirements of this Regulation as well as on additional legislative documents adding information and assisting in the implementation of these requirements can be found in Annex XX.

³⁰ Commission Regulation (EC) No 2160/2003 on control of Salmonella and other specified food-borne zoonotic agents (2003). Official Journal of the European Union, L 325/1

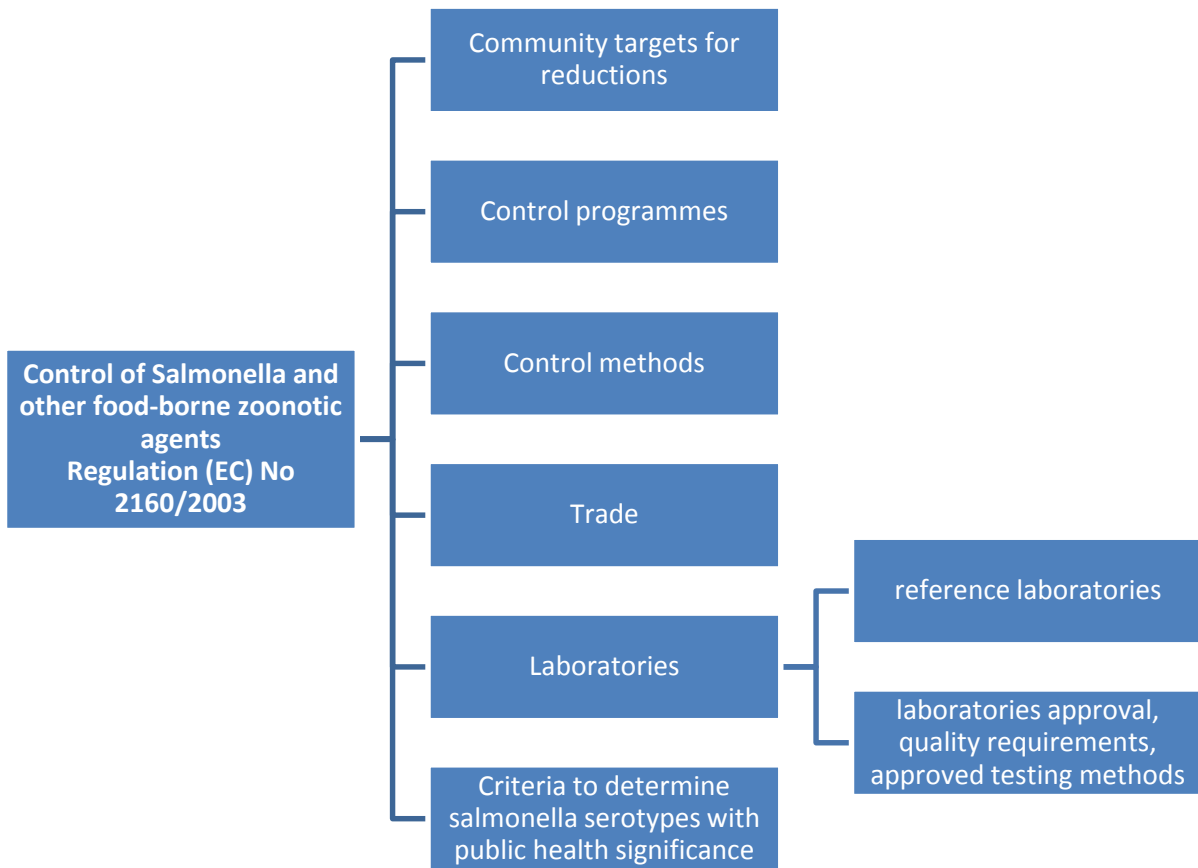


Figure 30: Summary of the provisions of Regulation (EC) No 2160/2003 on the control of Salmonella and other food-borne zoonotic agents

5.5. Directive 2003/99/EC of the European Parliament and of the Council on the monitoring of zoonoses and zoonotic agents

Directive 2003/99/EC³¹ aims to ensuring the appropriate monitoring of zoonoses, zoonotic agents and related antimicrobial resistance, as well as at the epidemiological investigation of food-borne outbreaks, in order to allow the Community to evaluate relevant trends and sources. It details the provisions for Member States to collect, analyse and communicate any relevant data. Member States must also designate a competent authority tasked with notifying the Commission on issues related to this Directive, but also with cooperating closely with other competent authorities.

The Directive lays down the rules on the monitoring of zoonoses and zoonotic agents across all stages of the food chain and lays down the relevant duties of the food business operators, but also establishes the possibility for the organisation of coordinated monitoring programmes in case routine monitoring data are not sufficient for the purposes of this Directive.

Directive 2003/99/EC also implements the monitoring of antimicrobial resistance according to the requirements of its Annex II for the generation of comparable data. It also lays down the procedure for the epidemiological surveillance of food-borne outbreaks. Final requirements are established for the exchange of information between Member States and the Commission on the subjects covered, the designation and coordination of Community and national reference laboratories within the scope of the Directive and the requirement for the Commission to consult EFSA for any related matter.

Figure 31 provides a graphical representation of the main content and requirements of Directive 2003/99/EC. More detailed information on the basic requirements of this Directive as well as on additional legislative acts that add implementing information to these requirements can be found in Annex XXI.

³¹ Directive 2003/99/EC of the European Parliament and of the Council on the monitoring of zoonoses and zoonotic agents amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (2003). Official Journal of the European Union, L 325/31

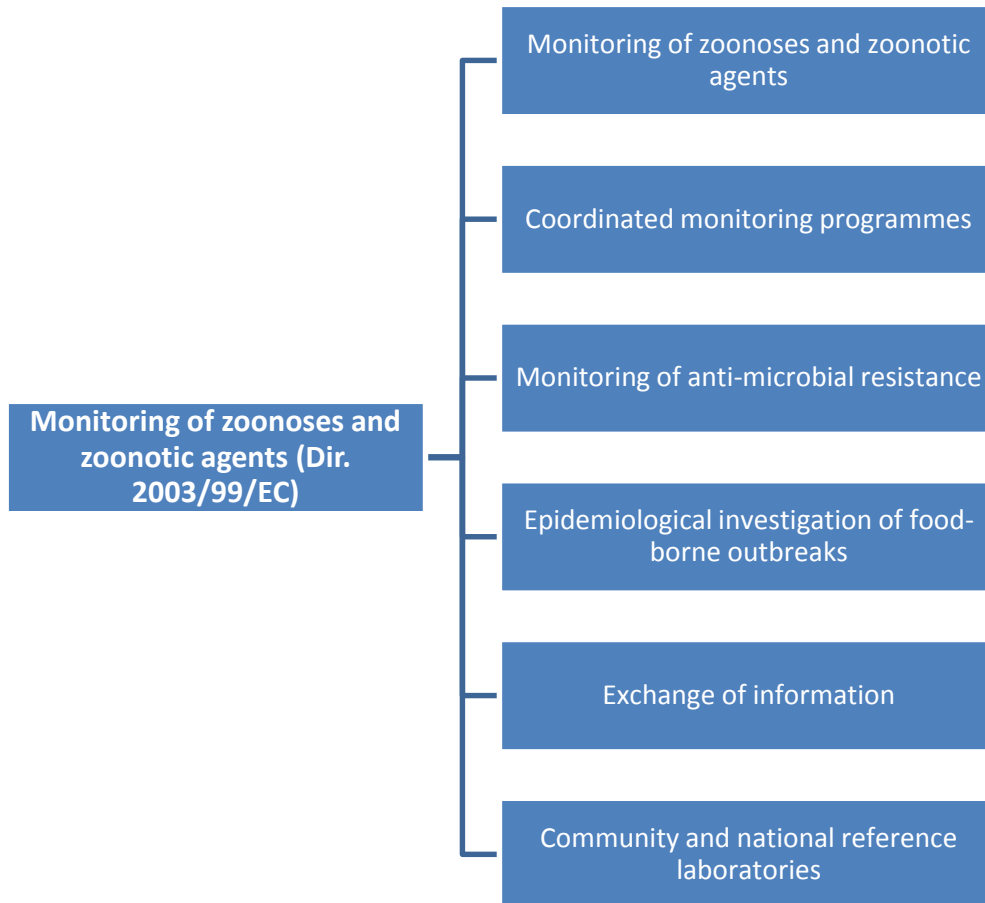


Figure 31: Summary of the requirements of Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents

Figure 32 summarises the most important legal documents in the field of microbiological criteria for foodstuffs, control of food-borne zoonotic agents and of monitoring of zoonoses, zoonotic agents and antimicrobial resistance and provides the cross-links between this documents.

6. Legislation related to the manufacturing step of the food chain

6.1. Food improvement agents

6.1.1. Regulation (EC) No 1331/2008 on a common authorisation procedure for food additives, enzymes and flavourings

Regulation (EC) No 1331/2008 lays down a common procedure for the assessment and authorisation of food additives, enzymes and flavourings aiming to assist the free movement of food and ensure the protection of human health and consumer interests. Approved substances are included in Community lists which must be published and updated. The common procedure for updating such lists can be initiated either by Community initiative or after a request of any Member State or interested party. The Commission may consult EFSA during the procedure. The common procedure ends with the adoption of a Regulation implementing the update by the Commission, unless the Commission decides that such an update is not justified.

Regulation (EC) No 1331/2008 describes in detail the procedure to be followed, establishes timelines for the different steps and procedures for urgent situations. It highlights the principle of transparency in the activities of the Authority and lays down provisions for the confidentiality of certain data.

6.1.2. Regulation (EC) No 1333/2008 on food additives

Regulation (EC) No 1333/2008 lays down requirements for food additives, substances not normally consumed as food themselves but added to food intentionally to serve a technological purpose, thus resulting in their presence as components of the food. The Regulation provides for lists of approved food additives, conditions for their use in food or within food additives, food enzymes and food flavourings and lays down rules for the labelling of food additives intended for sale. It also lists products that are not considered as food additives and defines processing aids.

Food additives or foods containing food additives must not be placed on the market if they do not comply with the provisions of the Regulation. Additives are included in the Community lists if it can be demonstrated that, at their level of use, they do not pose any risk to consumer health, they are necessary for specific technological functions for which there are no alternatives and their use does not mislead the consumer. Some specific conditions for the use of certain additives, sweeteners and colours are also laid down.

Depending on the principal technological function they serve, food additives are categorised in certain functional classes which are laid down in Annex I of the Regulation. Additives however may be used for more than one function. For the additives included in the Annexes to the Regulation the Community list must also specify their name and E number, the foods in which they may be added and the conditions of use and whether there are any restrictions in their sale to the consumer. Levels of use must generally be established at the lowest possible level to achieve the intended function and must consider any acceptable daily intake established or for specific consumer groups. Certain food additives may be used according to the principle of *quantum satis*, meaning in accordance with good manufacturing practice and at a level no higher than necessary

to achieve the intended purpose and without misleading the consumer. Also special provisions are laid down for the prohibition of use of certain additives in specific traditional food products in certain Member States.

The Regulation establishes that food additives manufactured in significantly different ways than the one of the original entry of the food additive in the list of the Regulation must be considered as new additives and new entries will be required. Food additives must not be used in unprocessed foods or in foods for infants and young children, unless specifically provided for. The Regulation also allows for the presence of certain food additives in compound food products, where their presence is permitted in one of their ingredients and they have been carried to the final products through those ingredients and provided they have no function in the finished product (carry-over principle). Finally the Regulation lays down rules for the labelling of food additives intended for sale to the final consumer or not, as well as for products that contain food colours.

The Regulation requires producers and users of food additives to inform the Commission with regard to new information on the safety of food additives. Also Member States are required to monitor the consumption and use of food additives and inform the Authority and the Commission.

Figure 33 provides a graphical representation of the main content and requirements of Regulation (EC) No 1333/2008. More details on legislation adding information for the implementation of this Regulation can be found in Annex XXII.

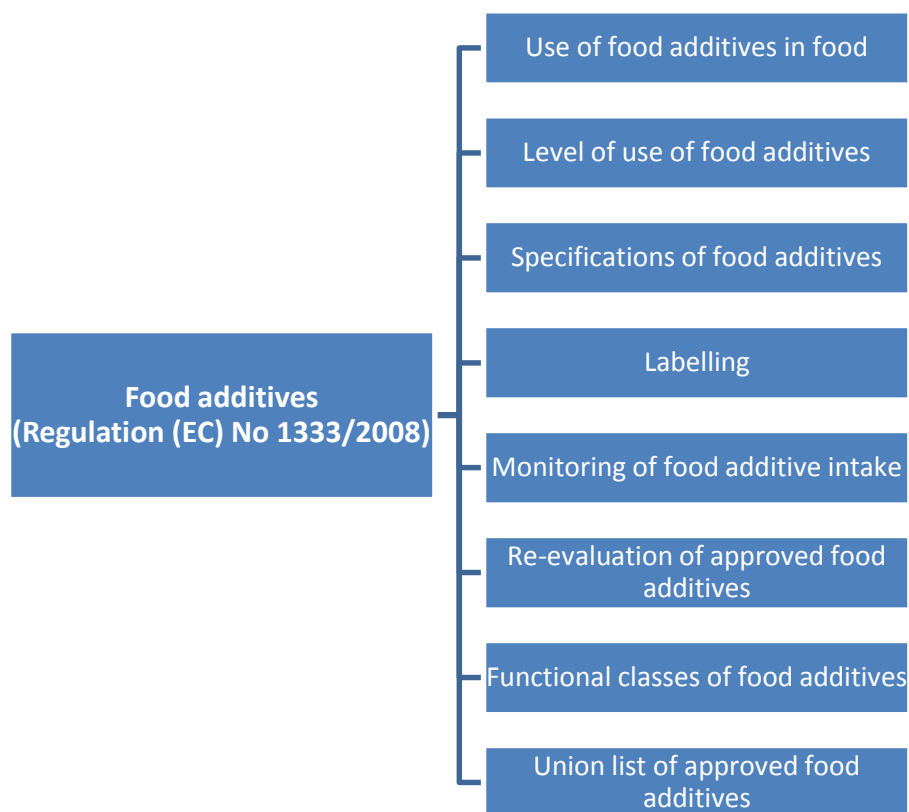


Figure 33: Summary of the requirements of Regulation (EC) No 1333/2008 on food additives

6.1.3. Regulation (EC) No 1332/2008 on food enzymes

Regulation (EC) No 1332/2008 on food enzymes covers enzymes used in food and those used as processing aids and establishes a Community list of approved enzymes, the conditions of use of enzymes in food and rules for their labelling when sold as such. Enzymes used in the manufacture of food additives or processing aids are excluded from the scope of this Regulation as well as microbial cultures used in the production of food that may produce enzymes. Enzymes that do not comply with the provisions of this Regulation or food containing such enzymes may not be placed on the market. The Regulation also lays down conditions for the inclusion of enzymes in the Community list: they pose no safety concern to consumer health, there is a reasonable technological need for their use and they do not mislead the consumer. The details that need to be included in the Community list for each approved additive are also listed.

The Regulation also lays down details on the labelling of food enzymes and food enzyme preparations intended or not for sale to the final consumer. The producers or users of food enzymes are required to inform the Commission of any scientific and technical information relevant to the safety assessment of food enzymes, of any changes in the production method or starting materials used, or of the actual use of the enzyme.

Figure 34 provides a graphical representation of the main content and requirements of Regulation (EC) No 1332/2008. Details of legislation adding implementation information to the Regulation can be found in Annex XXIII.

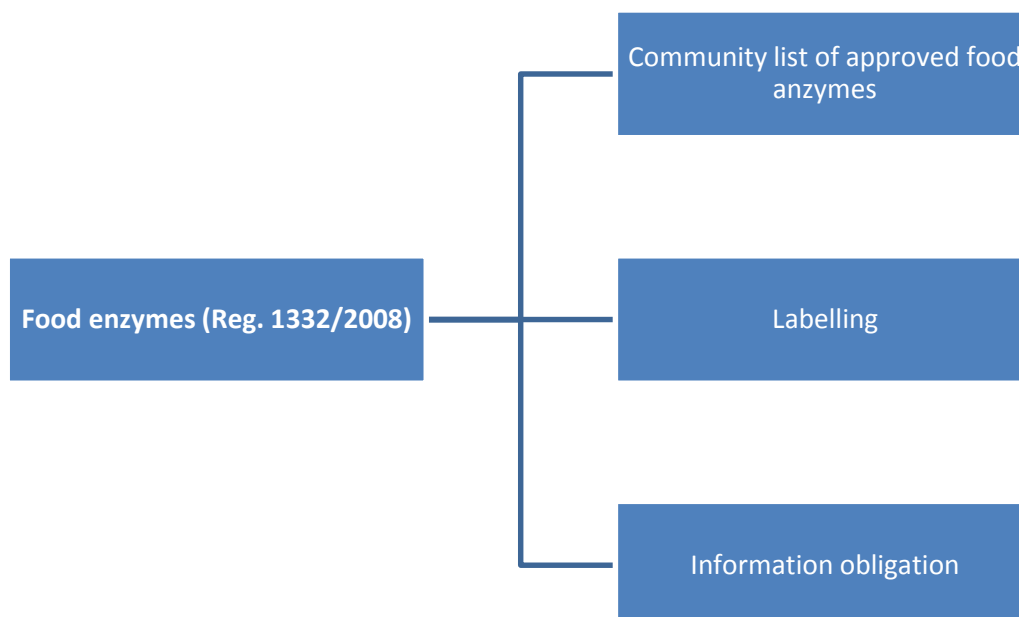


Figure 34: Summary of the provisions of Regulation (EC) No 1332/2008 on food enzymes

6.1.4. Regulation (EC) No 1334/2008 on food flavourings

Regulation (EC) No 1334/2008 establishes a list of approved flavourings and source materials for their production, conditions for their use in food and rules on the labelling

of flavourings. Definitions are laid down for flavourings, flavouring substances, natural flavouring substances, flavouring preparations, thermal process flavourings, smoke flavourings, flavour precursors and other flavourings. Flavourings may only be used in food if they do not pose any safety risk and their use does not mislead the consumer.

Annex III to the Regulation lays down a list of substances which must not be added as such to food. Also the same Annex lists maximum levels for certain naturally present substances in flavourings and food ingredients with flavouring properties in compound foods to which flavourings or ingredients with flavouring properties have been added. Annex IV lays down a list of source materials which must not be used for the production of flavourings or food ingredients with flavouring properties and a list of source materials that may be used but the flavourings or food ingredients with flavouring properties produced from those must meet the conditions specified in the Annex. Also the Regulation lays down a list of flavourings and food ingredients with flavouring properties for which an evaluation is not required, provided they are safe and not misleading.

The Regulation also specifies flavourings and source materials for the use of which an evaluation and approval is required in accordance with Reg. (EC) No 1331/2008. Those approved must be included in the Community list of flavourings and source materials and their use must conform to the conditions specified therein.

Specific provisions are established for the use of the term "natural" for the description of flavourings in different contexts and finally for the labelling of flavourings for sale directly to the final consumer.

Regulation (EC) No 1334/2008 establishes the requirement for producers and users of flavourings to inform the Commission of the amounts and substances they use. Also production methods for flavourings significantly different from the one originally included in the risk assessment must be communicated to EFSA as well as any new scientific and technical knowledge that may affect the safety assessment of flavouring substances.

Member States must establish systems to monitor the consumption and use of flavourings and of restricted substances included in the Regulation and a common methodology must be adopted for gathering this information.

Figure 35 provides a graphical representation of the main content and requirements of Regulation (EC) No 1334/2008 while details on legislation related and adding to certain of the requirements of this Regulation can be found in Annex XXIV.

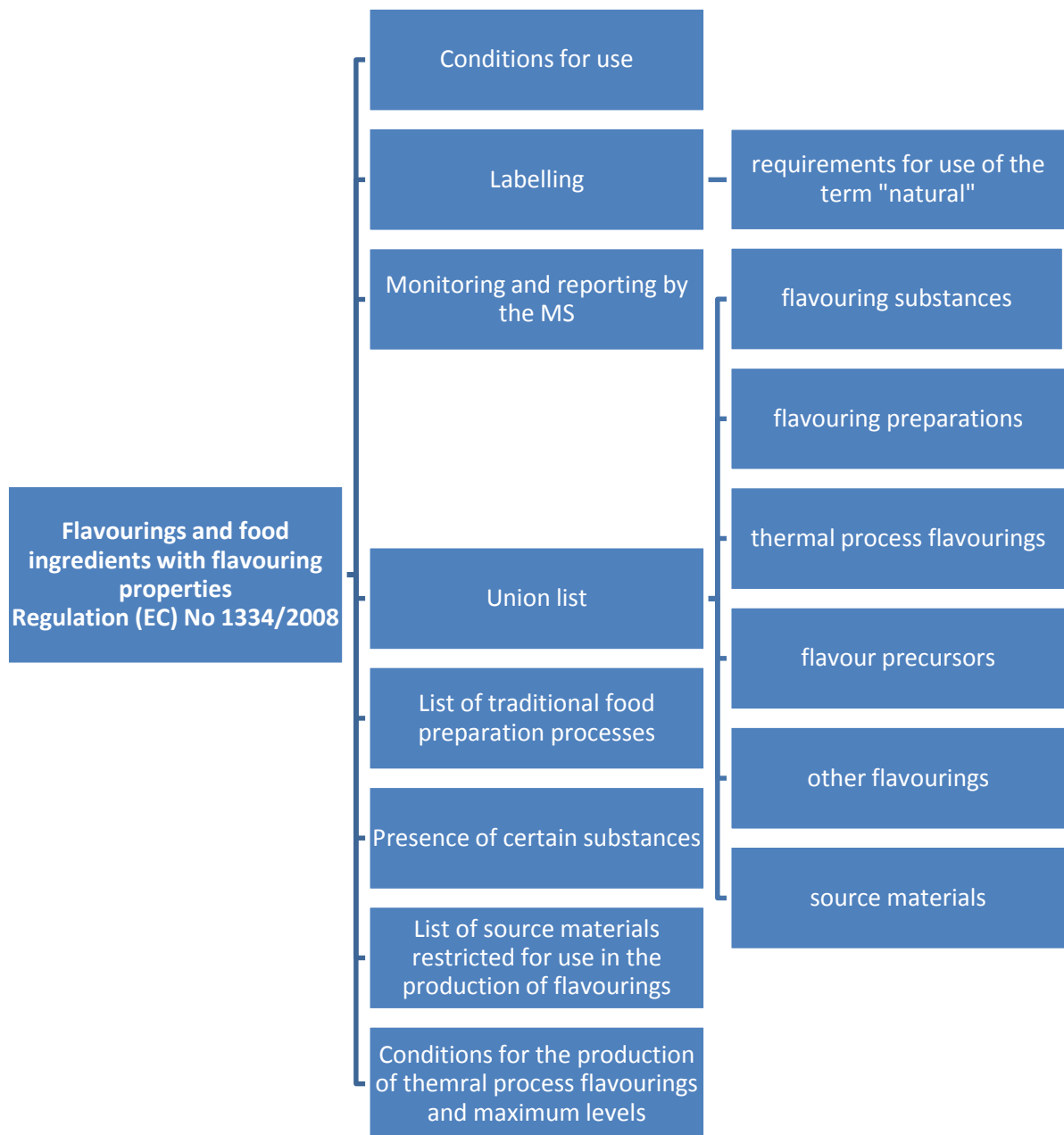


Figure 35: Summary of the provisions of Regulation (EC) No 1334/2008 on flavourings and food ingredients with flavouring properties

6.1.5. Regulation (EC) No 2065/2003 on smoke flavourings

Regulation (EC) No 2065/2003 lays down the Community procedure for the evaluation and authorisation of primary smoke condensates and primary tar fractions for use in or on foods or for the production of smoke flavourings as well as the procedure for the establishment of Community lists of the above substances and the conditions for their use in food.

The Regulation lays down the safety requirements for smoke flavourings as well as the conditions for their production. It implements the establishment of a Community list of authorised primary products and the procedure for such an authorisation. The Regulation also lays down certain responsibilities for the food business operators that place smoke flavourings on the market.

The below figure provides a graphical representation of the main content and requirements of Regulation (EC) No 2065/2003. Details on additional legislation laying down implementing measures for certain of the requirements of the Regulation can be found in Annex XXV.

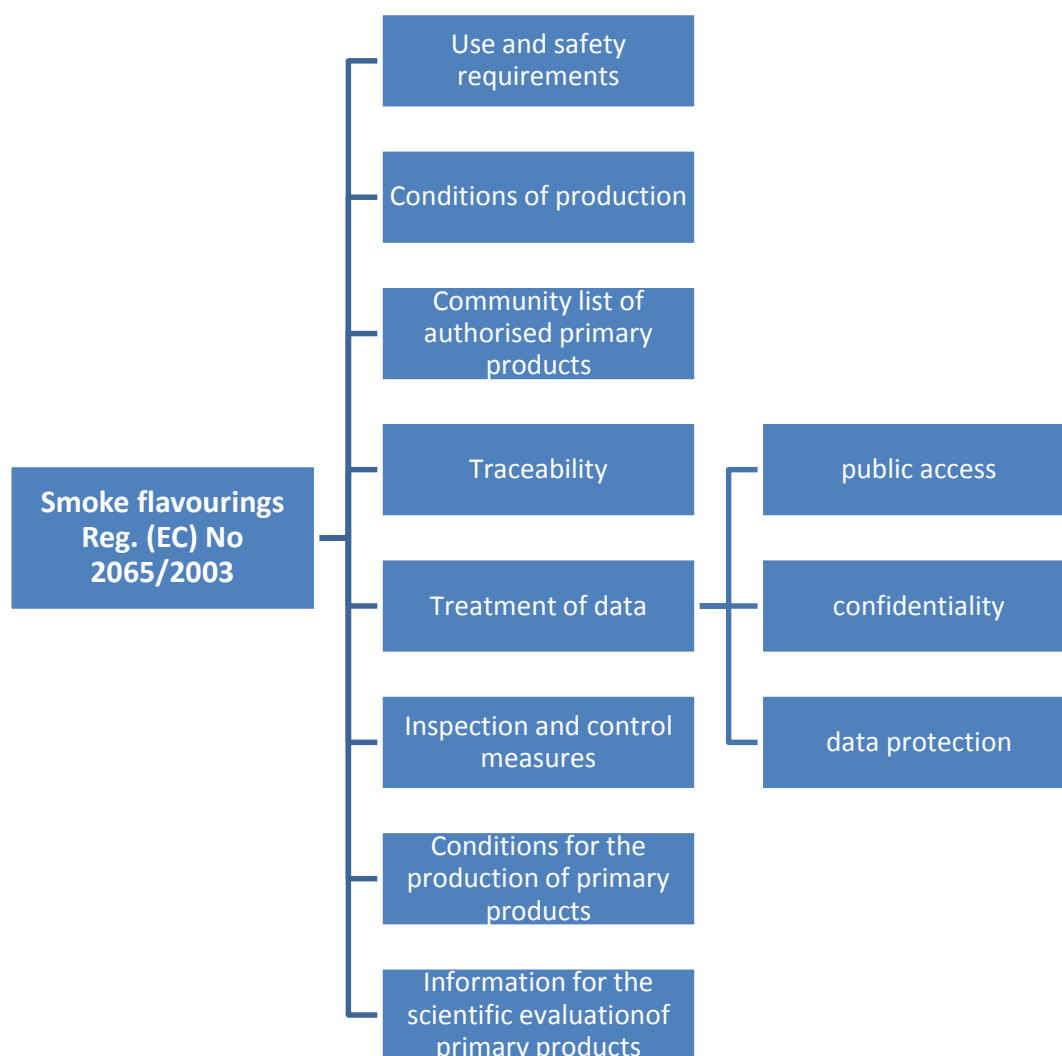


Figure 36: Summary of the provisions of Regulation (EC) No 2065/2003 on smoke flavourings used or intended to be used in or on food

6.1.6. Directive 2009/32/EC on extraction solvents used in the production of foods and food ingredients

Extraction solvents used for the production of food additives, vitamins and nutritional additives are excluded from the scope of this Directive, unless included in its Annex I. The substances listed in Annex I must be authorised in the Member States under the conditions of use and maximum limits specified within the Annex. However, Member States must not authorise other substances, nor extend the conditions of use or residues authorised.

The Directive also specifies purity criteria for the authorised extraction solvents of Annex I and requires the establishment of Community procedures for the amendment of this Annex and of methods of analysis to ensure compliance with its requirements. Specific details are also provided on the information that must be indicated on the packaging and containers of extraction solvents for use in foodstuffs. Also the Directive applies to extraction solvents used in the production of foodstuffs to be imported in the Community. Figure 37 summarises the basic requirements of Directive 2009/32/EC.

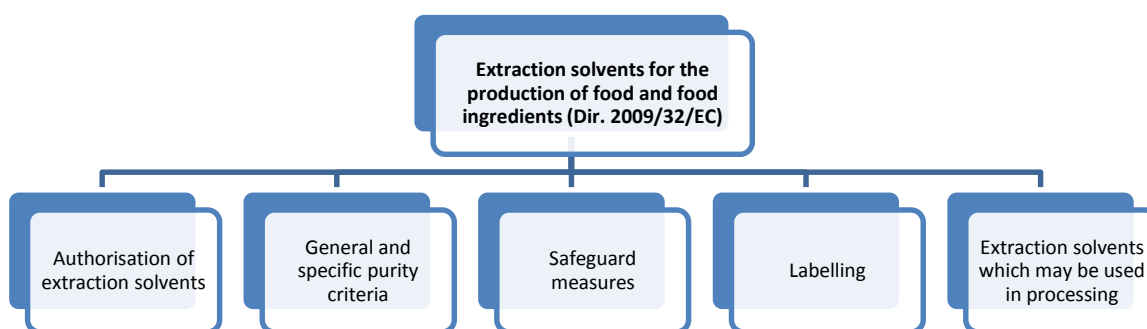


Figure 37: Summary of the provisions of Directive 2009/32/EC on extraction solvents for the production of food and food ingredients.

The following figure summarises the most important legal documents in the field of chemical food additives, food enzymes and food flavourings and their inter-relationships.

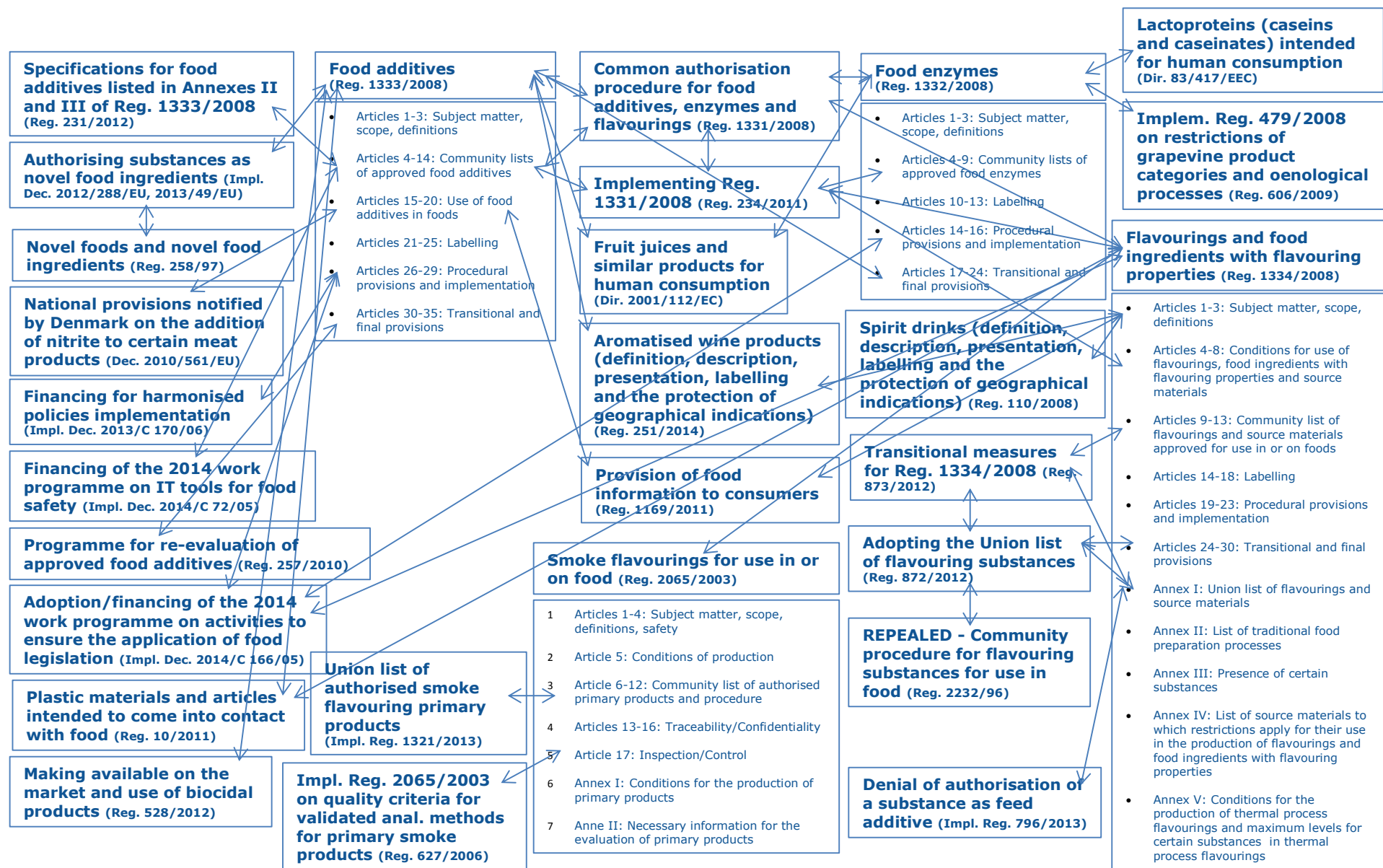


Figure 38: Summary of the most important legal documents in the field of food additives, food enzymes and food flavourings

6.2. Contaminants

6.2.1. Council Regulation (EEC) No 315/93 laying down Community procedures for contaminants in food

Regulation (EEC) No 315/93 lays down Community procedures for contaminants in food. The Regulation is aimed to cover any substance present in food as a result of the production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding of food or as a result of environmental contamination, while extraneous matter that can be present in food is excluded from the scope.

Contaminant levels in food must be kept as low as can be reasonably achieved (ALARA) by using good practices in all the above stages of manufacturing or related processes, while food containing contaminants at levels that are considered not acceptable must not be placed on the market. The Regulation requires the establishment of limits for different contaminants in different foodstuffs as well as methods for the sampling and analysis for such substances and detection limits. Any product that complies with these provisions must not be restricted from placement on the market for any reason.

Figure 39 provides a graphical representation of the main content and requirements of Regulation (EEC) No 315/93, while more detailed information on legislative documents adding implementing information to the above Regulation is provided in Part I of Annex XXVI.

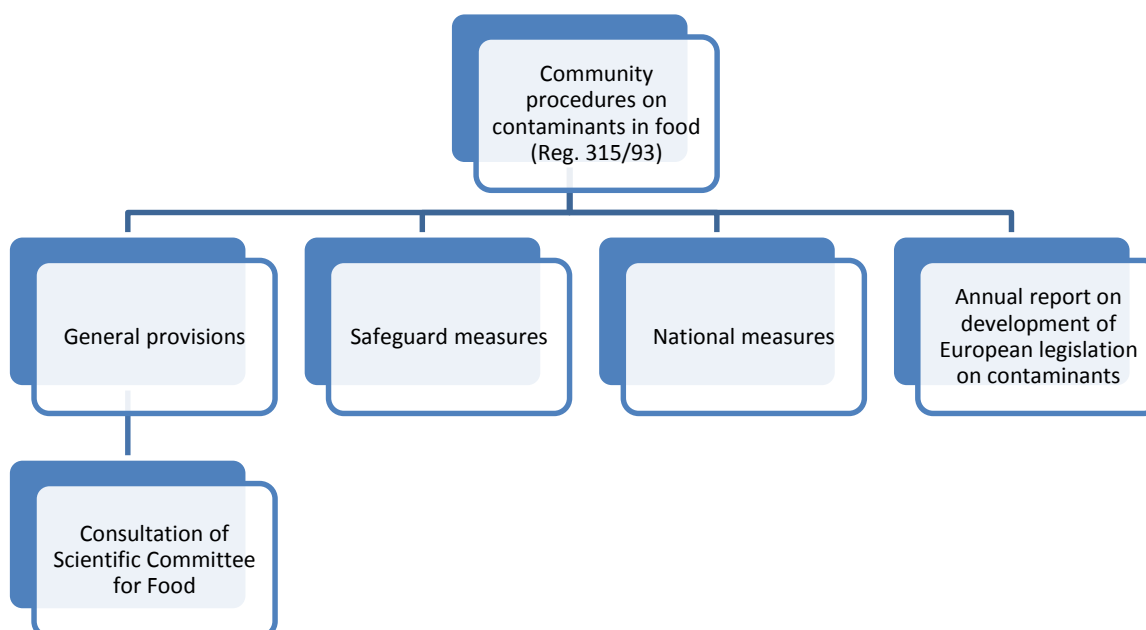


Figure 39: Summary of the requirements of Regulation (EEC) No 315/93 on Community procedures for contaminants in food

6.2.2. Commission Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs

Regulation (EC) No 1881/2006 lays down maximum levels for certain contaminants in foodstuffs. In order to protect public health, contaminants must be kept at levels that are toxicologically acceptable. These maximum levels are strict but reasonably achievable when following good practices and take into account the risk from consuming the food. For contaminants that are genotoxic carcinogens and the exposure of populations is close to or exceeds the tolerable daily intake, maximum levels are established under the principle of "as low as reasonably achievable" (ALARA). These measures ensure that food business operators take measures to prevent and reduce contamination. The Regulation lays down maximum levels for certain contaminants in different foodstuffs and products that exceed these levels must not be placed on the market. These maximum levels must be applied taking into consideration concentration changes due to drying, dilution, relative proportions of ingredients but also considering the analytical limit of quantification. Specific concentration or dilution factors must be applied by the operators, which must also be available to the authorities for inspection.

When foodstuffs do not comply with the maximum levels established, they must not be used as food ingredients, they must not be mixed with foodstuffs that meet the maximum levels or that are intended for sorting or other physical treatment and they must not be detoxified by chemical treatments. Sampling and analysis must be performed according to specific Commission provisions. Member States have the obligation to monitor contaminant levels in different products and communicate these to EFSA and they must report on the results of applying different prevention measures for different contaminants.

Figure 40 provides a graphical representation of the main content and requirements of Regulation (EC) No 1881/2006. More detailed information on legislation related and adding to the main requirements of this Regulation can be found in Part II of Annex XXVI.

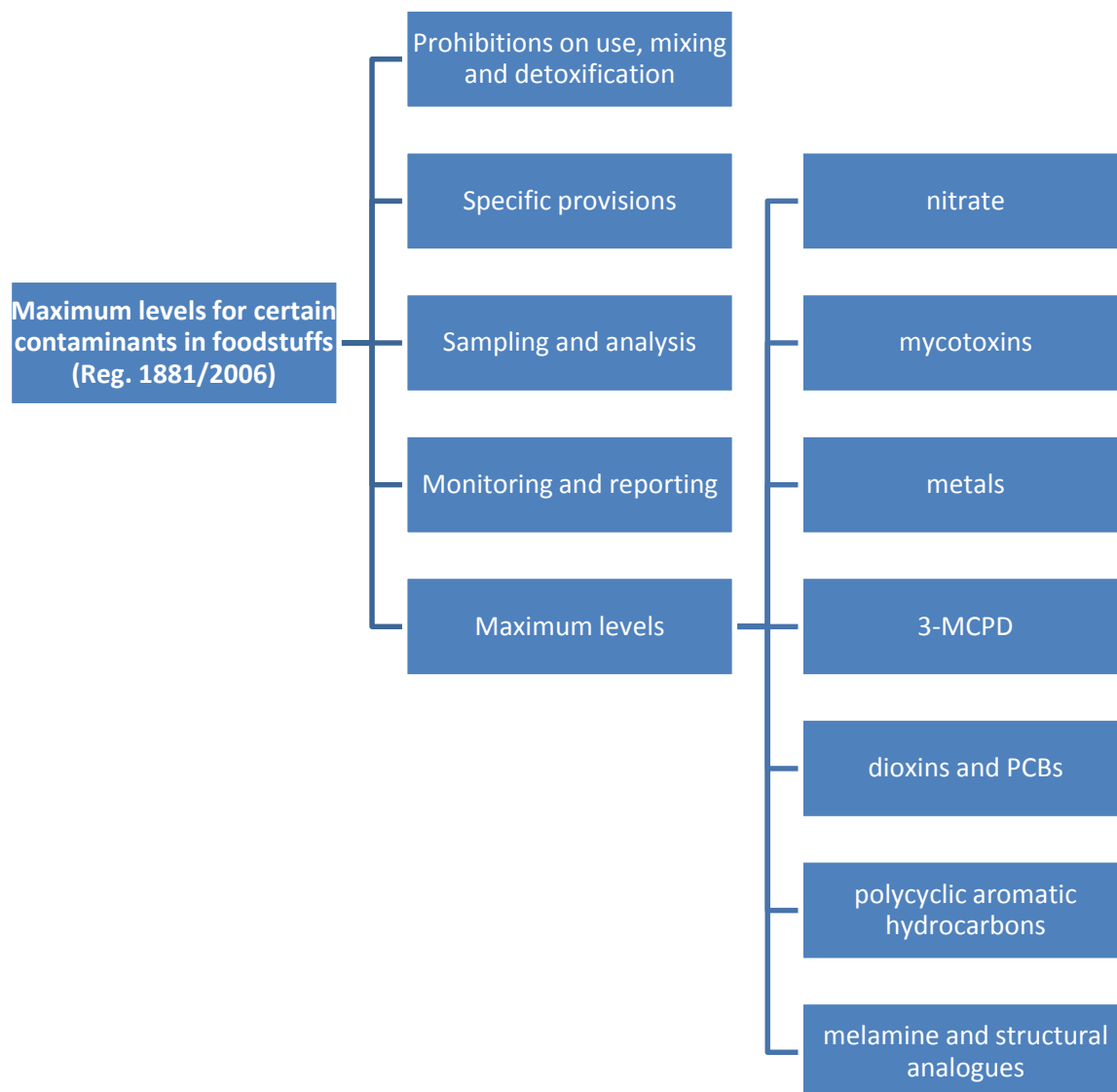


Figure 40: Summary of the requirements of Regulation 1881/2006 on maximum levels for certain contaminants in foodstuffs

Figure 41 provides a summary of the most important legal documents in the field of contaminants in foodstuffs.

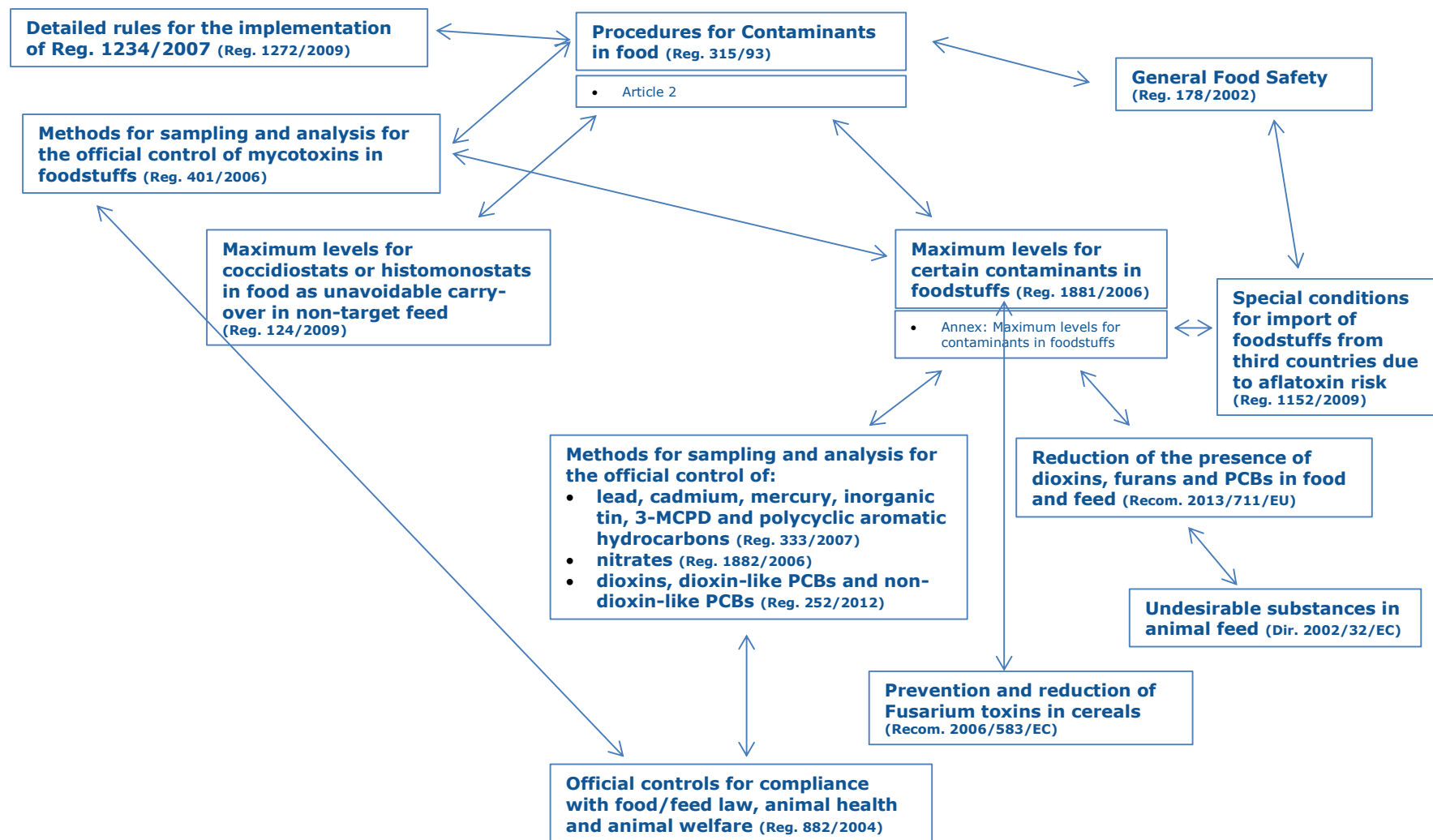


Figure 41: Summary of the most important legal documents in the field of contaminants in foodstuffs.

6.3. Food and food ingredients treated with ionising radiation

6.3.1. Directive 1999/2/EC of the European Parliament and of the Council on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation

Directive 1999/2/EC applies to the manufacturing, marketing and importation of foods and food ingredients treated with ionising radiation excluding foods exposed to ionising radiation generated by measuring or inspection devices and foods intended for patients on a sterile diet. Irradiated foodstuffs may only be placed on the market if they comply with this Directive. The Directive lays down conditions for the authorisation of treatment of foodstuffs with ionising radiation. Foodstuffs must be wholesome at the time of treatment. It also lays down the sources of irradiation that may be used, while treatments must follow the FAO/WHO Codex Alimentarius Commission Recommended International Code of Practice for the Operation of irradiation facilities used for the treatment of foods. The Directive indicates how to calculate the overall average absorbed irradiation dose in treated products. It requires the establishment of a Community list of foodstuffs that may be treated with ionising irradiation and the maximum authorised doses that may be applied in partial doses or in a single dose. Treatment with ionising radiation may not be used in combination with any other chemical treatment for the same purpose. Provisions are also laid down for the labelling of treated foodstuffs, while such treatment must always be indicated in the accompanying documents.

Directive 1999/2/EC requires the competent authorities appointed for the purposes of its implementation to be communicated to the Commission. Irradiation facilities may only be approved if they meet the requirements of the above-mentioned Code of Practice and if they have appointed a person responsible for the compliance with the requirements related to such treatments. The Commission must have the details of all irradiation facilities operating in the Member States and the results of all checks carried out in these facilities in relation to types and quantities of treated products and doses administered, as well as results at the marketing step. This will enable the Commission to publish a relevant report. Irradiation facilities must also keep records of all treatments carried out and their details.

The Directive also lays down requirements for the import of treated products that may only originate from facilities approved and included in the Community list. Packaging materials used for irradiated products must be suitable for the purpose. The Scientific Committee for Food must be consulted for all issues related to the scope of this Directive. Finally the Directive allows for amendments in light of new scientific and technical information and for safeguard measures. More detail and additional legislation relevant for the implementation of Directive 1999/2/EC are provided in Annex XXVII.

Figure 42 summarises the legislative acts in the field of treatment of food and food ingredients with ionising radiation.

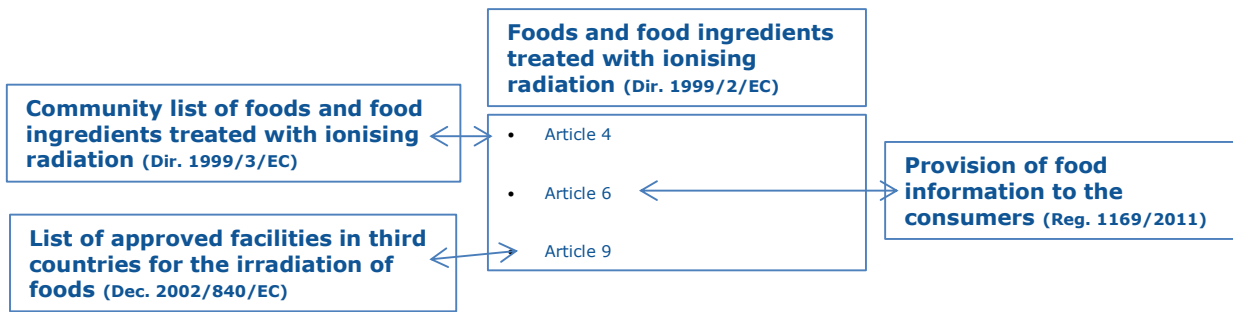


Figure 42: Summary of legislative acts in the field of treatment of food and food ingredients with ionising radiation

6.4. Novel foods and novel food ingredients

Foods and food ingredients that have not been used for human consumption to a significant degree in the EU before 15 May 1997 are considered novel foods and novel food ingredients. These products are regulated by Regulation 258/97 concerning novel foods and novel food ingredients, which is currently subject to revisions with main focus foods from clones. (More details on the revision process can be found here: http://ec.europa.eu/food/food/biotechnology/novelfood/initiatives_en.htm)

6.4.1. Regulation (EC) No 258/97 concerning novel foods and novel food ingredients

Reg. (EC) 258/97 lays down the rules for authorisation of novel foods and food ingredients and requires test to be carried out prior to placement on the market demonstrating that these products do not pose any risk to both the environment and consumer's health. Foods and food ingredients that are not yet used for human consumption are defined as novel foods. It applies to foods: with a modified primary molecular structure, that consists of microorganisms, foods that contain ingredients isolated from plant or animals. This Regulation does not apply to food additives, flavourings, extraction solvents and food enzymes. Genetically Modified Organisms (GMO) are now regulated by Regulation (EC) 1823/2003³² and are no longer covered by Reg. (EC) 258/97. Applicants shall submit their application along with scientific information and risk assessment report to the MS authority and a copy of the request to the Commission. The MS authority shall provide the initial decision, which can a) be that the product can be placed on the market (no additional assessment is necessary and no reasoned objection from the Commission or other EU countries) or b) that an authorisation decision is required. In the event of objections then an authorisation decision is required, in accordance with the rules governing the Standing Committee on Food Chain and Animal Health. For novel foods which are likely to have an effect on public health, the Scientific Committee for Food is also consulted. As of the labelling of such products, without prejudice to labelling laws, they should also mention: composition and nutrition characteristics, presence of materials that might have health implications or raise ethical concerns. If a MS considers that a product can pose risk to the consumers or the environment, because of new information made available, it can suspend or temporarily restrict the marketing of this product and notify the Commission.

Figure 43 provides a summary of the legislation relevant for the implementation of Regulation 258/97 while more details on the related legislation is provided in Annex XXVIII.

³² Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. Official Journal of the European Union (2003). L. 268/1

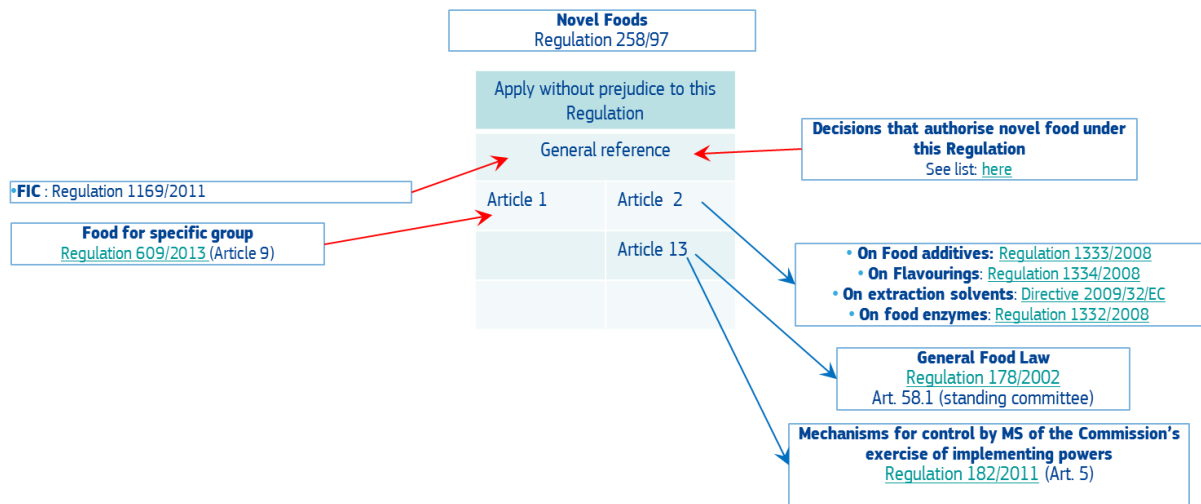


Figure 43: Summary of the legislation on novel foods and cross interaction with other legal acts. Red arrows correspond to legislation referring and /or adding to the main novel foods legislation. Blue arrows correspond to legislation referred in the Novel Foods legislation

7. Legislation related to the packaging step of the food chain

7.1. Packaging materials and materials in contact with food

7.1.1. Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food

Regulation (EC) No 1935/2004 lays down provisions for materials and articles intended to come into contact with food (directly or indirectly) to be placed on the market with the aim to protect human health and consumer interests and ensure the effective functioning of the internal market. The scope also includes active and intelligent materials and articles, but excludes antiques, covering and coating materials and water supply equipment. Materials and articles intended to come into contact with food must be manufactured according to Good Manufacturing Practice (GMP) and the aim is that their constituents are not transferred in food in such quantities as to pose a threat to human health or affect the composition or the organoleptic properties of the food. It is also mentioned that the labelling, presentation and advertising of such materials and articles must not mislead the consumer.

Special provisions are laid down for active and intelligent materials and articles. Until more specific provisions are established for such materials, incorporated substances must be authorised and must meet the requirements of the Regulation. They must be considered as food ingredients and their use must not mislead the consumer in any way. The labelling of such materials must indicate their active or intelligent function and allow consumers to distinguish possible non-edible parts. The Regulation also lays down a list of materials and articles for which more specific measures must be established. In the absence of such more specific measures, Member States may adopt national provisions. If these provisions are likely to affect public health, EFSA must be consulted. Materials and articles covered by the above provisions must be accompanied by a written declaration of compliance and appropriate documentation must be in place to demonstrate this.

Substances may only be used in the manufacture of materials and articles to come into contact with food, if they are authorised and included in positive lists. Alternatively they must be subjected to an authorisation procedure and the details are laid down in the Regulation. Provisions are also laid down for modifications to such authorisations and for emergency situations. This information must be publicly available, however the confidentiality of certain information is also recognised. Sharing of certain data between applicants for the purposes of authorisation is encouraged. Member States must designate competent authorities for the purposes of this Regulation and they must notify their details to the Commission and EFSA.

Some additional labelling requirements are laid down for materials not yet in contact with food but intended for such use. These must be accompanied by the words "for food contact" or a more specific indication of their intended use and by the symbol of Annex II to the Regulation. The Regulation emphasises that traceability of materials and articles must be ensured at all stages. It is the responsibility of the food business operator to be able to identify the businesses from and to which materials and articles or substances within the scope of this Regulation are supplied. Also materials and articles placed in the Community market must be identifiable by an appropriate system. Finally official controls must be carried out in the Member States to ensure compliance with the requirements of this Regulation and sanctions are in place in case of infringements.

The following figure shows the main requirements of Regulation (EC) No 1935/2004. More detail on some of these requirements as well as additional information on related implementing measures is provided in Annex XXIX.

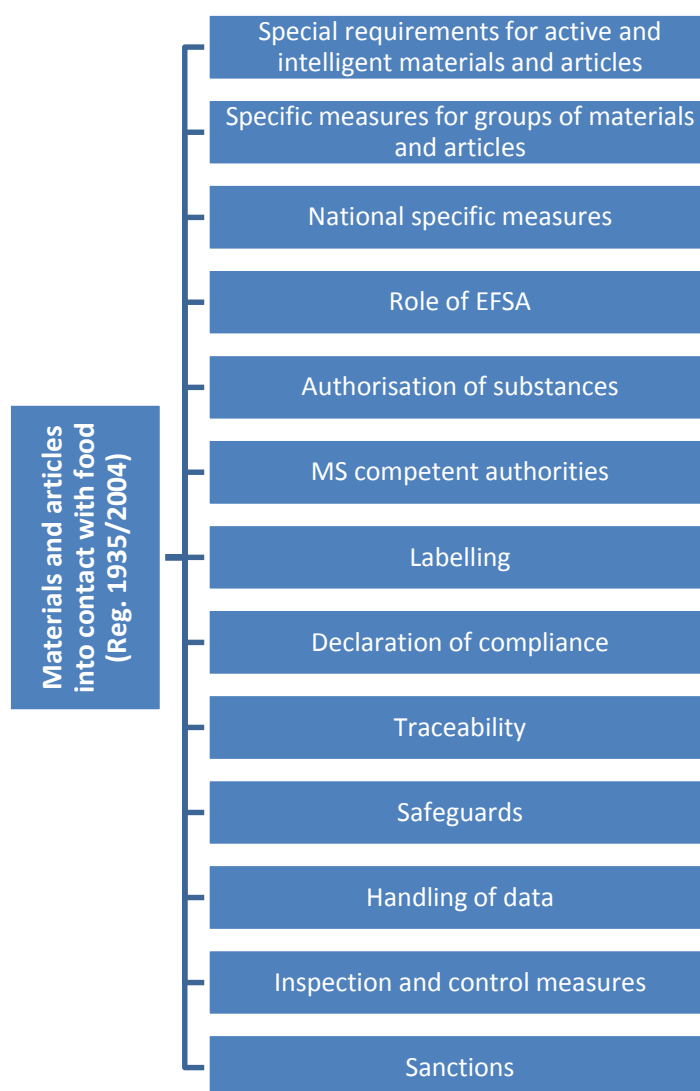


Figure 44: Main provisions of Regulation (EC) No 1935/2004

7.1.2. Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs

Directive 82/711/EEC applies to plastic materials and articles intended to come into contact with food. It indicates that migration of constituents of these materials in food must not exceed the specifically established limits. Compliance of materials with the migration limits must be verified under the most extreme conditions of use and with the conventional tests laid down in the Annex. It also lays down the rules for migration testing and details on food simulants, migration test conditions and fat tests for specific

and overall migration. Figure 45 shows the main requirements of Directive 82/711/EEC. More information on certain of the requirements of the Regulation and on additional legislation complementing the implementation of its provisions is provided in Annex XXX.

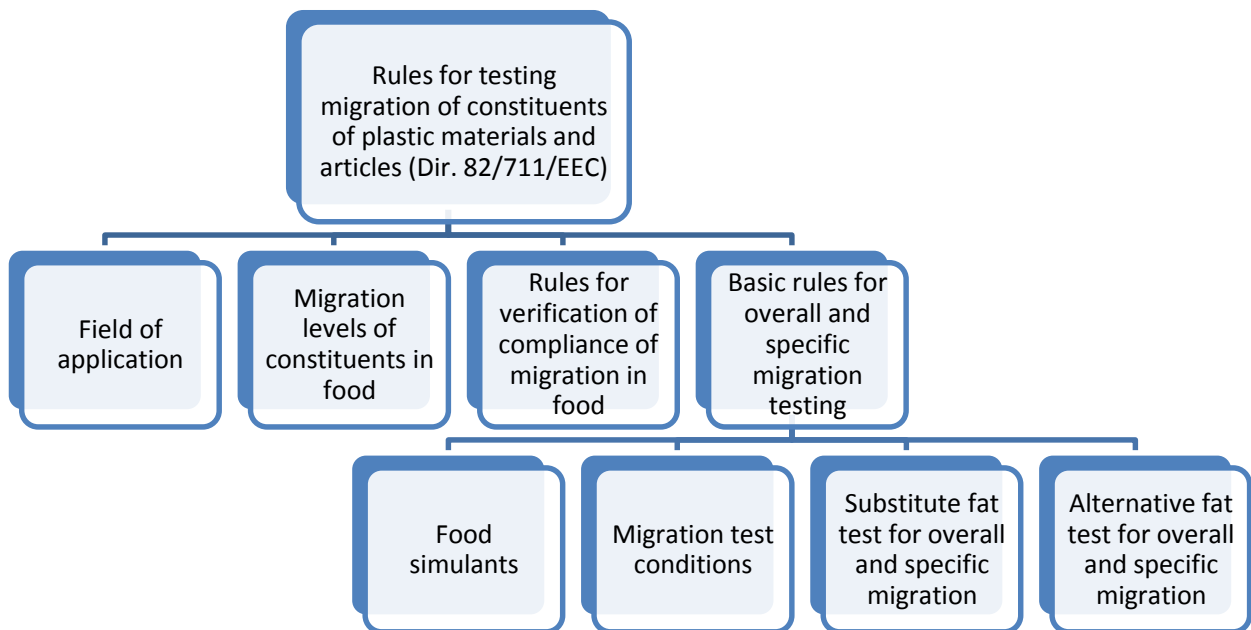


Figure 45: Main provisions of Directive 82/711/EEC

Figure 46 summarises the legal documents in the field of materials and articles intended to come into contact with food and their inter-relationship.

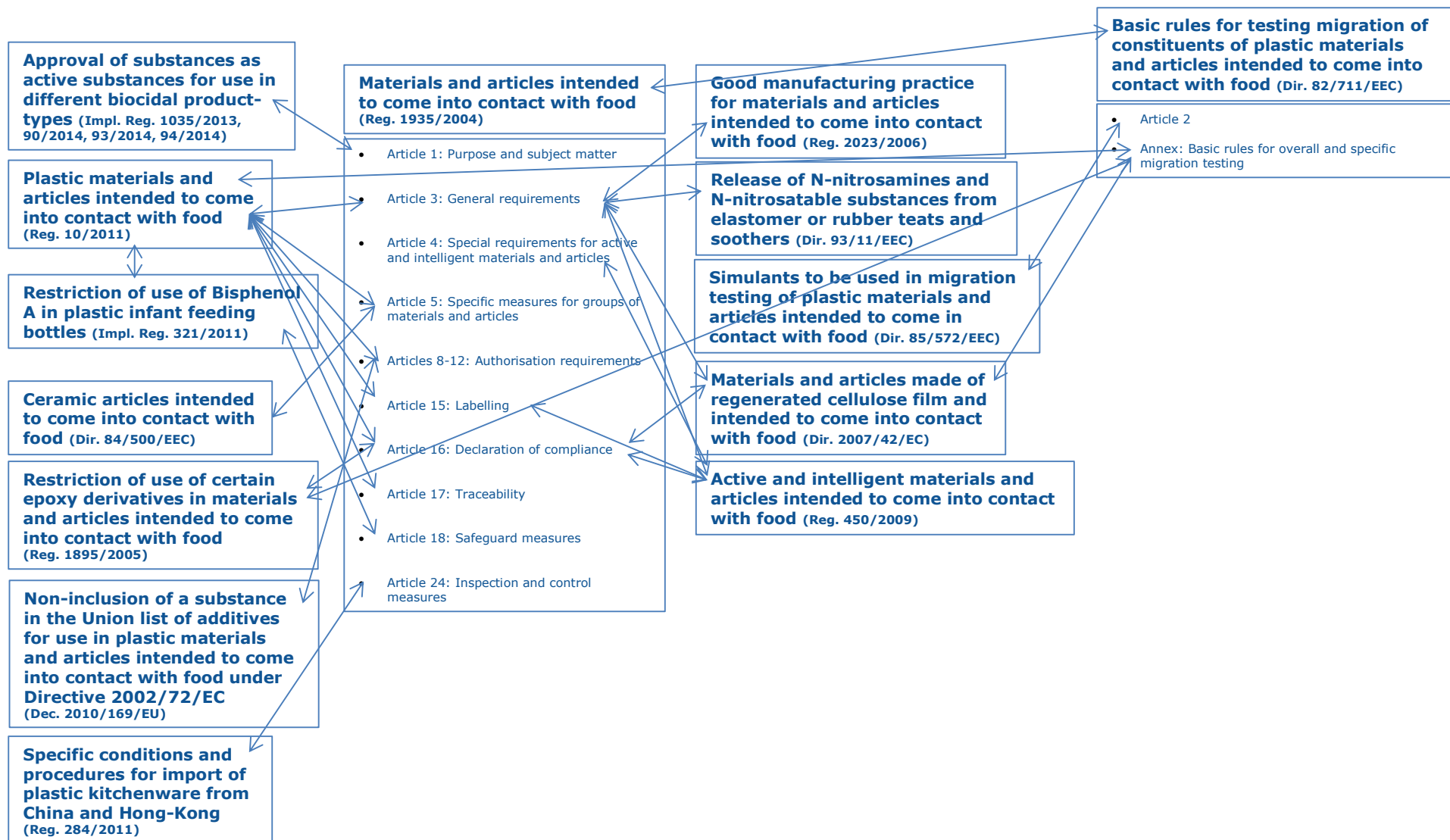


Figure 46: Summary of the legal documents in the field of materials and articles intended to come into contact with food

8. Legislation related to placing foods on the market

8.1. Food Information to Consumers

Regulation (EU) 1169/2011 on the provision of food information to consumers was adopted by the European Parliament and the Council, entered into force on 12 December 2011 and applies from 13 December 2014, while the obligation to provide nutrition information will apply from 13 December 2016. Any reference to the repealed Directives 2000/13/EC on labelling, presentation and advertising of foodstuffs and 90/496/EEC on nutrition labelling for foodstuffs shall be considered as references to Reg. 1169/2011.

8.1.1. Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

This Directive provides the general principles for labelling, presentation and advertising of pre-packaged foodstuffs. Compulsory information shall include: name, list of ingredients (in descending order of weight), quantity of ingredients or categories of ingredients expressed as a percentage, net quantity for pre-packaged foods, date of minimum durability (d/m/y) and shall be preceded by the words: "Best before ..." or "use by" date (for highly perishable foodstuffs), any special storage conditions or conditions of use, the name or business name and address of the manufacturer or packager, the place of origin or provenance where failure to give such particulars might mislead the consumer, instructions for use, indication of the alcoholic strength by volume of beverages containing more than 1.2 % by volume of alcohol. These mandatory particulars must be easy to understand, visible, legible and indelible and some of them must appear in the same field of vision.

Several Regulations and Directives lay down additional information necessary for the implementation of the different provisions of Regulation (EU) No 2000/13/EC. More detail on the information relevant to these legal texts can be found in Annex XXXI.

The following figures summarise these documents and their interactions.

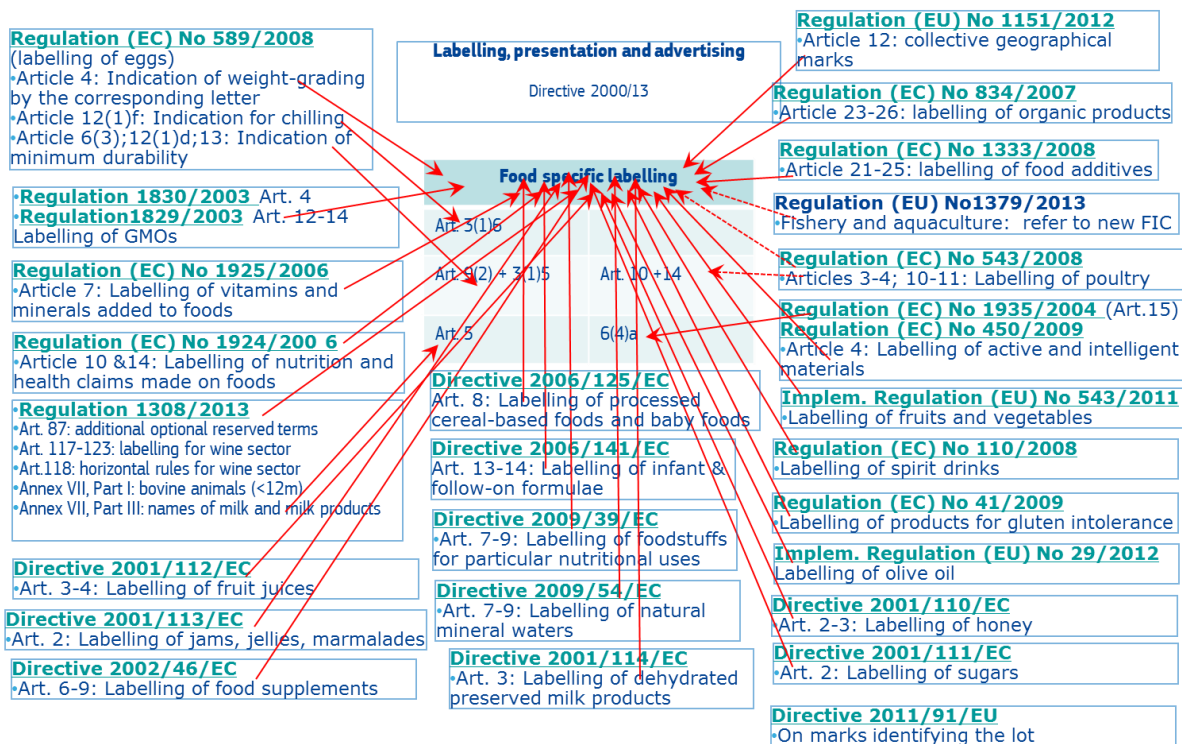


Figure 47: Summary of the legislation on labelling, presentation and advertising of foodstuffs and cross interaction with other legal acts.

8.1.2. The New Framework Regulation: Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

This Regulation provides the basis for the general principles, requirements and responsibilities governing food and nutrition information (food labelling), in order to guarantee the right of consumers to information and reassure the high level of consumer protection. This legal act establishes rules for mandatory and voluntary food and nutrition information in relation to their content, calculation, expression and presentation and applies and sets responsibilities to food business operators at all stages of the food chain. Under this regulation it is mandatory to: provide nutrition information on processed foods; provide origin labelling of unprocessed meat from pigs, sheep, goats and poultry; highlight allergens in the list of ingredients also for non pre-packed foods (e.g. sold in restaurants, cafés) and ensure better legibility (e.g. minimum size of text). In addition, the regulation requires that labelling presentation and advertisement shall not be misleading regarding properties or effects of the food and shall not attribute properties of preventing or curing disease unless it also covers the provisions of other laws (e.g. foods for specific groups). Other mandatory particulars are: name, list of ingredients, substances causing allergies /intolerances, quantity of certain ingredients or categories of ingredients, net quantity, minimum durability or 'use by' date, special storage conditions and/or conditions of use; details of food business operator or importer, the country of origin or place of provenance for certain types of meat, milk or where its absence might be misleading, instructions for use where appropriate, alcoholic strength by volume (where they contain more than 1.2 %), and nutritional declaration (energy, fat, saturated fat, carbohydrates, sugars, protein and salt). These mandatory particulars must be easy to understand, visible and clearly legible (the height of the characters must be at least 1.2 mm). For pre packed foods, this information should

appear on the packaging or on the label attached to it. For non-prepacked, this information must be sent to the operators receiving the foodstuffs so that they can provide the information to the end consumer. Certain mandatory particulars can be omitted for some glass bottles, very small packages etc. The operator is responsible for the presence and accuracy of the provided information. Old Dir. 2000/13/EC on food information has been repealed and the new rules apply from 13 December 2014. The obligation to provide nutrition information will only apply from 13 December 2016.

Several Regulations and Directives lay down additional information necessary for the implementation of the different provisions of Regulation (EU) No 1169/2011. These include specific requirements for the labelling and marketing of diverse food products such as, foods for infants and special medical purposes, olive oil, aromatised wine products, fishery, aquaculture as well as agricultural products. More detail on the information relevant to these legal texts can be found in Annex XXXII. The following figures summarise these documents and their interactions.

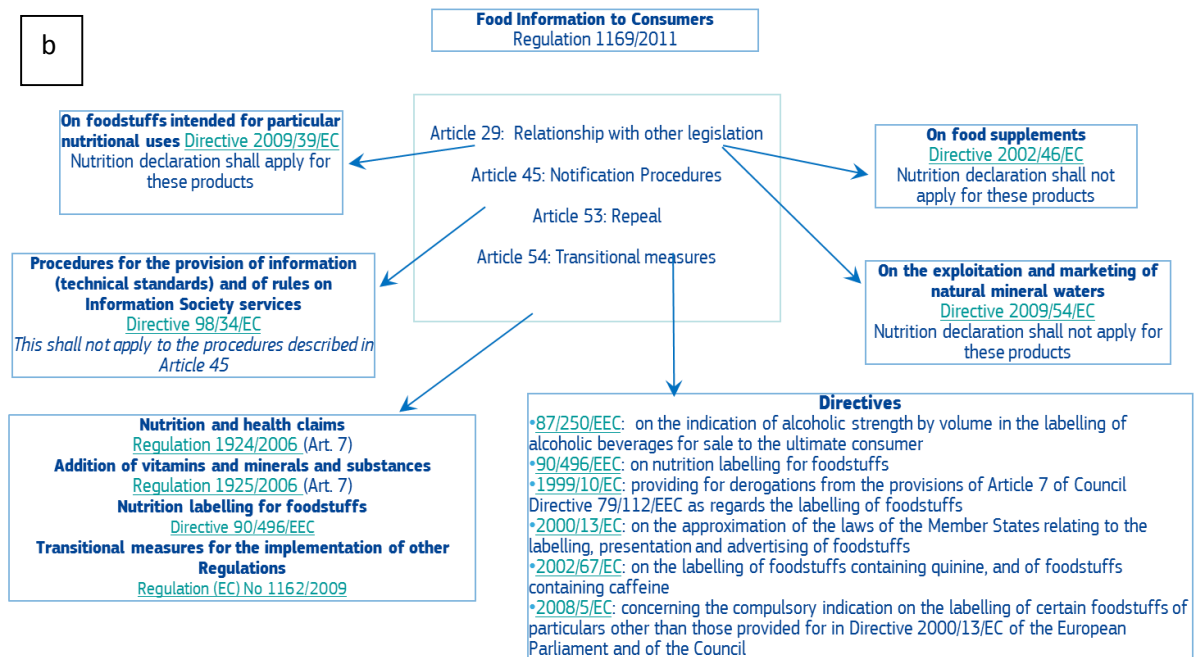
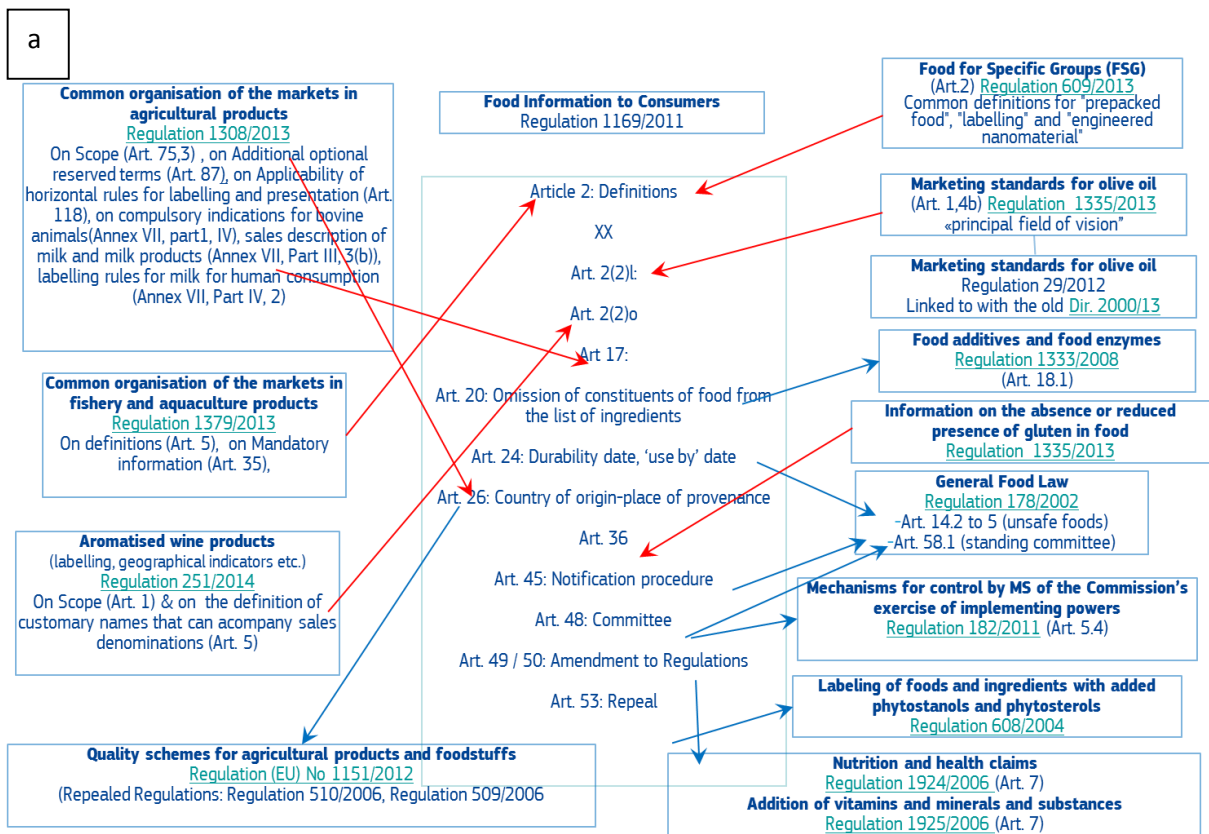


Figure 48 (a and b): Summary of the legislation on Food Information to Consumers (FIC) and cross interaction with other legal acts. Red arrows correspond to legislation referring and /or adding to the FIC legislation. Blue arrows correspond to legislation referred in the FIC legislation.

8.1.3. Council Directive 90/496/EEC of 24 September 1990 on nutrition labelling for foodstuffs

As stated in the introduction of Chapter 8.1, Directive 90/496/EEC³³ has been repealed from 13 December 2014 and any reference to it shall be considered as references to Reg. 1169/2011. However, Directive 90/496/EEC is still valid since the obligation to provide nutrition information will fully apply from 13 December 2016.

Directive 90/496/EEC regards nutrition labelling as optional, but becomes compulsory if a nutrition claim is made. The information given shall consist of the energy value and the amount of nutrients contained, *i.e.* protein, carbohydrate, sugars, fat, saturates, fibre and sodium. It may also include amounts of starch, polyols, mono- and poly-unsaturated fats, cholesterol, and any of the minerals or vitamins listed in the Annex that present in significant amounts. The nutrition claims allowed are only those in relation to the energy value and the amount of nutrients contained. The energy value and amount of nutrients must be expressed per 100g or per 100ml, but also per package or per portion of the food as sold or as prepared for consumption. Information on vitamins and minerals must also be expressed as a percentage of the recommended daily allowance. All of these must be presented in a tabular or linear form, in a clearly visible place and in a language easily understood. National laws shall determine how this information is communicated in the case of non pre-packed foods.

Several Regulations and Directives lay down additional information necessary for the implementation of the different provisions of Directive 90/496/EEC and more detail on the information relevant to these legal texts can be found in Annex XXXIII.

³³ Council Directive 90/496/EEC on nutrition labelling for foodstuffs. Official Journal of the European Communities (1990). L 276/40

8.2. Nutrition and Health Claims

According to Regulation (EC) 1924/2006³⁴, a health claim is "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health" and a nutrition claim is "any claim which states, suggests or implies that a food has particular beneficial nutritional properties" due to: The energy it (i) provides; (ii) provides at a reduced or increased rate; or (iii) does not provide; and/or The nutrients or other substances it (i) contains; (ii) contains in reduced or increased proportions; or (iii) does not contain.

8.2.1. Regulation (EC) No 1924/2006 on nutrition and health claims made on food

Regulation (EC) 1924/2006 lays down the rules that harmonise nutrition and health claims. It applies to claims intended for labelling, presentation and advertising and to all types of food intended for final consumers, including foods at restaurants, hospitals, canteens etc. This Regulation prohibits information that is false, misleading (not scientifically substantiated) or difficult to understand. Nutrition labelling is mandatory on products for which a nutrition or health claim is made, with the exception of generic advertising (denomination), and shall include energy value; amounts of fats, carbohydrates, sugars, proteins and salt.

Nutrition claims:

A general condition of use is that the presence, absence or reduced content of a nutrient or other substance for which the claim is made must have a beneficial nutritional or physiological effect, and be scientifically proven. The types of nutritional claims allowed are only those listed in the Annex of Reg. (EC) 1924/2006 ; examples include: "with no added sugars", "very low sodium", "source of [vitamin] and [mineral], contains [nutrient/substance]", "reduced/increase [nutrient]" etc.

Health claims:

There are two types of health claims:

a) Article 13 ("function") health claims referring i) to the growth, development and the functions of the body, ii) to psychological and behavioural functions, and iii) to slimming, weight-control, hunger reduction or increase of satiety.

The Commission has adopted a list of permitted Article 13 health claims. Article 13 claims which are based on newly developed scientific evidence and/or proprietary data shall an authorisation procedure based on individual applications (laid down in Article 18)

b) Article 14 health claims: reduction of disease risk claims and claims referring to children's development and health.

These claims follow a different authorisation procedure (laid down in Articles 15, 16, 17 and 19 of this Regulation) based on individual applications. More specifically,

³⁴ Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims made on foods. Official Journal of the European Union (2006). L. 404/9

authorisation for a new claim is granted (or not) with a Commission decision following an opinion from EFSA and the Standing Committee on the Food Chain and Animal Health.

Labelling, presentation and advertisement of health claims requires additional information to be provided such as: a statement indicating the importance of a varied diet or the quantity and pattern of consumption which ensures the claimed effect, a statement for those who should avoid using the food, and warning that might bear risks if consumed in excess (Article 10). Claims with reference to the rate or amount of weight loss, to properties for the prevention, treatment or cure of a human disease, to an individual doctor or health professional and claims that suggest that health could be affected by not consuming the food are prohibited (Article 12). Amendments made to the first and second paragraph of Article 7 of this Regulation by the new Regulation 1169/2011 require: mandatory nutrition labelling of products on which a nutrition and/or health claim is made, mandatory declaration of the exact amount of a nutrient for which a nutrition and/or health claim is made and finally, for substance(s) for which a nutrition or health claim is made and the amount does not appear in the nutrition labelling then it shall be stated in the same field of vision as the nutrition labelling and be expressed in accordance with this regulation.

The legal texts that lay down additional information for the implementation of the provisions of Regulation (EC) No 1924/2006 are described in more detail in Annex XXXIV. A summary of this legislation is presented in Figure 49.

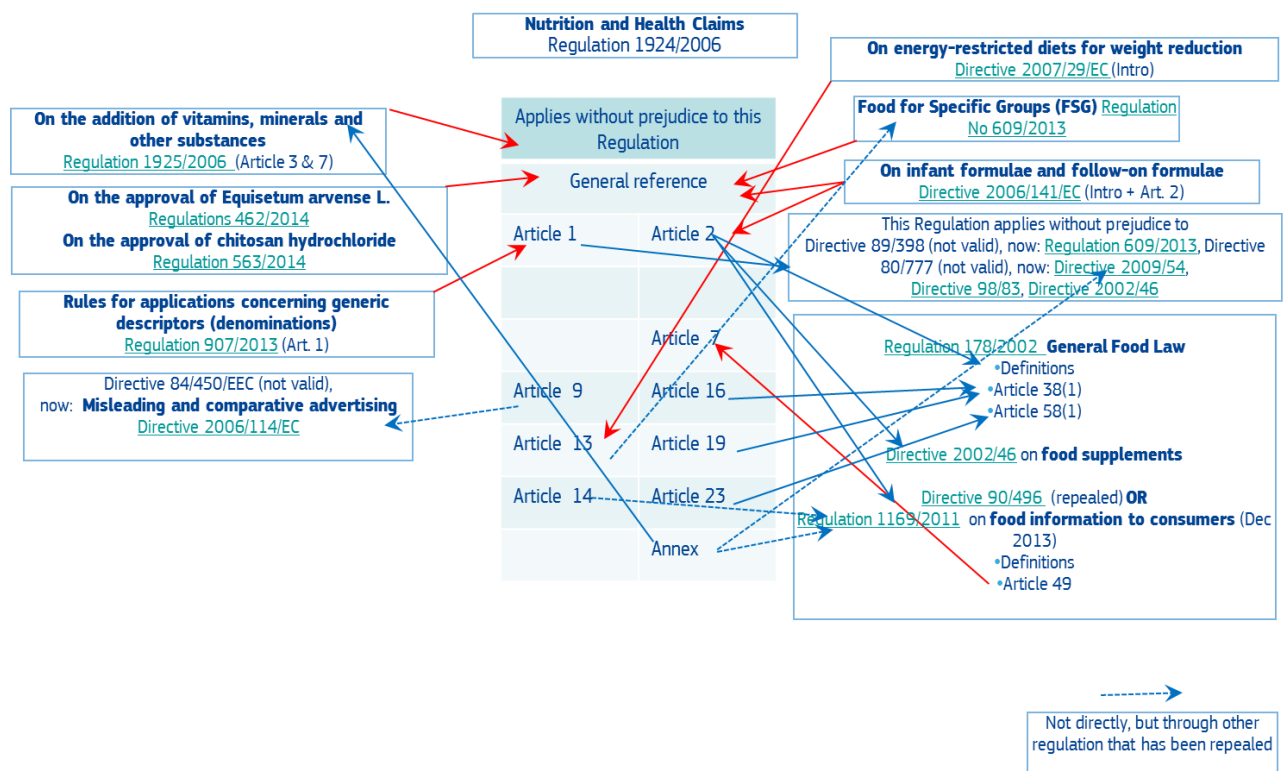


Figure 49: Summary of the legislation on Nutrition and health claims and cross interaction with other legal acts. Red arrows correspond to legislation referring and /or adding to the Nutrition and Health Claims legislation. Blue arrows correspond to legislation referred in the Nutrition and Health Claims legislation.

8.3. Food for specific groups (FSG)

Currently, the "Framework Directive" – Directive 2009/39/EC on foodstuffs intended for particular nutritional uses - establishes general rules for foods for particular nutritional uses. These are defined as "foods specially manufactured to satisfy the particular nutritional requirements of specific groups of people", such as baby foods, foods for people suffering from gluten or lactose intolerance; foods for special medical purposes etc. This Directive is accompanied by a series of four other legislative acts for each one of the specific groups. The validity of the Framework Directive ends when the new Regulation 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control comes into effect, *i.e.* July 2016.

8.3.1. Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses

This Directive concerns foodstuffs that fulfil the particular nutritional requirements of i) persons whose digestive processes or metabolism are disturbed, ii) persons who are in a special physiological condition, and iii) infants or young children. Foodstuffs intended for the two first categories of person mentioned above may bear the words "dietetic" or "dietary". General rules include: i) It is allowed to enrich foodstuffs by adding nutritional substances in order to meet particular nutritional needs, ii) these foodstuffs shall comply with the general labelling rules (Directive 2000/13) but the designation must be accompanied by additional information on the composition or manufacturing process, the energy value, the carbohydrate, protein and fat content of product, iii) they shall only be allowed on the market in pre-packaged form, iv) notifying the competent authority of the Member State (by forwarding them a label of the label used or an indication of the recipient of the first notification) is a prerequisite for placing such a product on the market for the first time and v) a Member State may suspend a foodstuff if it does not comply with this Directive or the specific directives.

Such detailed provisions in relation to the nature or composition of products and their labelling have been adopted for the following groups of foodstuffs:

- a) infant formulae and follow-on formulae (Directive 2006/141/EC);
- b) processed cereal-based foods and baby foods for infants and young children (Directive 2006/125/EC);
- c) foods intended for weight reduction (Directive 96/8/EC);
- d) dietary foods for special medical purposes (Directive 1999/21/EC ³⁵); and
- e) foodstuffs for persons who are gluten-intolerant

Certain delegated acts that will be repealed from the date of application of the new Regulation 609/2013 (FSG) on Food for Specific Groups that shall be adopted by 20 July 2015, as well as Regulations and Directives that lay down additional information

³⁵ Commission Directive 1999/21/EC on dietary foods for special medical purposes. Official Journal of the European Communities (1999). L. 91/29

necessary for the implementation of the different provisions of Directive 2009/39/EC can be found in Annex XXXV.

8.4. Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

Reg. (EU) 609/2013 on food for specific groups establishes compositional and labelling requirements for: a) infant formula and follow-on formula, b) processed cereal-based food and baby food, c) food for special medical purposes and d) total diet replacement for weight control. Moreover, it establishes a Union list of substances allowed to be used in the above mentioned food categories and lays down the rules applicable to the updating of that list. This Regulation also requires the Commission to adopt delegated acts for specific compositional and labelling rules for all categories. These delegated acts will replace Directive 2006/141/EC (for infant and follow-on formulae), Directive 2006/125/EC (for processed cereal-based foods and baby foods), Directive 1999/21/EC (foods for special medical purposes), and Directive 96/8/EC (for foods intended for low calorie and very low calorie diets). Finally, Reg. (EU) 609/2013 foresees that the Commission should prepare a report on milk-based drinks (growing-up milks) and similar products for young children as well as a report on foods for sportspeople, in order to analyse the necessity to establish special compositional and information rules for this kind of products. Reg. (EU) 609/2013 will apply from 20 July 2016.

Regulation 609/2013, being a recent regulation, is only mentioned in one legal document, namely the Commission Delegated Regulation 1155/2013 that updates Reg. (EC) 1169/2011 on the information that is provided to consumers on the absence or reduced presence of gluten in food (see also 8.3.2.v)

Figure 50 summarises the legislation on Food for Specific Groups (FSG) and cross-interactions with other legal acts adding information to the FSG legislation or referred in the FSG legislation.

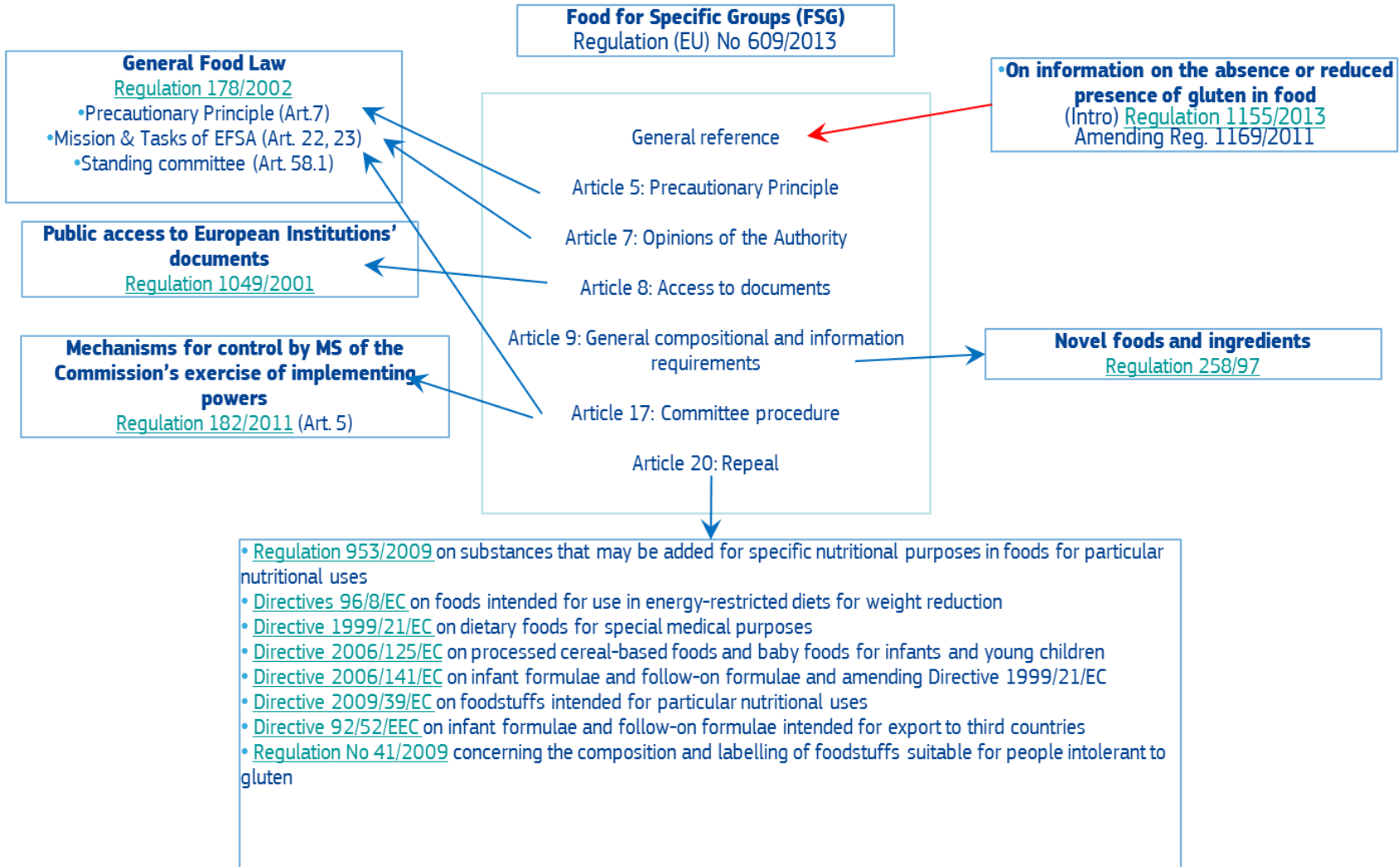


Figure 50: Summary of the legislation on Food for Specific Groups (FSG) and cross interaction with other legal acts. Red arrows correspond to legislation referring and /or adding to the FSG legislation. Blue arrows correspond to legislation referred in the FSG legislation.

8.5. Further relevant nutrition policies

8.5.1. EU Platform on Diet, Physical Activity and Health

The EU Platform on Diet, Physical Activity and Health³⁶ was set up in 2005 with the aim of providing a common forum for all interested stakeholders. This European Commission (EC) chaired forum includes participants ranging from food industry and food science associations to NGOs; in order to participate, stakeholders must make voluntary commitments aimed at improving health, diets and physical activity. The platform meets regularly and is monitored and evaluated every year, and also has joint meetings with the High Level Group. Since its establishment, the Platform has resulted in over 300 commitments made by the participating stakeholders in the fields of marketing and advertising, composition of foods (reformulation, portion sizes), advertising of food to children, consumer information and labelling, education, physical activity promotion and information exchange³⁷. A number of these commitments are specifically targeted at vulnerable groups such as children or older adults.

8.5.2. White Paper on "A strategy for Europe on Nutrition, Overweight and Obesity Related Health Issues"

The White Paper (2007-2013) on a "strategy for Europe on nutrition, overweight and obesity related health issues"³⁸ was the basis of the EU strategy between 2007 and 2013, aiming to improve citizen health via better nutrition and reduced overweight and obesity, through a series of nutrition and lifestyle initiatives. The White paper proposed an integrated approach involving all stakeholders, ranging from public to private and from an EU or national to a regional/local level, which is summarised in the Paper's four basic principles: i) Its actions aimed to address the root causes of health related risks, therefore contributing in reducing the risk factors linked to poor diets and sedentary lifestyles. ii) The horizontal implementation of actions across various policy areas, and the vertical implementation at different levels of managing bodies. iii) Policy actions should include a wide range of private and societal actors, such as the private food industry and the local community. iv) all actions should be monitored effectively, in order to assess their impact and allow corrective actions when deemed necessary.

To promote better stakeholder co-operation, the White Paper recognised the value of the EU Platform as a key tool for implementing its strategy and stated the interest of the Commission to pursue and further develop its activities. In addition, the White Paper called for the formation of a High Level Group focused on nutrition and physical activity, to ensure the exchange of policy ideas and practices between Member States.

The White Paper focused on specific key areas which spearheaded policy implementation:

- **Better informed consumers:** Building on previous legislative initiatives legislations aiming to provide clear, precise and non-misleading food information to the consumers (Directives 90/496/EEC, 2000/13/EC, as well as Regulation EC 1924/2006) the European Commission has adopted Regulation (EU) 1169/2011, providing a set of basic rules and principles to be used in food labelling. In addition, and following up on the report of the EU Round Table on advertising and

³⁶ EU Platform for Action on Diet, Physical Activity and Health website
http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.htm (► 07/11/2014)

³⁷ Monitoring the EU Platform on Diet, Physical Activity and Health – Annual Report 2014

³⁸ White Paper on A Strategy for Europe on Nutrition, Overweight and Obesity related health issues. Com(2007) 279 final

self-regulation³⁹, the Commission has adopted the Audiovisual Media Services Directive⁴⁰ (2010/13/EU) was introduced, encouraging policy makers to take an active role in influencing media service providers, including commercial advertising of foods to children.

- Making the healthy option available: Based upon the Common Agricultural Policy (CAP), the Common Market organisation aims to promote consumption of healthy diets in specific sensitive environments such as school. To this end, the School Fruit Scheme and the School Milk Scheme were introduced. Another initiative aiming at making the healthy option available are the voluntary efforts of the food industry on reformulating processed foods; these voluntary efforts come in the form of pledges taken from the participants of the EU Platform on Diet, Physical Activity and Health.
- Encourage physical activity: It is of foremost importance to construct the required living environment in order to encourage European citizens to increase their physical activity; to this end, the European Commission published the Action Plan on Urban Mobility⁴¹ and the White Paper on Sport⁴² as well as the EU Physical activity guidelines⁴³.
- Priority groups: This action focused on children and lower socio-economic groups; the 2007-2013 Lifelong Learning Programme⁴⁴ addressed health and physical education as priority, while the Fruit School Milk and Fruit Scheme contributed in creating a healthy dietary environment in schools. More actions focused on children's diets are included in the EU Action Plan on Childhood Obesity 2014-2020, a follow-up action of the White Paper. Another priority group focus was the active workforce of the population, addressed in the EU Cohesion Policy 2007-2013⁴⁵, which aimed to promote the contribution of cities to growth and jobs and to maintain a healthy workforce.
- Supporting policy making with scientific evidence: Recognizing the role of research in better understanding the role of nutrition and lifestyle in diseases such as obesity, diabetes and cancer, as well as the role of individual food choices, the 7th Framework Programme⁴⁶ funded research into consumer behaviour, health impact of food and nutrition, prevention of obesity in target groups (infants, children and adolescents) as well as effective dietary interventions. The European Food Safety Authority has also contributed by supporting the Commission with scientific opinions for foods bearing health claims, as well as on the setting of dietary reference values for nutrient intake.
- Monitoring systems: To counteract the lack of harmonisation observed at national level on issues such as food intake, obesity etc., the White Paper called for a strengthening of monitoring efforts, based on three key aspects: i) Consistent and comparable data on progress indicators, identification of initiatives by Member States and monitoring of individual projects and programmes.

The White Paper also stressed the importance of international collaborations, e.g. with the World Health Organisation (WHO) and its 2nd Food and Nutrition Action Plan for

³⁹ Round Table on advertising self-regulation: A report of some discussion among interested parties (2006)

⁴⁰ Directive 2010/13/EU on the coordination of certain provisions laid down by law, regulation or administrative action in member states concerning the provision of audiovisual media services (Audiovisual Media Services Directive). Official Journal of the European Union (2010) L95/1

⁴¹ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions – Action Plan on Urban Mobility COM(2009) 490 final

⁴² White Paper on Sport Com(2007) 391 Final

⁴³ EU Physical Activity Guidelines – Recommended Policy Actions in Support of Health-Enhancing Physical Activity (2008)

⁴⁴ Lifelong Learning Programme (LLP) of the European Union http://eacea.ec.europa.eu/llp/index_en.php (► 07/11/2014)

⁴⁵ Council Decision 2006/702/EC on Community strategic guidelines on Cohesion. Official Journal of the European Union (2006) L291/11

⁴⁶ EU Seventh Framework Programme website http://cordis.europa.eu/fp7/home_en.html (► 07/11/2014)

Europe 2007-2012⁴⁷ and its European Childhood Obesity Surveillance Initiative⁴⁸ (COSI). Although the White Paper was foreseen for the 2007-2013, its activities and actions still carry on and have given birth to new initiatives such as the Action Plan on Childhood obesity 2014-2020.

8.5.3. High Level Group on Nutrition and Physical Activity

The High Level Group (HLG) on Nutrition and Physical Activity was set up in 2007 following the White Paper "A strategy for Europe on Nutrition, Overweight and Obesity Related Health Issues", and consists of representatives from Member States governments, plus Norway and Switzerland, and is led by the EC. HLG members inform each other on national policies on nutrition and physical activity and share policy ideas and practices. In addition, the HGL holds joint meetings with the EU Platform for Diet, Physical Activity and Health, improving collaborations between governments and the Platform members in order to facilitate public-private partnerships. One of the focus areas of the HLG was fighting childhood obesity, and this led to the adoption of the EU Action Plan on Childhood Obesity for 2014-2020. Two other examples of HLG initiatives were the EU Framework for national initiatives on reduction of selected macro-nutrients. The salt reduction initiative⁴⁹ aimed at a 16% reduction between 2008-2012 applicable to all food products as well as foods consumed in restaurants, canteens and catering facilities in general; the EU selected nutrients initiatives focused in saturated fats in particular, proposing a general reduction (compared to 2012) of a minimum of 5% until 2016 and an additional 5% reduction by 2020⁵⁰.

8.5.4. School Fruit and Milk Schemes

The School Fruit Scheme (SFS) and School Milk Scheme (SMS) are EU wide aid schemes intended to improve children's dietary habits and the distribution of agricultural products to children; the main target groups are children in nurseries, pre-schools, as well as primary or secondary level schooling establishments administered by the relevant authorities in MS.

The school fruit scheme started in 2009, following the EU common market organisation reform for Fruit and Vegetables in 2007, which aimed also at encouraging a greater consumption of fruits and vegetables⁵¹. The SFS aims to provide fruits and vegetables, processed fruits and vegetables as well as bananas to school children and to encourage their healthy eating habits. Apart from provision of fruits and vegetables, participating MS need to set up complementary strategies such as educational and awareness initiatives. The products to be included must be chosen by the MS, on the basis of criteria such as environmental considerations/sustainability, seasonality, variety and availability of produce, giving priority where possible to EU products and in particular to

⁴⁷ WHO European Action Plan for Food and Nutrition Policy 2007-2012 (2008)

⁴⁸ WHO European Childhood Obesity Surveillance Initiative website (► 07/11/2014)

⁴⁹ EU Framework for national salt initiatives

⁵⁰ EU Framework for national initiatives on selected nutrients Ares(2012)6999700

⁵¹ Fruit and vegetable reform – Memo/07/28 (2007)

local markets. The legal basis for SFS lies with regulation EC/1234/2007⁵² and regulation (EC) No 288/2009⁵³ (amended by 34/2011⁵⁴).

The school milk scheme is an EU wide initiative aiming to encourage dairy product consumption among school children. It started in 1977 and aims at increasing consumption of milk and milk products in children and young people. The legal basis within CAP was introduced with regulations EC/1234/2007 and EEC/657/2008⁵⁵. As with SFS, the SMS scheme also has an educational character and includes not only milk but also processed milk products.

Both aid schemes were revisited by regulations (EU) 1306/2013⁵⁶ and (EU) 1308/2013⁵⁷, while in early 2014 the commission presented a legislative proposal⁵⁸ (probably to take effect by 2016), accompanied by an impact assessment, to reform the two schemes and bring them together in a joint framework. Key points include creating a joint legal and financial framework for the distribution of fresh fruit, vegetables and milk, educational measures to improve awareness on farming, healthy eating habits and environmental issues, new funding rules, and simplified implementation rules.

8.5.5. 3rd EU health programme (2014-2020)

Bound by the founding treaty of the EU to ensure the protection of human health in all policies, the EU health strategy "Together for Health" is supporting the overall Europe 2020 strategy, which apart from smart, sustainable and inclusive economy promoting growth also has a healthy population as a main prerequisite. The 3rd programme (2014-2020)⁵⁹ draws its legal basis from Reg. (EU) No 282/2014⁶⁰ and is the main instrument to implement the EU health strategy, and has four overarching objectives: i) promote health, prevent diseases and foster supportive environment for healthy lifestyles ii) protect citizens from serious cross-border health threats, iii) contribute to innovative, efficient and sustainable health systems and iv) facilitate access to better and safer healthcare for EU citizens. The EU health programme is implemented by annual work plans, setting out priority areas and criteria for funding specific actions. Under the "Promote health, prevent disease and foster supportive environment for health lifestyles" area, Paragraph 1.1 refers to the need of cost-effective promotion and prevention strategies on alcohol and nutrition, including actions supporting the exchange of evidence-based successful practices for tackling risk factors such as alcohol abuse,

⁵² Council Regulation (EC) No 1234/2007 establishing a common organization of agricultural markets and on specific provisions for certain agricultural products. Official Journal of the European Union (2007) L 299/1

⁵³ Commission Regulation (EC) No 288/2009 laying down detailed rules for applying Council Regulation (EC) No 1234/2007 as regards to Community Aid for supplying fruit and vegetables, processed fruit and vegetables and banana products to children in educational establishments, in the framework of a School Fruit Scheme. Official Journal of the European Union (2009) L 94/38

⁵⁴ Commission Regulation (EU) No 34/2011 amending Regulation (EC) 288/200. Official Journal of the European Union (2011) L14/6

⁵⁵ Commission Regulation (EC) No 657/2008 laying down detailed rules for applying Council Regulation (EC) No 1234/2007 as regards Community aid for supplying milk and certain milk products to pupils in educational establishments. Official Journal of the European Union (2008) L 183/17

⁵⁶ Regulation (EU) No 1306/2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 362/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008. Official Journal of the European Union (2013) L 347/549

⁵⁷ Regulation (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) 234/79, (EC) No 1307/2001 and (EC) 1234/2007. Official Journal of the European Union (2013) L 347/671

⁵⁸ Proposal for a Regulation amending Regulation (EU) No 1308/2013 and Regulation (EU) 1306/2013 as regards the aid scheme for the supply of fruit and vegetables, bananas and milk in the educational establishments. 2014/0014 (COD)

⁵⁹ EU Health Programme 2014-2020 website http://ec.europa.eu/health/programme/policy/2014-2020/index_en.htm (10/11/2014)

⁶⁰ Regulation (EU) No 282/2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC (2014). Official Journal of the European Union L 86/1

unhealthy dietary habits and physical inactivity, taking into account the public health aspects of underlying factors, e.g. those of a social and environmental nature.

8.5.6. EU Action Plan on Childhood Obesity

The EU Action Plan on Childhood Obesity was published by the HLG on Nutrition and Physical Activity in 2014⁶¹, following a Reflection Process⁶², and aims at halting the rise in overweight and obesity in children and young people (0-18 years) by 2020. The action plan calls for the participation of many actors on different levels, including the EU Member States, the European Commission, international organisations such as the WHO as well as civil society partners such as Non-governmental organisations (NGOs), research institutes and the private industry. The action plan identifies specific pillars for action: Support a healthy start in life, promote healthier environments (especially schools and pre-schools), make the healthy option the easier option, restrict marketing and advertising to children, inform and empower families, encourage physical activity, increase research and implement monitor and evaluation mechanisms. In addition, it proposes MS to engage in a joint action and urges the Platform to come up with new commitments.

8.5.7. Dietary Reference Values (DRVs)

The European Food Safety Authority (EFSA) has been asked by the Commission to review and update the reference intake values for nutrients, micro-nutrients and energy⁶³, which were first established in 1993 by the Scientific Committee on Food⁶⁴. EFSA's role was to develop DRVs, i.e. quantitative reference values of intakes for healthy individuals and populations, which could be used for the assessment and planning of diets. The DRVs include:

- Population reference intakes (PRIs): *"the level of nutrient intake that is adequate for virtually all people in a population group"*.
- Average requirement (AR): *"the level of (nutrient) intake that is adequate for half of the people in a population group, given a normal distribution of requirement"*
- Lower Threshold Intake (LTI): *"the level of intake below which, on the basis of current knowledge, almost all individuals will be unable to maintain "metabolic integrity", according to the criterion chosen for each nutrient"*
- Adequate Intake (AI): *"the value estimated when a Population Reference Intake cannot be established because an average requirement cannot be determined. An Adequate Intake is the average observed daily level of intake by a population group (or groups) of apparently healthy people that is assumed to be adequate"*
- Reference Intake ranges for macronutrients (RI): *"the intake range for macronutrients, expressed as % of the energy intake. These apply to ranges of*

⁶¹ EU Action Plan on Childhood Obesity 2014-2020 (2014)

⁶² Council of the EU: Reflection process: Innovative approaches for chronic diseases in public health and health-care systems Final Report (2013). 12983/13 LIMITE SAN 304

⁶³ Scientific Opinion on principles for deriving and applying Dietary Reference Values. EFSA Journal 2010; 8(3):1458

⁶⁴ Food – Science and Techniques: Reports of the Scientific Committee for Food (31st series): Nutrient and Energy Intakes for the European Community (1993). ISBN 92-826-6409-0

intakes that are adequate for maintaining health and associated with a low risk of selected chronic diseases."

The scientific opinions of EFSA on the DRVs could be used by MS authorities when making nutrient recommendations or establishing dietary guidelines (taking into account national dietary factors and the health status of the target population). So far, EFSA has produced opinions on DRVs⁶⁵ for energy, macronutrients (carbohydrates, dietary fibre, fats, protein) and water, as well as for micronutrients (fluoride, molybdenum, vitamin C, manganese, biotin, pantothenic acid, iodine, niacin, zinc, chromium, selenium, and folate, which is about to be published).

⁶⁵ EFSA webpage on DRVs: <http://www.efsa.europa.eu/en/topics/topic/drv.htm> (11/11/2014)

9. Implementation of EU legislation in the Member States

The effective functioning of the internal European food market and the achievement of the ultimate goal of ensuring safe and nutritious food for the 500 million European citizens relies on the effective implementation of food legislation in all Member States.

The initiative for the development of European legislation remains with the European Commission which is also responsible for monitoring the implementation of the European legislation. The European Parliament and the Council have then the power under the "ordinary legislative procedure" for co-decision on the adoption or not of draft EU law.

9.1. Responsibilities

The General Food Law requires food business operators at all stages of production that all food and feed they place on the market satisfy the requirements of food law, i.e. that all food is placed on the market must not be injurious to health or unfit for human consumption. Food business operators are required to verify whether those requirements are met and the competent authorities in the Member States shall in turn verify that food business operators obey the rules of the General Food Law. For doing this, Member States shall maintain a system of competent authorities and official controls. The proper operation of this system and implementation of food law in the Member States is monitored and audited by the Food and Veterinary Office, which is part of DG SANCO. An overview of food law implementation actors at global, EU and national level is provided in Figure 51.

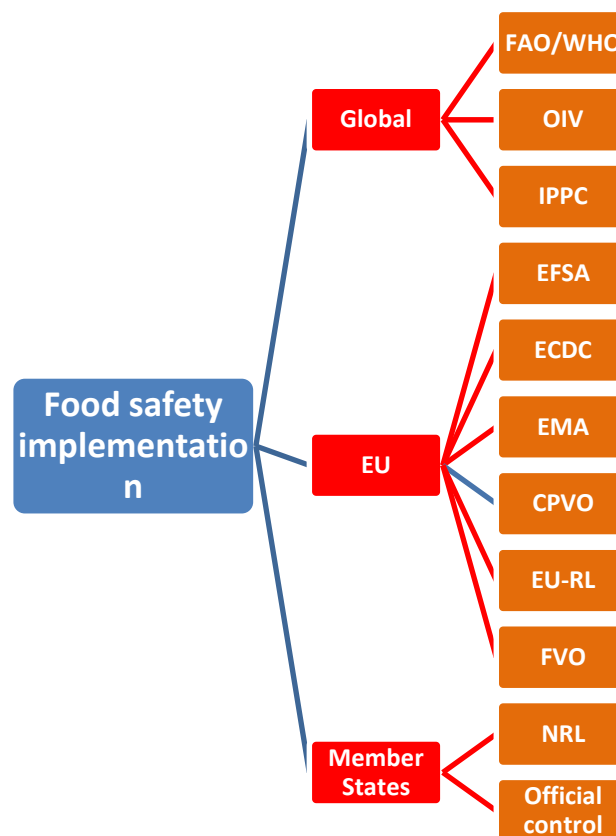


Figure 51: An overview of actors at global, EU and national level

9.2. Competent authorities and official food control

In most Member States the responsibility for the safety of the food chain is shared by the ministry of health (or its equivalent) and the ministry of agriculture (or its equivalent). In many Member States the ministries of health are responsible for food safety, animal health and animal welfare, and the ministries of agriculture for feed, plant health and plant protection products, although other distributions of responsibilities exist as well. Several Member States have created 'food safety agencies', centralising to a various degree coordination of risk assessment, communication with stakeholders, science advice to policy making, standard setting, and inspection and laboratory activities (e.g. Food Standards Agency (FSA); UK, Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES), FR, Agencia Española de Seguridad Alimentaria y Nutrición (AESAN), ES).

Various models exist how to organise food inspection services, official control activities and law enforcement. A graphical representation is found in Figure 52.

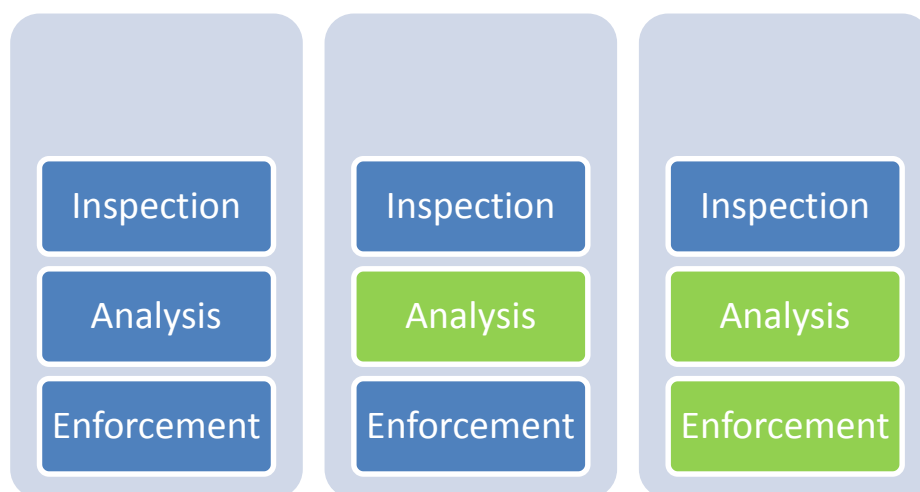


Figure 52: An overview of actors at global, EU and national level

The three basic elements of a food control system can be combined in one organisational entity or be separated to various degrees (e.g. inspection and enforcement is carried out by one organisation and laboratory analysis by another, which could even be a commercial service provider).

9.3. International and EU level organisations

To enable and facilitate international trade in food products a system of global governance is necessary. The Codex Alimentarius Commission, which is a joint FAO/WHO undertaking, coordinates harmonisation of food standards and requirements for contaminants, residues, additives, labelling rules, etc. The World Organisation for Animal Health (OIE) develops normative documents relating to rules that Member Countries can use to protect themselves from the introduction of diseases and pathogens, without setting up unjustified sanitary barriers. The organisation is placed under the authority and control of a World Assembly of Delegates consisting of Delegates designated by the Governments of all Member Countries. The International Plant Protection Convention (IPPC) aims to protect cultivated and wild plants by preventing the introduction and spread of pests. The standards set by the three mentioned organisations, sometimes referred to as the 'three sisters', are recognised by the World Trade Organization (WTO) as reference international sanitary and phyto-sanitary (SPS) rules. The SPS Agreement confirms the right of WTO member countries to apply measures to protect human, animal and plant life and health. The Agreement covers all relevant laws, decrees, regulations; testing, inspection, certification and approval procedures; and packaging and labelling requirements directly related to food safety. WTO Member States are asked to apply only those measures for protection that are based on scientific principles, only to the extent necessary, and not in a manner which may constitute a disguised restriction on international trade.

At EU level several agencies under the responsibility of DG SANCO are tasked with specific functions related to ensuring the safety in the food chain:

- European Food Safety Authority
- European Medicines Agency
- European Centre for Disease Prevention and Control
- Community Plant Variety Office

The EU established a series of European Union Reference Laboratories (EURLs) for food and feed, as well as animal health. coordinate a network of national reference laboratories (NRLs) to obtain high quality results by the provision of reference methods, reference materials, proficiency testing schemes and training to laboratory staff. They support the creation of a well performing network of laboratories throughout the Union. The work of the EURLs leads to better implementation of EU legislation, e.g. by enforcing legislative limits and reducing the need to repeat testing. As a result the functioning of the EU internal market is strengthened and consumers benefit from safe food and products in the market.

10. Other food policies

10.1. Global food safety and nutrition governance

Global food governance refers to the international organizations and mechanisms that are in place and may impact global governance and cooperation in food and nutrition. In an interconnected world, food safety and nutrition related issues can be of concern on a bilateral, regional or even global scale. This is of even greater importance with the current trends that foresee an increased role of emerging powers in the global market system. As a result, international food governance can have an important impact in both regional and global food systems, especially to ensure safe trade and/or effective nutrition policies. Specific impacts can be on harmonizing and enforcing food safety standards, exchanging food safety alerts and information via rapid communication networks, sharing best practices on food safety as well as coordinating policies and strategies in nutritional issues such as global food security, malnutrition, public health nutrition action plans etc. Albeit their voluntary application or adoption, the global food standards, guidelines and best practices that have been put in place by Codex Alimentarius not only form the basis of many specific national food legislations, but are also used as reference by the WTO, which potentially increases their relevance. Other relevant intergovernmental organizations include the World Organization for Animal Health, which is also recognized as a reference for animal health, as well as the International Plant Protection Convention, a global treaty on plant health. In addition, international industry initiatives or private food standards could be of increased relevance and may affect global food safety governance

The Codex Alimentarius⁶⁶ of the Food and Agriculture Organisation (FAO) of the United Nations (UN), established in 1963, is a set of guidelines, codes of practice, standards and advisory documents that are aimed at protecting the health of the consumers and ensure fair practices in the food trade. The Codex includes various standards⁶⁷; general standards e.g. on food additives, health claims made on foods and labelling in general, specific standards on maximum residue levels (MRLs) for veterinary drugs and pesticides, as well as thematic compilations, e.g. on prevention and reduction of food and feed contamination, food import and export inspection and certification systems, specific food categories such as fresh fruits and vegetables, milk and milk products etc. Currently the Codex Alimentarius Commission has 186 nation-members (including the EU⁶⁸ as a member organisation) which cover 99% of the world's population, as well as 224 observers (intergovernmental organisations-IGOs, NGOs and UN organisations). Codex is voluntary reference standard and adherence to its standards is voluntary also for its members, however the Codex standards serve in many cases as the basis for national legislation. In addition, the World Trade Organisation uses the Codex as an international reference standard when resolving trade disputes, under the Agreement on Sanitary and Phytosanitary measures⁶⁹ (SPS Agreement), meaning that the Codex can have even more important and long-reaching impacts.

Other standards

The World Organisation for Animal Health (OIE), created in 1924, is an intergovernmental organisation aiming to improve animal health and welfare; it numbers

⁶⁶ Codex Alimentarius International Food Standards website <http://www.codexalimentarius.org/codex-home/en/> (► 10/11/2014)

⁶⁷ Codex Alimentarius list of standards <http://www.codexalimentarius.org/standards/en/> (► 10/11/2014)

⁶⁸ Council decision 2003/882/EC on the accession of the European Community to the Codex Alimentarius Commission (2003). Official Journal of the European Union L309/14

⁶⁹ Agreement on the Application of Sanitary and Phytosanitary Measures (1995) World Trade Organisation

180 members, and, via the SPS agreement, it is recognised by WTO as a reference for standards related to animal health and zoonoses⁹⁹.

The International Plant Protection Convention (IPPC, 1952) is an international treaty on plant health, which aims to protect cultivated and wild plants by preventing the introduction and spread of pests; it currently numbers 181 signatories and is supported by FAO⁹⁹.

The Global Food Safety Initiative (GFSI) is an industry driven programme, which aims to provide leadership and guidance on food safety management, ensuring the safety of the food supply chain, and involves collaborations between leading experts from manufacturing, retail and food services businesses, as well as international organisations, governments and academia.

Private food standards also exist and have risen in importance since the 1990s, e.g. the Food Technical Standard by UK retailers in 1998 or the ISO 22000 standard in 2005. In addition, private food standards have also emerged, especially in developing countries, to cope for gaps in public standards, however their impact and future remains uncertain.

The increased trade, bilateral or international, of foods and food raw materials, both of agricultural and animal origin, results in an increased importance of surveillance systems to contain the spreading contaminated foods or raw materials and protect the integrity of both national and global food chains. WHO supports a number of international networks on food safety, such as the INFOSAN and FOSCOLLAB, with the aim of rapidly diffusing information on food safety emergencies or act as a global data hub for food safety information and experiences. The Global Early Warning System for animal diseases is jointly run by WHO, FAO and OIE; the latter also operates the World Animal Health Information System, monitoring and informing on the epidemiology of animal diseases.

The International Food Safety Authorities Network (INFOSAN) is a WHO-run networks which assist member states in managing food safety risks; this is achieved by ensuring rapid dissemination of information on food safety emergencies, aiming to contain spread of contaminated food material. INFOSAN also acts as a platform to share experiences and optimized practices and interventions between countries.

Another WHO-run system is FOSCOLLAB, a global platform for food safety data and information, dedicated to food safety professionals, and aiming at rapid access of food safety data, utilization of existing experiences and sources to avoid efforts duplication, as well as integration and better generation of data.

The Global Early Warning System for major animal diseases (GLEWS) is a FAO, WHO and OIE jointly run system, aimed at combining and coordinating the various information and alert mechanisms of WHO, FAO and OIE, as well as performing joint risk assessment.

OIE also operates the World Animal Health Information System (WAHIS), an on-line, real-time animal disease monitoring tool, composed of an early warning system of animal health epidemiological events for OIE members, as well as a monitoring system for presence of absence of animal diseases over time. Data generated from WAHIS is stored in the World Animal Health Information Database (WAHID), including follow-up reports, as well as monthly and annual reports on animal health in OIE members.

Global nutrition governance

While half of the planet is exhibiting increasingly poor dietary behaviors and suffers from over-nutrition, leading to obesity and increasing the risk of major Non-communicable diseases, the other half is faced with food insecurity and under nutrition. Under this scope FAO and WHO have designed a number of policies to fight this double burden.

Action plans and policies to combat NCDs and obesity have been put forward, such as the WHO Global and European action plans with at 2020 horizon or the 2025 Global Targets for maternal, infant and child nutrition. In parallel, the World Food Programme, as well as the UN committee on World Food Security are providing global leadership on the fight against food insecurity.

Non-communicable diseases (NCDs) are responsible for the majority of deaths worldwide, and represent a significant burden for individual health as well as for national health systems. Health compromising lifestyles, such as unhealthy diets are risk factors for major NCDs, e.g. cardiovascular diseases, Type 2 diabetes and cancer; in addition, unhealthy dietary behavior is a major determinant for overweight and obesity, which in turn is a risk factor for the above mentioned NCDs. And while half of the planet is suffering from malnutrition in the sense of obesity, the other half is suffering from under nutrition and is threatened by food insecurity, in the so called "double burden".

The Food and Agriculture Organization of the UN (197 member nations) aims to eradicate hunger, malnutrition and food insecurity, eliminate poverty and drive forward economic and social progress, and utilize agricultural production and natural resources in sustainable way. FAO's main activities are comprised of a) providing support for a transition to sustainable agriculture, share experience in agricultural policies and strengthen political will, improve smallholder agriculture by bolstering public private collaborations, apply experience and knowledge to the field, as well as support countries in preventing or mitigating risks to agriculture, food and nutrition.

The World Health Organization of the United Nations is responsible for providing global leadership on health related issues, setting norms and standards, shaping the health research agenda, as well as presenting evidence-based policy options and providing technical support and health monitoring.

On the topic of nutrition, various recent initiatives and policy actions have been set forward by WHO; the Vienna Declaration On Nutrition and Non-communicable Diseases in the Context of Health 2020 , the Global Action Plan for the prevention and control of non-communicable disease 2013-2020 , the European Food and Nutrition Action Plan 2015-2020, the global targets for 2025 to improve maternal, infant and young child nutrition, via its World Health Assembly Policy Brief Series on Global nutrition Targets for 2025 , the commitment with FAO and participating movements during the high-level intergovernmental meeting during the 2nd International Conference on Nutrition (ICN2, 2014) as well as the resulting Rome Declaration on Nutrition and Action Framework aimed at establishing national policies to tackle malnutrition in all forms and transform food systems to make nutritious diets available to all.

The UN Standing Committee on Nutrition (UNSCN, 1977) is the UN forum dedicated to food and nutrition policy harmonization, and aims to strengthen cooperation among the various UN agencies and partner organizations, with the ultimate goal to end all forms of malnutrition.

The World Food Programme (WFP) of the UN is the world's largest agency committed to fighting hunger on a global level, providing food both during emergency situations such as conflicts and national disasters as well on the aftermath in order to help affected communities rebuild their lives.

The committee on World Food Security (CFS, 1974), is another intergovernmental forum in the UN, focusing on reviewing food security policies, including availability of- and accessibility to- food. Another UN food security initiative is the High Level Task Force (HLTF) on the Global Food Security Crisis, which was created after the 2008 spikes in food prices and aims to support national authorities in facing food and nutrition insecurity.

The Agricultural Market Information System (AMIS) is a G20 initiative aiming to enhance food market transparency as well as to promote coordination of policy actions responding to market uncertainty; the main focus is on four major crops of significant international food market importance, i.e. wheat, maize, rice and soybeans.

10.2. EU food safety information exchange networks and early warning systems⁹⁹

The increased trade, bilateral or international, of food or food raw materials, both of agricultural and animal origin, results in an increased importance of surveillance systems to contain the spreading contaminated foods or raw materials and protect the integrity of both national and global food chains. On an EU level, RASFF acts as an early warning information sharing system for food hazards, and it is complemented by TRACES, an EU-wide veterinary health monitoring and notification network, and by ADNS, an animal disease notification system between competent authorities. Similarly, EUROPHYT acts as a notification system for plant diseases. In addition, EFSA's Information Exchange Platform and the European Commission's Better Training for Safe Food projects act as hubs for sharing risk assessment or food safety practices respectively.

The Rapid Alert System on Food and Feed (RASFF) of the EU was created in 1979 to enable efficient information sharing on food safety risks between the national food authorities of the 28 MS, Norway, Lichtenstein, Iceland and Switzerland, as well as the Commission and EFSA. The legal basis of RASFF lies with General Food Law Regulation (EC) No 178/2002, article 50, which establishes RASFF as a network. Information exchange via RASFF can lead to product recalls and alleviation of food safety hazards for the EU consumers. RASFF can issue notifications, when a food, feed or food contact material present in the market bears serious risks for which rapid action is or might be required in a country other than the one emitting the alert. RASFF can also issue Information notifications, which concern food, feed or food contact materials which bear risks that do not however require immediate action. RASFF also includes border rejection notifications.

The Trade Control and Expert System (TRACES) is a EU-wide veterinary health network dedicated to monitoring, as well as carrying out notifications and certifications of imports, exports and trade in live animals and animal products. The TRACES system is supplemented by the Animal Disease Notification System (ADNS), an early warning notification system aimed at direct communication between competent authorities and registering and documenting major infectious animal disease outbreaks to ensure rapid containment actions.

The European Union Notification system for Plant Health Interceptions (EUROPHYT) is a rapid alert and notification system that deals with intercepting plant pathogens and pests in plants imported from third countries or from intra-EU trade.

Another EU-level food safety information network is EFSA's Information Exchange Platform (IEP, 2008); its aim is to connect and inform EFSA's advisory forum and focal point members on food risk assessment outputs by official bodies at a MS level; in addition, it acts as a database on requests to conduct risk assessment, results of risk assessment evaluations, work plans of food authorities as well as country – specific information on food safety (country profiles)

Apart from information exchange systems, the EC has also set up the Better Training for Safe Food initiative, covering food, feed, animal health and welfare and plant health rules, aiming to train MS and candidate country national authority staff that is involved in official controls in the above areas, keep the updated on EU food law and safety practices.

10.3. Better Training for Safer Food

"Better training for safer food" is a European Commission training initiative⁷⁰ covering food, feed, animal health and welfare and plant health rules, aiming to train MS and candidate country national authority staff that is involved in official controls in the above areas. The goal is to keep the participants updated with the latest EU legislation developments, therefore ensuring harmonised and efficient controls. Third country parties, especially from the developed world, can also participate, helping ease exportation of third country products into the EU. The training programmes cover various disciplines such as HACCP, animal welfare standards, animal by-products, audit systems, quality schemes such as organic or geographical indications, plant protection products, food hygiene and controls etc.

⁷⁰ Better training for safer food communication from the Commission to the council and the EU parliament COM(2006) 519

10.4. Resource efficiency and food waste

Resource efficiency in Europe is a Flagship Initiative of the Europe 2020 strategy towards a resource efficient, low-carbon economy to achieve sustainable growth⁷¹, calling for resource-efficient policies that will weight down different options, for example when land is used to produce food and could compete with land use for energy production. The Roadmap to a Resource Efficient Europe⁷² which followed provides outlines on how to achieve a sustainable European economy by 2050, with specific milestones and plans of action to achieve them. Concerning food, the milestone foresees that by "2020 incentives to healthier and more sustainable food production and consumption will be widespread and will have driven a 20% reduction in the food chain's resource inputs. Disposal of edible food waste should have been halved in the EU". Specific Commission actions include assessing how to best limit waste throughout the supply chain, as well as ways to lower the environmental impact of food production, develop sustainability criteria for key food commodities and how to further access security of Pi supply and sustainable use. MS on the other hand should address food waste in their national waste prevention programs. The latest discussion took place in the food losses and food waste Working Group of the Commission's Advisory Group on the Food chain, Animal and Plant health, mainly on defining food losses and food waste, how to facilitate donations of surplus food to food banks, communicating food sustainability, resource use in the food and feed chain, innovation supporting food waste reduction and food sustainability, as well as on how to support awareness and exchange best practices⁷³. In addition, a number of good practices have been identified covering a wide range of initiatives on food waste reduction at local, regional or national levels on the areas of research and innovation, awareness information and education as well as policy, awards and self-imposed certification⁷⁴.

In line with the resource efficiency and waste reduction policies, the EU Ecolabel is a voluntary environmental labelling system, launched in 1992 and legally defined in 2010 with Reg. (EC) No 66/2010⁷⁵, aiming at facilitating the recognition of high-quality, eco-friendly products by the consumers. It can be awarded to products or services that have a lower impact as other similar products or services, but cannot apply to veterinary products or medical products or devices. A number of criteria have to be fulfilled prior to the awarding of the Ecolabel, which are in line with EU environmental and ethical policies (impact on climate change, biodiversity, energy consumption, waste generation, durability & re-usability, effects on consumer health and safety, compliance with social and ethical standards, reduced animal testing etc.)

⁷¹ A resource-efficient Europe – Flagship initiative under the Europe 2020 Strategy. COM(2011) 21

⁷² Roadmap to a Resource Efficient Europe communication – COM(2011) 571 Final

⁷³ 3rd Meeting Summary Report: Working Group On Food Losses & Food Waste Of The Advisory Group On The Food Chain, Animal And Plant Health (2014)

⁷⁴ DG Health and Consumers Good Practices website http://ec.europa.eu/food/food/sustainability/gp_policy_awards_certifications_en.htm (► 10/11/2014)

⁷⁵ Reg. (EU) No 66/2010 on the EU Ecolabel (2010). Official Journal of the European Union L 27/1

10.5. EU agricultural quality product policy – Single CMO and Green Paper

10.5.1. Single CMO and Green Paper

The EU has been developing an agricultural product policy since the creation of the Common Market Organisations (CMO) in the 1960's for several agricultural products. In the 2007 the "Single CMO" was adopted. The Single CMO refers to the legal framework that the EU has established for certain agricultural sectors, providing common rules for managing agricultural markets, standards for marketing, importing or exporting agricultural products to and from the EU. The legal basis lies with Reg. (EC) 1234/2007, and especially in Annex I and II where the specific agricultural sectors are mentioned. The salient points of 1234/2007 were:

- *Internal market:* Market intervention: system of price support in parallel with the introduction of direct support schemes, special intervention measures: exceptional measures to protect markets in crisis, Quota schemes: national production quotas for sugar and milk – foreseen to be lifted, Aid: sugar, milk and milk products, fruits and vegetables, promotion of fruit and milk product consumption in schools, wines)
- *Marketing and Production:* marketing standards for certain products, protection label in wine sectors, recognition of producer and inter-branch organisations
- *Trade with third countries:* Import licences for products of certain sectors, import tariff quotas, export licences, export funds to support exportation of certain products.

Legislation 1234/2007 has been repealed by Reg. (EU) 1308/2013 under the 2014-2020 CAP reform.

In 2008 the EU adopted the Green Paper on "Agricultural Product Quality: product standards, farming requirements and quality schemes"⁷⁶ after completing a consultations phase, which discussed policy on production requirements and marketing standards, specific EU quality schemes, as well as certification schemes. The Green Paper was followed by a Communication⁷⁷ on agricultural product quality, which laid down strategic orientations to improve EU agricultural product quality policy, before the introduction of the new quality regulation: Reg. (EU) 1151/2012.

10.5.2. EU agricultural quality product policy – Quality scheme

Apart from standard quality and safety of foodstuffs, the EU has also set down laws regarding quality schemes for foods and beverages produced with exact specifications, which also included wines and aromatised wines. Geographical indications and traditional specialities are covered under the Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) and Traditional Specialties Guaranteed (TSG) schemes, which protect and promote specialised agricultural products and foodstuffs. In specific, PDO covers agricultural products and foodstuffs which are produced, processed and prepared in a specific geographical zone using recognised know-how. PGI instead covers foods and agricultural products linked to a specific geographical area, for at least one of the stages of production, processing or preparation. Finally, TSG stresses the traditional

⁷⁶ Green Paper on agricultural product quality: product standards, farming requirements and quality schemes. COM(2008) 641 Final

⁷⁷ Communication on agricultural product quality policy COM(2009) 234 final

character, be it in the composition or in the production method. The Commission DOOR database⁷⁸ contains a registry of PDO, PGI and TSG products.

The food and agricultural products quality schemes were first introduced with Reg. (EC) 510/2006⁷⁹ for PDO and PGI and Reg. (EC) 509/2006⁸⁰ for the TSG scheme. All of these schemes were revised with Reg. (EU) 1151/2012⁸¹. This regulation introduced a simplified regime for several quality schemes, as well as provided a robust framework for the protection and promotion of quality products. The main points include

- more coherence and clarity in EU quality schemes, reinforcement of existing schemes for PDO and PGI (faster registration procedures, clarified rules on controls, use of PDO and PGI to become compulsory for products of EU origin from early 2016, legal basis for having non-EU GI, legal basis for defence of EU logos recognised role of producer groups)
- a new approach at the TSG scheme (simplified and strengthened, as well as stricter prerequisites, e.g. need to have been circulating in the market for 30 years)
- a new framework for the development of optional quality terms for further consumer information (e.g. introduction of mountain products).

Further legal support and clarification of specific details was provided with Regulations (EU) No 664/2014⁸² (certain rules on sourcing, procedures and transitions), 665/2014⁸³ (regarding the use of the optional term "mountain product") and 668/2014⁸⁴ (specific rules including naming, definition of geographical area, feed, proof of origin), which supplemented Reg. (EU) 1151/2012.

The E-BACCHUS database is the register for PDO and PGI wines, in accordance with Regulation (EC) 1234/2007⁵². The 2008 reform of the wine sector aimed at making EU wine more competitive, making market management rules simpler and clearer, and at preserving the best traditions of EU wine growing and boosting its social and environmental role in rural areas. The EU plans to lift restrictions on planting vines after 2015, allowing competitive producers to boost their production.

10.5.3. EU agricultural quality product policy – Organic farming and products

To harmonise the production, labelling and control of organic products, and to ensure a fair competition between producers as well as strengthen consumer confidence, the Commission has adopted Reg. (EC) No 834/2007⁸⁵, repealing Reg. (EEC) No 2092/91⁸⁶.

⁷⁸ European commission DOOR database:

<http://ec.europa.eu/agriculture/quality/door/list.html;jsessionid=pL0hLqgLXhNmFQyFI1b24mY3t9dJQPflg3xbL2YphGT4k6zdWn34!-370879141> (► 11/11/2014)

⁷⁹ Reg. (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs (2006) Official Journal of the European Union L 93/12

⁸⁰ Reg. (EC) No 509/2006 on agricultural products and foodstuffs as traditional specialities guaranteed (2006) Official Journal of the European Union L 93/1

⁸¹ Reg. (EU) 1151/2012 on quality schemes for agricultural products and foodstuffs (2012). Official Journal of the European Union L 343/1

⁸² Delegated Reg. (EU) No 664/2014 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to the establishment of the Union symbols for protected designations of origin, protected geographical indications and traditional specialities guaranteed and with regard to certain rules on sourcing, certain procedural rules and certain additional transitional rules (2014). Official Journal of the European Union L 179/17

⁸³ Delegated Reg. (EU) No 665/2014 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to conditions of use of the optional quality term 'mountain product' (2014). Official Journal of the European Union L 179/23

⁸⁴ Delegated Reg. (EU) No 668/2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (2014). Official Journal of the European Union L 179/36

⁸⁵ Reg. (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (2007). Official Journal of the European Union L 189/1

Detailed rules concerning the implementation of 834/2007 were specified with Reg. (EC) No 889/2008⁸⁷. The legislation applies to products which bear or intend to bear indications referring to organic methods of production, and includes non-processed crop and livestock, farmed livestock, agricultural crop and livestock intended for human consumption that are processed mainly from one or more agricultural crop or livestock, as well as animal feeds. The regulation lays down rules of production as well as inspection rules and indications of conformity. The legislation also allowed for synthetic resources to be permitted in organic production, when no alternative suitable can be found. With the introduction of Reg. (EU) No 271/2010⁸⁸ (amending 889/2008), the EU organic logo was introduced and defined.

The European Commission has recently adopted a legislative proposal⁸⁹ for a new regulation on organic production and labelling of organic products, aiming at adjusting the EU legislation to the actual situation of the EU organic market, which has grown considerably in the last decade, so the sector can further develop. The legislative proposal is accompanied by an impact assessment⁹⁰. In addition, the EU has adopted an Action Plan⁹¹ regarding the future of European organic production, which aims to help organic producers and retailers to adjust to policy changes and to better prepare for future challenges.

10.5.4. EU agricultural quality product policy – Food Quality Certification schemes

An increasing number of voluntary certification schemes operate in the market, in parallel with the EU agricultural products and foodstuffs quality schemes. Voluntary certification schemes aim to assure that certain aspects and/or requirements of the production method, or the product itself, have been adhered to. Such schemes cover a wide range of initiatives at different stages of the supply chain, and can also may make use of logos.

The Commission has communicated (2010/C 341/04⁹²) specific guidelines to highlight best practices for the development and operation of such voluntary certification schemes. An inventory⁹³ compiled in 2010 counted 441 schemes for agricultural products and foodstuffs, which range from compulsory production standards, requirements for environmental protection to fair trade and animal welfare.

⁸⁶ Reg. (EEC) No 2092/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs. Official Journal of the European Union L 198/1

⁸⁷ Reg. (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control (2008). Official Journal of the European Union L 250/1

⁸⁸ Reg. (EU) No 271/2010 amending Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007, as regards the organic production logo of the European Union (2010). Official Journal of the European Union L 84/19

⁸⁹ Proposal for a regulation on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007. COM(2014) 180 Final, 2014/0100 (COD)

⁹⁰ Executive summary of the impact assessment regarding the proposal for a regulation on on organic production and labelling of organic products, amending Regulation (EU) No XXX/XXX of the European Parliament and of the Council [Official controls Regulation] and repealing Council Regulation (EC) No 834/2007. SWD (2014) 66 final

⁹¹ Action Plan for the future of Organic Production in the European Union. COM(2014) 179 final

⁹² Commission Communication 2010/C 341/04. EU best practice guidelines for voluntary certification schemes for agricultural products and foodstuffs (2010). Official Journal of the European Union C 341/5

⁹³ Inventory of certification scheme for agricultural products and foodstuffs marketed in the EU Member States – Data Aggregations (2010) Areté Research & Consulting in Economics

10.6. Common Agricultural Policy (CAP)

CAP is the Common Agricultural Policy framework of the EU. CAP is one of the oldest policies of the EU, dating back to 1962, and has been reformed on a number of occasions. The four main legislative texts related to the latest CAP reform (2014-2020) were introduced in late 2013 and cover the areas of rural development – Reg. (EU) No 1305/2013⁹⁴, horizontal issues such as funding and controls – Reg. (EU) No 1306/2013⁹⁵, direct payments for farmers – Reg. (EU) No 1307/2013⁹⁶ and market measures – Reg. (EU) No 1308/2013⁹⁷, as well as Reg. (EU) 1310/2013⁹⁸ that concerns transitional provisions regarding the application of the four main regulations during 2014.

The CAP reform 2014-2020⁹⁹ moves from product to producer support, and a more land-based approach to tackle challenges in three specific areas:

- i) Economic, focusing on food security, globalisation, declining productivity growth, price volatility, pressures of production costs, deteriorating position of farmers in the food chain, environmental and territorial changes.
- ii) Environmental, dealing with issues relating to resource efficiency, soil/water quality, threats to habitats/biodiversity
- iii) Territorial, addressing demographic decline in rural areas as well as social developments such as depopulation and relocation of businesses

The new CAP maintains the older CAP pillars of market and price support and rural development policy, but aims to increase the links between them, under a more holistic approach to policy support. To achieve a more competitive and sustainable agricultural sector, the new policy framework addresses some specific issues:

- Enhancing competitiveness of EU agriculture. Production quotas and volume restrictions on sugar, dairy and the wine sector will be lifted, allowing farmers to respond to growing world demand and enhancing competitiveness. Other outdated commodity aid schemes will be abolished, while others will be modernised. CAP also foresees facilitating producer co-operation under both pillars by improved access to credit for farmers and reducing their costs, setting up support for producer groups as well as implementing short supply chains. Added value will come from product differentiation, quality programs promotion and on-farm processing. Other policies include start-up aid for young farmers, as well as restructuring and modernisation measures. Bridging the gap between science and practice will be done via the Farm Advisory system, as well as training programmes, adapting farmers to new trends and technologies in order to become more resource efficient. The new CAP also offers more responsive safety net

⁹⁴ Reg. (EU) No 1305/2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) and repealing Council Regulation (EC) No 1698/2005. Official Journal of the European Union (2013) L 347/287

⁹⁵ Reg. (EU) No 1306/2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 (2013). Official Journal of the European Union L 347/649

⁹⁶ Reg. (EU) No 1307/2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009. Official Journal of the European Union (2013) L 347/608

⁹⁷ Reg. (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007. Official Journal of the European Union (2013) L 347/671

⁹⁸ Reg. (EU) No 1310/2013 laying down certain transitional provisions on support for rural development by the European Agricultural Fund for Rural Development (EAFRD), amending Regulation (EU) No 1305/2013 of the European Parliament and of the Council as regards resources and their distribution in respect of the year 2014 and amending Council Regulation (EC) No 73/2009 and Regulations (EU) No 1307/2013, (EU) No 1306/2013 and (EU) No 1308/2013 of the European Parliament and of the Council as regards their application in the year 2014. Official Journal of the European Union (2013) L 347/865

⁹⁹ Overview of CAP reform 2014-2020 (2013) Agricultural Policy Perspectives Brief No5/2013

measures and strengthens the EU's capacity for crisis management, via efficient market measures dealing with market disturbances, as well as more flexible exceptional measures. Thus measures also include a new crisis reserve of €400 million annually (deduction of direct payments, and unused amounts to be reimbursed to farmers in the consecutive budget years). Finally new CAP includes a new risk-management system with schemes for crops, animals and plants.

- Sustainable EU agriculture. The new CAP introduces a number of sustainability-driven measures aimed at improving its environmental performance. Concerning basic environmental requirements to receive CAP funding, simplified and more targeted cross-compliance procedures will be implemented. In addition, from 2015 and on the Green Payment is introduced, accounting for 30% of national direct payment envelope, rewarding farmers for respecting sustainability the practices of maintaining permanent grasslands, ecological focus areas and crop diversification. Since Green Payment is compulsory, it is expected to drive these environmentally-friendly practices. Concerning rural development, 30% of budget of rural development programmes must be reserved for voluntary measures that are environmental friendly (such as organic farming, areas of natural constraints, forestry measures etc.).

- Effective and efficient CAP: It is crucial to be able to distribute resources in a way that maximizes the achievement of CAP objectives; better targeting for support, more equitable distribution of payments across MS and a strategic approach to spending can enhance the effectiveness and efficiency of CAP. Direct payments will be limited to those who are actively engaged in agricultural activities. In addition, from 2015, all young farmers will have the opportunity to get an additional first pillar payment, which can be complementary to the start-up aid mentioned above. MS can also target direct payments through other optional schemes, such as redistributive payments to the first hectares of a farm, providing support for smaller farmers. Finally, CAP aims to reduce the disparities of direct payments between Ms (external convergence), by adjusting the level of direct payments per hectare (currently based on historic parameters in many countries) with the introduction of a minimum national average direct payment per hectare across all Ms by 2020. Payments will not be based on uneven historical records but on a fairer and more converging per hectare payment at national or regional level.

- Strategic approach to Rural Development spending: As in the past, rural development policy will be implemented through national/regional development programmes (RDPs). However, the new cap will improve policy by strengthening its strategic approach, since MS would have to base their RDPs on at least four out of six common EU rural development priorities:

- | |
|--|
| <i>1. Fostering knowledge transfer and innovation in agriculture, forestry, and rural areas</i> |
| <i>2. Enhancing farm viability and competitiveness of all types of agriculture in all regions and promoting innovative farm technologies and sustainable management of forests</i> |
| <i>3. Promoting food chain organisation, including processing and marketing of agricultural products, animal welfare and risk management in agriculture</i> |
| <i>4. Restoring, preserving and enhancing ecosystems related to agriculture and forestry</i> |
| <i>5. Promoting resource efficiency and supporting the shift towards a low carbon and climate resilient economy in agriculture, food and forestry sectors</i> |
| <i>6. Promoting social inclusion, poverty reduction and economic development in rural areas</i> |

Regarding EU quality and traditional foods, the CAP scheme foresees also information and promotion measures of agricultural products and their method of production (as well as for food products based on agricultural products) for internal or third country markets, as described in Regulation (EC) No 3/2008¹⁰⁰ and 501/2008¹⁰¹. Such informational and promotional measures can be financed in part by the EC budget. The measures include promotion and advertising to draw attention to the intrinsic properties and advantages of EU products, such as on their quality and safety, nutritional and health aspects, related animal welfare as well as sustainable production. In addition, the measures include informational campaigns on high quality products such for PDOs, PGIs and TSGs, as well as organic and other labelling schemes and symbols in foods and wines. The latest example comes from an €39 million EU support for 27 programmes such as fresh and processed fruits and vegetables, dairy, quality products (PDOs, PGIs, TSG, organic), flowers, as well as sheep meat¹⁰².

¹⁰⁰ Council Regulation (EC) No 3/2008 on information provision and promotion measures for agricultural products on the internal market and in third countries (2008) Official Journal of the European Union L 3, 5.1.2008, p.1). Amendments: (EC) No 479/2008. No 72/2009, No 153/2009

¹⁰¹ Council Regulation (EC) No 501/2008 laying down detailed rules for the application of Council Regulation (EC) No 3/2008 on information provision and promotion measures for agricultural products on the internal market and in third countries (2008) Official Journal of the European Union L 147/3

¹⁰² European Commission Press Release: €39 million EU support for the promotion of agricultural products. 30/10/2014

10.7. Common Fisheries Policy (CFP)

The EU's Common Fisheries Policy is a set of rules managing EU fishing fleets and aiming to conserve fish stocks. The CFP was first introduced in the 1970s, while the latest reform was in early 2014, introduced by Reg. (EU) No 1380/2013¹⁰³. The aim of CFP is to *"ensure that fishing and aquaculture is environmentally, economically and socially sustainable and that they provide a source of healthy food for EU citizens. Its goal is to foster a dynamic fishing industry and ensure a fair standard of living for fishing communities"*¹⁰⁴. CFP stipulates that between 2015-2020 environmentally sustainable catch limits should be set. CFP has four main policy areas:

i) Fisheries management, aimed at safeguarding stock reproduction for long term yield, conserving marine resources, sharing fishing opportunities, reducing unwanted catches and wasteful practices (e.g. introducing the landing obligation, from 2015-2019).

ii) International policy; more than a quarter of the fish in the EU is actually caught by EU boats outside EU waters. Around 8% of fish catches are made under fishing agreements with non EU countries, while approx. 20% are caught on high seas. As a major fishing power, the EU therefore plays an important role in promoting better governance through a number of international organisations or agreements with its partners. As far as trade is concerned, every three years the EU can reduce tariff rates in order to increase the import/supply of raw materials to the EU fish processing industry when the EU supply is not sufficiently high to meet internal demands

iii) Market and trade policy; the common organisation of the markets was set up to stabilise markets and to guarantee fair income for producers, evolving from a system doing market interventions to a system focused on sustainability, as well as give more responsibility for managing their sector to fisheries and aquaculture. The common markets organisation scheme covers mainly two areas; Organisation of the fishery and aquaculture sector (producer organisations, associations of such organisation, as well as market instruments), and marketing of fishery and aquaculture products (common marketing standards for fishery products sold in the EU, consumer information and labelling requirements, as well as market intelligence – European Market Observatory for Fishery and Aquaculture Products.

iv) Funding of the policy; this involves the EU fisheries fund (funding for all sectors of the industry, sea/inland fishing, aquaculture, processing and marketing of fish products, attention to fishing communities affected by recent changes in the industry), as well as the EU Maritime and Fisheries Fund (helps fishermen in transition towards sustainable fishing, supports coastal communities in diversifying their economies, finances projects for new jobs and quality of life along the EU coast, makes access to funding easier)

¹⁰³ Reg. (EU) No 1380/2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC. Official Journal of the European Union (2013) L 354/22

¹⁰⁴ European Commission's Common Fisheries Policy website: http://ec.europa.eu/fisheries/cfp/index_en.htm (► 10/11/2014)

10.8. Audio-visual Media Services

The Audio-visual Media Services Directive¹⁰⁵ (AVMS), which amended and replaced the Television without Frontiers Directive¹⁰⁶, aimed at providing less detailed but more flexible regulation on the EU's audio-visual policies as well as modernising television advertising rules. Concerning food, the AVMS directive states that the Commission and the MS should encourage media providers to establish and follow codes of conduct regarding *"inappropriate audio-visual commercial communications, accompanying or included in children's programmes, of foods and beverages containing nutrients and substances with a nutritional or physiological effect, in particular those such as fat, trans-fatty acids, salt/sodium and sugars, excessive intakes of which in the overall diet are not recommended"*. The first evaluation report of 2012¹⁰⁷ concludes that more efforts are needed to create support and best practices for codes of conduct concerning inappropriate advertisement to children of foods high in fat, salt and sugar, that the effectiveness of such codes of conduct should be further assessed. In addition, it states that the Commission will support the development of more stringent age and audience thresholds for advertising and marketing, as well as more consistent nutritional benchmarks.

¹⁰⁵ Directive 2010/13/EU on the on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audio-visual media (2010). Official Journal of the European Union L 95/1

¹⁰⁶ Council Directive 89/552/EEC on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the pursuit of television broadcasting activities (1989). Official Journal of the European Union L 298/23

¹⁰⁷ First Report on the application of Directive 2010/13/EU "Audiovisual Media Services Directive" Com(2012) 203 Final

10.9. Transatlantic Trade and Investment Partnership (TTIP)

The Transatlantic Trade and Investment Partnership¹⁰⁸ is a trade agreement that is currently being negotiated between the EU and the US, and aims at removing barriers to trade in a broad spectrum, facilitating trade of goods but also services. TTIP therefore extends to opening markets for investment, services as well as public procurement procedures. As a result, TTIP is not only about cutting tariffs across all sectors, but is also particularly focused on "behind the border" barriers, such as difference in regulations, standards and approval procedures. The main elements of the EU mandate¹⁰⁹ (which does not include audiovisual services) for negotiations are:

- Market access: i) As far as *tariffs* are concerned, the goal is to remove as much as possible the number of duties on transatlantic trade in industrial and agricultural products ii) Concerning *rules of origin*, the aim is to bring together the EU and US approaches to rules of origin in order to facilitate trade, taking into consideration the interests of EU producers iii) *Trade defense measures:* The EU aim is to establish a dialogue on anti-dumping and anti-subsidy measures with the US, maintaining its right to use such measures in the framework of WTO rules iv) *Services:* The goal is to open the services sectors to an extent that is at least equal to other trade agreements, as well as open services markets to new sectors, such as in the transport sector. The EU aims at having European professional qualifications recognized in the US and that EU companies will be able to operate in the US under the same conditions as domestic companies v) As far as *investment* is concerned, the aim is to achieve the highest levels of liberalization and investment protection that nowadays exist in other trade deals between the EU and the US vi) *Public Procurement:* The aim is to create new business opportunities by opening up access to governmental procurement in the US.
- Regulatory issues and non-tariff barriers: This addresses non-tariff related barriers but "behind the border" issues that could impede trade, and which currently represent the most significant trade barriers. Therefore, a high potential economic benefit lies within the regulatory area. The aim is to remove unnecessary regulatory/procedural obstacles to trade and investment, by reaching a regulatory compatibility for goods and services, via increased recognition, harmonization and cooperation between regulators. As far as Sanitary and Phytosanitary (SPS) measures (health and hygiene standards, e.g. for food products) are concerned, EU¹¹⁰ and US will establish provisions based on the WTO SPS and existing veterinary agreement, introducing subjects such as plant health. In addition, and apart from the principles of the WTO SPS agreement, the negotiations on SPS measures should be based on science and on international standards or scientific risk assessment, leaving however room to each party to assess and manage risk in accordance with the level of protection that each side deems appropriate. This is particularly important when scientific evidence is insufficient; however this process should be transparent and applied only to the extent necessary to protect human animal or plant health. Finally, the agreement should achieve full transparency regarding SPS measures applicable to trade, and "*in particular establish provisions for the recognition of equivalence, implementation of pre-listing of food-producing establishments, preventing implementation of pre-clearance, recognition of disease-free and pest-free health*

¹⁰⁸ The Transatlantic Trade and Investment Partnership EU home page <http://ec.europa.eu/trade/policy/in-focus/ttip/> (► 12/11/2014)

¹⁰⁹ Directives for the negotiation on the Transatlantic Trade and Investment Partnership between the European Union and the United States of America. Declassified document 11203/13 DCL1

¹¹⁰ Initial EU position paper: EU-US transatlantic trade and investment partnership: Sanitary and Phytosanitary Issues

status of the Parties and the principle of regionalisation for both animal diseases and plant pests". In addition, regulatory compatibility will be dealt with in sectors such as chemical, pharmaceutical and health sectors (e.g. medical devices). Since all regulatory differences cannot be eliminated in a single step, both parties foresee an evolving agreement that allows progressively greater regulatory convergence via specific milestones.

- Addressing Shared Global Trade Challenges and Opportunities in the 21st century: The agreement goes beyond bilateral trade and will also contribute to the strengthening of the multilateral trading system on specific issues: intellectual property rights and trade and sustainable development.

As far as food safety is concerned, some critical points that are expected to be extensively discussed during the negotiations include, but are not limited to, the following:

- The EU's Precautionary Principle, which relies on preventive decision making in the case of risk; the Precautionary Principle may be only invoked after specific conditions have been met: the identification of potentially adverse effects, the evaluation of the available scientific data, as well as the evaluation of the extent of scientific uncertainty. Under the Precautionary Principle, where existing scientific data do not allow for a certain evaluation of a particular human, animal, plant or environmental risk, then the production or distribution of a potentially hazardous product may be stopped or the product could be withdrawn.
- EU restrictions on genetically modified organisms: GMOs have to undergo a strict authorisation procedure involving national agencies, EFSA and the GM reference labs of the JRC, before obtaining market approval or ability to be cultivated within the EU. Currently, for food/feed use, only one GM maize plant is commercially cultivated in the EU (GM maize, MON 810), in 5 MS (Spain, Portugal, Czech Republic, Romania and Slovakia). In 2010, a GM starch potato (Armflora) was authorised for industrial applications, however it is no longer cultivated since 2011. With the latest council decision (June 2014), MS have now more possibilities to restrict or ban the cultivation of GMOs that have been authorised on an EU level, in all or parts of their territory.
- EU ban on the use of veterinary growth hormones; the EU has banned the use of veterinary growth hormones since the 1981, and as a result has banned also imports of hormone-treated meat, in particularly beef from the US. Hormones banned included among others estradiol, progesterone, testosterone, zeranol. In the US, growth hormones for beef are still in use, and this has led to a lengthy EU-US dispute and various WTO formal appeals, consultations, settlement panels and arbitration proceedings¹¹¹. Other EU bans that could be focused by the TTIP negotiations include the growth hormone promoter ractopamin, used in pigs and cattle, as well as carcass treatment procedures such as chlorinated rinses of poultry carcasses.

The use of Investor-State Dispute Resolution (ISDR), i.e. the ability of investors to sue governments and ask compensation over rules that can affect expected trade profits, even though it is argued that both the EU and US legal systems are perfectly capable of resolving such disputes without the need of a trade mechanism.

¹¹¹ The US-EU Beef Hormone Dispute (2010) Congressional Research Service

Annex I: Additional implementing measures for selected Articles of Regulation 178/2002 and their respective requirements

In the following paragraphs certain requirements of Reg. 178/2002 are highlighted and regulatory documents adding details for their implementation are described.

a) Article 7 on the precautionary principle

The precautionary principle, as established by Article 7 of Regulation (EC) 178/2002, indicates that when risk assessment identifies the possibility of harmful effects to life or health but scientific uncertainty persists, provisional risk management measures may be adopted in order to ensure the highest level of health protection. These measures should be appropriate for the circumstances and not more restrictive to trade than necessary and should also consider technical, economic and other factors. Also the measures should be reviewed within a reasonable period of time, once more scientific information allows for a more comprehensive risk assessment. In 2000 a communication document was published by the Commission on the precautionary principle (COM(2000) 1 final).

b) Article 9 on public consultation

Article 9 of Regulation (EC) 178/2002 establishes public consultation during the preparation, evaluation and revision of food law under the principle of transparency. In that respect, Commission Decision 2004/613/EC established an Advisory Group on the food chain, animal and plant health attached to the Commission. The Commission must consult this group on issues of food/feed safety, food/feed labelling and presentation, human nutrition legislation, animal health and welfare and crop protection, plant protection products and their residues. The Decision also specifies the group's structure and operation and highlights the importance of publicity of its work and confidentiality. A list of the members of the group was subsequently published under Article 3 of Decision 2004/613/EC. More recently, additional members were added to the Advisory Group and a new list with all the members was published by Decision 2011/242/EU.

c) Article 18 on traceability

Article 18 of Regulation (EC) 178/2002 specifies requirements related to traceability at all stages of the food chain. The food business operators must be able to identify the business from which they have been supplied food and the businesses to which they have supplied food. This is known as "one step back-one step forward" approach. Also accurate records and documentation must be in place to allow traceability in case of emergency. However, information and experience from previous food crises has shown that the documentation gathered is not always sufficient to allow full traceability leading to huge economic costs, in particular in the animal origin food sector. In that respect, Implementing Regulation (EC) No 931/2011 (EU, 2011b) requires the food business operators in the field of food of animal origin to supply specific information to the businesses to which they supply products. This information should be maintained in accurate records and in case of an emergency it should be made available to the Authorities.

d) *Article 25 on management board*

Article 25 of Regulation (EC) 178/2002 lays down detailed provisions for the composition of the Management Board of the European Food Safety Authority, their background and their term of service. On the basis of this Article, a series of Council Decisions have been published on the appointment of the EFSA members of Management Board (i.e. Council Dec. 2013/C 187/06, 2012/C 192/01, 2010/C 171/05).

e) *Article 28 on Scientific Committee and Scientific Panels*

Article 28 of Regulation 178/2002 defines the responsibilities of the Scientific Committee and the Scientific Panels of the European Food Safety Authority, their composition, the number and names of the different Panels and also procedures for operation and decision making. When required by scientific and technical developments, the introduction of new Panels or their renaming can be fulfilled through the publication of Regulations amending Regulation 178/2002 (i.e. Com. Reg (EC) No 575/2006, Com. Reg. (EC) No 202/2008).

f) *Article 29 on scientific opinions*

Article 29 of Regulation 178/2002 provides details on the operation of the European Food Safety Authority and specifically on the issuing of Scientific Opinions. Regulation (EC) No 1304/2003 lays down the procedure to be followed by the Authority on the requests for scientific opinions. A register of the different types of requests must be established which must be available to the public. The Authority forwards the requests to the relevant scientific panels to prepare the opinion. Timelines are also established and procedures for the handling of urgent requests. The Authority maintains the right to refuse a request for an opinion under specific conditions with reasoning for doing so.

g) *Article 36 on networking of organisations operating in the fields within the Authority's mission*

Article 36 of Regulation (EC) 178/2002 specifies that EFSA must promote networking between the organisations operating in the different fields under its umbrella. A list of these organisations in the different Member States must be made publicly available. Commission Regulation (EC) 2230/2004 (EC, 2004b) lays down detailed rules for the implementation of the above requirements. It specifies the criteria that the organisations must meet in order to be included in the list, the requirement for evidence of compliance to these criteria and timelines for review of their competence. It also specifies the scientific and technical tasks that can be entrusted to these organisations and performance criteria for the monitoring of their competence.

h) *Article 44 on the implementation of the Authority's budget*

Article 44 of Regulation 178/2002 establishes the detailed procedure for the implementation of EFSA's budget, together with the persons' responsibilities and timelines. Each financial year a report is published on the management of the budget.

i) *Article 51 on implementing measures (for the RASFF)*

Article 51 of Regulation (EC) 178/2002 expresses the need for the establishment of implementing measures with regard to the conditions and procedures for the transmission of notifications and any additional information under the Rapid Alert

System for Food and Feed (RASFF) established by Article 50. Regulation (EU) No 16/2011 implements these measures, specifies the duties of the different members in the RASFF network, details for the alert notification procedure and the submission procedure and timelines where required, as well as for follow-up notifications. It also lays down a procedure for the withdrawal of notifications and details for the exchange of information with third countries.

j) Article 53 on emergency measures for food or feed of Community origin or imported from a third country

Article 53 of Regulation (EC) No 178/2002 allows for the establishment of emergency measures for food or feed originating from the Community or from third countries when the products might be of serious risk to human or animal health or the environment. Such measures may be the suspension of placement on the market or of imports of the products under consideration or other appropriate measures to reduce the risk. These emergency measures may be published in the form of Implementing Decisions or Implementing Regulations. The following table shows examples of such implementing acts:

k) Article 55-57 on crisis management

Articles 55-57 of Regulation (EC) 178/2002 on Crisis Management prescribe that the Commission must establish a general plan for crisis management in food and feed safety in collaboration with EFSA and the Member States. When risks cannot be handled by the established emergency measures a crisis unit must be set up and its tasks are specified by Commission Decision 2004/478/EC. This Decision specifies the situations and procedures that can lead to the necessity to adopt a crisis plan. It also provides information on how to establish a network of crisis coordinators in different Member States, how to establish a crisis unit, its role and action to be taken and how this information can be used in the decision-making process by the Commission. Crisis management decisions are not taken by the unit but in accordance with the Committology procedures. Nevertheless, the principle of transparency is highlighted and also information is given on the communication aspects and confidentiality.

l) Extended scope of Regulation (EC) No 178/2002

Regulation (EC) No 1635/2006 lays down rules for the imports of agricultural products from third countries following the accident at the Chernobyl nuclear power station. To that respect, RASFF applies for the notification of products that are not in compliance with the limits for radioactivity established by Council Regulation (EEC) 737/90 (repealed by Council Regulation 733/2008).

Table 1: Implementing Regulations and Implementing Decisions establishing emergency measures for the import of products from third countries under Article 53 of Reg (EC) No 178/2002

Implementing Regulations	Scope	Notes
Reg. (EC) No 297/2011	Special conditions for the import of food or feed originating or consigned from Japan following the accident at the Fukushima nuclear power station	Amended by: - Reg. 351/2011 - Reg. 506/2011 - Reg. 657/2011 Repealed by Reg. 961/2011
Reg. (EC) No 961/2011	>>	Amended by: - Reg. 1371/2011 - Reg. 250/2012 Repealed by Reg. 284/2012
Reg. (EC) No 284/2012	>>	Amended by: - Reg. 561/2012 Repealed by Reg. 996/2012
Reg. (EC) No 996/2012	>>	Amended by: - Reg. 495/2013
Dec. 2008/352/EC	Special conditions on the import of guar gum from India due to contamination risks with pentachlorophenol and dioxins	Amended by: - Reg. 258/2010 - Reg. 647/2011
Reg. (EC) No 91/2013	Special conditions on the import of groundnuts from Ghana and India, okra and curry leaves from India and watermelon seeds from Nigeria	Amending Regulations 669/2009 and 1152/2009
Dec. 2006/504/EC	Special conditions for certain foodstuffs imported from third countries due to the risk of contamination with aflatoxins	Amended by: - Dec. 2007/459/EC - Dec. 2007/563/EC - Dec. 2007/759/EC - Dec. 2009/669/EC Repealed by Regulation 1152/2009/EC
Reg. (EC) No 1152/2009	Special conditions for the import of foodstuffs from third countries due to aflatoxin contamination risk	Amended by: - Reg. 274/2012 - Reg. 91/2013

Reg. (EC) No 601/2008	Protective measures for fishery products imported from Gabon and intended for human consumption	Amended by: - Reg. 1114/2011
Reg. (EC) No 884/2007	Emergency measures suspending the use of E128 Red 2G as food colour	Repealed by Reg. (EU) No 1129/2011
Dec. 2008/388/EC	Special conditions on the import of sunflower oil from Ukraine due to contamination risk by mineral oil	Repealed by Dec 2008/433/EC. Repealed by Reg. 1151/2009
Dec. 2008/866/EC	Suspending imports from Peru of certain bivalve molluscs intended for human consumption	Amended by: - Dec. 2009/297/EC - Dec. 2009/862/EC - Dec. 2010/641/EC - Dec. 2011/723/EC Replaced by 2012/729/EC Amended by: - Dec. 2013/636/EC
Dec. 2010/381/EC	Emergency measures for consignments of aquaculture products imported from India and intended for human consumption	Amended by: - Dec. 2012/690/EC
Dec. 2010/220/EC	Emergency measures for farmed fishery products imported from Indonesia and intended for direct human consumption	Repealed by: - Dec. 2012/690/EC
Dec. 2011/884/EC	Emergency measures on unauthorised genetically modified rice in rice products from China	Amended by: - Dec. 2013/287/EC
Dec. 2011/402/EU	Emergency measures on fenugreek seeds and certain seeds and beans imported from Egypt	Amended by: - Dec. 2011/662/EC - Dec. 2011/718/EC - Dec. 2011/880/EC
Dec. 2008/630/EC	Emergency measures applicable to crustaceans imported from Bangladesh and intended for human consumption	Amended by: - Dec. 2010/387/EC - Dec. 2011/742/EC
Dec. 2006/601/EC	Emergency measures regarding the non-authorized genetically modified organism "LL Rice 601" in rice products	Amended by: - Dec. 2006/754/EC - Dec. 2008/162/EC Repealed by Dec. 2010/315/EC
Dec. 2010/220/EC	Emergency measures for farmed fishery products imported from Indonesia and intended for direct human consumption	
Dec. 2009/835/EC	Special conditions on official controls on the import of pears from	

	Turkey due to high residue levels of amitraz	
Dec. 2010/219/EC	Special conditions on fishery products imported from Indonesia and intended for human consumption	
Dec. 2007/642/EC	Emergency measures for fishery products imported from Albania and intended for human consumption	
Dec. 2007/82/EC	Emergency measures suspending imports of fishery products from the Republic of Guinea intended for human consumption	
Dec. 2005/317/EC	Emergency measures regarding the non-authorized genetically modified organisms Bt-10 in maize products	Repealed by Dec. 2007/157/EC
Dec. 2006/694/EC	Prohibiting the placing on the market of curd cheese manufactured in a dairy establishment in the UK	Repealed by Dec 2007/148/EC
Dec. 2006/698/EC	Emergency measures for fishery products from Brazil for human consumption	Related to Reg. 853/2004 with regard to the max. levels for histamine in fishery products
Dec. 2006/27/EC	Special conditions on meat and meat products of equidae imported from Mexico and intended for human consumption	
Dec. 2005/402/EC	Emergency measures regarding chilli, chilli products, curcuma and palm oil	Repealed by Reg. (EC) No 669/2009
Dec. 2004/629/EC	Protective measures with regards to poultry meat and poultry products from Brazil intended for human consumption	
Dec. 2002/251/EC	Protective measures on poultrymeat, fishery and aquaculture products for human consumption from Thailand	Amended by: - Dec. 2003/477/EC - Dec. 2003/559/EC - Dec. 2003/895/EC
Dec. 2002/805/EC	Protective measures for products of animal origin for animal nutrition imported from Ukraine	

Annex II: Additional implementing measures for selected Articles of Regulation 882/2004 and their respective requirements

In the following paragraphs the main requirements of Reg. 882/2004 are highlighted and regulatory documents that add requirements or assist in the implementation of this Regulation are described.

a) Article 3 on general obligations with regard to the organisation of official controls

Regulation 178/2002 on general food law establishes the Rapid Alert System for Food and Feed (RASFF) and also requires implementing measures to be set with regard to the procedures for the transmission of notifications and other supplementary information. Regulation 882/2004 establishes the official controls for ensuring compliance with food and feed law. RASFF allows for the rapid communication of food and feed risks, thus allowing Member States to meet their responsibilities according to Regulation 178/2002. Regulation 16/2011 lays down implementing measures for the RASFF system. Specifically with regard to border rejection notifications, the Regulation requires the Commission contact point to transmit such rejections to designated points of entry (as established under Regulation 882/2004).

Regulation 142/2011 implements Regulation 1069/2009 on health rules for animal by-products and derived products not intended for human consumption and indicates that the competent authority is responsible for the official controls at all stages of the chain which should be carried out according to Article 3 of Reg. 882/2004. Regulation 1069/2009 also indicates that all controls related to the products covered by this Regulation shall be carried out according to the control plans of Reg. 882/2004. Specific reference is made to Articles 41 and 42 of Reg. 882/2004 on multi-annual control plans, Article 46 on Community controls in third countries, Article 50 on support for developing countries and Article 52 on third country controls in Member States, which apply directly to the scope of Regulation 1069/2009.

Regulation 1169/2011 on the provisions of food information to the consumers indicates that Member States should carry out official controls to enforce the requirements of this Regulation in accordance with the provisions of Regulation 882/2004.

b) Articles 4-5 on designation of competent authorities, operational criteria and delegation of specific tasks related to official controls

Article 4 of Regulation 882/2004 indicates that Member States must designate the competent authorities responsible for the official controls and must also lay down their operational criteria. When official controls are conferred to non-central, regional or local authorities, efficient and effective coordination must be ensured between all authorities involved, as well as between different units involved.

Regulation 1143/2014 on the prevention and management of the introduction and spread of invasive alien species indicates that Member States must put in place functioning structures to carry out the appropriate risk-based controls in product categories to be specified in the Union list (to be published), when these are brought into the Union, for the prevention of the intentional introduction in the Union of invasive alien

species of concern. If for these products official controls are already required at the borders or at points of entry by Regulation 882/2004 or Directive 2000/29/EC on protective measures against the introduction in the Community of organisms harmful to plants or plant products and against their spread within the Community, these will be conferred to the authorities of Article 4 above.

On a different context, Regulation 1306/2013 on the financing, management and monitoring of the common agricultural policy and specifically Article 90, requires that Member States take all necessary steps to stop the unlawful use of designations of origin, geographical indications and protected traditional terms and that they designate the competent authority responsible for carrying out the checks in order to meet the obligations of Regulation 1308/2013 for different grapevine products according to the criteria of Article 4 of Reg. 882/2004. It is also required that the competent authority or any of the control bodies as established by Article 5 of Reg. 882/2004 verify compliance with the product specification either during the production or during or after the conditioning of the wine.

In a similar context, Regulation 1151/2012 on quality schemes for agricultural products and foodstuffs establishes quality schemes that provide the basis for the identification and protection of names or terms which indicate or describe agricultural products with value-adding attributes or characteristics. Regulation 882/2004 requires Member States to designate competent authorities to carry out official controls in order to verify compliance with the legal requirements related to the quality schemes established by Regulation 1151/2012, and also competent authorities and control bodies to verify compliance with the product specifications for protected designations of origin, geographical indications and traditional specialities guaranteed. Also Member States must ensure that activities for the control of the above obligations are specifically included in a separate section in the multi-annual control plans according to the specifications for these control plans laid down in Articles 41-44 of Reg. 882/2004.

Under the same scope of designating competent Authorities, their operational criteria and delegating specific tasks related to official controls, Regulation 834/2007 on organic production and labelling of organic products requires all Member States to set up a system of controls in accordance with the requirements of Reg. 882/2004, comprising at least the application of precautionary and control measures. The Regulation also specifies conditions under which a competent authority may delegate control tasks to a particular control body according to Article 5 of Reg. 882/2004, certain criteria to be considered by the competent authority when approving a control body, as well as specific tasks that should not be attributed to control bodies, procedures for the withdrawal of a delegation, additional provisions to those of Article 5 and finally the requirement that each Member State must attribute a specific number to each control authority/body performing control tasks.

c) *Article 11 on methods of sampling and analysis*

Article 11 of Regulation 882/2004 lays down requirements for methods of sampling and analysis used for official controls. Regulation 10/2011 on plastic materials and articles intended to come into contact with food requires that analytical methods for testing the migration and residual content of substances in food must comply with the criteria established in this Article. With regard to substances (or groups of similar compounds) not listed in the Union list or in provisional lists, used in the manufacture of a plastic layer not in direct contact with food and separated from food by a functional barrier in plastic multilayer materials and articles, their migration in food or food simulants should be non-detectable with statistical certainty using a method of analysis set in Article 11 of Reg. 882/2004 with a limit of detection of 0.01 mg/kg expressed in the food or food simulant. Similarly, Regulation 450/2009 on active and intelligent materials and articles

intended to come into contact with food indicates that the migration into food of substances from components not in direct contact with food or the environment surrounding food must not exceed 0.01 mg/kg as measured with statistical certainty with a method of analysis that meets the requirements of Article 11 of Reg. 882/2004.

The 5th paragraph of Article 11 of Regulation 882/2004 establishes the right of the food business operator whose products are being subjected to official controls to apply for a supplementary expert opinion. Annex II of Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China, laying down methods for the sampling and analysis for the official control of such products, requires for a second laboratory sample to be constituted from the bulk samples being examined, in order to meet the above requirement of Reg. 882/2004.

d) Article 12 on official laboratories

Article 12 of Regulation 882/2004 indicates that the competent authority can designate laboratories to carry out the analysis of samples taken during official controls, provided they are accredited according to European standards.

Commission Implementing Decision 2013/652/EC lays down detailed rules for the harmonised monitoring and reporting of antimicrobial resistance (AMR) in zoonotic and commensal bacteria and allows for the competent authority to designate laboratories other than the national reference laboratory for AMR to perform the specific analytical tests required and laid down in the Annex to the Decision.

Commission Decision 2010/346/EU on protective measures with regard to equine infectious anaemia in Romania lays down specific obligations for the country. Romania must ensure that the official laboratory carrying out the Agar Gel Immunodiffusion tests for Equine infectious anaemia (AGID) meets the requirements of Article 12 of Reg. 882/2004 and undergoes each year an annual proficiency testing in collaboration with the European Union Reference Laboratory for equine diseases other than African horse sickness.

In a broader scope, Regulation 273/2008 lays down detailed rules for the application of Council Regulation 1255/1999 regarding methods for analysis and quality evaluation of milk and milk products. The Regulation specifies that such products may only be analysed in laboratories that have an analytical quality assurance system in place including internal quality control procedures. However laboratories that are accredited in accordance with Article 12 of Reg. 882/2004 are exempt from the obligation to participate in proficiency testing.

e) Article 19 on action following official controls on feed and food from third countries

Article 19 of Regulation 882/2004 lays down details on action to be taken following official controls in case products do not comply with the requirements of food and feed law.

Regulation 258/2010 imposing special conditions on imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, implements that products containing more than 0.01 mg/kg pentachlorophenol following official controls performed as specified within the Regulation must not enter the food chain and they must be disposed of according to the above provisions of Reg. 882/2004.

Regulation 1151/2009 imposing special conditions governing the import of sunflower oil originating in or consigned from Ukraine due to contamination risks by mineral oil, indicates that sunflower oil imported into the Community must not contain more than 50 mg/kg of mineral paraffin. Also it is required that each consignment of sunflower oil intended for import into the Community is accompanied by a certificate and an analytical report issued by an accredited laboratory indicating the analytical result as well as the measurement of uncertainty and limits of detection and quantification of the analytical method used. The competent authorities must check that each consignment is accompanied by these documents. In case of non-compliance, measures must be taken in accordance with Article 19 of Reg. 882/2004.

f) Article 27 on fees and charges

Article 27 of Regulation 882/2004 lays down provisions on how Member States may collect the fees and charges in order to cover the costs associated with official controls. Decision 2008/946/EC implementing Directive 2006/88/EC as regards the requirements for quarantine of aquaculture animals, indicates that certain activities relating to quarantine fall under the definition of official controls of Regulation 882/2004 and therefore the costs related with such activities must be covered by Article 27 of Reg. 882/2004. Also this Decision lays down some minimum conditions for the construction and equipment of quarantine facilities as defined under Reg. 882/2004, as well as for their management.

g) Article 31 on registration/approval of feed and food business establishments

Article 31 of Regulation 882/2004 lays down requirements for the registration and approval of food business establishments and requires the competent authorities to maintain up-to-date lists of approved establishments. Regulation 2074/2005 laying down implementing measures for Reg. 882/2004 sets out requirements for these lists of approved establishments. Specifically each Member State is required to provide the Commission with a link to a single website where an up-to-date list of all approved establishments for products of animal origin under Regulation 853/2004 can be found. More specific details are provided for this list in the Regulation, as well as the requirement that this website is developed by the competent authority designated in each Member State for the purposes of official controls according to Article 4 of Reg. 882/2004.

Council Decision 2011/408/EU lays down some simplified rules and procedures for the sanitary controls of fishery products, live bivalve molluscs, echinoderms, tunicates, marine gastropods, their by-products and products derived from their by-products originating from Greenland. Specifically, Member States do not need to apply veterinary controls and these products from Greenland may be placed on the market under the sanitary controls applicable in the European Community provided that Denmark and Finland meet certain conditions one of which is the maintenance by the competent authorities in the two countries of up-to-date lists of the food and feed business operators that have been registered according to the above Article of Reg. 882/2004.

h) Article 32 on Community reference laboratories

Article 32 of Regulation 882/2004 lays down the responsibilities of the different Community reference laboratories. Implementing Decision 2012/767/EU, taking into consideration that the Pirbright Institute in the UK fulfils all the responsibilities for the EU reference laboratories provided by the above Article, prolongs the designation of this

Institute as the EU reference laboratory for foot-and-mouth disease for an undetermined period of time.

Implementing Regulation 844/2012 laying down provisions for the implementation of the renewal procedure for active substances as provided for in Regulation 1107/2009 on the placing of plant protection products on the market, indicates that EFSA may request the Commission to consult one of the European Union reference laboratories in order to verify whether the analytical method proposed by the applicant for the determination of residues of the active substance due for renewal is satisfactory and complies with the requirements of Regulation 1107/2009.

Article 32 of Regulation 882/2004 also implements that Community Reference Laboratories could be granted financial contribution from the Community. Details are laid down in Implementing Regulation 926/2011 on provisions for financial aid to the EU reference laboratories for food and feed and animal health sector and Regulation 652/2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare and relating to plant health and plant reproductive material.

Decision 2009/961/EU, on financial aid from the Union for 2010 for certain Community reference laboratories in the field of animal health and live animals, grants financial assistance to the AFFSA laboratory in France to carry out responsibilities as established under Article 32 of Reg. 882/2004 as a Community reference laboratory for brucellosis. Similarly, Decision 2008/332/EC laid down financial aid as above for 2008 and Decision 2007/336/EC for 2007. Decision 2008/912/EC lays down the Community financial contribution for 2009 for certain Community reference laboratories in the field of food and feed control.

Regulation 470/2009 implements Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin. The Regulation establishes that, when necessary for the functioning of the controls of Reg. 882/2004, the Commission may establish reference points for action for residues of pharmacologically active substances. These must be detected and confirmed by official control laboratories according to Reg. 882/2004 and by methods validated according to Community requirements. Also the Community reference laboratories established according to Reg. 882/2004 must be consulted for the establishment of analytical methods for residues from pharmacologically active substances. The European Medicines Agency must provide advice on such methods to the Community and the national reference laboratories.

j) Article 45 on Community controls in Member States

Article 45 of Regulation 882/2004 lays down provisions for Community controls and specifically general and specific audits in the Member States. Regulation 1/2005 lays down provisions on the protection of animals during transport. For the purposes of ensuring uniform application of this Regulation, veterinary experts from the Commission together with Member States' authorities may make on-the-spot checks according to the procedures of Article 45 of Reg. 882/2004.

j) Article 48 on specific import conditions

Article 48 of Regulation 882/2004 allows for the implementation of specific import conditions not covered by Regulation 854/2004 on specific provisions for the organisation of official controls on products of animal origin intended for human consumption. In that respect, Regulation 605/2010 lays down animal and public health

and veterinary certification conditions for the introduction in the Community of raw milk and dairy products intended for human consumption.

Regulation 183/2005 lays down requirements for feed hygiene. Imports of feed from third countries are permitted only if the third country of dispatch appears in a list of third countries from where import of feed is permitted and if the establishment appears on a list of approved establishments from which import of feed is permitted, both established under the requirements of Reg. 882/2004.

k) Article 51 on training of control staff

Article 51 of Regulation 882/2004 allows for the organisation of training courses for staff of the competent authorities that undertake official control activities. Commission Implementing Decision 2013/770/EU establishing the Consumers Health and Food Executive Agency, includes between the objectives and tasks of this Authority the implementation of food safety training measures covered by Reg. 882/2004.

l) Article 54 on action in case of non-compliance

The scope of Regulation 882/2004 also covers animal health and animal welfare while Article 54 specifically lays down enforcement measures in case of non-compliance with its requirements. Regulation 1009/2009 on the protection of animals at the time of killing adds for further action to be taken in case non-compliance to Reg. 882/2004 is observed.

m) Annex III on characterisation of methods of analysis

Annex III of Regulation 882/2004 lays down specific criteria for the characterisation of methods of analysis for official controls of food. Commission Recommendation 2010/133/EC on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits and on the monitoring of ethyl carbamate levels in these beverages suggests that Member States use the criteria of Reg. 882/2004 during the analysis of ethyl carbamate in such products.

Similarly, Recommendation 2010/161/EC on the monitoring of perfluoroalkylated substances in food suggests that Member States use the criteria of Reg. 882/2004 during the analysis of these substances. It also suggests that a method of analysis shown to provide reliable results should be used and that the recovery rate of the method should be 70-120% while the limit of quantification 1 µg/kg.

Also Recommendation 2010/307/EC on the monitoring of acrylamide levels in food and Recommendation 2007/196/EC on the monitoring of the presence of furan in foodstuffs, indicate that these analyses should be carried out according to the criteria of Annex III of Reg. 882/2004.

n) Annex VI on criteria to be taken into consideration for the calculation of fees

Annex VI of Regulation 882/2004 lists certain items. The costs borne by the competent authorities in relation to these items allow for calculations to be made for the maximum fees collected for the purposes of official controls. Decision 2010/436/EU implementing Council Decision 2000/258/EC as regards proficiency tests for the purposes of maintaining authorisations of laboratories to carry out serological tests to monitor the

effectiveness of rabies vaccines indicates that from the 1st of January 2011 AFSSA Nancy may charge each laboratory taking part in the proficiency testing for carrying out the above tests a fee. This fee should be calculated taking into account the criteria set down in Annex VI of Regulation 882/2004.

o) Annex VII on European Union Reference Laboratories

Annex VII of Regulation 882/2004 lays down a list of the EU Reference Laboratories for feed and food and for animal health and live animals. Commission Decision 2007/142/EC establishes a Community Veterinary Emergency Team to assist the Commission in supporting Member States and third countries in veterinary matters relating to certain animal diseases. This team is composed of experts in order to provide assistance in control measures in case of outbreak or suspicion of certain animal disease subject to communication, as listed in Annex I of Council Directive 82/894/EEC. Assistance should be provided in coordination with the concerned Community Reference Laboratory listed in Annex VII of Regulation 882/2004.

Regulation 882/2004 also covers the official controls for verification of compliance with the safety of materials and articles intended to come into contact with food covered by Regulation 1935/2004. Compliance with Reg. 1935/2004 must be enforced through official controls carried out by the Member States. In this respect, the Community Reference Laboratory for materials and articles intended to come into contact with food as well as the national laboratories established under Reg. 882/2004 shall assist the Member States by contributing to a high quality and uniformity of analytical results.

p) Extended scope of Regulation (EC) No 882/2004

Regulation 1107/2009 lays down requirements for the placement of plant protection products on the market. With regards to the approval of an active substance, Regulation 1107/2009 indicates that in order to verify that the analytical method suggested in the dossier for the determination of residues of the substance is satisfactory and that any residues resulting from authorised uses and of toxicological, ecotoxicological or environmental relevance can be determined by appropriate methods with appropriate limits of determination on relevant samples, EFSA may ask the Commission to consult a Community reference laboratory designated under Reg. 882/2004. Furthermore, the applicant may be requested by the Community reference laboratory to submit samples and analytical standards to the authorities.

Commission Recommendation 2014/118/EU lays down recommendations for the monitoring of traces of brominated flame-retardants in food. The Recommendation indicates that the analysis of such compounds in food should be performed in accordance with Annex III of Reg. 882/2004 laying down criteria to characterise the different methods of analysis as well as instructions on how to select an appropriate method and using a method of analysis that has been proven to generate reliable results.

Commission Regulation 669/2009 implements Regulation 882/2004 with regard to the increased level of control for certain non-animal products from certain third countries and requires a Common Entry Document for prior notification of such products in the Community. Regulation 1152/2009 imposing special rules for the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins provides guidance for the implementation of the above requirements.

Regulation 110/2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks indicates that, within the Community, the verification of compliance with the specifications of geographical indications before placing a product on the market, must be ensured by one or more

competent authorities and one or more control bodies that operate as product certification bodies. The Regulation also implements that Member States are responsible for the control of spirit drinks and that they must take all measures for the compliance with this Regulation, as well as for the designation of the competent authorities for official controls according to Reg. 882/2004.

Council Directive 2007/43/EC lays down minimum rules for the protection of chickens kept for meat production. The competent authority must carry out inspections to ensure compliance with the requirements of this Directive according to the provisions on inspections of Regulation 882/2004.

Annex III: Additional implementing measures for selected Articles of Regulation 2003/2003 and their respective requirements

In the following paragraphs the main requirements of Regulation (EC) No 2003/2003 are highlighted and regulatory documents that add requirements or assist in the implementation of this Regulation are described.

a) Article 5 on free circulation

Article 5 of Reg. (EC) No 2003/2003 requires Member States to not restrict the placing on the market of EC fertilisers in compliance with the requirements of the Regulation. Commission Decision 2012/230/EU extending the period referred to in Article 114(6) of the Treaty on the Functioning of the European Union in relation to national provisions concerning the maximum admissible content of cadmium in fertilisers notified by the Kingdom of Sweden approves the request of Sweden to introduce national provisions derogating from Reg. (EC) No 2003/2003.

In the same context, Commission Decision 2012/719/EU on the national provisions notified by the Kingdom of Sweden concerning the maximum admissible content of cadmium in fertilisers rejected the related national conditions that Sweden notified to the Commission.

b) Article 37 on national provisions

Article 37 of Reg. (EC) No 2003/2003 requires Member States to notify their national provisions on indication of nutrient contents, control measures and penalties to the Commission. Under this Article, several Commission Decisions have been implemented, approving the national provisions of different Member States until harmonised measures are established, such as Dec. 2006/347/EC, 2006/348/EC, 2006/349/EC, 2006/390/EC.

c) Annex I on list of types of EC fertilisers, part. A.2 on phosphatic fertilisers

Annex I A.2 of Reg. (EC) No 2003/2003 lays down the list of phosphatic-type EC fertilisers. Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, indicates that only fertilisers included in Annex I to the Regulation may be used in organic plant production or seaweed cultivation and only to the extent necessary when the nutritional needs of plants cannot otherwise be met. These must meet the specification for the relevant products of Annex I A.2 of Reg. (EC) No 2003/2003.

d) Annex III on technical provisions for ammonium nitrate fertilisers with high nitrogen content

Annex III of Reg. (EC) No 2003/2003 lays down certain technical requirements for ammonium nitrate fertilisers with high nitrogen content. Decision 1348/2008/EC of the European Parliament and of the Council amending Council Directive 76/769/EEC as regards restrictions on the marketing and use of 2-(2-methoxyethoxy)ethanol, 2-(2-butoxyethoxy)ethanol, methylenediphenyl diisocyanate, cyclohexane and ammonium nitrate indicates that ammonium nitrate must not be placed on the market as a substance or in a preparation containing more than 28% by mass of nitrogen in relation

to ammonium nitrate for use as fertiliser, unless it meets the requirements of Annex III of Reg. (EC) No 2003/2003.

The same requirement is also laid down by Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency for ammonium nitrate.

The second part of Annex III of Reg. (EC) No 2003/2003 described the test of resistance to denotation of ammonium nitrate fertilisers with high nitrogen content. Directive 2012/18/EU of the Parliament and of the Council on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC lists certain hazardous substances which are subject to qualifying quantities. Amongst these substances are included the fertiliser grades of ammonium nitrate.

e) *Annex IV methods of sampling and analysis*

Annex IV lays down methods of sampling and analysis for fertilisers. Commission Implementing Regulation (EU) No 839/2012 concerning the authorisation of urea as a feed additive for ruminants indicates that for the determination of total nitrogen in the additive and of the biuret contribution of the additive certain methods of Annex IV of Reg. (EC) No 2003/2003 must be used.

Annex IV: Additional implementing measures for selected Articles of Regulation 1069/2009 and their respective requirements

In the following paragraphs only the main requirements of Regulation (EC) No 1069/2009 referring to use of animal by-products as fertilisers or soil improvers are highlighted and regulatory documents that add requirements or assist in the implementation of these provisions are described.

a) Article 3 on definitions

Article 3 of Reg. (EC) No 1069/2009 lays down definitions for animal by-products and derived products.

Annex IX of Regulation (EC) No 999/2001 of the European Parliament and of the Council laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies lays down rules for the importation into the Community of live animals, embryos, ova and products of animal origin. Specific rules are laid down for the import of rendered fats derived from Category 2 or Category 3 material of bovine, ovine and caprine origin and their starting materials or intermediate products, intended to be used as organic fertilisers and soil improvers. These products may only be imported if they are accompanied by a health certificate showing a negligible risk of spongiform encephalopathies.

Commission Decision 2007/275/EC concerning lists of animals and products to be subject to controls at border inspection posts under Council Directives 91/496/EEC and 97/78/EC lays down rules for veterinary checks to be carried out at border control posts for the above products. Chapter 31 of this Decision refers to animal fertilisers and specifically animal-derived products in an unadulterated form, manure and manure mixed with animal protein for use as fertiliser for which veterinary checks must be carried out. Specific requirements for these products are laid down in Annex XIV of Reg. (EU) No 142/2011.

b) Articles 9 and 10 on Categories 2 and 3 materials

Article 9 and 10 of Reg. (EC) No 1069/2009 lay down provisions for Category 2 and 3 animal by-products. Commission Regulation (EC) No 889/2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, indicates that when the nutritional needs of plants cannot be met by the measures of Regulation 834/2007, only fertilisers and soil conditioners contained in Annex I of Reg. (EC) No 889/2008 may be used in organic production and to the extent necessary, while operators must keep evidence of the need of use of these products. Annex I of Reg. (EC) No 889/2008 contains biogas digestate containing animal by-products co-digested with material of plant or animal origin (Category 2 and 3 animal by-products) not from factory farming origin under the conditions that the processed must be in accordance with Reg. (EU) No 142/2011 and that the products must not be applied to the edible parts of the crop.

c) Article 15 on implementing measures

Article 15 of Reg. (EC) No 1069/2009 lays down the requirement for the establishment of additional implementing measures for the application to land of animal by-products,

organic fertilisers and soil improvers. Article 32 of the Regulation lays down conditions for the placement on the market and use of organic fertilisers and soil improvers and the requirement for additional implementing measures to be established. Commission Regulation (EU) No 142/2011, implementing Regulation (EC) No 1069/2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive and specifically its Annex XI lays down implementing provisions for the placement on the market and use of organic fertilisers and soil improvers.

Annex V: Additional implementing measures for selected Articles of Regulation 1107/2009 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 1107/2009 and provide additional regulatory documents that add to the main text or assist in the implementation of this main text.

a) Article 8 of Regulation 1107/2009 on dossiers

Article 8 of Regulation 1107/2009 indicates the information that must be included in a summary dossier submitted for the authorisation of an active substance. Some of the required data include those for active substances and plant protection products set out in Directive 91/414/EC (now repealed by Regulation 1107/2009) which were implemented by Reg. 544/2011. Regulation 283/2013 lays down the detailed data requirements for the authorisation of active substances as required by Article 8 of Reg. 1107/2009 and repeals Reg. 544/2011.

Similarly, Regulation 284/2013 lays down detailed data requirements for the authorisation of plant protection products (and repeals Reg. 545/2011).

b) Article 13 of Regulation 1107/2009 on approval Regulation

Article 13 of Regulation 1107/2009 lays down the procedure for adopting an approval Regulation for an active substance further to the review report presented by the Commission, any accompanying comments and also taking into account the precautionary principle. Commission Implementing Regulation 788/2011 approves the active substance fluazifop-P in accordance with Reg. 1107/2009, specifies the conditions of use and amends the Annex to Implementing Reg. 540/2011. Several similar Regulations have also been adopted for the approval or not of other active substances in accordance with Reg. 1107/2009. When the Regulations concern the non-approval of an active substance, these are published as amendments to Commission Decision 2008/934/EC concerning the non-inclusion of certain active substances in Annex I of Directive 91/414/EC (repealed by Reg. 1107/2009) and the withdrawal of authorisations for plant protection products containing these substances.

During the evaluation and decision-making process for a possible approval of an active substance, Commission Decisions may be published for the extension of provisional authorisations with effect for a defined length of time. For example, Commission Implementing Decision 2012/363/EU allows Member States to extend provisional authorisations granted for the new active substances bixafen, *Candida oleophila* strain O, fluopyram, halosulfuron, potassium iodide, potassium thiocyanate and spirotetramat.

c) Articles 14-21 of Regulation 1107/2009 on renewal and review

Articles 14-21 of Regulation 1107/2009 lay down requirements on the renewal and review process for active substances, safeners, synergists and co-formulants. Specifically Article 15 establishes timelines during which the application for renewal must be submitted, while Article 17 allows for certain extensions to these timelines. Under these two Articles, Regulation 823/2012 allows for derogation from the provisions of Reg. 540/2011 with regard to the expiry of the approval of certain active substances.

Article 19 on implementing measures indicates that a Regulation must be published establishing the procedures for the implementation of the renewal process for active substances and where relevant also a work programme. Implementing Regulation 686/2012 allocates to Member States, for the purposes of the renewal procedure, the evaluation of active substances the approval of which expires by 31st of December 2018 at latest. Also Commission Implementing Regulation 844/2012 lays down the provisions necessary for the implementation of the renewal procedure for active substances as provided for in Reg. 1107/2009.

d) Article 29 of Regulation 1107/2009 on requirements for the authorisation for placing on the market

Article 29 of Reg. 1107/2009 lays down the requirements for the authorisation of placing plant protection products on the market. It is required that uniform principles are applied for the evaluation and authorisation of such products and that certain of the requirements of Directive 91/414/EC (repealed by Reg. 1107/2009) should be maintained. Regulation 546/2011 implements Reg. 1107/2009 with regards to the uniform principles for evaluation and authorisation of plant protection products which is also required under Article 84 of Reg. 1107/2009 (on certain Regulations that need to be adopted further to Reg. 1107/2009).

e) Article 55 of Regulation 1107/2009 on use of plant protection products

Article 55 of Reg. 1107/2009 lays down the requirement for the proper use of plant protection products in accordance with Good Plant Protection Practice (GPPP), with the instructions provided on the label of the product based on the authorisation requirements and also with the principles of integrated pest management. Regulation 1305/2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) indicates that support under the advisory, farm management and farm relief services may be provided to individual farmers, young farmers and other land managers if it is linked to at least one Union priority for rural development and covers at least one of certain elements, one of which is compliance with Article 55 of Reg. 1107/2009 and specifically compliance with the principles of integrated plant management.

Similarly, in order to meet the requirements on proper use of plant protection products of Article 55 of Reg. 1107/2009 and also of Article 14 of Dir. 2009/128/EC on the framework for sustainable use of pesticides and specifically the integrated pest management policy, Regulation 1306/2013 on the financing, management and monitoring of the common agricultural policy implements the farm advisory system, a system to provide advice on different issues related to land and farm management, including the above requirements.

Within the scope of Article 55 of Reg. 1107/2009 and in order to enforce users' compliance with the requirement for proper use of plant protection products, Commission Recommendation 2014/63/EU on measures to control *Diabrotica virgifera virgifera* Le Conte in Union areas where its presence is confirmed, suggests that Member States should ensure that any guidelines for integrated pest management relevant to *Diabrotica* and addressed to maize farmers or professional users are in accordance with the requirements of Article 55 of Reg. 1107/2009.

f) Article 65 of Regulation 1107/2009 on labelling

Article 65 of Regulation 1107/2009 lays down requirements on the labelling of plant protection products. Further to the repeal of Directive 91/414/EEC, it is necessary for the implementation of Reg. 1107/2009 to adopt a Regulation on the labelling requirements for plant protection products. These are now implemented by Regulation 547/2011.

Regulation 649/2012 lays down provisions for the import and export of hazardous chemicals. Chemicals intended for export must be subject to the above provisions of Reg. 1107/2009 on packaging and labelling of plant protection products.

g) Article 67 of Regulation 1107/2009 on record-keeping

Article 67 of Regulation 1107/2009 with regard to controls of plant protection products to be placed on the market requires producers, distributors, suppliers and importers/exporters of plant protection products to maintain records of the products they produce, import/export, use or store for certain lengths of time. Professional users must also maintain records of the products used and the time, dose and area of application. Regulation 1185/2009 on statistics on pesticides requires Member States to collect data on statistics on the placing on the market and use of pesticides as required under Annexes I and II. For this purpose, information collected under Article 67 of Reg. 1107/2009 may be used, along with data from surveys and administrative sources.

h) Article 76 of Regulation 1107/2009 on expenditure by the Commission

Article 76 of Regulation 1107/2009 indicates that the Commission shall cover certain expenses related to activities covering the requirements of Regulation 1107/2009. Commission Implementing Decision 2014/C 72/05 sets out the financing of the 2014 work programme on IT tools in the field of food safety, animal health, animal welfare and plant health.

Also under the same Article, Commission Decision 2013/C 170/06 sets out the financing for 2013 of activities in the veterinary field related to the European Union's information policy and support of international organisations and to several measures necessary to ensure the application of the food and feed and the plant health legislation.

i) Article 83 of Regulation 1107/2009 on repeal

Article 83 of Regulation 1107/2009 implements the repeal of Directive 91/414/EEC, however the active substances included in Annex I of the Directive must be considered as approved under Reg. 1107/2009. Thus, for the implementation of Reg. 1107/2009 a Regulation containing the list of approved active substances of Annex I of Dir. 91/414/EEC must also be adopted. This is implemented by Commission Implementing Regulation 540/2011 implementing Reg. 1107/2009 as regards the list of approved active substances.

j) Extended scope of Regulation (EC) No 1107/2009

Regulation 1107/2009 lays down provisions for the authorisation of active substances, but also provisions for the review of approvals (Article 21) as well as for the withdrawal or amendment of authorisations (Article 44). Directive 2008/105/EC lays down environmental quality standards in the field of water policy and requires the Commission to submit a report to the European Parliament and to the Council on the outcome of the assessment of whether the EU and the Member States have sufficient measures in place

to achieve the environmental quality standards for priority substances and the phasing-out of priority hazardous substances in accordance with Directive 2000/60/EC (establishing a framework for Community action in the field of water policy). If the results of the report show that for certain substances approved under Regulation 1107/2009 additional measures are necessary at European or national level to meet the requirements of the above Directives, then the above Articles 21 and 44 of Regulation 1107/2009 on the review, amendment or withdrawal of the authorisation must be applied.

Regulation 1107/2009 lays down requirements for the placement of plant protection products on the market. Directive 2009/128/EC establishes a framework for Community action for the sustainable use of pesticides. The specific provisions for the protection of the aquatic environment and drinking water must be compatible with and support the requirements of Reg. 1107/2009.

Directive 2006/42/EC on machinery lays down requirements for different machinery, including for pesticide application machinery used for the application of plant protection products.

Annex VI: Additional implementing measures for selected Articles of Regulation 396/2005 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 396/2005 and provide additional regulatory documents that add to the main text or assist in the implementation of this main text.

a) Article 7 of Regulation 396/2005 on requirements relating to applications for MRLs

Article 7 of Regulation 396/2005 details the particulars and documents that must be included in an application for an MRL. Regulation 1107/2009 on the placing of plant protection products on the market indicates that the dossier submitted together with the application for the approval of an active substance must include a copy of the application for the MRL according to the above Article. Also with regard to the placing of plant protection products on the market, such products may only be authorised if maximum residue levels have been established in accordance with Reg. 396/2005.

Regulation 188/2011 lays down rules for the implementation of Dir. 91/414/EC (repealed by Reg. 1107/2009) with regards to the assessment of active substances that were not on the market 2 years after the notification of the Directive. Where appropriate, the dossier submitted for the approval of the substance must contain a copy of an application for the establishment of relevant MRLs or a justification for not supplying such a document.

Implementing Regulation 844/2012 laying down the provisions for the implementation of the renewal procedure for active substances as provided for in Regulation 1107/2009 concerning the placing of plant protection products on the market, indicates that the supplementary dossier to be submitted to the rapporteur Member State for renewal of the approval of an active substance must contain, where relevant, a copy of the application for MRLs or a justification for not supplying such a document.

b) Article 16 of Regulation 396/2005 on the procedure for setting temporary MRLs in certain circumstances

Article 16 of Reg. 396/2005 lays down the procedure for the establishment of MRLs under certain circumstances. The Annex to Regulation 283/2013 sets the data requirements that need to be included in the dossier for active substances in accordance with Reg. 1107/2009 and also indicates that in certain exceptional cases MRLs may be based on monitoring data.

c) Article 29 of Regulation 396/2005 on Community control programme

Article 29 of Reg. 396/2005 lays down the requirement for the Commission to prepare a coordinated multiannual Community control programme in order to assess consumer exposure to pesticide residues and the application and compliance with Community legislation. This has been implemented for the years 2015, 2016 and 2017 by Implementing Regulation 400/2014.

d) Article 36 of Regulation 396/2005 on support measures relating to harmonised pesticide MRLs

Article 36 of Reg. 396/2005 lays down support measures to be established at Community level related to harmonised pesticide MRLs. One of these measures is the establishment of a database of all Community legislation on pesticide MRLs. Commission Implementing Decision 2014/C 72/05 on the financing of the 2014 work programme on IT tools in the field of food safety, animal and plant health and animal welfare lays down the work programme and the distribution of the budget between different projects for these implementing measures.

e) Annex I of Regulation 396/2005 on products of plant and animal origin

Annex I of Reg. 396/2005 lists products of plant or animal origin to which maximum residue levels for pesticides apply. The same categorisation of products is also used in Regulation 1881/2006 setting maximum levels for certain contaminants in foodstuffs.

f) Extended scope of Regulation 396/2005

Regulation 396/2005 lays down maximum residue levels of pesticides in food and feed of plant or animal origin. Directive 91/414/EEC on the placing of plant protection products on the market (repealed by Reg. 1107/2009) indicates that plant protection products may not be authorised unless, amongst other conditions, MRLs have been established for the agricultural products affected by the use indicated in the authorisation.

Regulation 528/2012 lays down conditions for the making available on the market and use of biocidal products. A biocidal product may be granted authorisation provided, where appropriate, maximum residue levels have been established in food or feed for the active substances contained in the product, in accordance with Reg. 396/2005.

Implementing Regulation 91/2013 lays down some specific provisions for the import of groundnuts from Ghana and India, okra and curry leaves from India and watermelon seeds from Nigeria. Specific provisions are established for okra and curry leaves from India with regard to the method for analysis of pesticide residues which must be in compliance with the requirements of Reg. 396/2005 and the frequency of physical and identity checks at import.

Annex VII: Additional implementing measures for selected Articles of Regulation 3954/87 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 3954/87 and provide additional relevant regulatory documents required for their implementation.

a) Articles 2 and 3 of Regulation (EURATOM) 3954/87

Article 2 and 3 of Regulation (EURATOM) 3954/87 indicate that a Regulation must be adopted laying down maximum levels of radioactive contamination in foodstuffs and feed in case of nuclear accident or other radiological emergency. Council Regulation 2219/89 on the special conditions for exporting foodstuffs and feedingstuffs following a nuclear accident or any other case of radiological emergency indicates that food with levels of radioactive contamination higher than those laid down in the above Articles of Reg. 3954/87 must not be exported.

Until the entry into force of such a Regulation as required under Reg. 3954/87 above and before 31 March 2020, Council Regulation 733/2008 on the conditions governing imports of agricultural products originating in third countries following the accident at the Chernobyl nuclear power station indicates that products originating from third countries may be released for free circulation provided they comply with the maximum levels laid down in Article 2 of the Regulation.

b) Article 7 of Regulation (EURATOM) 3954/87

Article 7 of Regulation (EURATOM) 3954/87 indicates that for the application of this Regulation further Regulations must be adopted to establish rules for its implementation and maximum levels of radioactive contamination in certain minor foodstuffs and feed.

Commission Regulation (EURATOM) 944/89 lays down maximum permitted levels for radioactive contamination in minor foodstuffs following a nuclear accident or any other case of radiological emergency.

Commission Regulation (EURATOM) 770/90 lays down maximum permitted levels for radioactive contamination of feedingstuffs following a nuclear accident or any other case of radiological emergency.

c) Annex to Regulation (EURATOM) 3954/87

The Article to Regulation (EURATOM) 3954/87 lays down maximum permitted levels of radioactive contamination in food and feed. Commission Implementing Regulation 996/2012 imposes special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station and repealing Implementing Regulation (EU) No 284/2012 lays down maximum levels for the sum of caesium-134 and caesium-137 in food and feed originating or consigned from Japan. These levels replace the ones established by Reg. 3954/87 on a provisional basis. This Regulation was valid until the 31st March 2014. Since that date, the above scope is covered by Commission Implementing Regulation 322/2014 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station.

Annex VIII: Additional implementing measures for selected Articles of Directive 2001/18/EC and their respective requirements

The following paragraphs highlight the main requirements of Directive 2001/18/EC and provide additional relevant regulatory documents required for the implementation of the Directive.

a) Articles 1-2 of Directive 2001/18/EC on objectives and definitions

Articles 1 and 2 of Directive 2001/18/EC lay down the scope and definitions for the purposes of deliberate release into the environment of GMOs. Council Directive 68/193/ECC on the marketing of material for the vegetative propagation of the vine indicates that GM vine varieties may be accepted for inclusion in the member States' catalogues of officially accepted varieties for certification and as standard propagating material, provided appropriate measures have been taken to avoid adverse effects on human health and the environment. Specifically, an environmental risk assessment must be carried out in accordance with the requirements of Directive 2001/18/EC.

b) Article 4 of Directive 2001/18/EC on general obligations

Article 4 lays down the general obligations of the Member States under the precautionary principle, to ensure that all measures are taken in order to prevent any adverse effects to human or animal health or the environment from the deliberate release of GMOs to the environment. The competent authorities of the Member States must also organise inspections and controls as well as measures for the termination of an unauthorised release and initiation of remedial action. In this respect, Commission Recommendation 2005/637/EC lays down measures to be taken by the consent holder to prevent any damage to health and the environment in the event of the accidental spillage of an oilseed rape (*Brassica napus* L., GT73 line – MON-00073-7) genetically modified for tolerance to the herbicide glyphosate.

Also, in a similar context, Commission Decision 2007/232/EC on the placing on the market of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium indicates that Member States may carry out checks and additional monitoring in order to identify any accidental spillage of the above oilseed rape products and any associated adverse effects.

c) Articles 5-11 of Directive 2001/18/EC (Part B) on deliberate release of GMOs for other purpose than placing on the market

Part B of Directive 2001/18/EC lays down provisions for the deliberate release of GMOs in the environment for other purposes than placing on the market.

Regulation 726/2004 on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency indicates that the application for authorisation of medicinal products for human or veterinary use consisting of or containing GMOs must be accompanied by a copy of the competent authority's written consent for the deliberate release of GMOs in the environment for research and development purposes according to the requirements of the above section of Dir. 2001/18/EC.

Regulation 1107/2009 on the placing on the market of plant protection products indicates that the derogation established under Article 53 of Reg. 1107/2009 for placement on the market under special and emergency circumstances for limited and controlled uses and for specified short periods of time must not be authorised for plant protection products containing or composed of GMOs unless such a release has been approved under the requirements of Dir. 2001/18/EC. Similarly, permits for trial purposes for experiments or tests involving the release into the environment for research and development purposes may not be granted to plant protection products containing or composed of GMOs, unless such a release has been approved under the requirements of Dir. 2001/18/EC.

d) Article 10 of Directive 2001/18/EC on reporting by notifiers on releases

Article 10 of Directive 2001/18/EC indicates that at certain intervals after the release of a GMO into the environment for purposes other than placing on the market, the notifier must provide the competent authority with the results of the release, in particular in relation to risks to health and the environment as well as information on products that the notifier intends to release at a later stage. The Directive indicates that a specified format must be established for the submission of this information, which is provided by Commission Decision 2003/701/EC.

e) Article 11 of Directive 2001/18/EC on exchange of information between competent authorities and the Commission

Article 11 of Directive 2001/18/EC indicates that the Commission shall set up a system for the exchange of information contained in notifications for the deliberate release of GMOs for purposes other than placing on the market and requires a specified format to be developed for this summary information. This is implemented by Council Decision 2002/813/EC.

f) Articles 12-24 of Directive 2001/18/EC (Part C) on placing on the market of GMOs as or in products

Articles 12-24 of Directive 2001/18/EC lay down the information required for the authorisation of GMOs for placing on the market as such or in products. Article 5 of Regulation 1829/2003 indicates that when a GMO has been authorised under Part C of Dir. 2001/18/EC above, the application for authorisation of GMOs or food containing or consisting of GMOs under Reg. 1829/2003 must also include a copy of the above authorisation decision.

Article 7 of Regulation 1829/2003 indicates that references in Parts A and D (general and final provisions respectively) of Dir. 2001/18/EC to GMOs authorised under part C of Dir. 2001/18/EC are equally applicable to GMOs authorised under Reg. 1829/2003. Similar requirements are also established under Article 17 of Reg. 1829/2003 on applications for the authorisation of GM feed.

Directive 2001/82/EC on the Community code relating to veterinary medicinal products indicates that for such products containing or consisting of GMOs the authorisation application must also include the information required under Part C of Dir. 2001/18/EC. Also the relevant information required for the environmental risk assessment of the release of such products may be presented according to Dir. 2001/18/EC and Reg. 726/2004 considering any relevant guidance documents.

Regulation 546/2011 implements Reg. 1107/2009 with regards to the uniform principles for evaluation and authorisation of plant protection products. According to this Regulation, in order for GMOs to be authorised for use as plant protection products, an evaluation under Dir. 2001/18/EC and the relevant decision by the competent authorities must be submitted and taken into account.

g) Article 13 of Directive 2001/18/EC on notification procedure

Article 13 of Directive 2001/18/EC lays down the information required during the notification procedure for a GMO to be placed on the market. One of the details that need to be submitted with the notification is a summary of the dossier which must be provided in a specified format. Council Decision 2002/812/EC establishes, pursuant to Directive 2001/18/EC, this summary information format for the placing on the market of GMOs as or in products.

h) Article 18 of Directive 2001/18/EC on Community procedure in case of objections

Article 18 lays down the procedure to be followed in case the competent authority of a Member State raises and maintains an objection on the placing on the market of a GMO or GM product. Commission Decision 2004/643/EC concerning the placement on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea Mays L.* line NK603) genetically modified for glyphosate tolerance requires the competent authority of Spain to issue a written consent for the placement of the above product on the market and also lays down specific conditions that must be met by the consent. Similarly, Commission Decision 2005/465/EC, on the placing on the market in accordance with Directive 2001/18/EC of an oilseed rape product (*Brassica napus L.*, GT73 line) genetically modified for tolerance to the herbicide glyphosate, requires the competent authority of the Netherlands, that originally had raised an objection for the placement of this product on the market, to grant a written consent, as there is no reason to believe that there might be a risk to human or animal health or the environment from the above product. It also specifies the conditions that this consent must be subject to. Similar requirements are also laid down by several Commission Decisions (2005/608/EC, 2005/635/EC, 2005/772/EC, 2007/232/EC).

Commission Decision 2008/470/EC on the provisional prohibition of use and sale in Austria of GM maize (*Zea mays L.* line T25) pursuant to Directive 2001/18/EC, requests Austria to terminate the prohibition of import and use into food and feed of the above product, as this is not justified under Article 23 of the Directive on safeguard clause. Similar requirements are also laid down under Decision 2008/495/EC.

i) Article 19 of Directive 2001/18/EC on consent

Article 19 indicates that a GMO or GM product may only be used throughout the Community without further notification, provided a written consent has been granted for the placing on the market of that product and any relevant conditions are strictly adhered to. Regulation 1107/2009 of the European Parliament and of the Council on the placing of plant protection products on the market indicates that plant protection products that contain GMOs may only be authorised under this Regulation provided they have already been granted a written consent under the above Article.

j) Article 21 of Directive 2001/18/EC on labelling

Article 21 laying down provisions for the labelling of GMOs for placement on the market as or in products, requires for a minimum threshold to be established below which products are exempt from the above labelling requirement and implements such a threshold for products intended for direct processing. This threshold is implemented by Article 7 of Regulation 1830/2003.

k) Article 26a of Directive 2001/18/EC on measures to avoid the unintended presence of GMOs

This Article indicates that appropriate measures must be taken by the Member States in order to avoid the unintended presence of GMOs in other products and that the Commission must provide guidance on the coexistence of GM, conventional and organic crops. This guidance is provided by Commission Recommendation 2010/C 200/01.

In order to achieve the development of this guidance, this Article also requires the Commission to gather and coordinate information based on studies conducted at Community or Member State level and to follow relevant developments. Commission Decision 2005/463/EC implements this requirement establishing a network group for the exchange and coordination of information concerning coexistence of GM, conventional and organic crops.

l) Article 30 of Directive 2001/18/EC on Committee procedure

Article 30 of Directive 2001/18/EC indicates that the Commission must be assisted by a Committee. Commission Recommendation 2004/787/EC on technical guidance on sampling and detection of GMOs and material produced from GMOs as or in products, in the context of Regulation 1830/2003, indicates that the above Committee has been consulted in developing this guidance document.

Commission Regulation 65/2004 establishing a system for the development and assignment of unique identifiers for GMOs lays down certain measures in accordance with the opinion of the above Committee.

m) Article 31 of Directive 2001/18/EC on exchange of information and reporting

Article 31 of Directive 2001/18/EC requires the Commission to establish one or several registers for recording the information on genetic modification of GMOs which can be used for detecting and identifying specific GMO products during the post-marketing control and inspection. This is implemented by Commission Decision 2004/204/EC laying down detailed arrangements for the operation of the registers for recording the information on genetic modifications in GMOs. The information required includes details of nucleotide sequences or other information necessary for the identification of the GMO product and its progeny such as methods for detection and identification of the GMO, including methods for the detection of thresholds established under Dir. 2001/18/EC. This information must be extracted by the competent authorities from the information that is included in the notification under Article 13 of Dir. 2001/18/EC. These registers must be made publicly available according to Article 25 of Dir. 2001/18/EC.

Commission Implementing Decision 2014/C 72/05 sets out the financing of the 2014 work programme on IT tools in the field of food safety, animal health, animal welfare and plant health. The budget for the financing of the registers on the information on the genetic modifications in the GMOs is also part of this programme.

n) Article 32 of Directive 2001/18/EC on implementation of the Cartagena Protocol on biosafety

Article 32 of Directive 2001/18/EC invites the Commission to implement the requirements of the Cartagena Protocol on biosafety. Regulation of the European Parliament and of the Council No 1946/2003 aims to implement a common system of notification and information for trans-boundary movements of GMOs and to ensure coherent implementation of the requirements of the Cartagena Protocol in order to ensure the safe transfer, handling and use of GMOs for the conservation and sustainable use of biological diversity and considering the risks to human health. With regards to the international information procedure, Member States must notify to the Biosafety Clearing House any decision on the deliberate release of GMOs into the environment under Part B of Directive 2001/18/EC, any decision on safeguard measures under Article 23 and any summary of risk assessments or environmental assessments of GMOs carried out according to Annex II of Dir. 2001/18/EC.

o) Annex I of Directive 2001/18/EC on techniques of genetic modification

Annex I of Directive 2001/18/EC lays down the different techniques that may be used for genetic modification. Commission Regulation 283/2013 lays down the data requirements for active substances in accordance with Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market. The Regulation indicates that for micro-organisms to be used as active substances their identity must be provided including their name and species category as well as whether any of the techniques of genetic modification of the above Annex have been used. In this case, all known differences between the modified and the parent strain must be provided.

p) Annex II of Directive 2001/18/EC on principles for the environmental risk assessment

Annex II of Directive 2001/18/EC lays down the objectives, general principles and methodology for the environmental risk assessment required under Directive 2001/18/EC as well as certain other elements to be considered. This Annex is supplemented by Commission Decision 2002/623/EC which establishes relevant guidance notes and is incorporated as an amendment to the text of the Directive.

Regulation 726/2004 on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency, indicates that the application for authorisation of medicinal products for human or veterinary use consisting of or containing GMOs must be accompanied by an environmental risk assessment in accordance with the principles of Annex II above.

Commission Implementing Regulation 503/2013 on applications for authorisation of GM food and feed in accordance with Reg. 1829/2003 requires, among other details, a risk assessment in accordance with the requirements of Annex II of Dir. 2001/18/EC for the purpose of compliance with the requirements of the Cartagena Protocol on Biosafety to the Convention of Biological Diversity.

q) Annexes III and IV of Directive 2001/18/EC on information required in the notification and additional information

Annexes III and IV of Directive 2001/18/EC lay down additional requirements for information that needs to be included in a notification under Directive 2001/18/EC for the release of specific types of GMOs and in notifications for GMOs to be placed on the

market or for GMOs to be used under contained conditions or for deliberate releases for purposes other than placement on the market. Article 5 of Regulation 1829/2003 indicates that a technical dossier containing this information must also be submitted with applications under the scope of this Regulation for GMOs or food containing or consisting of GMOs together with the conclusions of the risk assessment carried out under Annex II of Dir. 2001/18/EC. Similar details are also established under Article 17 of Reg. 1829/2003 on applications for the authorisation of GM feed.

Regulation 726/2004 on Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency indicates that the application for authorisation of medicinal products for human or veterinary use consisting of or containing GMOs must be accompanied by a complete technical dossier containing the information required under the above two Annexes. A similar requirement for inclusion of the information contained under the above two Annexes is also laid down in Commission Implementing Regulation 503/2013 on applications for authorisation of GM food and feed in accordance with Reg. 1829/2003.

Annex IV of Directive 2001/18/EC requires that proposed labelling information is included in the notification for placing a GMO or GM product on the market. Commission Regulation 641/2004 on rules for the implementation of Reg. 1829/2003 indicates that together with the application for the authorisation of GM food and feed, a proposal for labelling complying with the requirements of Annex IV above must also be provided.

r) Annex VII of Directive 2001/18/EC on monitoring plan

Annex VII of Directive 2001/18/EC describes the objective and general principles to be followed for the design of a monitoring plan to be carried out following the placing on the market of a GMO and indicates that technical guidance may be provided for the implementation of this Annex.

Regulation 1829/2003 indicates that the application for the authorisation of GMOs or food containing or consisting of GMOs under Reg. 1829/2003 must also be accompanied by a monitoring plan conforming with Annex VII above as well as a proposal for the duration of the monitoring plan.

Commission Decision 2010/419/EU renewing the authorisation for continued marketing of products containing, consisting of or produced from GM maize Bt11, authorising food and food ingredients containing or consisting of field maize Bt11 pursuant to Regulation (EC) No 1829/2003 and repealing Decision 2004/657/EC indicates that the information entered in the Community register for the above product must also include details of a monitoring plan for environmental effects in accordance with the requirements of Annex VII of Dir. 2001/18/EC. A similar requirement is also laid down in Commission Decision 2006/197/EC authorising the placing on the market of food containing, consisting of, or produced from GM maize line 1507 (DAS-Ø15Ø7-1) and renewing the authorisation to place on the market feed produced from such maize pursuant to Regulation (EC) No 1829/2003. Also similar requirements are laid down by the following Commission Decisions: 2007/701/EC, 2007/702/EC, 2007/703/EC, 2008/730/EC, 2008/933/EC.

With regard to the requirement for the provision of technical guidance, this is provided by Council Decision 2002/811/EC establishing guidance notes supplementing Annex VII to Directive 2001/18/EC. Also, Commission Decision 2009/770/EC lays down in its Annexes standard reporting formats that should be used as technical guidance notes for presenting the monitoring results of the deliberate release into the environment of GMOs and GMOs in products for the purpose of placing on the market pursuant to Directive 2001/18/EC. These formats should facilitate the implementation of the requirements of Annex VII.

s) *Extended scope of Directive 2001/18/EC*

The scope of Directive 2001/18/EC is to protect human health and the environment during the deliberate release of GMOs in the environment for either placement on the market or for other purposes.

Regulation 178/2002 laying down the general principles and requirements of food law, establishing EFSA and laying down procedures in matters of food safety indicates that the mission of the Authority also involves providing scientific opinions for products other than food and feed, relating to GMOs within the scope of Directive 2001/18/EC.

Different Commission Decisions have been published rejecting national provisions related to banning of GMOs in certain regions in different Member States. For example, Dec. 2003/653/EC rejects national provisions on banning the use of GMOs in the region of upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty.

Directive 2001/83/EC lays down the Community code for medicinal products for human use. The part of the Directive on requirements that must be submitted with the marketing authorisation dossier indicates that an environmental risk assessment must be included, which must be presented in accordance with the requirements of Dir. 2001/18/EC and any related guidance document published by the Commission.

Commission Decision 2004/842/EC lays down implementing rules for Member States to be able to authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of agricultural plant species or vegetable species has been submitted. As previously described under Reg. 1829/2003, in the case of GM varieties, authorisations may only be granted if there are measures in place to avoid adverse effects to human health or the environment and the variety is already approved under Dir. 2001/18/EC or Reg. 1829/2003.

Council Directive 2008/90/EC on the marketing of fruit plant propagating material and fruit plants intended for fruit production indicates that a GM propagating material or fruit plant variety may only be registered officially if the GM organism of which it consists has been authorised under Dir. 2001/18/EC or Reg. 1829/2003.

Directive 2005/34/EC of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage establishes a framework of environmental liability for the prevention and remediation of environmental damage based on the principle that the polluter has to pay. This Directive also applies to environmental damage or threat of such damage caused by any deliberate release in the environment, transport or placement on the market of GMOs as defined in Dir. 2001/18/EC.

Council Decision 2008/971/EC on the equivalence of forest reproductive material produced in third countries indicates that forest reproductive material may be imported in Europe from the third countries listed in Annex I to the Decision, if it satisfies the requirements of Directive 2001/18/EC.

Annex IX: Additional implementing measures for selected Articles of Regulation 1829/2003 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 1829/2003 and provide additional relevant regulatory documents required for their implementation.

a) Articles 3 and 15 of Regulation 1829/2003 on the scope of the authorisation and supervision of GM food and feed

Articles 3 and 15 of Regulation 1829/2003 lay down the scope of the measures applicable to the authorisation and supervision of GM food and feed respectively. Council Directive 68/193/ECC on the marketing of material for the vegetative propagation of vine indicates that for products derived from vine-propagating material and intended to be used as or in GM food or feed falling within the scope of the above two Articles of Reg. 1829/2003, the vine variety concerned may only be accepted if it has been authorised in accordance with the requirements of Reg. 1829/2003.

Council Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species indicates that for material intended to be used in feed under the scope of Reg. 1829/2003, the variety may only be accepted for inclusion in the common catalogue of agricultural plant species of certain varieties of products that may be marketed under the provisions of specific Directives for the marketing of those products, if it has previously been approved under the requirements of Reg. 1829/2003.

Similarly, Directive 2002/55/EC on the marketing of vegetable seed indicates that material derived from a plant variety and intended to be used in food or feed falling under the scope of the above two articles shall be accepted for inclusion in the common catalogues only if it has been approved in accordance to the requirements of Reg. 1829/2003.

Directive 2008/90/EC on the marketing of fruit plant propagating material and fruit plants intended for fruit production indicates that such material consisting of GMOs may only be placed on the market if they have been authorised under Reg. 1829/2003. Also if products derived from fruit plants or propagating material are intended to be used in GM food or feed authorised under Articles 3 or 15 of Reg. 1829/2003, the propagating material or the fruit plants concerned may only be placed on the market if the food or feed derived from this material has been authorised under Reg. 1829/2003. Directive 2008/90/EC also indicates that GM propagating material or fruit plant variety may only be registered officially if the GM organism of which it consists has been authorised under Reg. 1829/2003 or under Dir. 2001/18/EC.

b) Articles 4 and 16 of Regulation 1829/2003 on the authorisation requirements for GM food and feed

Articles 4 and 16 lay down the requirements that GM food and feed must meet in order to be placed on the market. GM food and feed must not be placed on the market unless an authorisation has been granted under Reg. 1829/2003 once it has been demonstrated that the product meets all the requirements established therein. Commission Decision 2010/428/EU authorises the placement on the market of products, containing, consisting or produced from GM maize 59122x1507xNK603 (DAS-59122-7xDAS- Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation 1829/2003 according to the conditions laid down in

the Decision. Similar Decisions authorise the placement on the market of other GM food and feed products (i.e. Dec.2010/432/EU).

Commission Implementing Decision 2011/884/EU lays down emergency measures regarding unauthorised GM rice in rice products originating from China. These measures apply to certain products listed in Annex I to the Decision. In order to ensure compliance with the above Articles of Reg. 1829/2003, Member States may carry out random physical checks to other products originating from China in accordance with Annex II to the Decision.

c) Articles 5 and 17 of Regulation 1829/2003 on application for authorisation

Articles 5 and 17 of Regulation 1829/2003 lay down the procedure that has to be followed for a GMO for food/feed or use in food/feed to be authorised. The Articles indicate that implementing rules must be established. These rules are implemented by Commission Regulation 641/2004 on detailed rules for the implementation of Reg. 1829/2003 as regards the application for authorisation of new GM food and feed, the notification of existing products and adventitious and unavoidable presence of GM material which has benefited from a favourable risk evaluation. Also Reg. 641/2004 requires the applicant to specify whether the information provided may be notified to the biosafety clearing house under the Cartagena Protocol. If not, the procedure of Article 44 of Reg. 1829/2003 must be followed. Implementing Regulation 503/2013 on applications for authorisation of GM food and feed in accordance with Reg. 1829/2003 applies to applications for authorisation of GM plants submitted under Reg. 1829/2003 and also amends Regulations 641/2004 and 1981/2006.

Articles 5 and 7 also require the applicant to submit samples of the product seeking authorisation and their control samples. Annexes I and II of Reg. 641/2004 lay down detailed requirements with regard to the above samples and details for the analytical method and the reference samples. Reg. 641/2004 also lays down information on how to provide the summary of the dossier in a standardised form as requested by the above Articles of Reg. 1829/2003.

d) Articles 6 and 18 of Regulation 1829/2003 on opinion of the Authority for the authorisation of GM food and feed

Articles 6 and 18 of Regulation 1829/2003 lay down details for the procedure to be followed by the Authority in providing its opinion after receiving an application for the authorisation of GM food and feed. Regulation 2230/2004 lays down detailed rules for the implementation of Regulation 178/2002 with regard to the network of organisations operating in the fields within EFSA's mission. The Regulation requires Member States to forward to the Commission the details of the designated organisations, evidence that they comply with the requirements of Reg. 2230/2004 and details of their specific field of competence, in this case in the field of safety assessment of GM food and feed. The Authority may entrust any of the tasks referred in Articles 6 or 18 of Reg. 1829/2003 to any of these organisations in order to assist with scientific or technical support.

e) Article 7 of Regulation 1829/2003 on authorisation

Article 7 of Regulation 1829/2003 lays down the details of the authorisation procedure and the timelines from receipt of the Authority opinion to the adoption and publication of a final decision. For example Commission Decision 2006/197/EC authorises the placing on the market of food that contains, consists of or is produced from GM maize line 1507

(DAS-Ø15Ø7-1) and renews the authorisation to place on the market feed produced from such maize in accordance with the requirements of Reg. 1829/2003. Similar Decisions are published for the authorisation to place on the market of other GM products (i.e. Dec. 2007/692/EC, 2007/701/EC).

f) Articles 8 and 20 of Regulation 1829/2003 on the status of existing products

Articles 8 and 20 of Reg. 1829/2003 lay down conditions and procedures to be followed for the continuation of placement on the market of GM food and feed products that have been lawfully placed on the market before the date of application of the Regulation. If the required information is not provided within the timeframe established or they are found to be incorrect, the Commission must adopt measures for the withdrawal from the market of the product concerned and the products derived from it. Commission Decision 2007/305/EC implements the withdrawal from the market of Ms1xRf1 (ACS-BNØØ4-7xACS- BNØØ1-4) hybrid oilseed rape and its derived products. Similar Decisions have implemented the withdrawal from the market of other GM products (i.e. Decision 2007/306/EC, Decision 2007/307/EC, 2007/304/EC, 2007/305/EC).

g) Articles 9 and 21 of Regulation 1829/2003 on supervision of GM food and feed

Articles 9 and 21 of Regulation 1829/2003 lay down the requirement for the supervision of compliance with the requirements of Reg. 1829/2003 and with any conditions or restrictions imposed after an authorisation has been granted for a GM food or feed product. Commission Decision 2009/770/EC establishes standard reporting formats for presenting the monitoring results of the deliberate release into the environment of GMOs, as or in products, for the purpose of placing on the market pursuant to Directive 2001/18/EC and details are laid down in the Annexes to the Regulation concerning both monitoring for cultivation and monitoring for GMO uses other than cultivation.

h) Articles 11 and 23 of Regulation 1829/2003 on the renewal of authorisations of GM food and feed

Articles 11 and 23 of Regulation 1829/2003 lay down details on the procedure to be followed for the renewal of authorisations of GM food and feed. Commission Decision 2010/419/EU renews the authorisation for the continued marketing of products containing, consisting of, or produced from GM maize Bt11 (SYN-BTØ11-1) and authorises foods and food ingredients containing or consisting of field maize Bt11 (SYN-BTØ11-1) pursuant to Reg. 1829/2003.

i) Articles 12 and 24 of Regulation 1829/2003 on the labelling of GM food and feed

Articles 12 and 24 of Regulation 1829/2003 lay down thresholds for the adventitious or technically unavoidable GM content of food and feed products that contain or are produced from GMOs. These thresholds are of relevance for the labelling of these products. Regulation 1830/2003 lays down rules for the labelling and traceability of products that contain or are produced from GMOs, however products that fall under the above thresholds are exempt from these requirements.

Directive 2014/63/EU amending Council Directive 2010/110/EC relating to honey lays down specific details for the labelling of honey that contains GM pollen and as a

consequence falls under the requirements of Reg. 1829/2003, unless its presence is under a specified level and is adventitious or unavoidable.

j) Articles 13 and 25 of Regulation 1829/2003 on the labelling requirements of GM food and feed

Articles 13 and 25 of Regulation 1829/2003 lay down specific labelling requirements for GM food and feed products. Commission Decision 2010/428/EU authorising the placement on the market of products, containing, consisting or produced from GM maize 59122x1507xNK603 (DAS-59122-7xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation 1829/2003, lays down some additional labelling requirements that must appear on the label of the product authorised under this Decision. Similar requirements are also laid down by other Decisions authorising the placement on the market of different GM food and feed products (i.e. Dec. 2010/432/EU, Dec. 2005/608/EC).

In the same context, Commission Decision 2005/448/EC authorising the placement on the market of foods and food ingredients derived from GM maize line NK 603 as novel foods or novel food ingredients under Regulation (EC) No 258/97, lays down labelling requirements for the above products. Similarly, further Decisions lay down labelling requirements for other similar products, for example Commission Decision 2006/68/EC.

k) Article 27 of Regulation 1829/2003 on products likely to be used as both food and feed

Article 27 of Regulation 1829/2003 indicates that when a product is likely to be used both as food and feed a single application under Articles 5 and 17 of the Reg. must be submitted requiring a single opinion by the Authority and a single Commission Decision. Regulation 641/2004 on detailed rules for the implementation of Reg. 1829/2003 implements that if an application is limited to one of the two uses, a verifiable justification must be included in the application explaining the reason.

l) Article 28 of Regulation 1829/2003 on Community register

Article 28 of Regulation 1829/2003 lays down the requirement for the establishment and maintenance of a Community register of GM food and feed. Commission Decision 2010/428/EU authorising the placement on the market of products, containing, consisting or produced from GM maize 59122x1507xNK603 (DAS-59122-7xDAS-Ø15Ø7-1xMON-ØØ6Ø3-6) pursuant to Regulation 1829/2003, requires that the information of the Annex to the Decision is entered in the Community register. Similar requirements are also laid down by other Decisions authorising the placement on the market of different GM food and feed products (Dec.2010/432/EU). Other Decisions implement modifications to the Community register (Dec. 2008/279/EC).

Commission Implementing Decision 2014/C 72/05 sets out the financing of the 2014 work programme on IT tools in the field of food safety, animal health, animal welfare and plant health. The budget for the financing of the register of approved GM food and feed is also part of this programme.

m) Article 30 of Regulation 1829/2003 on confidentiality

Article 30 of Regulation 1829/2003 lays down rules related to the confidentiality of information submitted with an application for authorisation of GM food/feed products. Regulation 641/2004 on detailed rules for the implementation of Reg. 1829/2003 requires that the application clearly states which parts are to be treated as confidential and provide a justification for the reason.

n) Article 32 of Regulation 1829/2003 on the Community Reference Laboratory

Article 32 of Regulation 1829/2003 implements the establishment of the Community Reference Laboratory – the Commission's Joint Research Centre – the duties and tasks of which are detailed in the Annex to the Regulation. It also provides information on how the costs related to its tasks may be covered. Detailed rules for the implementation of this Article are provided by Regulation 1981/2006.

Regulation 1830/2003 indicates that the Commission must develop and publish technical guidance in order to assist Member States to fulfil the requirements for inspection and control established within the Regulation. While developing this guidance, the Commission shall consult the work of the national competent authorities, of the Standing Committee of the Food Chain and Animal Health and of the Community Reference Laboratory established by Reg. 1829/2003.

o) Article 44 of Regulation 1829/2003 on information to be provided in accordance with the Cartagena Protocol

Article 44 of Regulation 1829/2003 implements that any authorisation or any renewal, modification, suspension or revocation of an authorisation of GMOs or GMO products must be notified by the Commission to the Parties of the Cartagena Protocol through the biosafety clearing house and lays down the details of this procedure. Reg. 641/2004 requires the applicant for an authorisation under Articles 5 or 17 of Reg. 1829/2003 to specify whether the information provided may be notified to the biosafety clearing house under the Cartagena Protocol. If not, the procedure of Article 44 of Reg. 1829/2003 must be followed.

p) Article 47 of Regulation 1829/2003 on transitional measures for adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation

Articles 47 of Regulation 1829/2003 lays down certain conditions under which the presence of GM material in food or feed in an amount of no higher than 0,5% shall not be considered a breach of the requirements of the Regulation. Directive 2001/18/EC on the deliberate release into the environment of GMOs indicates that the placement on the market of GMO traces or combinations of GMOs in products for use in food, feed or processing shall be exempt from the notification and monitoring and labelling requirements laid down in the Directive, provided they meet the above conditions of Art. 47 of Reg. 1829/2003.

Also Regulation 1830/2003 on the labelling and traceability of products that contain or are produced from GMOs indicates that products that fall under the above thresholds and meet the above conditions of Reg. 1829/2003, are exempt from its labelling and traceability requirements.

q) Annex of Regulation 1829/2003 on the duties and tasks of the Community Reference Laboratory

The Annex to Regulation 1829/2003 lays down the duties and tasks of the Community Reference Laboratory. Regulation 882/2004 on the official controls performed to ensure compliance with feed and food law and animal health and welfare lists the Community Reference Laboratories in the different areas of food and feed law, establishes the Joint Research Centre of the European Commission as the Community Reference Laboratory for GMOs.

Commission Decision 2005/635/EC concerning the placement on the market in accordance with Directive 2001/18/EC of an oilseed rape product (*Brassica napus L.*, GT73 line) genetically modified for tolerance to the herbicide glyphosate. This product can be placed on the market from the date that a method for the detection of the above material is validated by the Community Reference Laboratory established by the Annex to Reg. 1829/2003 and in accordance with the details of Regulation 641/2004. Similar Decisions are also published for other GM products (i.e. Dec. 2007/232/EC).

r) Extended scope of Regulation 1829/2003

Regulation 258/97 lays down provisions on novel foods and novel food ingredients. Regulation 1829/2003 indicates that foods and food ingredients authorised under this Regulation should be exempt from the requirements of Reg. 258/97, unless they fall under one of the product categories to which Reg. 258/97 applies for a characteristic that has not been considered for the purposes of authorisation under Reg. 1829/2003.

Regulation 1831/2003 on feed additives for use in animal nutrition lays down the procedure for the authorisation of such additives in order to ensure the protection of consumer and animal health. Regulation 1829/2003 also covers feed additives containing, consisting or produced from GMOs. Since the scope of the two Regulations is different, feed additives should undergo both authorisations. In the same context, Regulation 429/2008 lays down detailed rules for the implementation of Reg. 1831/2003 as regards the preparation and presentation of applications and the assessment and the authorisation of feed additives. Applicants are required to indicate whether the additive consists, contains or is produced from GMOs and to provide the details of the authorisation granted or of the application for authorisation submitted.

Regulation 834/2007 indicates that GMOs and products produced by GMOs may not be used in organic production at any step as food, feed, seeds, processing aids, plant protection products, fertilisers, soil conditioners, vegetative propagating material, microorganisms or animals. Food business operators may rely for this information on the labelling of the products in accordance with the requirements of Reg. 1829/2003.

Regulation 1332/2008 on food enzymes indicates that food enzymes falling within the scope of Reg. 1829/2003 may be included in the Community list of food enzymes only if they are authorised under Reg. 1829/2003. For food enzymes already included in the Union list that are produced from a different source falling within the scope of Reg. 1829/2003, a new authorisation is not required provided the new source is authorised under Reg. 1829/2003 and the food enzyme complies with the specifications of Reg. 1332/2008. Similar provisions are also laid down in Regulation 1333/2008 on food additives. Food additives falling under the scope of Reg. 1829/2003 may be included in Annexes II and III of the Community list of food additives only if they are authorised under Reg. 1829/2003 and for food additives already in the Community list that are produced from a different source falling within the scope of Reg. 1829/2003, a new authorisation is not required provided the new source is authorised under Reg. 1829/2003 and the food additive complies with the specifications of Reg. 1333/2008. Similarly, the above provisions relevant to the authorisation and the inclusion in the Community list are also established by Regulation 1334/2008 for food flavourings and source materials that fall within the scope of Reg. 1829/2003.

Regulation 234/2011 implements Regulation 1331/2008 on the common authorisation procedure for food additives, food enzymes and food flavourings. An application for an update of the list of approved substances (food additives, enzymes or flavourings) requires a technical dossier to be submitted containing all the administrative data for the substance. These include any information on authorisation of the substance under the scope of Regulation 1829/2003.

Commission Decision 2004/842/EC lays down implementing rules for Member States to be able to authorise the placing on the market of seed belonging to varieties for which an application for entry in the national catalogue of agricultural plant species or vegetable species has been submitted. In case of GM varieties, the authorisation may only be granted if there are measures in place to avoid adverse effects to human health or the environment and the variety is already approved under Reg. 1829/2003 or Dir. 2001/18/EC.

Regulation 1829/2003 implements the establishment of the Community Reference Laboratory. Commission Recommendation 2004/787/EC lays down technical guidance on sampling and detection of GMOs and material produced from GMOs as or in products in the context of Regulation 1830/2003. The Recommendation indicates that alternative testing strategies to the ones recommended may be applied provided they are approved by the Community Reference Laboratory. Also the Community Reference Laboratory may provide further guidance and assistance on sampling or testing methods. The Recommendation also indicates that further protocols for the sampling and detection should continue to be developed considering any amended threshold values as established by Reg. 1829/2003 or Directive 2001/18/EC.

Regulation 1829/2003 lays down provisions for the authorisation of GM feed but also for when the authorisation is pending or has expired as well as rules for the presence of residues of GM material. Commission Regulation 619/2011 lays down the methods for sampling and analysis for the official control of feed as regards presence of GM material for which an authorisation procedure is pending or the authorisation of which has expired.

Commission Decisions have been published rejecting certain provisions that Member States intended to implement in their national law. For example Commission Decision 2006/255/EC rejected the implementation by Cyprus of national provisions imposing on supermarkets an obligation to place GM foods on separate shelves from non-GM, pursuant to Article 95(5) of the EC Treaty. Similarly, Commission Decision 2008/62/EC relating to Articles 111 and 172 of the Polish Draft Act on Genetically Modified Organisms notified by the Republic of Poland pursuant to Article 95(5) of the EC Treaty rejected derogations from the provisions of Directive 2001/18/EC on the deliberate release in the environment of GMOs.

The authorisation of GMOs for release in the environment is subject to health and environmental risk assessments while Reg. 1829/2003 also lays down procedures for the establishment of emergency measures and restriction or prohibition of the cultivation of GMOs if deemed necessary in light of new scientific information. Commission Recommendation 2010/C 200/01 lays down guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops.

Annex X: Additional implementing measures for selected Articles of Regulation 1830/2003 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 1830/2003 and provide additional relevant regulatory documents required for their implementation.

a) Article 8 of Regulation 1830/2003 on unique identifier

Article 8 of Regulation 1830/2003 requires the Commission to establish a system for development and assignment of unique identifiers to GMOs. Regulation 1831/2003 on additives for use in animal nutrition indicates that the Regulations granting authorisation to additives consisting, containing or produced from GMOs should also include the name of the authorisation holder and the unique identifier attributed to the GMO in accordance with the above provisions.

b) Extended scope of Regulation 1830/2003

Regulation 834/2007 indicates that GMOs and products produced by GMOs may not be used in organic production at any step as food, feed, seeds, processing aids, plant protection products, fertilisers, soil conditioners, vegetative propagating material, microorganisms or animals. Food business operators may rely for this information on the labelling of the products in accordance with the requirements of Reg. 1830/2003.

Annex XI: Additional implementing measures for selected Articles of Directive 2001/82/EC and their respective requirements

The following paragraphs highlight the main requirements of Directive 2001/82/EC and provide additional regulatory documents that add to the main text or assist in the implementation of this main text.

a) Article 5 of Directive 2001/82/EC on marketing authorisation

Article 5 of Directive 2001/82/EC indicates that veterinary medicinal products may only be placed on the market if they have been authorised in accordance with Directive 2001/82/EC or in accordance with the provisions of Regulation 726/2004. Regulation 726/2004 indicates that any marketing authorisation granted in accordance with its requirements must have the same validity throughout the Community and in each of the Member States as an authorisation granted in the same Member States according to Directive 2001/82/EC.

Regulation 1177/2006 implementing Regulation 2160/2003 on requirements for the use of specific control measures in the framework of the national programmes for the control of salmonella in poultry indicates that generally antimicrobials must not be used as a means of controlling salmonella in poultry, unless under the exceptional circumstances described in the Regulation and only provided they have been authorised according to the requirements of Article 5 of Directive 2001/82/EC or according to Regulation 726/2004. Also Regulation 1177/2006 indicates that live salmonella vaccines must not be used within the framework of the national control plans for salmonella in laying hens during production, unless they are safe for use and they have been authorised according to Directive 2001/82/EC.

Directive 2006/88/EC on animal health requirements for aquaculture animals and products thereof and on the prevention and control of certain diseases in aquatic animals indicates that vaccines for the control of exotic aquatic diseases may only be used if they have been authorised according to Directive 2001/82/EC and Regulation 726/2004.

b) Article 10 of Directive 2001/82/EC

Article 10 of Directive 2001/82/EC lays down special measures for the administration of veterinary medicinal products to non-food producing animals and equidae in the absence of a suitable authorised veterinary medicinal product. Regulation 504/2008 lays down methods for the identification of equidae. According to this Regulation equidae are intended for human consumption unless irreversibly declared as non-food producing due to the administration of veterinary medicinal products according to Directive 2001/82/EC. Article 10 also indicates that the Commission must establish a list of substances that are essential for the treatment of equidae or bring added clinical benefits compared to other treatments and have a withdrawal period of at least six months. These are laid down by Commission Regulation 1950/2006 which also details the conditions for their use. In case an equine animal is treated with such products, Regulation 504/2008 indicates that the veterinarian must indicate this treatment in the identification documents of the animal, as well as the date of the last administration and also must inform the keeper of the date when the withdrawal period has lapsed.

c) Article 11 of Directive 2001/82/EC

Article 11 of Directive 2001/82/EC lays down provisions for the treatment of food-producing animal species in the absence of suitable authorised veterinary medicinal products. The Article also lays down the withdrawal periods that must be observed for the substances listed in Regulation 2377/90 (now repealed by Regulation 470/2009). Regulation 889/2008 lays down detailed rules for the implementation of Regulation 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control. Special rules are laid down with regard to the withdrawal periods after the administration of veterinary medicinal products in animals intended for the production of organic foodstuffs for the purposes of either treating or preventing disease.

d) Articles 12-14 of Directive 2001/82/EC

Articles 12-14 of Directive 2001/82/EC and Annex I to the Directive provide details of the information that must be submitted with each application for an authorisation of a veterinary medicinal product in a Member State. Under Regulation 726/2004, each application must include the particulars detailed in the above articles and Annex I of Directive 2001/82/EC and must include the use of a single name for the product. Two of the particulars required for the market authorisation of the veterinary medicinal product are details on manufacturing method and control. In that respect, Regulation 726/2004 requires the holder to follow technical and scientific developments in these two fields in order to be able to make any variations as may be required and apply for their approval. These must then be communicated to the Agency.

Article 13 of Directive 2001/82/EC exempts applicants from the requirement to provide certain details if they can prove that the medicinal product is a generic of a reference medicinal product already authorised in a Member State or the Community within a certain timeframe. Products authorised under Regulation 726/2004 can also benefit from these provisions of Directive 2001/82/EC.

Regulation 469/2009 lays down provisions on supplementary protection certificates for medicinal products in a Member State. A product may be the subject of a certificate if it is protected by a patent in the Member State and not already the subject of a certificate and if a valid and first authorisation has been granted under Directive 2001/82/EC for the product to be placed on the market as a veterinary medicinal product. Details are also provided on the application procedure for this certificate as well as on the procedure for the withdrawal of this certificate in case of a withdrawal of the marketing authorisation of the product.

e) Article 38 of Directive 2001/82/EC

Article 39 of Directive 2001/82/EC lays down the procedure by which the final decision for granting a marketing authorisation is taken by the Commission. The following Commission Communications have been published on the summary of Decision for marketing authorisations since 2010 (2010/C 258/02, 2010/C 295/02). They list new, maintained, modified but also suspended, refused or revoked marketing authorisations and provide details on the name, the pharmaceutical form, the strength and the route of administration of the medicinal product as well as details on the applicant.

f) Article 39 of Directive 2001/82/EC

Article 39 of Directive 2001/82/EC indicates that a variation to a marketing authorisation may be granted, after an application by the authorisation holder to all the Member

States that have authorised the veterinary medicinal product concerned. Regulation 1234/2008 lays down provisions on the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products. Details for the notification procedures for the different types of variations are laid down in Chapter II of the Regulation.

Further on the same subject, Commission Communication 2010/C 17/01 lays down guidelines on the details of the different categories of variations to the terms of marketing authorisations for medicinal products for human or veterinary use. Similarly Commission Communication 2009/C 323/04 provides guidelines on the operation of the procedures of Reg. 1234/2008 on variations to marketing authorisation of medicinal products.

g) Titles IV, VII and VIII of Directive 2001/82/EC on manufacture and imports, pharmacovigilance and supervisions and sanctions

Titles IV, VII and VIII of Directive 2001/82/EC lay down requirements on the manufacture and imports, the pharmacovigilance and the supervision and sanctions related to veterinary medicinal products in the Community. Regulation 726/2004 requires the competent authorities of the Member States to verify on behalf of the Community that the holders of veterinary medicinal products' authorisations or the manufacturers or the importers of such products fully conform to all the above requirements of Directive 2001/82/EC. In case the opinions of Member States on the conformance to the above issues differ significantly, the Commission may request inspections to be carried out.

h) Article 67 of Directive 2001/82/EC on veterinary prescriptions

Article 67 of Directive 2001/82/EC lays down the requirement for a veterinary prescription in order to supply certain veterinary medicinal products to the public. However, under certain conditions established by the Commission, products may be exempt from this requirement in the Member States. Directive 2006/130/EC implements Directive 2001/82/EC as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription.

i) Articles 80-82 of Directive 2001/82/EC on supervisions and sanctions

Articles 80-82 of Directive 2001/82/EC lay down provisions on how the competent authorities of the Member States can ensure that the requirements of the Directive relevant to veterinary medicinal products can be met. Regulation 658/2007 lays down provisions for financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation 726/2004. It is indicated that the Agency may request the authorities to cooperate in the investigation following an infringement by performing inspections and other supervisory methods as in Directive 2001/82/EC.

j) Extended scope of Directive 2001/82/EC

Regulation (EC) No 297/95 lays down the fees payable to the European Medicines Agency with the application for the marketing authorisation of veterinary medicinal

products under Articles 13 and 34 and 35 of Directive 2001/82/EC. The fees depend on the number of pharmaceutical forms, strengths and presentations.

Regulation 726/2004 lays down procedures for the authorisation and supervision of medicinal products for human and veterinary use in the Community and establishes the European Medicines Agency. The Regulation lays down the conditions under which a generic medicinal product of a reference medicinal product authorised by the Community may be authorised by the competent authorities of the Member States under Directive 2001/82/EC. The Regulation also details the procedure followed by the Committee for Medicinal Products for Veterinary Use in order to prepare its opinion on an authorisation. In case of an unfavourable decision, the Agency must notify the applicant on the particulars that are not satisfactory. If the opinion is favourable, certain of the particulars submitted with the application according to the requirements of Directive 2001/82/EC are annexed to the decision. If the labelling and packaging information provided is not in accordance with the requirements of Directive 2001/82/EC, the authorisation can be refused.

Directive 2001/82/EC lays down provisions for the authorisation of veterinary medicinal products. Directive 96/22/EC on the prohibition of the use in stock-farming animals of certain substances with hormonal or thyrostatic action or beta-agonists indicates that certain products with oestrogenic, androgenic or gestagenic action or hormonal products and beta-agonists may be authorised for administration to farm animals for the purposes of zootechnical treatment provided they meet the requirements of Directive 2001/82/EC. Also the possession of substances listed in Annexes II and III of Directive 96/22/EC is only restricted to persons authorised by the provisions of Directive 2001/82/EC.

Directive 2009/35/EC on colouring matters that may be added to medicinal products indicates that only colouring matters permitted under the provisions of Directive 94/36/EC may be added to veterinary medicinal products for human or animal use.

Directive 2005/94/EC lays down Community measures for the control of avian influenza. It indicates that only influenza vaccines authorised in accordance to Directive 2001/82/EC or in accordance with Regulation 726/2004 can be used and only such vaccines can be stored in the Community vaccine bank for Community reserves of avian influenza vaccines. Similarly, within the scope of contingency planning, only avian influenza vaccines authorised under Directive 2001/82/EC may be stored in national vaccine banks. Similar requirements are also laid down in Decision 2006/147/EC on introducing preventive vaccination against highly pathogenic avian influenza H5N1 and related provisions for movement in the Netherlands and in Decision 2006/148/EC for France. Vaccines can be used only if they are authorised in accordance with Directive 2001/82/EC or Regulation 726/2004. Several Commission Decisions implement similar provisions for protection measures or for emergency vaccination against avian influenza or foot-and-mouth disease in the different Member States and some examples are provided in the following Table.

Directive 2008/105/EC on environmental quality standards in the field of water policy lays down quality standards for priority substances and other pollutants in order to achieve good surface water chemical status. A watch-list of substances must be established by the Commission for which monitoring data are to be gathered in the European Union to support prioritisation exercises and monitoring programmes. For selecting the substances for this list, information gathered according to Directive 2001/82/EC may also be used.

Table 2: examples of Commission Decisions implementing provisions for protection measures or for emergency vaccination against certain diseases in the different Member States

Commission Decision	Topic
Decision 2006/147/EC	Preventive vaccination for against highly pathogenic avian influenza H5N1 and related provisions for movement in the Netherlands
Decision 2006/148/EC	Preventive vaccination against highly pathogenic avian influenza H5N1 and related provisions for movements in France
Decision 2007/590/EC	Preventive vaccination for against highly pathogenic avian influenza H5N1 and related provisions for movement in the Netherlands
Decision 2007/598/EC	Measures to prevent the spread of highly pathogenic avian influenza to other captive birds kept in zoos and approved bodies, institutes or centres in the Member States
Decision 2008/341/EC	Community criteria for national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses
Implementing Decision 2013/651/EU	Approving a preventive vaccination plan against low pathogenic avian influenza in a holding keeping mallard ducks in Portugal and certain provisions for their movement and products thereof (valid until 31/12/2014)

Annex XII: Additional implementing measures for selected Articles of Regulation 470/2009 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 470/2009 and provide additional regulatory documents that add to the main text or assist in the implementation of this main text.

a) *Article 10 on pharmacologically active substances contained in biocidal products used in animal husbandry*

Article 10 of Regulation 470/2009 lays down procedures for the establishment of maximum residue limits of pharmacologically active substances for use in biocidal products. Regulation 528/2012 concerning the making available on the market and use of biocidal products lays down procedures for granting authorisation for biocidal products not eligible for the simplified authorisation procedure. For granting such an authorisation, one of the requirements is that, where appropriate, maximum levels for food and feed must have been established for the substance under Reg. 470/2009. An application must be submitted for the establishment of such residue limits. If maximum limits have not been established at the time of approval of the active substance through a request by the Commission or a Member State (Article 9 of Reg. 470/2009), or if such limits require amendment, then the maximum residue limits must be established after an application to the European Medicines Agency according to Articles 3 and 8 of Reg. 470/2009.

b) *Article 14 on classification of pharmacologically active substances*

Pharmacologically active substances must be classified by the Commission according to their maximum residue limits. The list must also contain information on the therapeutic classes to which they belong, while the maximum limits must be expressed in relation to specific foods or species. Consignments of certain products may be imported into the EU provided they are accompanied by analytical results of official sample tests, aimed at detecting the presence of certain substances, indicating they are safe for human consumption. If residues of pharmacologically active substances are present, either classified according to Article 14 of Reg. 470/2009 and above the maximum residue limits, or not classified under Article 14, these must be notified to the Commission under RASFF. Commission Decision 2010/381/EU lays down emergency measures for aquaculture products imported from India and intended for human consumption.

c) *Article 23 on placing on the market*

Article 23 of Regulation 470/2009 indicates that food of animal origin containing residues of pharmacologically active substances at levels exceeding the maximum specified, or exceeding the reference points for action where such have been established, must be considered as non-compliant with Reg. 470/2009. Commission Decision 2008/630/EC establishes emergency measures for crustaceans imported from Bangladesh and intended for human consumption. These can be placed on the market provided the requirements of Article 23 of Reg. 470/2009 are met.

d) *Article 27 on classification of pharmacologically active substances under Regulation 2377/90*

Article 23 of Regulation 470/2009 requires the Commission to adopt a Regulation incorporating pharmacologically active substances and their classification based on the maximum residue levels as established under Reg. 2377/90. This requirement is implemented by Regulation 37/2010 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin.

Annex XIII: Additional implementing measures for selected Articles of Directive 96/23/EC and their respective requirements

The following paragraphs highlight the main requirements of Directive 96/23/EC and provide additional regulatory documents that add to the main text or assist in the implementation of this main text.

a) Articles 3-8 on monitoring plans for the detection of residues of substances

Articles 3-8 of Directive 96/23/EC lay down the requirements for the establishment of monitoring plans in the Member States in order to detect the presence of residues and substances in animals and animal products. Council Decision 2011/408/EU on simplified rules and procedures on sanitary controls of fishery products, live bivalve molluscs, echinoderms, tunicates, marine gastropods, by-products thereof and products derived from these by-products from Greenland, requires Greenland and Denmark to submit their monitoring plans for the detection of residues and substances in aquaculture animals in Greenland to the Commission, in accordance with the requirements of Directive 96/23/EC.

Article 5 of Directive 96/23/EC requires the Member States to submit monitoring plans and the national measures in place in order to detect groups of residues of substances in different animals. Several Commission Decisions have been published approving the monitoring plans presented by different Member States (i.e. Dec. 98/151/EC, 98/152/EC, 98/390/EC).

Article 8 of Directive 96/23/EC also requires Member States to monitor the residues of substances in animals and animal products and to communicate the results to the Commission. Commission Implementing Decision 2012/C 204/03 on the financing of the 2012 work programme on IT tools in the field of food safety, animal health, animal welfare and plant health provides for the financing of certain projects supporting the implementation of Directive 96/23/EC amongst others. Specifically this funding is aimed at supporting the creation and maintenance of IT tools for the successful implementation of the monitoring requirements of the official controls and for the purposes of Directive 96/23/EC the residue monitoring plans. In the same context Implementing Decisions 2013/C 127/03 and 2014/C 72/05 provide for similar financing for the 2013 and 2014 work programmes.

b) Article 11 on official control measures

Article 11 of Directive 96/23/EC allows Member States to conduct official random checks aimed at detecting the possession or presence of prohibited substances during the manufacture, handling, storage, distribution or sale of substances with anabolic effects and of unauthorised substances, as well as during the production and distribution of animal feed and during the production of animals and of materials of animal origin. In case of positive results or detection of fraud, the measures established in the Directive shall apply. Directive 96/22/EC on the prohibition of use in stockfarming of substances with hormonal or thyrostatic action implements that in addition to the official controls relevant to the placing on the market of different products, the above official random checks of Dir. 96/23/EC should aim at ensuring that prohibited substances listed in its Annexes are not administered to animals for fattening purposes or for illegal treatment

and that the correct withdrawal times and restrictions of use in the case of use for therapeutic purposes or for zootechnical treatment are being observed. Also Directive 96/22/EC requires that the drinking water of animals, the places where they are kept, their body fluids, animal tissues and animal products are tested for the presence of the above substances in accordance with Annexes III and IV to Dir. 96/23/EC. In the case infringements are identified, the above substances must be confiscated and the affected animals and their products placed under supervision while appropriate penalties must be implemented by the competent authority.

In a broader scope and for the purposes of covering the inspection and control costs implemented by Dir. 96/23/EC, Directive 85/73/EEC on the financing of veterinary inspections and controls indicates that a Community fee must be collected. Annex B to the Directive lays down the procedure for establishing this fee for the control of live animals and of products of animal origin.

c) *Article 14 on national reference laboratories*

Article 14 of Directive 96/23/EC requires Member States to designate at least one national reference laboratory for the detection and analysis of residues and lays down their responsibilities and the requirement that a specific residue or residue group may not be assigned to more than one laboratory. A list of these laboratories is provided by Commission Decision 98/536/EC.

d) *Article 15 on official samples*

Article 15 of Directive 96/23/EC indicates that the Commission must establish detailed rules for the taking of official samples, as well as for the routine and reference methods used for the analysis of these samples. Commission Decision 2002/657/EC implements Dir. 96/23/EC with regard to the performance of analytical methods and the interpretation of the results obtained from the official samples. Specific values are established for the α error for substances having anabolic effect and for unauthorised substances (of Annex I of Dir. 96/23/EC), while a different value is specified for all other substances. The Decision also specifies timelines for compliance with its provisions for the different substances listed in Annex I of Dir. 96/23/EC and some criteria for analytical techniques that can be used for screening purposes. The Decision also specifies a system of identification points that can be used to interpret the data obtained for different substances listed in Annex I of the Directive, when mass fragments are measured without using full-scan techniques.

e) *Article 16 on positive results*

Article 16 of Directive 96/23/EC indicates that where positive results are obtained during the examination of official samples, details of the non-conformance must be obtained and an investigation must be carried out by the competent authority. Article 24 of Regulation 470/2009 requires similar investigations and action to be taken in case of analytical results that confirm the presence of prohibited or non-authorised pharmacologically active substances.

f) *Article 29 on imports from third countries*

Article 29 of Directive 96/23/EC indicates that the inclusion and retention in the lists of third countries from where the import of animals and animal products is authorised is subjected to the submission of a plan setting guarantees relevant to the monitoring of certain groups of substances and their residues of at least equivalent effect to those laid

down in the Directive. The inclusion in the list may be suspended in case of non-compliance with the Directive's requirements. Directive 97/78/EC on the principles for the organisation of veterinary checks in products entering from third countries indicates that in case of serious or repeated infringements of the Community veterinary legislation by third countries that have been granted equivalence agreements and thus their consignments are checked less frequently, the Commission must cease these benefits until measures and corrective actions have been taken.

In the same context, Commission Decision 2011/163/EU on the approval of plans submitted by third countries in accordance to Article 29 of Dir. 96/23/EC lays down some special rules for third countries that use raw material imported from other third countries and cannot provide a residue monitoring plan equivalent to the one requested by Dir. 96/23/EC. Special statements that must accompany the plan are also provided.

g) Annex III of Directive 96/23/EC on sampling strategy

Annex III of Directive 96/23/EC lays down provisions for the sampling strategy for the residue control plan. Commission Decision 98/179/EC lays down detailed rules on official sampling for the monitoring of certain substances and their residues in live animals and animal products. It indicates that sampling must be unforeseen and unexpected and must take place at different times during the year (considering that certain substances are more likely to be administered at specific times of the year), at different establishments such as farms, slaughterhouses, dairies, fish processing plants and egg collecting and packing stations.

h) Annex IV of Directive 96/23/EC on sampling levels and frequency

Annex IV to Directive 96/23/EC lays down the sampling levels and frequencies for the detection of certain substances in different animals and animal products. Decision 97/747/EC fixing the levels and frequencies of sampling provided for by Dir. 96/23/EC, supplements the ones set out in Annex IV to the Directive.

Annex IV of Directive 96/23/EC lays down provisions with regard to the minimum number of animals that must be sampled for the detection of one or more substances. Commission Decisions allow for financial aid from the Community to the Member States for the operation of certain Community reference laboratories in the veterinary field undertaking analysis for the detection of residues of certain substances in certain animal products (98/587/EC, 1999/760/EC).

Chapter 2 of Annex IV lays down specific requirements for the following animals: broiler chickens, spent hens, turkeys and other poultry. In order to perform the monitoring tasks laid down within this Chapter for the detection of residues of certain substances, the Commission grants specific financial assistance to specific Institutes through Commission Decisions (i.e. 2004/142/EC for the year 2004, 2005/161/EC for the year 2005, 2006/195/EC, 2009/863/EC, 2010/736/EU).

i) Extended scope of Directive 96/23/EC

Directive 96/23/EC lays down provisions for the monitoring of certain substances and their residues in animals and animal products and also some requirements for the authorisation of veterinary medicinal products for species intended for human consumption.

Directive 97/78/EEC on the principles for organisation of veterinary checks on products from third countries allows for derogation and less frequent checks for certain products

for which import conditions have been harmonised and which originate from third countries that offer satisfactory health guarantees. Products must also come from approved establishments with already issued certificates and a report must have been submitted to the Standing Veterinary Committee beforehand, taking into account a list of requirements including the rules for authorisation of substances of Directives 96/22/EC and 96/23/EC. Directive 97/78/EEC also requires that each consignment originating from a third country is subjected to veterinary checks at the border inspection posts. More detailed rules for these checks are laid down by Commission Decision 2005/34/EC laying down harmonised standards for the testing for certain residues in products of animal origin imported from third countries. More specifically, when the presence of residues of substances for which minimum required performance limits have been established in imported products of animal origin by Decision 2002/657/EC is confirmed by the tests carried out under Directive 97/78/EEC, Decision 2005/34/EC lays down the reference points for action and the action to be taken once non-compliance has been confirmed.

Regulation 1257/1999 lays down provisions for support for rural development from the EAGGF. The Regulation however excludes from such financial support producers, the animals of which have been found positive to substances unauthorised or illegally used according to the requirements of Directives 96/23/EC and 96/22/EC, or when the producers obstruct the inspections carried out according to the provisions of the two Directives.

Regulation 252/2012 lays down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs. Annex II specifies the sampling methods and the sampling plans. With regard to the number of incremental samples and in accordance with the provisions of Decision 97/747/EC (fixing the levels and frequencies of sampling provided for by Directive 96/23/EC), the aggregate sample size for hen eggs must be at least 12 for both bulk lots and lots consisting of individual packages.

Regulation 1069/2009 lays down health rules for animal by-products and derived products not intended for human consumption. The Regulation specifies that products of animal origin in which substances are detected in breach of Dir. 96/3/EC should be classified as Category 1 or 2 products depending on the risk they pose to the food and feed chain. Specifically, by-products from animals that have been subjected to illegal treatment and by-products that contain residues of other substances and environmental contaminants as listed in Annex I to Dir. 96/23/EC, exceeding the permitted levels established by Community or national provisions, can be categorised as Category 1 products. Animal by-products exceeding the permitted levels of authorised substances or contaminants of Article 15 of Dir. 96/23/EC must be classified as Category 2 materials.

Regulation 142/2011 implementing Regulation 1069/2009 allows for the use of certain animal products that have been submitted to illegal treatments according to Dir. 96/23/EC under specific conditions. Also Annex XII to Regulation 142/2011 allows for the import and transit of intermediate products destined for the production of medical devices and derived from animal products subjected to illegal treatment for use in *in vitro* diagnostic medical devices and laboratory reagents.

Commission Regulation 1266/2007 lays down implementing rules for Directive 2000/75/EC regarding the control, monitoring, surveillance and restrictions of movement of certain animals and of susceptible species in relation to bluetongue. Annex IV lays down specific criteria for the competent authorities to consider for the purpose of designating certain slaughterhouses for exemption from the exit ban and used for channelling the movement of animals from a holding in a restricted zone for immediate slaughter, based on a risk assessment. One of these criteria is the possible use of insecticides and repellents in compliance with Directive 96/23/EC.

Regulation 396/2005 lays down maximum residue levels of pesticides in or on food and feed of plant and animal origin. The Regulation requires EFSA to draw up annual reports on pesticide residues based on the information provided by the Member States. The Regulation also specifies the minimum information that must be contained in these reports, which among others includes an assessment of the exposure of consumers to pesticide residues based on the results of the official controls performed, as well as on the results originating from the controls performed under Directive 96/23/EC.

Annex XIV: Additional implementing measures for selected Articles of Directive 96/22/EC and their respective requirements

The following paragraphs highlight the main requirements of Directive 96/22/EC and provide additional regulatory documents that add to the main text or assist in the implementation of this main text.

a) Article 1 of Directive 96/22/EC

Article 1 of Directive 96/22/EC lays down certain definitions, one of which is "zotechnical treatment". Council Directive 98/58/EC on the protection of animals kept for farming purposes indicates that no other substances may be given to animals except of those that have a therapeutic or prophylactic effect or for the purposes of zotechnical treatment, unless they have no detrimental effect to the health or welfare of the animal.

Article 1 also provides a definition for "illegal treatment". Regulation 1069/2009 laying down health rules for animal by-products and derived products not intended for human consumption indicates that animal by-products from animals subjected to illegal treatment defined as above must be considered as Category 1 material for the purposes of Reg. 1069/2009. Also Commission Regulation 142/2011, implementing Regulation (EC) No 1069/2009 on health rules related to animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive, allows for the use of material that has gone through "illegal treatment" under the above meaning to be used in certain products not for human consumption under specific conditions.

b) Articles 3 and 4 of Directive 96/22/EC

Articles 3 and 4 of Directive 96/22/EC prohibit the use of certain substances in farm animals. Commission Regulation 1272/2009 lays down rules for the implementation of Regulation 1234/2007 with regards to the buying and selling of agricultural products under public intervention, according to which the conditions and controls for the taking over of beef require the absence of substances mentioned in the above Articles of Dir. 96/22/EC which must be verified by analysis of samples according to the relevant provisions.

c) Article 6 of Directive 96/22/EC

Article 6 of Directive 96/22/EC lays down provisions for the administration of substances with hormonal effects and beta-agonists. These substances must meet the requirements of Dir. 2001/82/EC (on Community code for veterinary medicinal products). Directive 97/78/EC on the principles for the organisation of veterinary checks in products entering from third countries allows for derogations to be granted by the Commission for less frequent physical checks under specific conditions, provided a report has been previously submitted to the Standing Veterinary Committee taking into account the rules on the authorisation of substances in the third country and the compliance to the requirements of Article 6 above.

This Article also lays down certain prohibitions of use of such substances, some also related to withdrawal periods. Directive 96/23/EC indicates that the official veterinarian

of a slaughterhouse may postpone the slaughter of animals, if he suspects that the withdrawal periods have not been accurately followed, by a period that should not be less than the ones specified in Article 6 above, or the ones of the marketing authorisation of the products.

d) *Article 11 of Directive 96/22/EC*

Article 11 lays down the requirement for Member States to prohibit imports from third countries of farm or aquaculture animals and meat and meat products that have been administered with substances that fall under the scope of this Directive. Directive 96/23/EC implements that third countries, in order to be included in the list of countries from where animals and animal products may be imported, must submit a plan covering their guarantees for the monitoring of residues of substances included in the Annex; these must have an at least equivalent effect to the requirements of Article 11 above.

e) *Extended scope of Directive 96/22/EC*

Regulation 1257/1999 lays down provisions for support for rural development from the European Agricultural Guidance and Guarantee Fund (EAGGF). However, in case animals are found positive to substances unauthorised or illegally used under Directive 96/22/EC or when such substances are present in the producers' premises, the producer must be excluded from such financial support.

Commission Decision 2006/27/EC on special conditions governing meat and meat products of equidae imported from Mexico and intended for human consumption indicates that Member States must ensure that every consignment of meat or meat products of equidae is compliant with the requirements of Directive 96/22/EC for substances with hormonal action and beta-agonists through appropriate sampling and detection measures.

Commission Regulation 37/2010 lays down pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin. Included in the list are certain substances that may only be used for specific therapeutic or zootechnical purposes in accordance with the provisions of Directive 96/22/EC.

Regulation 1306/2013 on the financing, management and monitoring of the Common Agricultural Policy (CAP) indicates that the requirements of Directive 96/22/EC (Articles 3, 4, 5 and 7) are considered as Statutory Management Requirements in the area of food safety in the field of public health, animal and plant health under the rules of cross-compliance of Article 93 of the Regulation for beneficiaries receiving direct payments under the scope of this Regulation.

Annex XV: Additional implementing measures for selected Articles of Regulation 852/2004 and their respective requirements

The following paragraphs highlight the main requirements of Reg. 852/2004 and provide details of regulatory documents that add requirements or assist in the implementation of the main Regulation.

a) Article 4 on general and specific hygiene requirements

Article 4 of Regulation 852/2004 lays down specific hygiene requirements one of which is the compliance of food business operators with the microbiological criteria for foodstuffs. Commission Regulation 2073/2005 lays down the microbiological criteria for certain microorganisms as well as implementing rules for the food business operators. Operators are also required to conduct studies for the compliance of their products with the microbiological criteria throughout their shelf-life. Reg. 2073/2005 indicates that these may be conducted in accordance with guidelines included in guides to good practice, as per Article 7 of Reg. 852/2004.

Article 4 also indicates that more specific hygiene criteria, requirements and targets must be established by the Commission. In that respect, Regulation 1086/2011 establishes specific measures for *salmonella* in fresh poultry meat and poultry carcasses and provides sampling rules and guidelines, amending Regulations 2160/2003 on the control of salmonella and other specific food-borne zoonotic agents and 2073/2005 on microbiological criteria for foodstuffs.

b) Article 6 on official controls, registration and approval

Article 6 of Regulation 852/2004 requires that food business operators cooperate with the competent authorities and notify them on the establishments where food production, processing and distribution is carried out for the purposes of registration and approval after on-site visit confirms they are compliant with the food hygiene requirements. Article 31 of Regulation 882/2004 on official controls for compliance with feed and food law, animal health and animal welfare lays down requirements for the registration and approval (conditional or full) of food establishments and recommends the draw up of an up-to-date relevant list. Also there are provisions for the withdrawal or suspension of establishment approvals. In the same context, Article 4 of Reg. 853/2004 on specific hygiene measures for food of animal origin implements that animal products may only be placed on the market if they are registered with the Competent Authority under the requirements of Reg. 852/2004.

Also under the scope of Article 6 of Reg. 852/2004, Regulation 210/2013 (EU, 2013a) implements the requirement for approval of the establishments that produce sprouts by the competent authorities, provided they comply with the requirements of Annex I of Reg. 852/2004 as well as with the requirements established in the Annex of this Regulation on the design, layout, facilities, washing sinks, equipment and procedures.

c) Article 8 on national guides

Article 8 of Reg. 852/2004 encourages the voluntary development of national guides for the application of HACCP and good practice in food hygiene by food business sectors. Article 3 of Reg. 589/2008 on the implementation of Regulation 1234/2007 regarding the marketing standards for eggs, encourages the development of national guides for

the application of good practice by food business operators in egg-washing systems. This is addressed to Member States which authorised egg-washing in packing centres on 1 June 2003, provided that they operate in accordance with the national guides.

d) Article 9 on Community guides

Article 9 of Reg. 852/2004 allows for preparation of Community Guides on good practice for the hygiene and application of HACCP principles. Notice 2012/C 8/06 publishes a list of approved guides on the hygiene of foodstuffs after assessment by the Standing Committee of Food Chain and Animal Health.

e) Articles 10 and 11 on imports and exports

Articles 10 and 11 of Reg. 852/2004 refer to the hygiene requirements of imported and exported foodstuffs. The requirements of Article 3-6 of this Regulation must be fulfilled, as well as the relevant requirements of food law referred in Articles 11 and 12 of Regulation 178/2002 for imports or exports respectively.

f) Article 12 on Transitional measures

Article 12 of Regulation 852/2004 allows for the implementation of additional transitional measures and further specifications on the requirements of the Regulation. The following Decisions have been implemented under this Article:

- Commission Decision 2009/852/EC which lays down transitional measures for the processing of non-compliant raw milk in certain milk processing establishments in Romania and the structural requirements for these establishments.

- Decision 2010/89/EC which establishes transitional measures for specific structural requirements for establishments for meat, fishery, egg products and cold stores in Romania. The country is also requested to submit a report with the progress made by the above establishments in implementing the specific requirements. Until then, products may only be placed in the Romanian market and must bear a health or identification mark different from the one of Regulation 853/2004.

Also Regulation 2073/2005 on microbiological criteria for foodstuffs allows for derogation in the compliance with the values for *Salmonella* in minced meat, meat preparations and meat products as established in Annex I of the Regulation for a specific Member State.

g) Article 13 on amendment and adaptation of Annexes I and II

Article 13 (2) of Regulation 852/2004 allows for derogations from Annexes I and II of the Regulation in order to help small businesses into incorporating the HACCP principles provided the objectives of the Regulation can still be met. Regulation 2074/2005 allows for specific derogations for foods with traditional characteristics with regards to the rooms where the foodstuffs are prepared so that they can develop their particular characteristics, the type of materials from which the equipment and utensils used for the manufacture of the products are made and the cleaning and disinfectant measures. These derogations must be notified to the Commission and the other Member States.

h) Annex I of Regulation (EC) No 852/2004 on primary production

Part A, III of Annex I of Regulation 852/2004 lays down requirements for record-keeping relevant to the general hygiene provisions for primary production and associated operations. In line with these requirements, Annex II of Regulation 853/2004 on food chain information requires food business operators of slaughterhouses to only accept animals in the slaughterhouse after they have requested, received, checked and acted upon this information from the records of the establishment of origin at least 24 hours in advance.

Also in the same context, Article 20 of Reg. 589/2008 on the implementation of Regulation 1234/2007 regarding the marketing standards for eggs, lays down requirements with regards to record-keeping by producers. When there is an indication of the feed used for the laying hens on the pack of eggs, then the producers must keep records of the type and quantity of feed supplied or mixed on the site and the date of delivery of the feed.

i) Annex II, Chapter II of Regulation (EC) No 852/2004

Chapter II of Annex II of Regulation 852/2004 lays down requirements for the rooms where foodstuffs are prepared, treated or processed. Due to the difficulties for certain establishments in Bulgaria and Romania to meet the structural requirements of this Regulation, Commission Decisions provide for some transitional measures:

- Decision 2007/716/EC: certain establishments in Bulgaria are exempt from the above structural requirements until a specified date. Products may only be placed in the domestic market and must bear a health mark different than the one specified by Regulation 853/2004.

- Decision 2007/27/EC: provides a list of establishments in Romania that meet the requirements of Reg. 852/2004 and may process "non-compliant" milk as per Reg. 853/2004. Products however may only be placed in the domestic market and must bear a different health mark than the one specified by Regulation 853/2004.

j) Annex II, Chapter X of Regulation (EC) No 852/2004

Chapter X of Annex II of Reg. 852/2004 lays down requirements for the wrapping and packaging of foodstuffs. Article 17 of Reg. 589/2008 on the implementation of Regulation 1234/2007 regarding the marketing standards for egg provides specifications for the quality of packaging for eggs. Egg packs must be shock-resistant, dry, clean, in good condition and the materials they are made of must protect the eggs from extraneous odours and of other quality deterioration.

k) Annex II, Chapter XI of Regulation (EC) No 852/2004

Chapter XI of Annex II of Reg. 852/2004 lays down requirements for the heat treatment of foodstuffs and for the monitoring of the process. Annex III, Section IX, Chapter II of Regulation 853/2004 lays down additional specifications for the heat treatment of dairy and colostrum-based products.

l) Extended scope of Regulation (EC) No 852/2004

Several of the legal texts under Article 53 of Regulation 178/2002 on emergency measures for food and feed also refer to the hygiene Regulation 852/2004.

Regulation 1187/2009 establishes detailed rules for the application of Regulation 1234/2007 as regards export licences and export refunds for milk and milk products. Article 3 of the Regulation specifies that for export refunds to be granted, the products must meet the requirements of Regulations 852/2004 and 853/2004 and specifically preparations in an approved establishment and compliance with the identification marking requirements.

Regulation No 1069/2009 lays down health rules for animal by-products and derived products not intended for human consumption. Products from fishing vessels compliant with Regulations 852/2004 and 853/2004 are excluded from the scope of this Regulation, unless the fish material shows signs of disease or parasites transmissible to humans. Also establishments producing animal by-products that are registered or authorised in accordance with Regulations 852/2004 and 853/2004 do not need any further notification to the Authorities, while registered food businesses should carry out treatment, processing and storage of animal by-products in such a way as to avoid cross-contamination or in separate establishments.

Decision 2000/572/EC lays down the animal, public health and veterinary certificate conditions for the import of meat preparations in the European Union. For such products to be imported, the requirements of Regulations 178/2000, 852/2004 and 853/2004 must be met. The establishments where the products are produced must operate under the principles of HACCP (852/2004) and products must be frozen at no more than -18°C. Requirements are also established with regards to the health certificates that must accompany all consignments of such products.

Directive 2005/94/EC lays down Community measures for the control of avian influenza. Regulations 852/2004 and 853/2004 on the hygiene of foodstuffs can be applied under certain conditions to the hygiene of eggs originating from establishments where poultry may be infected with the avian influenza. The competent authority may authorise the dispatch of eggs from holdings where an influenza outbreak is suspected directly to establishments for the manufacture of egg products that meet the requirements of Regulation 853/2004 if they are heat treated according to the specific conditions of Chapter XI of Annex II of Reg. 852/2004. Provisions and derogations are also established for eggs originating from establishments within protection and surveillance zones as well as for eggs in relation to vaccination areas. The competent authorities may also allow for derogations for establishments where an influenza outbreak has been confirmed under specific conditions. Based on Directive 2005/94/EC, Commission Decision 2006/416/EC establishes transitional measures with regards to highly pathogenic avian influenza in poultry or other captive birds in the Community. Similar provisions are also laid down in the following Decisions in specific Member States: Commission Decision 2007/590/EC introducing preventive vaccination against highly pathogenic avian influenza and related provisions for movements in the Netherlands; Commission Decision 2007/638/EC on emergency vaccination of poultry in Italy against low pathogenic avian influenza.

Regulation 578/2010 on the implementation of Regulation 1216/2009 as regards the system of granting export refunds for certain agricultural products exported and the criteria for fixing the amount of such refunds implements that refunds may only be granted for certain goods if they comply with the hygiene requirements of Reg. 852/2004, as well as with the requirements for the establishments and the hygiene marking of Regulation 853/2004.

Annex XVI: Additional implementing measures for selected Articles of Regulation 853/2004 and their respective requirements

The following paragraphs highlight the main requirements of Reg. 853/2004 and provide additional regulatory documents that add requirements or assist in the implementation of this main text.

a) Article 1 on the scope of the Regulation

According to Article 1 of Regulation 853/2004 the provisions of this Regulation do not apply to the direct supply of small quantities of meat of poultry and lagomorphs slaughtered on the farm by the producer to the final consumer or to local retail establishments directly supplying the final consumer. Regulation 1079/2013 on transitional measures for the application of Regulations 853/2004 and 854/2004, implements derogation from the above provisions considering the additional burdens for small producers posed by the limitation of supply of the above products to the final consumer as fresh meat only. This applies until the end of validity of this Regulation on the 31st December 2016.

b) Article 3 on the food business operators' obligations

Article 3 of Regulation 853/2004 lays down some general obligations for food business operators. Specifically they must not use any substance other than potable water for the surface decontamination of products of animal origin unless it has been approved by the Commission. Also any conditions of use specified must be followed. Regulation 101/2013 lays down provisions for the use of lactic acid for the reduction of microbiological surface contamination of bovine carcasses under specific conditions. Requirements are also established in order to ensure that the applicable food hygiene requirements are not compromised by this treatment. The food business operators are required to communicate the use of this treatment to the operators that receive the product and this communication must be documented.

c) Article 4 on registration and approval of establishments

Article 4 of Regulation 853/2004 lays down requirements for the registration and approval of establishments manufacturing products of animal origin. Annex IV of Regulation 1308/2013 establishing a common organisation of the markets in agricultural products, lays down requirements for the classification of carcasses of bovine animals aged eight months or more on the Union scale. The Regulation requires that slaughterhouses approved under Article 4 above ensure that the above products slaughtered in such establishments and bearing a health mark in accordance with the Reg. 854/2004 are classified and identified in accordance with the Union scale.

Regulation 543/2008 lays down detailed rules for the application of Reg. 1234/2007 (now repealed by Regulation 1308/2013) as regards marketing standards for poultry-meat. It is required that the registration number of the slaughterhouse or cutting plant according to Article 4 of Reg. 853/2004 appears on the packaging of pre-packaged poultry-meat, or a label attached to it, unless cutting and boning takes place at the point of sale.

d) Article 5 on health and identification marking

Article 5 of Regulation 853/2004 implements that products of animal origin handled in an establishment under approval may not be placed on the market unless it has either a health mark (according to Reg. 854/2004) or an identification mark (according to Annex II, Section I of Reg. 853/2004). Article 16 of Regulation 2075/2005 on specific rules on official control for *Trichinella* in meat requires that where the trichoscopic method is used, the competent authority must ensure that the health mark used on the products is clearly different than the one provided in Regulation 853/2004 and the meat is supplied directly to the final consumer or to the establishment supplying directly the final consumer and that the meat is not used for products where the manufacturing process does not kill *Trichinella*.

Implementing Decision 2013/764 on animal health control measures relating to classical swine fever in certain Member States lays down measures to prevent the spread of swine fever. Pig meat and meat preparations at risk of swine fever should be marked with special marks that cannot be confused with the identification mark provided by Regulation 853/2004. Also the health mark used for fresh pig meat at risk of swine fever should be clearly different than the health mark provided by Regulation 854/2004. Similar Decisions implement precautionary measures in different Member States, for example Dec. 2007/314/EC, or Dec. 2011/508 on protection measures in Lithuania. Decision 2013/764 also requires that products containing pig meat originating from establishments from certain areas in Bulgaria, Croatia, Latvia and Romania, are only dispatched to other Member States if there are guarantees that they are not at risk of swine fever. In any other case, products must be marked with different marks from the identification and health marks of Regulations 853/2004 and 854/2004.

Directive 92/119/EEC introduced Community measures for the control of certain animal diseases and specifically for swine vesicular disease. Meat originating from holding where the disease was detected and which have been decontaminated may be placed on the market if it is marked with an identification mark which is different from the one of Directive 2002/99/EC (on animal health rules covering the production, processing, distribution and introduction of products of animal origin for human consumption) and different from the one of Reg. 853/2004. The code of the approved country as well as of the approved establishment must feature on this identification mark.

Commission Decision 2007/30/EC lays down transitional measures for the marketing of products of animal origin from Bulgaria and Romania obtained until the 31st of December 2006. Such products can be placed on the domestic market bearing the national mark until the 31st of December 2007. The above products may also be traded in other Member States until the above date, provided they are produced in establishments authorised to supply the Community, they bear the Community health or identification mark according to Regulation 853/2004 and they are accompanied by a document certifying "Produced before 1 January 2007, in conformity with Commission Decision 2007/30/EC".

e) Article 6 on products of animal origin from outside the Community

Article 6 of Regulation 853/2004 implements specific conditions for the import in the Community of products of animal origin from third countries. Products may only be imported if they originate from a country that appears in the list of approved countries, if the establishment (or slaughterhouse, or production area) appears on the relevant permitted lists and if the product meets the requirements of Regulations 852/2004, 853/2004, 854/2004, the health marking requirements and any other import control conditions established by Community legislation. Products must be accompanied by specific documents certifying compliance with the above Regulations and the requirements for these documents are laid down in Regulation 854/2004. Further

completing these provisions, Regulation 2074/2005 (on implementing measures for certain products under Regulation 853/2004) provides model health certificates and documents for certain products of animal origin.

Regulation 1079/2013 on transitional measures for the application of Regulations 853/2004 and 854/2004 excludes the application of the above provisions to products of animal origin for which there are no public health import conditions established at Community level. Such products may be imported according to the public health import conditions in place at the Member State of import.

With regards to the import of fishery products under Article 6(2) of Regulation 853/2004, provisions are established by Article 15 of Regulation 854/2004. Specifically for products imported directly from a fishing or freezer vessel, the documentation required may be replaced by a document signed by the captain. This model document is provided in Appendix VII to Annex Vi of Regulation 2074/2005.

Article 6(4) of Regulation 853/2004 lays down provisions for the import of products that contain both products of plant origin and processed products of animal origin. These products must satisfy all the above requirements. Regulation 1079/2013 allows for an exemption from these requirements for food business operators that import such products, unless they are: composite products containing processed meat products, processed milk products, or containing half or more of their substance of processed fishery or egg products (as per Article 3(1) of Regulation 28/2012 on requirements for certification for import into and transit through the Union of certain composite products). For these products harmonised Union rules apply where applicable, or national rules of the Member States.

f) Article 8 on special guarantees

Article 8 of Regulation 853/2004 lays down special guarantees for *salmonella* in meat and egg products intended for placement on the market in Finland and Sweden. For eggs, packing centres must provide a guarantee that all consignments have been tested negative to specific microbiological tests. Regulation 1688/2005 lays down implementing measures for the above guarantees of Reg. 853/2004. According to Article 4 the sampling of flocks for the required test shall be carried out according to the minimum sampling plans of Part B of Annex II of Regulation 2160/2003.

Article 8 also specifies that the above provisions on any of the products covered by this Article may be extended wholly or partly to other Member States that have control programmes in place that can be recognised as equivalent to those of Sweden and Finland. In that respect, Implementing Regulation 427/2012 extends the special guarantees concerning salmonella in eggs intended for Sweden and Finland of Regulation 853/2004, to eggs intended for Denmark. The sampling of the flocks as well as the microbiological testing for salmonella must be carried out as described in Regulation 1688/2005 and the consignments must also be accompanied by a certificate as per this Regulation.

g) Article 9 on transitional measures

Article 9 of Regulation 853/2004 allows for transitional measures to be adopted in order to supplement the Regulation. Commission Decision 2009/861/EC establishes transitional measures with regard to milk non-compliant with the requirements of Regulation 853/2004 originating from certain establishments in Bulgaria, provided it is only used or further processed within the country. Bulgaria must submit reports to the Commission on the progress achieved towards meeting the requirements of Reg. 853/2004. Recent Decision 2013/686/EC amends Decision 2009/861/EC extending the

dates until when establishments in Bulgaria may continue to produce non-compliant milk. Further provisions are implemented indicating the target annual percentage reduction of establishments producing non-compliant milk that has to be met in Bulgaria. Also Commission Decision 2009/852/EC lays down transitional measures for the processing of non-compliant raw milk in certain milk processing establishments in Romania and structural requirements. Decision 2010/89/EC establishes transitional measures for specific structural requirements for establishments for meat, fishery, egg products and cold stores in Romania.

Decision 2007/29 established transitional measures for animal products that fall under the scope of Regulation 853/2004 but do not meet the relevant requirements and that were released for free circulation in Bulgaria and Romania from third countries before the 1st of January 2007. These products could be placed on the national markets until 31st December 2007, bearing the national mark and could not be processed in establishments preparing products for other Member States. They could be exported directly to third countries and any unused quantities on the 1st of January 2008 were destroyed at the expense of the food business operator. Similar provisions to the above are also established by Implementing Decision 2013/291/EC for products of animal origin introduced in Croatia from third countries before 1 July 2013.

Regulation (EC) No 1079/2013 lays down transitional measures and extends the deadline for the application of Regulations 853/2004 and 854/2004 from the beginning of 2014 until the end of 2016, repealing the previous Regulation 1162/2009.

Also under Article 9, Regulation 798/2008 lays down a list of third countries, territories, zones or compartments from which poultry products may be imported into and transit through the Community and the veterinary certification requirements. Similarly, Regulation 119/2009 lays down conditions for the import into or transit through the European Union of wild leporidae, certain wild land mammals and of farmed rabbits as well as a list of countries from where these products may be imported and the veterinary certification requirements.

Regulation No (EU) 605/2010 lays down conditions for animal and public health and veterinary certification for the import of raw milk and dairy products for human consumption in the EU and establishes a list of countries from where such products can be introduced. Authorised consignments should be accompanied by a health certificate, drawn up and completed according to the instructions provided in the Regulation which certifies that the product meets the health requirements of Reg. 853/2004 and Directive 2002/99/EC.

Regulation 206/2010 lays down specific veterinary certification requirements for the import in the European Union of ungulates, bumble bees and queen bees and bumble bees and fresh meat and lists of third countries from where the above products may be introduced.

h) Article 10 on amendment and adaptation of Annexes II and III

Article 10 of Regulation 853/2004 allows for amendments and adaptations of the Annexes II and III to the Regulation in order to take into account guides to good practice, experience gained, technological developments, consumer expectations, scientific advice, microbiological and safety criteria for foodstuffs and changes in patterns of consumption. Several Regulations have been adopted under this Article amending the Annexes to Regulation 853/2004 (i.e. Regs. 1243/2007, 558/2010, 150/2011, 1276/2011, 786/2013).

j) Article 11 on specific decisions

Article 11 of Regulation 853/2004 allows for implementing measures and amendments to the Annexes of the Regulation to be adopted on varying issues.

In that respect, freshness criteria and limits for histamine and total volatile nitrogen need to be established for fisheries products. These are provided by Annex II of Regulation 2074/2005 on implementing measures for certain products under Regulation 853/2004 and include the obligations of the food business operators and details for the visual inspection of fisheries products, the obligations of the competent authorities and the limits for total volatile nitrogen and relevant methods for analysis.

Also implementing measures according to Reg. 853/2004 are required on recognised testing methods for detecting certain marine biotoxins. These analytical methods are also implemented by Annex III to Regulation 2074/2005 and must be used by the competent authorities to ensure compliance with the maximum limits for marine biotoxins established in Annex III, Section VII, Chapter V(2) as well as by food business operators where appropriate.

Reg. 853/2004 also allows for implementing measures to specify the calcium content that is not significantly higher than that of minced meat in respect of mechanically separated meat (MSM). Annex IV of Regulation 2074/2005 specifies the maximum calcium content of MSM as determined by an international standardised method.

j) Annex I of Regulation (EC) No 853/2004 on Definitions

Annex I of Regulation 853/2004 lays down definitions for meat products and for treated stomachs, bladders and intestines. Commission Decision 2007/777/EC lays down the animal and public health conditions and model certificates for imports of the above meat products from third countries for human consumption.

k) Annex II, Section I of Regulation (EC) No 853/2004 on Identification marking

Regulation 657/2008 lays down detailed rules for the application of Regulation 1234/2007 (now repealed by Regulation 1308/2013) with regard to supplying milk and milk products to pupils in the educational establishments. Such products must be in compliance with the hygiene requirements of Regulation 852/2004, must be produced in approved establishments and must bear the identification health mark indicated in Reg. 853/2004.

Decision 2011/408/EU lays down simplified rules and procedures on sanitary controls of certain fishery products, by-products and products derived from the by-products coming from Greenland. Consignments of products dispatched from Greenland to the European Union must bear the identification mark for Greenland according to the rules of Section I(B) of the above Annex.

l) Annex II, Section III on Food Chain Information

Annex II, Section III of Regulation 853/2004 requires food business operators of slaughterhouses to request, receive, check and act upon food chain information for all the animals to be sent to the slaughterhouse. Regulation 2074/2005 on implementing measures for certain products under Regulation 853/2004, lays down obligations for both the food business operators and the competent authorities with regard to the food chain information.

Regulation 504/2008 (implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae) requires food business operators to obtain the above information of Reg. 853/2004 while for domestic solipeds they should request the accompanying passports. However, an equine animal may be authorised for slaughter without the above passport, if it is transported directly from the holding of birth to the slaughterhouse within the same Member State and provided the consignment is accompanied by the food chain information of Annex II of Reg. 853/2004 which should also make a reference to the animal's unique identification.

m) Annex III on specific requirements for products of animal origin

Annex III to Regulation 853/2004 lays down specific requirements for the hygiene during the slaughter of specific animal products. Commission Decision 2006/563/EC lays down certain protection measures in relation to highly pathogenic avian influenza of subtype H5N1 in wild birds in the Community. In case H5N1 is detected in a Member State, control and monitoring areas must be established around the area where the virus was detected as well as control measures and prohibitions. As derogation from these prohibitions, fresh meat from poultry or game, and certain meat products may be dispatched from the control area for placement on the market or export provided it has been produced in accordance to the provisions of Sections II, III, V and VI of Annex III to Regulation 853/2004 and controlled in accordance to Regulation 854/2004. There is an array of Commission Decisions introducing preventive vaccination against H5N1 or other related provisions for meat products or eggs for movement in the different Member States (i.e. 2006/147, 2006/135, 2006/115, 2006/105, 2006/104, 2006/94, 2006/91, 2006/90, 2006/416, 2006/415, 2006/148).

Annex III of Regulation 853/2004 also lays down structural requirements for the establishments where foodstuffs of animal origin are prepared. Due to the difficulties for certain establishments in Bulgaria to meet these requirements, Commission Decision 2007/716/EC (on transitional measures for structural requirements of certain establishments in the meat and milk sectors in Bulgaria provided for in Regulations 852/2004 and 853/2004) provides for transitional measures and certain establishments in Bulgaria are exempt from the above requirements until a specified date. Products may only be placed in the domestic market and must bear a health mark different than the one specified by Regulation 853/2004.

Annex III, Section V, Chapter III of Regulation 853/2004 lays down hygiene requirements during and after production for specific meat products. Regulation 2073/2005 on microbiological criteria for foodstuffs establishes *salmonella* criteria specific to mechanically separated meat produced by the techniques of the above Annex.

Annex III, Section V, Chapter IV of Regulation 853/2004 lays down specific requirements for the labelling of minced meat, meat preparations and MSM. In addition to the requirements established by the food labelling Regulations, packages containing minced meat from poultry and solipeds, or meat preparations containing MSM intended for sale to the final consumer must bear a note that the product must be cooked before consumption. In addition to these provisions, Regulation 1169/2011 on the provision of food information to the consumers also requires that the following expressions appear on the packages of such products: "*percentage of fat content under...*" and "*collagen/meat protein ration under...*".

Annex III, Section VIII to Reg. 853/2004 lays down specific requirements for fishery products. Regulation 1379/2013 on the common organisation of the markets in fishery and aquaculture products requires that such products may only be offered to the consumer if they display some mandatory consumer information, additional to the requirements of Regulation 1169/2011. Specifically the products need to display whether

they have been defrosted, unless they have been previously frozen for health safety purposes in accordance with Annex III, Section VIII to Reg. 853/2004.

Section IX of Annex III to Regulation 853/2004 lays down requirements for raw milk, colostrum, dairy products and colostrum-based products. Chapter I, Part III lays down specific criteria for the plate counts from milk of different animal species and residues of antibiotics for food business operators producing or collecting raw milk and colostrum. Also Chapter II, part II of this Annex lays down specific requirements for the heat treatments (pasteurisation and ultra-high temperature treatment - UHT) in addition to the requirements of Regulation 852/2004. Article 6a of Regulation 2074/2005 (on implementing measures for certain products under Regulation 853/2004) establishes analytical methods for compliance with the above requirements for the competent authorities and the food business operators.

Furthermore, Chapter II, part III of this Annex implements specific criteria for raw cow's milk beyond its period of acceptance and before heat treatment. Milk that complies with these requirements can be received and processed in establishments that are listed in Chapter II of the Annex to Commission Decision 2007/27/EC (on certain transitional measures concerning deliveries of raw milk to processing establishments and the processing of this raw milk in Romania with regard to the requirements of Regulations 852/2004 and 853/2004) together with non-compliant milk, provided the food business operators can guarantee the following: that the establishments comply with the requirements of Regulation 852/2004, the process is carried out in separate production lines, there are procedures to ensure separation of the different milks in the establishments and traceability, that a specific minimum heat treatment is carried out and that the identification mark of Reg. 853/2004 is only applied when appropriate. Also the above Decision requires competent authorities in Romania to verify the compliance of the establishments listed in the Annex, to carry out unannounced controls and appropriate analysis to ensure compliance of milk products with the specific criteria of Annex III, Chapter II to Regulation 853/2004, as well as the microbiological criteria for dairy products. Products from non-compliant milk produced in the establishments of Annex II of Dec. 2007/27 may only be placed on the domestic market or be further processed and must bear a different identification mark from the one of Reg. 853/2004.

Annex III, Section XIV, Chapter I(5) and Section XV, Chapter I(5) lay down specific requirements for the authorisation of collection centres and tanneries to supply raw materials for the manufacture of collagen and gelatine for human consumption, structural requirements and requirements for the cleanliness and segregation from non-compliant material. Regulation 1069/2009 on health rules for animal by-products and derived products not intended for human consumption indicates that raw materials for the production of gelatine and collagen not intended for human consumption may be stored, treated or processed in the above establishments, provided they are segregated from raw materials for the production of products of animal origin to prevent the risk of disease transmission.

n) Extended scope of Regulation (EC) No 853/2004

Directive 2005/94/EC lays down Community measures for the control of avian influenza. Regulations 852/2004 and 853/2004 on the hygiene of foodstuffs can be applied under certain conditions to the hygiene of eggs originating from establishments where poultry may be infected with the avian influenza

Regulation 1272/2009 lays down rules for the implementation of Regulation 1234/2007 (now repealed by Regulation 1308/2013) with regard to the buying and selling of agricultural products under public intervention. This Regulation makes reference to certain requirements of Reg. 853/2004. Specifically, only operators of bovine animal

slaughterhouses registered and approved under Reg. 853/2004 may participate in the public intervention scheme. Also the boning of beef can only be carried out in cutting plants that are registered and approved according to Reg. 853/2004 while boned cuts must also meet the hygiene requirements of this Regulation. Boned beef must be packed in cartons that bear an identification mark according to the provisions of Reg. 853/2004. Establishments for the production of butter and of skimmed milk powder must also be registered and approved under Reg. 853/2004, while raw milk used for the production of skimmed milk powder must meet the requirements of Annex III, Section IX of this Regulation and must also be free from antimicrobial substances.

Regulation 1069/2009 on health rules for animal by-products and derived products not intended for human consumption.

Regulation 142/2011 implementing Regulation 1069/2009 lays down health rules as regards animal products and derived products not intended for human consumption. Processing plants must not be situated on the same site as slaughterhouses approved under Reg. 853/2004, unless risks are mitigated. Also animal by-products must be accompanied by a commercial document as set out in the Annex to this Regulation or by a health certificate. However such a document is not required for milk and milk products which are to be returned to establishments approved under Reg. 853/2004. Specific requirements relevant to Regulation 853/2004 are also laid down for other product categories.

Regulation 1187/2009 establishes detailed rules for the application of Regulation 1234/2007 as regards export licences and export refunds for milk and milk products. Article 3 specifies that for export refunds to be granted, the products must meet the requirements of Regs 852/2004 and 853/2004 and specifically preparation in an approved establishment and compliance with the identification marking requirements.

Regulation 175/2010 lays down implementing measures for Directive 2006/88/EC with regard to the control of increased mortality of oysters of the species *Crassostrea gigas* in connection with the detection of Ostreid herpesvirus 1 μ var. When this virus is detected in oysters, the competent authority must establish a containment area. Consignments of oysters may only be removed from this area if they are intended for human consumption and they are packed in retail-sale packages as such according to the provisions of Reg. 853/2004.

Annex XVII: Additional implementing measures for selected Articles of Regulation 854/2004 and their respective requirements

The following paragraphs highlight the main requirements of Reg. 854/2004 and provide additional regulatory documents that add requirements or assist in the implementation of this main text.

a) Article 5 on fresh meat

Article 5 of Regulation 854/2004 establishes requirements for the official controls of fresh meat and details are provided in Annex I to the Regulation. Also requirements are laid down for the application of the health marking and specifically with regards to *Trichinella* examination, the health mark may only be applied once the negative testing results are available. Regulation 2075/2005 on specific rules for the control of *Trichinella* allows for derogation and thus the health mark may be applied prior to the *Trichinella* test results for establishments approved by the competent Authorities.

b) Chapter III (Articles 10-15) on procedures concerning imports

Chapter III of Regulation 854/2004 lays down procedures for the import of products of animal origin in order to ensure the uniform application of Regulations 178/2002 and 882/2004. Regulation 1079/2013 establishes transitional measures for the application of Regulations 853/2004 and 854/2004. Products of animal origin for which there are no harmonised import conditions, approved lists of import countries or establishments established at Community level are excluded from the above provisions. Such imports must comply with the import requirements laid down at national level in the importing Member States.

Article 11 of Reg. 854/2004 specifically requires the establishment of lists of third countries from where specific products of animal origin may be imported. Countries may only appear on the lists if Community controls have demonstrated that their competent Authorities can provide appropriate guarantees as required by Regulation 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. Commission Decision 2006/766/EC thus lays down a list of countries from where bivalve molluscs, tunicates, echinoderms and marine gastropods may be imported as well as a list of countries from where fishery products may be imported. Furthermore, Regulation 1251/2008 implementing Directive 2006/88/EC on the conditions and certification requirements for the placing on the market and import into the Community of aquaculture animals and products thereof and laying a list of vector species, implements that such products may only be imported in the Community from third countries and territories which are included in the above lists of Regulation 854/2004.

c) Article 12 on lists of establishments from which imports of specified products of animal origin are permitted

Article 12 of Regulation 854/2004, provides the conditions under which an establishment may be placed on a list of approved establishments for imports of specified products of animal origin. One of the conditions is that there are guarantees from the competent authorities in the third country that the particular establishment as well as any other establishments handling any of the raw materials used in the manufacture of the

products of animal origin concerned, comply with the Community legislation and in particular with the requirements of Regulation 853/2004. Regulation 1099/2009 on the protection of animals at the time of killing lays down some general requirements for the killing and stunning of animals, standard operating procedures and instructions for the use of restraining and stunning equipment. Also some additional structural and equipment requirements for slaughterhouses are described, monitoring procedures and finally the duties of an animal welfare officer to assist slaughterhouses in fulfilling the requirements of this Regulation.

Furthermore, with regard to approved establishments, a fishing vessel not appearing in the list of approved establishments for the import of animal products under Regulation 854/2004 should be one of the criteria of the benchmarks for port inspections. This is enforced by Regulation 1010/2009 laying down detailed rules for the implementation of Regulation 1005/2008 establishing a Community list to prevent, deter and eliminate illegal, unreported and unregulated fishing.

In addition, Article 14 of Regulation 2075/2005 on the official controls of *Trichinella* in meat allows for meat of domestic swine to be imported in the Community without having undergone a *Trichinella* test provided that it originates from an establishment officially recognised as free from *Trichinella* under Regulation 854/2004 or provided it has undergone a freezing treatment in accordance with Annex II to the Regulation.

d) Article 14 on documents

Article 14 of Regulation 854/2004 lays down requirements for the documents that must accompany consignments of products of animal origin to be imported in the Community certifying compliance with Regulations 852/2004, 853/2004 and 882/2004. The same Article also allows for exemptions from the above requirements when these can be guaranteed in a different way. In that respect, Regulation 2075/2005 requires that a document certifying the above requirements accompanies meat products to be imported, unless an exemption has been granted by the above provisions.

Commission Decision 2007/30/EC on transitional measures for the marketing of animal products from Bulgaria and Romania obtained until the 31st of December 2006 allows, as previously discussed, for such products to be placed on the domestic market under specific conditions.

e) Article 15 on special provisions for fishery products

Article 15 of Regulation 854/2004 lays down special provisions for fishery products imported from fishing or freezer vessels. Additional requirements as well as the model documents for this category of products are provided by Regulation 2074/2005.

f) Article 18 on specific decisions

Article 18 of Regulation 854/2004 lays down provisions for the establishment of implementing measures amending the Regulation for different criteria, rules etc. Amongst these, the cold treatment to be applied to meat in relation to trichinosis as well as the conditions for certification of establishments and regions as free from trichinae are included. In that respect, Regulation 2075/2005 lays down specific rules for the official controls of *Trichinella* in meat. When a slaughterhouse has a formally approved procedure by the competent authority for ensuring that no part of carcasses may leave the premises before the *Trichinella* tests is found to be negative, the health mark of Regulation 854/2004 may be applied before the *Trichinella* test results are available.

With regards to fishery products and the organoleptic criteria for their freshness, additional requirements are provided by Regulation 2074/2005. This Regulation also lays down the recognised chemical and biological methods for the detection of marine biotoxins in live bivalve molluscs.

g) Annex I: fresh meat

Annex I of Regulation 854/2004 lays down detailed requirements for the official controls of fresh meat. Some additional requirements with regards to the food chain information as well as for the controls in establishments carrying out discontinuous slaughtering are established by Regulation 2074/2005 (laying down implementing measures for Regulations 853/2004, 854/2004 and 882/2004 and derogating from Regulations 852/2004, 853/2004 and 854/2004). The Regulation also implements certain amendments to Annexes I, II and III of Reg. 854/2004.

Annex I to Regulation 854/2004 also specifies the tasks of the official veterinarians for different categories of meat products. Directive 2007/43/EC on minimum rules for the protection of chickens kept for meat production lays down additional requirements to those of Reg, 854/2004 with regard to the post-mortem examination of chickens to identify signs of poor welfare in the holding.

Chapter V of Section II of Annex I of Regulation 854/2004 lays down the conditions under which meat may be declared as unfit for human consumption. Regulation 504/2008 on methods for the identification of equidae implements that when the transponder cannot be recovered from an equine animal slaughtered for human consumption, the official veterinarian shall declare the meat or the part of the meat that contains the transponder as unfit for human consumption.

Annex I also establishes the scope of ante-mortem inspection to be able to determine signs of compromised animal welfare or the presence of zoonotic or other regulated animal diseases. Regulation 999/2001 on the prevention, control and eradication of certain transmissible spongiform encephalopathies requires all bovine animals older than 24 months of age to be tested for BSE when there are specific findings identified in accordance with Annex I of Regulation 854/2004. Also it establishes that carcasses used for this testing must not be marked with the health marking of Reg. 854/2004 before a negative test result has been obtained.

In light of the outbreaks of foot-and-mouth disease in the UK, meat products bearing the health mark according to the requirements of Chapter III, Section I of Annex I of Reg. 854/2004 are exempt from the prohibition of dispatching if originating from specific areas listed in the Annex to Decision 2007/554/EC, provided they also meet certain provisions laid down within the same Decision. Similar rules are also established in other countries by different Commission Decisions (i.e. 2007/718/EC).

Implementing Decision 2013/764/EU on animal health control measures relating to classical swine fever in certain Member States lays down measures to prevent the spread of swine fever. As already discussed, the health mark used for fresh pig meat and for products containing pig meat at risk of swine fever, originating from certain areas in Bulgaria, Croatia, Latvia and Romania should be clearly different than the health mark provided by Regulation 854/2004.

h) Annex II: Live bivalve molluscs

Regulation 2074/2005 implements certain amendments to Annex II of Regulation 854/2004 with regard to the production areas of such products.

j) Annex III: Fishery products

Regulation 2074/2005 implements certain amendments to Annex III of Regulation 854/2004 regarding the prohibition of placement on the market of certain fishery products derived from poisonous fish.

j) Extended scope of Regulation (EC) No 854/2004

Commission Decision 2006/415 lays down certain protection measures in relation to highly pathogenic avian influenza of the type H5N1 in poultry in the Community. In order to prevent the spread of the disease, products derived from wild feathered game intended for human consumption may not be dispatched from high or low risk areas to other Member States or to third countries. As derogation, fresh meat products originating outside of high or low risk areas but produced in establishments within such areas may be dispatched, provided they meet the requirements of Regulations 853/2004 and 854/2004.

Commission Decision 2006/563/EC lays down certain protection measures in relation to highly pathogenic avian influenza of subtype H5N1 in wild birds in the Community. As discussed before. In case H5N1 is detected in a Member State, fresh meat from poultry or game and certain meat products may be dispatched from the control area for placement on the market or export, provided it has been produced in accordance to the provisions of Sections II, III, V and VI of Annex III to Regulation 853/2004 and controlled in accordance with Regulation 854/2004. There is an array of Commission Decisions introducing related provisions for the movement of different products in the different Member States.

Annex XVIII: Legislation implemented under Directive 2002/99/EC and in particular Articles 8 and 9 on lists of approved third countries, special import conditions and certification documents

a) Conditions for milk and dairy products

Commission Regulation No (EU) 605/2010 lays down conditions for the animal and public health and the veterinary certification for the import of raw milk and dairy products for human consumption in the European Union. It also establishes a list of countries from which such products can be introduced in the Union. Milk products can be imported by specific countries provided they have undergone the heat treatments specified in the Regulation depending on the risk of foot-and-mouth disease. The same heat treatments apply for countries where there is a risk of the disease or where there has been an outbreak of the disease or relevant vaccination has been carried out in the last year. Authorised consignments should be accompanied by a health certificate, drawn up and completed according to the instructions provided in the Regulation. Also the above requirements apply for products in transit or storage in the European Union, which must also be accompanied by a certificate suitable for this purpose according to Regulation 136/2004. Regulation 605/2010 also lays down some specific provisions for products in transit through Croatia, or to Russia through certain countries. Also Decision 2011/44/EU lays down protection measures against foot-and-mouth disease in Bulgaria.

b) Conditions for certain animals and fresh meat

Commission Regulation (EU) No 206/2010 lays down specific veterinary certification requirements for the import in the European Union of ungulates, bumble bees and queen bees and bumble bees and fresh meat. It also establishes lists of third countries from which the above products may be introduced in the Union. The Regulation also provides protocols for the standardisation of materials and sampling and testing procedures needed for the purposes of testing for certain diseases for the veterinary certificates. Specific conditions are also established for the introduction of certain animal species in the EU, for the transport of live animals and for relevant time limits. Similarly detailed requirements are established for the import of fresh meat or transport, transit and storage requirements.

c) Conditions for live ungulate animals

Council Directive 2004/68/EC lays down the animal health rules for the import and transit of live ungulates into the European Union. Imports are only authorised from the listed countries and specific criteria are provided for the compilation of the country list which must also be published by the Commission. The Directive specifies animal health conditions for the animals to be imported, the guarantees that are required from the third country and finally details for the veterinary certificate. The Commission reserves the right to conduct audits and inspections in the third country.

d) Conditions for composite products

Council Regulation 28/2012 lays down requirements for the certification of certain composite products imported in the Union from third countries or in transit through the Union. Composite products, according to the definitions of Decision 2007/275/EC, may only be imported in the European Union by certain authorised countries and provided the establishments in which they are manufactured meet the requirements of Reg.

853/2004. These must be accompanied by a health certificate prepared according to Reg. 28/2012.

e) Conditions for meat of wild leporidae, wild land mammals and farmed rabbits

Commission Regulation 119/2009 lays down conditions for the import into or transit through the European Union of the above species, a list of countries from where these products may be imported and the veterinary certification requirements.

Annex XIX: Additional implementing measures for selected Articles of Regulation 2073/2005 and their respective requirements

The following paragraphs highlight the main requirements of Reg. 2073/2005 and provide additional regulatory documents that add requirements or assist in the implementation of this main text.

a) Article 1 on subject matter and scope

Article 1 of Regulation 2073/2005 indicates that the competent authority must verify compliance with the rules and the criteria laid down, in accordance with the provisions of Reg. 882/2004. Implementing Decision 2013/652/EU lays down provisions on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria. The monitoring of antimicrobial resistance (AMR) in *Salmonella* species should be focused to isolates obtained during the national control programme according to Reg. 2073/2005. If a Member State cannot meet the minimum number of *Salmonella* isolates required for antimicrobial resistance testing, the competent authority may use samples collected by food business operators, provided they have been obtained under the national control programme established by Reg. 2160/2003 and they meet the process hygiene criteria of Annex I of Reg. 2073/2005. The Annex to Implementing Decision 2013/652/EU lists certain animal populations and food categories from which samples must be collected for the purposes of AMR monitoring (in accordance with Regs. 2160/2003 and 2073/2005).

b) Annex I on microbiological criteria for foodstuffs

Annex I of Regulation 2073/2005 lays down the microbiological criteria for foodstuffs: food safety criteria, process hygiene criteria and rules for sampling and preparation of tests samples.

Regulation 101/2013 lays down provisions for the use of lactic acid for the reduction of microbiological surface contamination of bovine carcasses. The Regulation clarifies that the use of lactic acid should not be considered as a substitution of good hygienic slaughtering practices. It also specifies that sampling of carcasses for the purposes of assessing compliance with the microbiological requirements of Reg. 2073/2005 must be carried out before surface treatment of the carcasses with lactic acid.

Regulation 211/2013 lays down certification requirements for imports into the Union of sprouts and seeds for the production of sprouts. Consignments of these products must comply with the requirements of Regulations 852/2004 on the hygiene of foodstuffs, 208/2013 on traceability requirements and with the microbiological criteria of Reg. 2073/2005 in order to be imported into the European Union from third countries and they must be accompanied by a certificate in accordance with the model of the Annex to Reg. 211/2013.

Regulation 200/2012 lays down a Union target for the reduction of *Salmonella enteritidis* and *Salmonella typhimurium* in flocks of broilers in accordance with the requirements of Regulation 2160/2003 on the control of *salmonella* and other zoonotic agents. This target reduction is key, in order to meet the requirements of Regulations 2160/2003 and 2073/2005 for *Salmonella* in fresh meat of broilers.

Annex I to Regulation 854/2004 on specific rules for the organisation of official controls on products of animal origin intended for human consumption, lays down the tasks of

the official veterinarian for certain hazards. The process hygiene criterion for *Salmonella* on carcasses established by Reg. 2073/2005 should also be supervised in the pigmeat inspection and action should be enforced in case of non-compliance. Therefore, specific measures are added to Annex I of Reg. 854/2004 so that the competent authority can verify the correct implementation of the process hygiene criterion for *Salmonella* on pig carcasses by food business operators, also in accordance with the provisions of Article 5 of Reg. 2073/2005.

Commission Decision 2007/642/EC lays down emergency measures for fishery products imported from Albania and intended for human consumption. According to this Decision, Member States may only import fishery products originating from Albania, if they are accompanied by analytical results of tests carried out according to Annex I of Reg. 2073/2005 which show that the histamine levels are below the limits specified in that Regulation. Consignments of such products may be imported without test results, provided the competent authorities detain them until the importing country has conducted the above tests with favourable results. If the limits are exceeded, the Member State must immediately inform the Commission.

Annex XX: Additional implementing measures for selected Articles of Regulation 2160/2003 and their respective requirements

The following paragraphs highlight the main requirements of Reg. 2160/2003 and provide additional regulatory documents that add requirements or assist in the implementation of the Regulation.

a) Article 3 on competent authorities

Article 3 of Regulation 2160/2003 establishes the requirement that each Member State must designate a competent authority for the purposes of the Regulation and also lays down the responsibilities of this authority. These include the drawing of the national control programmes, collecting data and evaluating the results obtained through these programmes and carrying out checks in order to ensure compliance with the requirements of the Regulation. Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents indicates that each Member State must assess the sources and trends of zoonoses and zoonotic agents within its territory and they must provide the Commission every year with a report of the results. These must be public and must contain the results of the above evaluation carried out by the competent authority.

b) Article 4 on Community targets for the reduction of the prevalence of zoonoses and zoonotic agents

Article 4 of Regulation 2160/2003 lays down the requirement for Community targets to be established for the reduction of the prevalence of zoonoses and zoonotic agents and lays down detailed rules and specifications for these targets and timeframes for their establishment. Commission Decision 2004/665/EC requires the Commission to undertake a one-year baseline study on the prevalence of *Salmonella* spp. in flocks of laying hens of *Gallus gallus* for the production of table eggs at the end of their production period. The results of this study should be used for the establishment of the Community targets required by Article 4.

In the same context, Commission Decision 2005/636/EC provides a Community financial contribution for the costs involved for carrying out a one-year survey to assess the prevalence of *Salmonella* spp. in flocks of broilers of *Gallus gallus* sampled within three weeks of leaving the holding for slaughter. Similarly Commission Decision 2006/662/EC provides a Community financial contribution for carrying out a one-year survey to assess the prevalence of *Salmonella* spp. in fattening turkeys three weeks after leaving the holding for slaughter and in flocks of breeding turkeys within nine weeks before depopulation. The results of both surveys should be used, as above, for the establishment of the Community targets required by Article 4. Within the same context similar Commission Decisions provide for financial contribution for similar studies for assessing the prevalence of *Salmonella* in other animal species (Dec. 2006/668/EC, 2007/208/EC, 2007/219/EC). Also other Commission Decisions provide financial contribution for studies assessing the prevalence of antimicrobial resistance to different zoonotic agents in different animal species (2007/516/EC, 2008/55/EC).

c) Article 5 on National control programmes

Article 5 of Regulation 2160/2003 lays down the requirement for establishment of national control programmes in the Member States in order to achieve the Community

targets for the reduction of zoonoses and zoonotic agents. Implementing Decision 2013/652/EU lays down provisions on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria. If a Member State cannot meet the minimum number of *Salmonella* isolates required for antimicrobial resistance testing through the national control programme according to Reg. 2073/2005, samples collected by food business operators may be used, provided they have been obtained under the national control programme established by Reg. 2160/2003 and they meet the process hygiene criteria of Annex I of Reg. 2073/2005. Also the Annex to the above Implementing Decision lists certain animal populations and food categories from which samples must be collected for the purposes of AMR monitoring in accordance with Regs. 2160/2003 and 2073/2005.

d) Article 10 on imports from third countries

Article 10 of Regulation 2160/2003 indicates that the admission of third countries from which animals and hatching eggs may be imported in an approved list should depend on the submission of their national control programme for zoonoses and zoonotic agents which should provide equivalent guarantees to the European ones. Regulation 798/2008 lays down a list of third countries from where poultry and poultry products may be imported into the Community and Annex II to this Regulation lays down the veterinary certification requirements for these products and any additional specific conditions. Specifically, the veterinary certificates for the import of poultry, hatching eggs and day old chicks, meat and eggs from certain countries bear a specific requirement that the import is prohibited if there are no *Salmonella* control programmes in place in the country in accordance with Reg. 2160/2003 or they have not been approved by the Commission.

e) Annex I on specified zoonoses and zoonotic agents for which Community targets for the reduction of prevalence are to be established pursuant to Article 4

Annex I to Regulation 2160/2003 lists certain zoonoses and zoonotic agents and specific animal populations for the reduction of the prevalence of which, Community targets must be established. Directive 2003/99/EC implements that Member States must collect data in order to assess the risks related to specific zoonoses and zoonotic agents in specific animal populations and that this monitoring shall cover all stages of the food chain. It also indicates that if the results obtained during the routine monitoring programmes are not sufficient, coordinated monitoring programmes may be established. Coordinated monitoring programmes must make specific reference to the zoonoses, zoonotic agents and animal populations of Annex I to Regulation 2160/2003.

f) Annex II on control of zoonoses and zoonotic agents listed in Annex I

Annex II to Regulation 2160/2003 lays down provisions for the control of zoonoses and zoonotic agents specified in Annex I.

Part B of the Annex specifies minimum sampling requirements in order to test for the zoonoses and zoonotic agents of Annex I. Regulation 1688/2005 implementing Reg. 853/2004 as regards special guarantees concerning *Salmonella* for consignments to Finland and Sweden of certain meat and eggs indicates that the sampling of flocks of eggs according to the requirements of Regulation 853/2004 and intended for these two countries must be carried out according to the sampling plans of Part B of the Annex II.

Part E of the Annex specifies requirements for fresh meat. Fresh poultry meat from animal species listed in Annex I must meet the microbiological criteria set in Reg. 2073/2005, unless the meat is destined for heat or other treatment aimed at reducing salmonella. In that respect, Reg. 854/2004 section II of Annex I on action following controls indicates that the official veterinarian may impose requirements for meat where a treatment will be applied according to Annex II of Reg. 2160/2003.

Annex XXI: Additional implementing measures for selected Articles of Directive 2003/99/EC and their respective requirements

The following paragraphs highlight the main requirements of Directive 2003/99/EC and provide additional regulatory documents that add requirements or assist in the implementation of this main text.

a) Article 4 on general rules for the monitoring of zoonoses and zoonotic agents

Article 4 of Directive 2003/99/EC lays down the general rules for the monitoring of zoonoses and zoonotic agents. This information must also be provided under the requirements for the National Control programmes for the achievement of Community targets for the reduction of the prevalence of specific zoonoses and zoonotic agents included under Regulation 2160/2003.

Commission Decision 2008/425/EC lays down standard requirements for the submission by Member States of national programmes for the eradication, control and monitoring of certain animal diseases and zoonoses for Community financing. Specifically for the control of salmonellosis the Member States must submit a summary of the information on the occurrence of this zoonosis collected under the monitoring programme of Art. 4 of Directive 2003/99/EC, highlighting the prevalence values of the salmonella serotypes targeted.

b) Article 5 on coordinated monitoring programmes

Article 5 of Directive 2003/99/EC establishes the possibility for the organisation of coordinated monitoring programmes if the routine monitoring data collected are not sufficient for the monitoring purposes of this Directive. The data collected through these coordinated programmes may also be used for the purposes of Article 4 of Reg. 2160/2003 laying down the requirement of establishing Community targets for the reduction of the prevalence of zoonoses and zoonotic agents and providing detailed rules and specifications for the establishment of these targets and timeframes for their establishment.

c) Article 7 on monitoring of antimicrobial resistance

Article 7 of Directive 2003/99/EC lays down the requirement for Member States to obtain comparable data on the occurrence of antimicrobial resistance in zoonotic agents through monitoring programmes. Detailed rules must be adopted for the implementation of this Article. These are laid down by Implementing Decision 2013/652/EU on provisions for the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria, specifically with regard to the harmonised monitoring and reporting. Member States must assess the results obtained according to the requirements of this Decision and include them in the reports required under Article 9 of Dir. 2003/99/EC. In order to facilitate the implementation of the provisions of Decision 2013/652/EU and also considering the requirements of Reg. 882/2004 on official controls, the Community must contribute financially to the costs incurred. This is implemented by Commission Implementing Decision 2013/653/EC as regards a Union financial aid towards a coordinated control plan for antimicrobial resistance monitoring in zoonotic agents in 2014.

d) Article 8 of Directive 2003/99/EC on the epidemiological investigation of food-borne outbreaks

Article 8 lays down the procedure for the epidemiological investigation of food-borne outbreaks. This information is also required under the National Control programmes for the achievement of Community targets for the reduction of the prevalence of specific zoonoses and zoonotic agents included under Reg. 2160/2003.

e) Article 9 on assessment of trends and sources of zoonoses, zoonotic agents and antimicrobial resistance

Article 9 of Directive 2003/99/EC establishes the requirement that each Member State must assess the sources and trends of zoonoses, zoonotic agents and antimicrobial resistance within its territory and provide the Commission with a yearly report of the results and lays down specific rules for this procedure.

Commission Decision 2006/662/EC provides a Community financial contribution for carrying out a baseline survey on the prevalence of *Salmonella* in turkeys in the Member States. The results obtained through this survey should be used for the report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance requested under Article 9 above. Similarly, Commission Decision 2006/668/EC on a financial contribution from the Community towards a baseline survey on the prevalence of *Salmonella* in slaughter pigs to be carried out in the Member States, indicates that the results obtained should be used for the annual reports on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance under Directive 2003/99/EC. It also specifies some details on the sampling procedure and specific data on the animals tested, that should be included as a minimum in this report.

Commission Regulation 200/2010 implementing Regulation 2160/2003 as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in adult breeding flocks of *Gallus gallus*, indicates that the results and any additional information obtained under the testing scheme necessary to ascertain the achievement of the Union target for the reduction of the relevant *Salmonella* serotypes in these species must be reported as part of the report on trends and sources of zoonoses, zoonotic agents and antimicrobial resistance requested under Article 9 above.

Article 9 also requires the Commission to send the reports prepared by the Member States to EFSA. After examining them, EFSA must publish a summary report on the trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in the Community. Commission Implementing Decision 2013/652/EU on provisions for the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria indicates that EFSA must publish these national isolate-based quantitative antimicrobial resistance data.

f) Article 10 on Community and national reference laboratories

Article 10 of Directive 2003/99/EC lays down the requirement for the designation of Community and reference laboratories tasked with the analysis and testing for zoonoses and zoonotic agents and antimicrobial resistance. The responsibilities and tasks of these laboratories established by Commission Decision 2004/564/EC concerning Community reference laboratories for the epidemiology of zoonoses and for salmonella and national reference laboratories for salmonella, under the requirements of Directive 2003/99/EC and Reg. 2160/2003.

g) Annex IV on requirements for the reports to be submitted pursuant to Article 9(1)

Annex IV of Directive 2003/99/EC lays down the minimum information required to be submitted in the reports to be submitted to the Commission on the assessment of the sources and trends of zoonoses, zoonotic agents and antimicrobial resistance within the territories of the Member States. Commission Regulation 2075/2005 on official controls for *Trichinella* in meat indicates that the number of tests conducted for *Trichinella* in domestic swine, wild boar, horses, game and any other susceptible animals and their results must be included in the above reports and lays down some minimum information required for domestic swine.

Annex XXII: Additional implementing measures for selected Articles of Regulation 1333/2008 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 1333/2008 and provide additional regulatory documents that add requirements or assist in the implementation of this main text.

a) Article 6 of Regulation (EC) No 1333/2008 on general conditions for the inclusion and use of food additives in Community lists

Article 6 of Reg. 1333/2008 lays down certain conditions that substances must meet in order to be included as authorised food additives in the Community lists of Reg. 1333/2008. Regulation 234/2011, implementing Regulation 1331/2008 on a common authorisation procedure for food additives, food enzymes and food flavourings, requires that applications for updating the Community lists must include a summary dossier indicating that the use of the substance complies with the conditions laid down in Reg. 1333/2008.

b) Article 10 of Regulation (EC) No 1333/2008 on the content of the Community lists of food additives

Article 10 of Reg. 1333/2008 lays down requirements for the entry of food additives in the Community lists. This information must be amended and maintained in databases in accordance with the requirements of Reg. 1331/2008 on the common authorisation procedure. Implementing Decision 2014/C 72/05 lays down the financing of the 2014 work programme on IT tools in the field of food safety, animal health, animal welfare and plant health.

c) Article 14 of Regulation (EC) No 1333/2008 on specifications for food additives

Article 14 of Reg. 1333/2008 lays down the requirement for adoption of specifications of food additives relating in particular to the origin, purity criteria and other necessary information when a food additive is included in the Community lists of Annexes II and III of the Regulation for the first time. The same is also required by Article 30 of the Regulation on the establishment of Community lists of food additives. This requirement is fulfilled by Regulation 231/2012 laying down specifications for food additives listed in Annexes II and III of Reg. 1333/2008.

d) Article 18 of Regulation (EC) No 1333/2008 on the carry-over principle

Article 18 of Reg. 1333/2008 establishes the carry-over principle, according to which food additives may be present in a compound food product, provided they are permitted in any of its ingredients and have been carried over to the finished product through these and provided they have no technological function in the finished product. Also food additives may be present in a food intended to be used for the manufacture of a compound food that complies with the provisions of Reg. 1333/2008.

Regulation 1169/2011 on the provision of food information to consumers indicates that food additives present in a food as a result of the carry-over principle described in Reg. 1333/2008 do not need to be declared in the list of ingredients of the finished product, provided they have no technological function in that product.

e) Article 20 of Regulation (EC) No 1333/2008 on traditional foods

Article 20 of the Regulation allows Member States to continue to prohibit the use of certain additives in traditional foods. In that respect, Decision 2010/561/EU on national provisions notified by Denmark on the addition of nitrite to certain meat products implements that Denmark may continue to apply the restriction of use of certain additives and preservatives in the traditional Danish Køddele (meatballs) and Leverpostej (liver pate).

f) Article 29 of Regulation (EC) No 1333/2008 on Community financing of harmonised policies

Article 29 of Regulation 1333/2008 establishes the legal basis for financing certain measures resulting from the implementation of the Regulation. Commission Implementing Decision 2013/C 170/06 concerning the financing for the year 2013 of activities in the veterinary field relating to the European Union's information policy and support of international organisations, to several measures necessary to ensure the application of the food and feed and the plant health legislation, implements financial support measures for the gathering of information for the purposes of monitoring the consumption and use of food additives in the Member States for the determination of the dietary intake of such substances.

In the same context, Commission Implementing Decision 2014/C 166/05 implements the adoption of the work programme and the financing for the year 2014 of activities in the food and feed area to ensure the application of the food and feed legislation.

g) Article 32 of Regulation (EC) No 1333/2008 on re-evaluation of approved food additives

Article 32 of Regulation 1333/2008 lays down the requirement for a re-evaluation of all food additives that have been approved before 20 January 2009. This shall comprise a new risk assessment by EFSA, while an evaluation programme for these additives must be adopted and published. This programme has been implemented by Regulation 257/2010.

h) Extended scope of Regulation (EC) No 1333/2008

Regulation 1333/2008 lays down the Community lists of food additives approved for use in certain products and the conditions for their use.

Regulation 1331/2008 lays down a common authorisation procedure for food additives, enzymes and flavourings. This procedure shall indicate the details for updating the lists of substances approved under Regulations 1332/2008, 1333/2008 and 1334/2008.

Regulation 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on food indicates that flavourings may contain food additives as authorised under Regulation 1333/2008.

Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption indicates that the labelling of concentrated fruit juice must indicate the presence and quantity of added acidifying agents in accordance with the above Regulation. Also with regard to the manufacture of fruit nectars without added sugars or with reduced energy value, the Directive indicates that sugars may be replaced by sweeteners according to the provisions of Reg. 1333/2008. Additives may only be added in products covered by the Directive provided they meet the provisions of Reg. 1333/2008.

Regulation 251/2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products indicates that the provisions of Regulation 1333/2008 on food additives and colours also apply to aromatised wine products.

Regulation 10/2011 on plastic materials and articles intended to come into contact with food indicates that additives authorised as food additives or flavourings must not migrate into food in such quantities as to have a technological function in the product and must not exceed the maximum levels established by Regulations 1333/2008 and 1334/2008 or by Reg. 10/2011 in foods where their use is not authorised as additive or flavouring.

Annex III to Regulation 1169/2011 on the provision of food information to consumers lays down a list of additional labelling particulars that must be included in the labelling of products that contain specific additives in accordance with Reg. 1333/2008.

Implementing Decision 2012/288/EU authorises the placement on the market of gamma-cyclodextrin as a novel food ingredient under Reg. 258/97. Similarly Implementing Decision 2013/49/EU authorises the placement on the market of synthetic zeaxanthin as a novel food ingredient under Reg. 258/97. The intentional addition of these substances in food for technological purposes falls under the scope of Reg. 1333/2008.

Regulation 528/2012 concerning the making available on the market and use of biocidal products indicates that biocidal products eligible for a simplified authorisation procedure must meet certain conditions one of which is that all the active substances in the product are included in Annex I to the Regulation. This Annex also contains a list of substances authorised as food additives under Regulation 1333/2008.

Annex XXIII: Additional implementing measures for selected Articles of Regulation 1332/2008 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 1332/2008 and provide additional regulatory documents that add to the main text or assist in the implementation of this main text.

a) Article 6 of Regulation (EC) No 1332/2008 on general conditions for inclusion of food enzymes in the Community list

Article 6 of Reg. 1332/2008 indicates that food enzymes may be included in the Community list if their use has a reasonable technological function and does not mislead the consumer. Regulation 234/2011 implementing Regulation 1331/2008 on a common authorisation procedure for food additives, food enzymes and food flavourings requires that dossiers submitted for an application for the safety evaluation of a substance include information to verify compliance with the above two requirements.

b) Article 16 of Regulation (EC) No 1332/2008 on Community financing of harmonised policies

Article 16 of Reg. 1332/2008 indicates that financing measures resulting from Reg. 1332/2008 have their legal basis in Article 66 of Reg. 882/2004. Commission Implementing Decision 2014/C 72/05 lays down the financing of the 2014 work programme on IT tools in the field of food safety, animal health, animal welfare and plant health. IT Projects to support the RASFF must have an informed view on non-authorized substances and maintain registers of authorised substances including enzymes. The legal basis for the procurement of these Projects is Article 16 of Reg. 1332/2008.

c) Article 17 of Regulation (EC) No 1332/2008 on the establishment of the Community list of food enzymes

Article 17 of Reg. 1332/2008 lays down the Community list of food enzymes. From the date of application of this list, the authorisations for E1103 Invertase and E1105 Lysozyme of the old additives Directive 95/2/EC must be repealed.

d) Extended scope of Regulation (EC) No 1332/2008

Regulation 1332/2008 lays down requirements for food enzymes and establishes the Community list of food enzymes.

Directive 83/417/EEC on the approximation of the laws of the Member States relating to certain lactoproteins (caseins and caseinates) intended for human consumption lays down standards for edible rennet casein. According to these, rennet and other milk-coagulating enzymes must meet the requirements of Reg. 1332/2008 in order to be used in "edible rennet casein".

Directive 2001/112/EC lays down provisions on fruit juices and similar products intended for human consumption. Annex I to this Directive lays down provisions on ingredients, treatments and substances that may be used in products covered by the Directive.

Enzyme preparations, pectinases and amylases may be used provided they meet the requirements of Reg. 1332/2008.

Regulation 606/2009 laying down detailed rules for the implementation of Regulation 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions requires that enzymes and enzymatic preparations used in the authorised oenological practices and processes of the Annex to the Regulation should meet the requirements of Reg. 1332/2008.

Annex XXIV: Additional implementing measures for selected Articles of Regulation 1334/2008 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 1334/2008 and provide additional regulatory documents that add to the main text or assist in the implementation of this main text.

a) Article 3 of Regulation (EC) No 1334/2008 on definitions

Article 3 of Regulation 1334/2008 lays down the definitions for different categories of flavourings. Annex I to Regulation 251/2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products lists the flavouring products that are authorised for the flavouring of aromatised wines and those authorised for the flavouring of aromatised wine-based drinks and aromatised wine-product cocktails.

The above definitions are also used in Regulation 110/2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks to indicate the type of flavourings that may be used in different product categories.

Regulation 1169/2011 on the provision of food information to consumers also uses the above definitions in order to indicate the designation of flavourings in the list of ingredients of food products.

b) Article 4 of Regulation (EC) No 1334/2008 on general conditions for use of flavourings or food ingredients with flavouring properties

Article 4 of Reg. 1334/2008 indicates that only substances that do not pose a safety risk to consumer health and do not mislead the consumer may be used in or on foods. Regulation 234/2011 implementing Regulation 1331/2008 on a common authorisation procedure for food additives, food enzymes and food flavourings requires that applications for updating the Community list must include a summary dossier indicating that the use of the substance complies with the above conditions laid down in Reg. 1334/2008.

c) Article 25 of Regulation (EC) No 1334/2008 on introduction of the list of flavouring substances into the Community list of flavourings and source materials and traditional regime

Article 25 of Reg. 1334/2008 indicates that the Community list of flavouring substances must be established by introducing the list of flavouring substances of Article 2 of Regulation 2232/96 (now repealed by Implementing Reg. 872/2012) into Annex I of Reg. 1334/2008. It also allows for transitional measures for this process. This has been introduced by Commission Implementing Regulation 872/2012 adopting the list of flavouring substances of Reg. 2232/96 as the Union list and introducing it in Annex I of Reg. 1334/2008. However the Regulation indicates that for substances under evaluation at the date of implementation of the Union list, certain provisions of Reg. 2232/96 shall continue to apply.

Commission Implementing Decision 2014/C 72/05 lays down the financing of the 2014 work programme on IT tools in the field of food safety, animal health, animal welfare

and plant health. IT Projects to support the RASFF must have an informed view on non-authorised substances and maintain registers of authorised substances including flavourings. The legal basis for the procurement of these Projects is Article 25 of Reg. 1334/2008

d) Annex I of Regulation (EC) No 1334/2008 on the Union list of flavourings and source materials

Articles 9 and 10 of Reg. 1334/2008 indicate the flavourings and source materials for which an evaluation is required. Only approved flavourings and source materials that are included in the Union list (Annex I) may be placed on the market or used in food. Regulation 873/2012 lays down some transitional measures concerning the Union list of flavouring substances and source materials with regard to products lawfully placed on the market prior to the implementation of Reg. 1334/2008 but which do not comply with Annex I to the Regulation and the date until which they may be consumed.

e) Annex III of Regulation (EC) No 1334/2008 on the presence of certain substances

Annex III of Reg. 1334/2008 establishes some maximum levels for certain naturally present substances in flavourings and food ingredients with flavouring properties in compound foods to which flavourings or ingredients with flavouring properties have been added. Implementing Regulation 131/2012 concerning the authorisation of a preparation of caraway oil and lemon oil with certain dried herbs and spices as a feed additive for weaned piglets implements that the maximum levels for dried herbs and spices laid down in Part B of Annex III must be respected for the above preparation.

f) Extended scope of Regulation (EC) No 1334/2008

Regulation 1334/2008 lays down provisions for the use of flavourings and certain food ingredients with flavouring properties in and on foods.

Regulation 10/2011 on plastic materials and articles intended to come into contact with food indicates authorised flavourings must not migrate into food in such quantities as to have a technological function in the product and must not exceed the maximum levels established by Regulations 1334/2008 or 10/2011.

Annex I to Regulation 1334/2008 lays down the Union list of approved flavourings and source materials. 3-acetyl-2,5-dimethylthiophene was authorised and included in the Union list as a substance under evaluation for which more scientific data needed to be submitted. New data showed the substance is mutagenic and poses a risk to human health. The substance is considered to also pose a risk to animal health and therefore Implementing Regulation 796/2013 denies authorisation of this substance for use as a feed additive.

Annex XXV: Additional implementing measures for selected Articles of Regulation 2065/2003 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 1332/2008 and provide additional regulatory documents that add to the main text or assist in the implementation of this main text.

a) Article 6 of Regulation (EC) No 2065/2003 on the Community list of authorised primary products

Article 6 of Reg. 2065/2003 indicates that a Community list must be established containing all authorised primary products that may be used in or on foods and/or for the production of derived smoke flavourings. This Community list is implemented by Implementing Regulation 1321/2013 establishing a Union list of authorised smoke flavouring primary products for use as such in or on foods and/or for the production of derived smoke flavourings.

b) Article 17 of Regulation (EC) No 2065/2003 on inspection and control measures

Article 17 of Reg. 2065/2003 indicates that the Commission with the scientific assistance of EFSA may adopt quality criteria for validated analytical methods for the sampling, identification and characterisation of the primary products, as indicated in Annex II of the Regulation laying down the required information for the evaluation of the primary smoke products. These quality criteria are adopted by Regulation 627/2006 implementing Reg. 2065/2003.

Annex XXVI: Additional implementing measures for selected Articles of Regulations 315/93 and 1881/2006 and their respective requirements

Part I: Regulation 315/93

The following paragraphs highlight the main requirements of Regulation 315/93 and provide additional regulatory documents that add requirements or assist in the implementation of this main text.

a) Article 2 of Regulation (EEC) No 315/93

Article 2 of Regulation 315/93 allows for the establishment of maximum tolerances for certain contaminants in order to protect public health. Under this Article, Regulation 1881/2006 lays down maximum levels for certain contaminants in foodstuffs. This Regulation is analysed in more detail in Paragraph 6.2.2.

Under the same Article, Regulation 124/2009 lays down maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed. This may happen when residues of such substances used as legal feed additives remain in the production line and are transferred as carry-overs to the feed produced subsequently, but also in the other stages of the production and processing, storage or transport. This unavoidable presence of coccidiostats or histomonostats in feed, even below maximum levels as established in Directive 2002/32/EC, may result in the presence of residues in food products of animal origin. Foodstuffs listed in the Annex to the Regulation must not be placed on the market if they contain the contaminants listed at levels higher than the maximum established. It is also indicated that products with residue levels higher than the established must not be mixed with compliant foodstuffs. Finally, when applying the maximum levels, changes in the concentration of the contaminants due to drying, diluting or processing or due to the relative proportion of ingredients in a product must be taken into account.

b) Extended scope of Regulation (EEC) No 315/93

Regulation 401/2006 lays down methods for the sampling, sample preparation and analysis for the official control of mycotoxins in foodstuffs.

Article 7 of Regulation 1272/2009 on detailed rules for the implementation of Regulation 1234/2007 (on the buying-in and selling of agricultural products under public intervention) lays down some additional criteria for different products in order to be eligible for public intervention in addition to being sound, fair and of marketing quality. Cereals and in particular common wheat and durum wheat must meet the requirements for maximum contaminants levels of Regulation 315/93 and those of Regulation 1881/2006 for fusarium toxins.

Part II: Regulation 1881/2006

The following paragraphs highlight the main requirements of Regulation 1881/2006 and provide additional regulatory documents that add requirements or assist in the implementation of this main text.

a) Annex of Regulation (EC) No 1881/2006

The Annex to Regulation 1881/2006 lays down the maximum levels for certain contaminants in different food products. Amongst other contaminants, Regulation 1881/2006 lays down maximum levels for Ochratoxin A and implements that only compliant foodstuffs may be placed on the Community market. Implementing Regulation 844/2011 approves the pre-export checks carried out by Canada on wheat and wheat flour for presence of Ochratoxin A, in order to ensure compliance with Community legislation. Each consignment of products subjected to this pre-export check, must be accompanied by a report containing the results of sampling and analysis in accordance with Regulation 401/2006 and a certificate in accordance with the model set out in the Annex to Regulation 844/2011.

Regulation 1881/2006 also lays down maximum levels for dioxins, furans and PCBs in food, while Directive 2002/32/EC lays down maximum levels for such compounds in feed. Commission Recommendation 2013/711/EU on the reduction of the presence of dioxins, furans and PCBs in food and feed, indicates that in cases of non-compliances with the above maximum levels, Member States in collaboration with the food business operators should initiate investigations in order to identify the source of contamination and also take measures to reduce or eliminate the source. Also Member States are required to submit the occurrence data for the above contaminants to EFSA and inform the Commission on the results of their investigations and the action taken in case of non-conformances in order to eliminate the problem.

With regard to the maximum levels for aflatoxins laid down by Regulation 1881/2006, it has been observed that these have frequently been exceeded in certain products originating from certain countries. Commission Regulation 1152/2009 lays down some special conditions for the import of certain foodstuffs from certain third countries due to contamination risk with aflatoxins. These products may only be imported from the specified countries provided they are accompanied by the results of aflatoxin sampling and analysis (according to Regulation 401/2006) and a health certificate as specified in the Annex to the Regulation, verified and authorised by a representative of the competent Authority of the country. The Regulation also specifies the frequency of official controls for the products concerned.

Regulation 333/2007 lays down methods for sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and polycyclic aromatic hydrocarbons in foodstuffs. Instructions are provided on sampling methods, sampling plans, sample preparation and analysis. The importance of a representative and homogeneous laboratory sample free from secondary contamination is emphasised. Compliance or not of the sample with the levels of Reg. 1881/2006 is established on the basis of the results obtained from the laboratory sample. Also performance criteria are established for the methods of analysis for lead, cadmium, mercury and inorganic tin, which can help in choosing an appropriate validated method of analysis from specific matrices in the absence of official methods of analysis. The Annex also specifies that results must be expressed in the same units as the maximum levels of Reg. 1881/2006 and with the same number of significance figures. Also, if an extraction step has been used, the results must be corrected for recovery and the recovery level must also be reported. Finally, the Regulation explains how the analytical results should be interpreted and how a lot or subplot can be accepted or rejected.

Regulation 1882/2006 lays down methods of sampling and analysis for the official control of the level of nitrates in certain foodstuffs and specifically in spinach, lettuce, iceberg-type lettuce, baby foods and processed cereal-based foods for infants and young children. Samples taken from the field or lot according to the methods of sampling provided in the Annex to the Regulation are considered representative of the whole lot and compliance has to be established based on the results obtained for the laboratory sample.

Similar to the above, Regulation 252/2012 establishes provisions for the sampling, sample preparation, analysis, expression of the results obtained and acceptability of not of the samples for the official control of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs.

b) Extended scope of Regulation (EC) No 1881/2006

Regulation 1881/2006 on maximum levels for certain contaminants in foodstuffs requires Member States to examine foodstuffs other than those included in the Regulation for the occurrence of 3-MCPD, in order to consider whether it is required to establish further maximum limits in further foodstuffs. For example, the French authorities have discovered 3-MCPD in glycerol used in several different food products and therefore maximum levels should be established for 3-MCPD in this product in order to avoid contamination of other foods with 3-MCPD in levels above the acceptable. These levels are established by Regulation 231/2012 on specifications for food additives of Annexes II and III of Regulation 1333/2008.

Commission Recommendation 2006/583/EC lays down the principles for prevention and reduction of fusarium toxins in cereals and cereal products. Different risk factors that need to be taken into consideration in relation to Good Agricultural Practices are described and different ways for these to be managed at the different steps in the cereal production chain from crop planning through to harvesting, storage and transportation.

Annex XXVII: Additional implementing measures for selected Articles of Directive 1999/2/EC and their respective requirements

The following paragraphs highlight the main requirements of Directive 1999/2/EC and provide additional relevant regulatory documents required for their implementation.

a) Article 4 of Directive 1999/2/EC

Article 4 of Directive 1999/2/EC requires the establishment of an exhaustive Community list of foodstuffs that may be treated with ionising radiation also including the authorised maximum doses that may be applied. This is implemented by Directive 1999/3/EC on the establishment of a Community list of foods and food ingredients treated with ionising radiation.

b) Article 6 of Directive 1999/2/EC

Article 6 of Directive 1999/2/EC lays down requirements for the labelling of foodstuffs treated with ionising radiation. The terms "irradiated" or "treated with ionising radiation" must be used and details are provided on how these should appear under different conditions of sale or depending on whether the foodstuff is sold as a product or it is included as an ingredient in another product. Regulation 1169/2011 on the provision of food information to the consumers also indicates that foods treated with ionising radiation must bear the above indications in accordance with Directive 1999/2/EC.

c) Article 9 of Directive 1999/2/EC

Article 9 of Directive 1999/2/EC requires the Commission to establish lists of approved facilities from which the importation of foodstuffs treated with ionising radiation is permitted. Commission Decision 2002/840/EC adopts a list of approved facilities in third countries for the irradiation of foods which is set out in its Annex.

d) Extended scope of Directive 1999/2/EC

Directive 1999/2/EC lays down requirements for foodstuffs and food ingredients treated with ionising radiation. Commission Decision 2007/363/EC on guidelines to assist the Member States in preparing the single integrated multi-annual national control plan provided by Regulation 882/2004 of the European Parliament and of the Council indicates that the scope of the national controls plans should cover all legislation related to food and feed, thus including the legislation on irradiation covered by Directive 1999/2/EC.

Annex XXVIII: Additional implementing measures for selected Articles of Regulation (EC) No 258/97 and their respective requirements

The following legal documents add information required for the complete implementation of Regulation (EC) No 258/97.

a) Regulation 609/2013 (Foods for specific groups)

Substances falling within the scope of Reg. (EC) 258/97 shall be contained in products covered by Article 1 of Reg. (EU) 609/2013 provided that they fulfil the conditions for being placed on the market set out in both Regulations.

b) Regulation (EU) No 1169/2011 (Food information to consumers)

Regulation (EU) No 1169/2011 on the provision of food information to consumers, in the introductory part, calls the Commission to provide for a definition of engineered nanomaterials in the context of the upcoming review of this Regulation on novel foods.

c) Catalogue and Decisions that authorise novel food or novel food ingredients under Regulation 258/97

Decisions and Implementing Decisions that authorise the placing of products on the market as novel food or novel food ingredients can be found on the site of DG Health and Consumers.^{112 113}

¹¹² European Commission, DG Health and Consumers, Novel Food catalogue

http://ec.europa.eu/food/food/biotechnology/novelfood/nfnetweb/mod_search/index.cfm (► on 14/01/2015)

¹¹³ European Commission, DG Health and Consumers, Novel foods and novel food ingredients – Authorisations

http://ec.europa.eu/food/food/biotechnology/novelfood/authorisations_en.htm (► on 14/01/2015)

Annex XXIX: Additional implementing measures for selected Articles of Regulation 1935/2004 and their respective requirements

The following paragraphs highlight the main requirements of Regulation 1935/2004 providing additional relevant regulatory documents required for the implementation of the main text.

a) Article 1 of Regulation 1935/2004 on purpose and subject matter

Article 1 of Regulation 1935/2004 lays down the scope of the Regulation: the placing on the market materials and articles intended to come into contact with food while ensuring the effective functioning of the internal market and a high level of protection of human health and consumer interests. Commission Implementing Regulation 1335/2013 approving benzoic acid as an existing active substance for use in biocidal products for product-types 3 and 4 indicates that benzoic acid should not be used in materials and articles intended to come into contact with food, unless specific migration limits have been established for benzoic acid into food in accordance with Reg. 1935/2004, or it has been established that these are not necessary. A similar requirement is laid down:

- for decanoic acid by Commission Implementing Regulation 90/2014 approving decanoic acid as an existing active substance for use in biocidal products for product-types 4, 18 and 19,
- for octanoic acid by Commission Implementing Regulation 93/2014 approving octanoic acid as an existing active substance for use in biocidal products for product-types 4, 18 and 19,
- for iodine, including polyvinylpyrrolidone by Commission Implementing Regulation 94/2014 approving iodine, including polyvinylpyrrolidone as an existing active substance for use in biocidal products for product-types 1, 3, 4 and 22.

b) Article 3 of Regulation 1935/2004 on general requirements

Article 3 of Regulation 1935/2004 lays down the general requirements that materials and articles intended to come into contact with food must be manufactured under GMP, they must not transfer their constituents in food in quantities that may pose danger to human health or alter the composition and organoleptic properties of food and that their labelling, presentation and advertising must not be misleading.

Commission Regulation 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food lays down the GMP rules for the materials listed in Annex I to Reg. 1935/2004, their combinations and for recycled materials and articles used in their manufacture. Regulation 2023/2006 also lays down provisions for the formulation, application, handling and storage of printing inks in accordance with GMP, in order to avoid transfer of the inks to the food-contact side of the materials in levels that do not meet the requirements of Article 3 of Reg. 1935/2004.

Regulation 450/2009 on active and intelligent materials and articles intended to come into contact with food indicates that these materials may only be placed on the market if they meet the requirements of Article 3 of Reg. 1935/2004. Also it implements that substances to be used in the manufacture of intelligent materials and articles may only be placed on the Community list if they also meet the requirements of Articles 3 and 4 where applicable.

Commission Regulation 10/2011 on plastic materials and articles intended to come into contact with food indicates that plastic materials and articles may only be placed on the market if they meet the above requirements of Reg. 1935/2004. Regulation 10/2011 also indicates that the compliance with the requirements of Article 3 of Reg. 1935/2004 for certain substances covered by derogations to the Union list (such as polymer production aids, colourants, solvents, mixtures, monomers, additives of Art. 6 of Reg. 10/2011 and multi-material multi-layer materials and articles of Art 14 of Reg. 10/2011) must be assessed in accordance with internationally recognised principles of risk assessment.

Directive 93/11/EEC concerning the release into release-test liquid of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers lays down requirements that fall within the scope of Article 3 of Regulation 1935/2004.

c) Article 4 of Regulation 1935/2004 on special requirements for active and intelligent materials and articles

Article 4 of Regulation 1935/2004 indicated that for active and intelligent materials and articles additional and more specific rules to those of Reg. 1935/2004 should be established. It also lays down some specific requirements for such materials. These are implemented via Regulation 450/2009, which also indicates that for such materials to be placed on the market the additional requirements of Article 4 above must also be met. Regulation 450/2009 also implements that substances to be used in the manufacture of intelligent materials and articles may only be placed on the Community list if they also meet the requirements of Article 4 where applicable.

d) Article 5 of Regulation 1935/2004 on specific measures for groups of materials and articles

Article 5 of Regulation 1935/2004 indicates that specific measures must be adopted for the categories of materials listed in Annex I of the Regulation, as well as for materials manufactured by combinations or recycling of these materials and articles. Within the scope of this Article, the following legislative documents have been implemented:

- Commission Regulation 10/2011 on plastic materials and articles intended to come into contact with food, establishing specific requirements for the manufacturing and marketing of such materials.
- Commission Directive 2007/42/EC laying down specific requirements for materials and articles made of regenerated cellulose film and intended to come into contact with food.

e) Articles 8-12 of Regulation 1935/2004 on authorisation requirements

Articles 8-12 of Regulation 1935/2004 lays down requirements for the authorisation of substances to be used in the manufacturing of materials and articles. Commission Regulation 10/2011 on plastic materials and articles intended to come into contact with food indicates that only materials included in the Union list of approved substances of Annex I to the Regulation may be used in the manufacture of plastic layers for use in plastic materials and articles.

Article 9 of Reg. 1935/2004 specifically lays down the procedure for the authorisation of substances to be included in Community lists of substances for use in the manufacture of materials and articles and in active and intelligent materials and articles. Regulation

450/2009 on active and intelligent materials and articles intended to come into contact with food indicates that the Community list for such materials must be drawn up in accordance with the above requirements of Reg. 1935/2004. Reg. 450/2009 also specifies that the Community list must be adopted by the Commission in accordance with the provisions of Articles 10 and 11 of Reg. 1935/2004 which lay down the procedure to be followed by the Authority to give an opinion and for the Community authorisation. It also specified that the above provisions must also be followed for the addition of new substances in the Community list.

Article 11 specifically indicates that Community authorisations of substances to be used in active and intelligent materials and articles must be implemented via the adoption of a specific measure. Commission Decision 2010/169/EU implements the non-inclusion of 2,4,4'-trichloro-2'-hydroxydiphenyl ether in the Union list of additives which may be used in the manufacture of plastic materials and articles intended to come into contact with foodstuffs under Directive 2002/72/EC (now incorporated in Reg. 10/2011, repealing Dir. 2002/72/EC).

f) Article 15 of Regulation 1935/2004 on labelling

Article 15 of Regulation 1935/2004 lays down specific labelling requirements for materials and articles placed on the market but not yet in contact with food. Commission Regulation 10/2011 on plastic materials and articles intended to come into contact with food indicates that these may only be placed on the market, if they comply with the above requirements of Article 15. The same requirement is also expressed for materials falling within the scope of Regulation 450/2009 on active and intelligent materials and articles intended to come into contact with food. In addition, Regulation 450/2009 lays down some more specific labelling requirements for non-edible parts of active and intelligent materials and articles in order to enable them to be recognised as non-edible.

g) Article 16 of Regulation 1935/2004 on declaration of compliance

Article 16 of Regulation 1935/2004 indicates the materials and articles listed in Annex I of the Regulation and covered by the specific measures, must be accompanied by a written declaration confirming their compliance. This compliance must also be supported by appropriate documentation.

Council Directive 84/500/EEC on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with food indicates that ceramic articles not yet in contact with food at the marketing or retail stage must also be accompanied by the above declaration of compliance, signed by the manufacturer or the seller and including the information of Annex III to the Directive.

Similarly, a declaration of compliance must also accompany plastic materials and articles intended to come into contact with food and falling within the scope of Regulation 10/2011, as well as intermediate products of their manufacture or substances used during this process, at marketing stages other than retail sale. This written declaration must contain the information of Annex IV to the Regulation and be issued by the food business operator.

Commission Regulation 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food indicates that materials and articles that contain the substance 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE) and its derivatives must be accompanied by a written declaration of compliance in accordance with Article 16 of Reg. 1935/2004, at all stages of marketing other than retail.

A written declaration of compliance must also accompany materials and articles made of regenerated cellulose film and intended to come into contact with food falling under the scope of Commission Directive 2007/42/EC, at all stages of marketing other than retail. The same requirement also applies active and intelligent materials and articles intended to come into contact with food falling within the scope of Regulation 450/2009.

h) Article 17 of Regulation 1935/2004 on traceability

Article 17 of Regulation 1935/2004 requires that traceability of materials and articles is established at all stages, in order to be able to ensure control, product recalls, consumer information and attribution of responsibilities. Commission Regulation 10/2011 on plastic materials and articles intended to come into contact with food indicates that these may only be placed on the market, if they comply with this traceability requirement.

i) Article 18 of Regulation 1935/2004 on safeguard measures

Article 18 of Regulation 1935/2004 allows for safeguard measures for temporary restriction of use of a material or article in case a Member State has reasons to believe that a material or article may be posing a threat to human health and lays down the procedure to be followed. In that respect, Commission Implementing Regulation 321/2011 restricts the use of Bisphenol A in plastic infant feeding bottles. This Regulation is implemented as an amendment to Annex I of Regulation 10/2011 on plastic materials and articles intended to come into contact with food, which includes the Union list of approved substances for use in such materials and specifically as a restriction of use.

j) Article 24 of Regulation 1935/2004 on inspection and control measures

Article 24 of Reg. 1935/2004 lays down requirements for the official controls to be implemented by the Member States in order to ensure compliance with the requirements of the Regulation. Regulation 284/2011 lays down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China.

k) Extended scope of Regulation 1935/2004

Regulation 1935/2004 lays down requirements for materials and articles intended to come into contact with food. Regulation 450/2009 on active and intelligent materials and articles intended to come into contact with food lays down more specific requirements for this category of materials. Only substances that are included in Community lists of materials may be used in the manufacture of active and intelligent materials and articles. However, released active substances and substances which in order to have a technological effect in food must be incorporated in active materials and articles by techniques such as grafting or immobilisation, may be used without being included in a Community list.

Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption indicates that certain substances such as chemically inert filtration aids and precipitation agents and chemically inert adsorption aids may only be applied or added to products covered by the Directive if they comply with the requirements of Regulation 1935/2004.

Regulation 606/2009 lays down certain detail rules for implementing Council Regulation (EC) No 479/2008 as regards the categories of grapevine products, oenological practices and the applicable restrictions. According to these, ion exchange resins, cationic resins used for the tartaric stabilisation of wine or for acidification by cation exchangers and membranes used for acidification by electro-membranary treatment may be used as authorised oenological practices and processes provided they meet the requirements of Reg. 1935/2004. Also membranes used in the treatment for reduction of the sugar content of must by membrane coupling, those used in de-acidification by electro-membrane treatment and also those used in membrane-contractors for the management of dissolved gas in wine must comply with the requirements of Reg. 1935/2004 and Reg. 10/2011.

Directive 2009/48/EC on the safety of toys indicates that the requirements of Reg. 1935/2004 on materials and articles intended to come into contact with food may be considered by the Commission in order to adopt specific limits for chemicals used in toys intended for children younger than 36 months or for toys intended to be placed in the mouth.

Regulation 528/2012 of the European Parliament and of the Council on making available on the market and use of biocidal products indicates that biocidal products may be authorised provided specific migration limits have been established in accordance with Reg. 1935/2004.

Commission Implementing Decision 2013/674/EU on Guidelines on Annex I of Regulation 1223/2009 on cosmetic products indicates that the characteristics of the packaging materials which are in direct contact with cosmetic products are of particular importance for the safety of these products and therefore the requirements of Reg. 1935/2004 should be taken into consideration.

Annex XXX: Additional implementing measures for selected Articles of Directive 82/711/EEC and their respective requirements

The following paragraphs highlight certain requirements of Directive 82/711/EEC and provide the additional relevant regulatory documents for the implementation of the Directive.

a) Article 2 of Directive 82/711/EEC

Article 2 of Directive 82/711/EEC indicates that the overall and specific migration of plastic materials and articles into food or food simulants must not exceed the limits laid down by relevant legislation. The simulants to be used for the migration testing of plastic materials and articles intended to come into contact with foodstuffs are laid down in the Annex to Directive 85/572/EEC.

b) Annex to Directive 82/711/EEC on basic rules for overall and specific migration testing

The Annex to Directive 82/711/EEC lays down the rules for migration testing and provides details on the food simulants to be used, migration test conditions and details on fat tests for specific and overall migration. Commission Regulation 10/2011 on plastic materials and articles intended to come into contact with food indicates that from the 1st January 2013 and until the end of 2015 the supportive documents demonstrating compliance with the requirements of Dir. 82/711/EEC, such as testing conditions and results, calculations, modelling, analysis, safety evidence and reasoning of compliance that accompany materials, articles and substances placed on the market must be based on the rules for migration testing of Annex to Directive 82/711/EEC.

Commission Regulation 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food indicates that the migration testing for BADGE and certain of its derivatives must be carried out in accordance with the rules of Dir. 82/711/EEC.

Commission Directive 2007/42/EC laying down specific requirements for materials and articles made of regenerated cellulose film and intended to come into contact with food indicates that the verification of compliance with migration limits of materials falling within the scope of this Directive must be carried out in accordance with the rules of Dir. 82/711/EEC and must be tested on simulants in accordance with the provisions of Dir. 85/572/EEC.

Annex XXXI: Additional implementing measures for selected Articles of Directive 2000/13/EC and their respective requirements

The following Regulations and Directives lay down additional information necessary for the implementation of the different provisions of Directive 2000/13/EC.

a) Regulation (EC) No 589/2008 on implementing rules as regards marketing standards for eggs

Reg. (EC) 589/2008¹¹⁴ adds some egg-specific labelling rules to Dir. 2000/13/EC. Weight-grading of Class A eggs shall be indicated on the packaging by the corresponding letters or terms or both (S-small, M-medium, L-large, XL-extra large), which may be supplemented by the corresponding weight ranges (Article 4). An indication of advising consumers to keep eggs chilled after purchase shall also be added (Article 12(1)f). Moreover, the date of minimum durability shall be fixed at not more than 28 days after laying (Articles 6(3) -12(1)d- 13).

b) Regulation (EU) No 1151/2012 on quality schemes for agricultural products and foodstuffs

Article 12 of Reg. (EU) 1151/2012¹¹⁵ allows that the collective geographical marks, guarantee marks and certification marks authorised by Member States (as referred to in Article 15 of Directive 2008/95/EC to approximate the laws of the Member States relating to trade marks¹¹⁶) may be used on labels, together with the protected designation of origin or protected geographical indication.

c) Regulation (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91

Articles 23-26 of Reg. (EC) No 834/2007¹¹⁷ lay down specific labelling rules for organic products. Labelling, advertising or commercial documents may use terms such as "eco" and "bio" (*i.e.* as listed in the Annex) to describe an organic product, its ingredients, or raw materials. The labelling must be clearly visible on the packaging or in the ingredients' list (for processed foods, indicating which of the ingredients are organic), it must contain the code number of the control body that certifies the product, the Community logo (optional for products imported from third countries) accompanied by an indication of the origin of raw materials (EU or non-EU agriculture, or both) used in the product placed in the same field of vision. National and private logos may also be used in the labelling, presentation and advertising of products which satisfy the requirements set out under this Regulation. Competence authorities of Member States shall take additional measures to ensure compliance.

¹¹⁴ Commission Regulation (EC) No 589/2008 laying down detailed rules for implementing Council Regulation (EC) No 1234/2007 as regards marketing standards for eggs. Official Journal of the European Union (2008). L. 163/6

¹¹⁵ Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs. Official Journal of the European Union (2012). L. 343/1

¹¹⁶ Directive 2008/95/EC of the European Parliament and of the Council to approximate the laws of the Member States relating to trade marks. Official Journal of the European Union (2008). L. 299/25

¹¹⁷ Council Regulation (EC) No 834/2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91. Official Journal of the European Union (2007). L. 189/1

d) Regulation (EC) No 1333/2008 on food additives

Labelling of food additives must comply with the general labelling conditions defined in Dir. 2000/13/EC. In addition, Articles 21-25 of Reg. (EC) No 1333/2008¹¹⁸ lay down specific labelling rules for food additives. In particular, this information must include, among others: name and or E-number, information on batch or lot, manufacturer, the statement "for food" or the statement "restricted use in food", an indication of the maximum quantity that can be used, special conditions of storage, instructions of use, specific warnings for the food colours listed in Annex V and the sweeteners containing polyols and/or aspartame and/or aspartame-acesulfame salt and minimum durability or use-by date.

e) Regulation (EU) No1379/2013 on the common organisation of the markets in fishery and aquaculture products

Originally, it is Regulation (EC) No 2065/2001 that refers to Directive 2000/13/EC but it has been repealed by Regulation (EU) No 1379/2013 that in turn refers to the new Framework Regulation 2011/13. Please, refer to the respective part in the chapter dealing with this new Regulation.

f) Regulation (EC) No 543/2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultry meat

Originally, it was Regulation (EC) 1321/2002 amending Regulation (EEC) 1538/91 introducing detailed rules for implementing Council Regulation (EEC) No 1906/90 on certain marketing standards for poultry meat¹¹⁹ referring to Dir. 2000/13/EC. However, Reg. (EC) 1321/2002 has been repealed by Reg. (EC) No 543/2008¹²⁰ which lays down specific rules for the marketing of poultry meat (Articles 3-5). Hence, it is required that the accompanying commercial documents (as defined by Article 13(1)b of Reg. 2000/13/EC) of poultry meat shall also indicate: classification (Class A or Class B) according to the conformation and appearance of the carcasses or cuts and the condition in which the poultry meat is marketed (fresh, frozen, quick-frozen). For fresh poultry meat, the date of minimum durability shall be replaced by the "use by" date in accordance with Article 10 of Dir. 2000/13/EC. In the case of pre-packaged poultry meat, the following particulars shall also appear on the pre-packaging or on a label attached thereto: the class (as above), the total price and the price per weight unit at the retail stage (for fresh poultry), the registered number of the slaughterhouse or cutting plan, indication of the country of origin if imported by third countries. Where poultry meat is offered for sale to the ultimate consumer or to mass caterers without pre-packaging then, Article 14 of Dir. 2000/13/EC shall apply, *i.e.* the Member States shall adopt detailed rules concerning the manner in which the above mentioned particulars are to be shown. Other indications that may appear on the labelling include: the methods of chilling (air chilling, air-spray chilling, immersion chilling, Art.10) and types of farming (excluding biological/organic, and including statements as "fed with", "free range", "extensive indoor" etc., Art.11).

¹¹⁸ Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. Official Journal of the European Union (2008). L. 354/16

¹¹⁹ Commission Regulation (EC) No 1321/2002 amending Regulation (EEC) No 1538/91 introducing detailed rules for implementing Council Regulation (EEC) No 1906/90 on certain marketing standards for poultrymeat. Official Journal of the European Communities (2002). L. 194/17

¹²⁰ Commission Regulation (EC) No 543/2008 of 16 June 2008 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 as regards the marketing standards for poultrymeat. Official Journal of the European Union (2008). L. 157/46

g) Regulation (EC) No 1829/2003 on genetically modified food and feed and Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

Articles 12-14 of Reg. (EC)1829/2003¹²¹ and Article 4 of Reg. (EC) 1830/2003¹²² require mandatory labelling for products that consist of GMO or contain GMO and for products derived from GMO but no longer containing GMO. Operators of authorised products consisting of or containing GMOs shall ensure that the words "This product contains genetically modified organisms" or "This product contains (name of ingredient) produced from genetically modified [name of organism(s)]" or "produced from genetically modified (name of organism)" appear in the list of ingredients for pre-packaged products, and on, or in connection with, the display of the product for non-pre-packaged products. This labelling shall not apply to traces of GMOs in products provided that these traces are adventitious or technically unavoidable, in a proportion no higher than the thresholds established in accordance with Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms¹²³ and Reg. (EC) No 1829/2003.

h) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food

Materials and articles, which are not yet in contact with food when placed on the market, shall be accompanied by the words "for food contact" or a specific indication for their use, special instructions for safe and appropriate use, if necessary, and other information (e.g. related to traceability (trade name, processor, seller), according to Article 15 of Reg. (EC) 1935/2004¹²⁴. Under Article 4 of the same Regulation, active and intelligent food contact materials are considered as ingredients within the meaning of Article 6(4)(a) of Dir. 2000/13/EC and thus, shall be listed in the ingredients' list. Active and intelligent materials when in contact with food and to allow identification of non-edible parts shall a) be labelled so that it is clear that they are active and/or intelligent, and b) add a label that bears the words "DO NOT EAT" as well as (if possible) the respective symbol, as required in Article 11 and Annex I of Reg. (EC) 450/2009.

i) Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

Article 7 of Reg. (EC) 1925/2006¹²⁵ contains specific labelling provisions for vitamins and minerals added to foods that shall apply in addition to the requirements of Dir. 2000/13/EC and Regulation 1924/2006 on health and nutrition claims (see Directive

¹²¹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed. Official Journal of the European Union (2003). L. 268/1

¹²² Regulation (EC) No 1830/2003 of the European Parliament and of the Council concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. Official Journal of the European Union (2003). L. 268/24

¹²³ Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC. Official Journal of the European Communities (2001). L. 106/1

¹²⁴ Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. Official Journal of the European Union (2004). L. 338/4

¹²⁵ Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods. Official Journal of the European Union (2006). L. 404/26

90/496 on nutrition labelling), e.g. that the labelling, presentation and advertising of foods with added vitamins and minerals should not imply that a balanced and varied diet cannot achieve appropriate quantities of vitamins or minerals

j) Regulation (EC) No 1924/2006 on nutrition and health claims made on food

Reg. (EC) 1924/2006 complements the general principles of Dir. 2000/13/EC and lays down specific provisions concerning the use and labelling of nutrition and health claims concerning food. In particular, the labelling, presentation and advertising related to them must provide certain obligatory information, such as a statement indicating the importance of a varied and balanced diet and a healthy lifestyle, the quantity of the food and pattern of consumption which will ensure the claimed beneficial effect, a statement addressed to persons who should avoid the substance concerned, a warning of the health risks caused by excessive consumption (Article 10). Moreover, this Regulation prohibits: claims that imply that health could be affected by not consuming the particular food, health claims which refer to the rate or amount of weight loss, and references to an individual health professional or other associations (only national medical associations and health-related charities are allowed). Claims related to human disease or children's development and health (Article 14) can only be allowed if a) they have been authorised in accordance with Articles 15 to 18 of this Regulation, and b) it also bears a statement that a disease can have multiple risk factors and altering of one may or may not have a beneficial effect. For the nutrition labelling of such products see chapter 8.1.3

k) Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products

Originally, it is Regulation 700/2007 on the marketing of the meat of bovine animals aged 12 months or less that refers to Directive 2000/13. However, this Regulation has been repealed by Regulation (EC) No 361/2008 which amends Regulation (EC) No 1234/2007, which in turn has been repealed by Regulation (EU) No 1308/2013 which already partially applies since 2013 and only few provisions shall apply from 2015 and 2017 onwards. Since there are two legal acts for the labelling requirements of foodstuffs, for reasons of clarity, only Regulation 1308/2013 and its relation with Directive 2000/13 (or the new Framework Regulation 1169/2011) will be reported hereby. (For further details on Reg. 1169/2011, please refer to Ch. 8.1.2).

Thus, according to Article 87, a term shall be eligible to be reserved as an additional optional reserved term only if the conditions and use of the term are in conformity with Directive 2000/13 (or Regulation 1169/2011). For labelling and presentation in the wine sector, according to Article 118, horizontal rules of Directive 2000/13 (or Regulation 1169/2011) shall apply unless is otherwise provided by this regulation. Articles 117-123 lay down specific (mandatory and optional) labelling and presentation requirements for wine (e.g. category of the grapevine, indication of provenance, indication of the bottler, sugar content for sparkling wine, the vintage year, name of one or more wine grape varieties etc.). For meat of bovine animals aged less than 12 months, according to Annex VII, Part I, Point IV, operators shall label the meat with the sales description and the age of the animals on slaughter ("less than 8 months" or "from 8 to less than 12 months"). For milk and milk products, names that are actually used for milk products within the meaning of Article 5 of Directive 2000/13 (or Article 17 of Regulation 1169/2011) shall also be reserved exclusively for milk products (Annex VII, Part III, 3(b)).

l) Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors

Regulation (EU) 543/2011¹²⁶ (which repealed Regulation (EC) No 1580/2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector¹²⁷) refers to Dir. 2000/13/EC in relation to information particulars required by marketing standards of fruits and vegetables (Articles 5 and 6). The information particulars shall be shown legibly and obviously on one side of the packaging, either directly onto the package or on a label affixed to it, and should be available to consumers before purchase (e.g. in distance selling). For goods shipped in bulk, information particulars shall be given in a document accompanying the goods. The retailer should display prominently the information particulars relating to country of origin and, where appropriate, class and variety or commercial type. According to Annex I, general marketing standards in relation to labelling include: The name and the address of the packer and/or the dispatcher or of a seller (in case of pre-packages) and full name of the country of origin in the language of the country of origin or any other language understandable by the consumers of the country of destination. For apples, citrus fruit (lemons, oranges etc.), kiwifruit, lettuces and varieties, peaches and nectarines, pears, strawberries, sweet peppers, tomatoes and table grapes more specific requirements apply (Annex I, Part B, Part 1-10).

m) Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks

In Articles 7-14, Regulation (EC) 110/2008¹²⁸ provides specific labelling and presentation rules for spirit drinks in addition to labelling requirements of Dir. 2000/13/EC. In particular, where a raw material was used to produce the ethyl alcohol of agricultural origin, or the drink is comprised of mixtures, each agricultural alcohol ingredient used shall be mentioned in a descending order of the quantity used. If the spirit drink is a blend of two or more spirit drinks belonging to the same category then the term "blend", "blending" or "blended" may be used. Maturation period or age may be specified only where it refers to the youngest alcoholic component.

n) Regulation (EC) No 41/2009 of 20 January 2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten

Reg. (EC) 41/2009 provides the specific composition and labelling requirements for foodstuffs for people intolerant to gluten, in addition to rules laid down in Directive 2000/13. Products processed to contain a level of gluten less than 100 mg/kg, shall bear the term "very low gluten". They may bear the term "gluten-free" if the gluten content is less than 20 mg/kg in the food. These terms shall appear in proximity to the name under

¹²⁶ Commission Implementing Regulation (EU) No 543/2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors. Official Journal of the European Union (2011). L. 157/1

¹²⁷ Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules of Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector. Official Journal of the European Union (2007). L. 350/1

¹²⁸ Regulation (EC) No 110/2008 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89. Official Journal of the European Union (2008). L. 39/16

which the food is sold. Products intended for normal consumption or other particular use but are nevertheless suitable to meet the special dietary needs of people intolerant to gluten shall not bear the term "very low gluten". This Regulation ¹²⁹ has been repealed by Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control¹³⁰, which will only however apply from July 2016; Regulation (EU) 609/2013 states that "*For the sake of clarity and consistency, the rules on the use of the statements "gluten-free" and "very low gluten" should also be regulated under Regulation (EU) No 1169/2011.*"

o) Commission Implementing Regulation (EU) No 29/2012 of 13 January 2012 on marketing standards for olive oil

Regulation (EU) 29/2012 ¹³¹ lays down specific standards for retail-stage marketing of olive oils and olive-pomace oils (referred to in points 1(a) and (b), 3 and 6 of Annex XVI to Regulation (EC) 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products¹³²), in addition to the general provisions of Dir. 2000/13/EC. According to Articles 3-4: a) the labelling of oils shall bear in clear and indelible lettering, in addition to the name under which the product is sold, information on the category of oil (e.g. for extra virgin olive oil: "superior category olive oil obtained directly from olives and solely by mechanical means"), b) extra virgin olive oil and virgin olive oil shall bear a designation of origin on the labelling, c) in the case of blends of olive oils originating from more than one Member State or third country shall also be labelled as appropriate (e.g. "blend of olive oils of European Union origin" or a reference to the Union). Optional indications of Article 5 include: indication of the extraction system only for extra virgin or virgin olive oils (e.g. "first cold pressing", "cold extraction"), indications of organoleptic properties referring to taste and/or smell only for extra virgin or virgin olive oils, indication of the peroxide value, the wax content and the ultraviolet absorption. Indication of the acidity or maximum acidity may appear only if it is accompanied by an indication, in lettering of the same size and in the same visual field. Article 6 refers to specific provisions for blend of oils and the presence of oils in foodstuffs.

p) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin

This Regulation¹³³ lays down specific labelling hygiene standards for food of animal origin. These can be found in Annex II and III. In the case of frozen food of animal origin intended for human consumption, the food business operator should have information on the date of production and freezing. The form in which the information must be made available is up to the choice of the supplier of the frozen food, as long as the information requested will be clearly available. Requirements for specific products can be found in

¹²⁹ Commission Regulation (EC) No 41/2009 concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten. Official Journal of the European Union (2009). L. 16/3

¹³⁰ Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009. Official Journal of the European Union (2013). L. 181/35

¹³¹ Commission Implementing Regulation (EU) No 29/2012 on marketing standards for olive oil. Official Journal of the European Union (2012). L. 12/14

¹³² Council Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products. Official Journal of the European Union (2007). L. 299/1

¹³³ Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin. Official Journal of the European Union (2004). L. 139/55

Annex III and refer to foods such as minced meat, bivalve molluscs, raw cow's milk, dairy and egg products, gelatine.

q) Directive 2011/91/EU of the European Parliament and of the Council on indications or marks identifying the lot to which a foodstuff belongs

Directive 2011/91/EU¹³⁴ requires that an identification of the lot to which a foodstuff belongs shall be added on the label. The lot shall be determined by the business operator (producer, packager etc.) and shall be preceded by the letter "L". Date of minimum durability or "use by" date, may also serve as the lot identification, provided it is indicated precisely.

r) Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption

Labelling of fruit juices and similar products are subject to specific rules laid down in Directive 2001/112/EC¹³⁵. In addition to Dir. 2000/13/EC, specific provisions of Articles 3 and 4 include rules, for example, on the labelling of single or mixed fruit juices, on the presence of added sugars or the presence of fruit pulps.

s) Council Directive 2001/110/EC of 20 December 2001 relating to honey

According to Articles 2 and 3 of this Directive¹³⁶, in addition to the general provisions of Dir. 2000/13/EC, the labelling of honey must include the country of origin (or to indicate if the blend is a mix of EC, non-EC or both), the product names (Annex I: names, product descriptions and definitions), information on regional, territorial or topographical origin, or on floral or vegetable origin, or specific quality criteria.

t) Council Directive 2001/111/EC of 20 December 2001 relating to certain sugars intended for human consumption

In accordance with both Directive 2000/13/EC and Article 2 of Directive 2001/111/EC¹³⁷, labelling of certain sugars intended for human consumption must include: the term "crystallised" for invert sugar syrup incorporating crystals in the solution, the levels of dry matter and invert sugar content for invert sugar solutions and invert sugar syrup, the term "glucose-fructose syrup" or "fructose-glucose syrup" and "dried glucose-fructose syrup" or "dried fructose-glucose syrup" for glucose syrups which contain more than 5 % of fructose.

¹³⁴ Directive 2011/91/EU of the European Parliament and of the Council on indications or marks identifying the lot to which a foodstuff belongs. Official Journal of the European Union (2011). L. 334/1

¹³⁵ Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption. Official Journal of the European Communities (2002). L. 10/58

¹³⁶ Council Directive 2001/110/EC relating to honey. Official Journal of the European Communities (2002). L. 10/47

¹³⁷ Council Directive 2001/111/EC relating to certain sugars intended for human consumption. Official Journal of the European Communities (2002). L. 10/53

u) Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption

According to Article 2 of Directive 2001/113/EC¹³⁸, labelling of these products shall include: the product name supplemented by an indication of the fruit or fruits used (in descending order of weight), fruit content per 100 grams of product, total sugar content (if no nutrition claim is made for sugars on the labelling) and residual content of sulphur dioxide where it is more than 10 mg/kg.

v) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

In accordance with both Dir. 2000/13/EC and Articles 6-9 of Directive 2002/46/EC¹³⁹, labelling of food supplements that are marketed as foodstuffs and presented as such, must include: the names of the categories of the nutrients or substances, the portion of the product recommended for daily consumption, a declaration that the supplement is not a substitute for a varied diet, the reference "This is not a medicinal product" where the its presentation is similar to that of a medicinal product and the warning "should be stored out of the reach of young children". The labelling of food supplements must not contain statements attributing properties of preventing or treating a disease nor any mention stating or implying that a balanced and varied diet cannot provide appropriate quantities of nutrients in general. The amount of the nutrients or substances shall be declared on the labelling in numerical form, per portion, as recommended for daily consumption, expressing average values based on the manufacturer's analysis of the product.

w) Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC

Directive 2006/141/EC¹⁴⁰, in Articles 13 and 14, adopts additional labelling and advertising rules to those of Dir. 2000/13/EC, on infant formulae and follow-on formulae in order to promote and protect breast feeding. In particular, infant formulae and follow-on formulae can be sold under the name: "infant formulae" and "follow-on formulae", unless they are entirely manufactured from cows' milk proteins and the name shall be: "infant milk" and "follow-on milk" respectively. Mandatory particulars include statements: on the superiority of breast feeding, that the product is suitable for particular nutritional use by infants from birth when they are not breast fed or by infants aged over six months, recommendation for use after advice from qualified professionals, the energy value and protein, carbohydrate and fat content, instructions concerning the preparation etc. The labelling of infant formulae shall not include pictures of infants. Advertising shall be restricted to publications specialising in baby care and scientific publications and MS shall ensure that it does not favour bottle-feeding over breast feeding. These rules shall only be valid until the implementation of Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, *i.e.* July of 2016.

¹³⁸ Council Directive 2001/113/EC relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption. Official Journal of the European Communities (2002). L. 10/67

¹³⁹ Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements. Official Journal of the European Communities (2002). L. 183/51

¹⁴⁰ Commission Directive 2006/141/EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC. Official Journal of the European Union (2006). L. 401/1

x) Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children

Article 8 of Directive 2006/125/EC¹⁴¹ lays down additional labelling rules to those of Dir. 2000/13/EC, on processed cereal-based foods and baby foods. Labelling must bear the following mandatory information: i) the age from which the product may be used (not less than four months), ii) the presence or absence of gluten (if for less than six months), iii) energy value, protein, carbohydrate and lipid content, average quantity of each mineral substance and of each vitamin (expressed in numerical form, per 100 g or 100 ml of the product), iv) instructions for appropriate preparation. Non-mandatory information includes the average quantity of the other nutrients set out in Annex IV or information on vitamins and minerals expressed as a percentage of the reference values. These rules shall only be valid until full implementation of Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, *i.e.* July of 2016.

y) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses

Foodstuffs intended for particular nutritional uses shall comply with the general rules of Directive 2000/13/EC. However, according to Articles 7-9 of Regulation 2009/39/EC¹⁴², the designation under which a dietetic product is sold must be accompanied by an indication of its particular nutritional characteristics and include information on: the composition or manufacturing process, the energy value (in Kj and Kcal), the carbohydrate, protein and fat content per 100 grams or 100 millilitres of product. These products shall only be allowed on the market in pre-packaged form. These rules shall only be valid until full implementation of new Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, *i.e.* July of 2016.

z) Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters

Directive 2009/54/EC¹⁴³, in Articles 7-9, adopts additional labelling rules to those of Dir. 2000/13/EC, on natural mineral waters. Mandatory labelling information includes: the statement of analytical composition, the name of the spring and the place of exploitation, information on any treatments. Claims attributing properties relating to the prevention or treatment of a disease are prohibited. Member States may authorise the indications "stimulates digestion", "may facilitate the hepato-biliary functions" or similar indications, under certain circumstances.

¹⁴¹ Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children. Official Journal of the European Union (2006). L. 339/16

¹⁴² Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses. Official Journal of the European Union (2009). L. 124/21

¹⁴³ Directive 2009/54/EC of the European Parliament and of the Council of 18 June 2009 on the exploitation and marketing of natural mineral waters. Official Journal of the European Union (2009). L. 164/45

aa) Council Directive 2001/114/EC of 20 December 2001 relating to certain partly or wholly dehydrated preserved milk for human consumption

Article 3 of Directive 2001/114/EC ¹⁴⁴ adopts additional provisions to those of Directive 2000/13 on labelling of preserved milk products. Thus, the labels must state: the percentage of fat (except for condensed milk, sweetened condensed partly skimmed milk, and dried skimmed milk), the percentage of fat-free dried milk extract (for the different types of partially dehydrated milk), the method of dilution or reconstitution (for dehydrated milk), that the product 'is not intended as a food for infants under twelve months' (for dehydrated milk).

¹⁴⁴ Council Directive 2001/114/EC of 20 December 2001 relating to certain partly or wholly dehydrated preserved milk for human consumption. Official Journal of the European Communities (2002). L. 15/19

Annex XXXII: Additional implementing measures for selected Articles of Regulation (EU) No 1169/2011 and their respective requirements

These regulations include specific requirements for the labelling and marketing of diverse food products such as, foods for infants and special medical purposes, olive oil, aromatised wine products, fishery, aquaculture as well as agricultural products.

a) Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

The labelling of these products shall be regulated by Reg. (EU) 1169/2011 (see respective section of Regulation 609/2013)

b) Regulation (EU) No 1335/2013 amending Regulation (EU) No 29/2012 on marketing standards for olive oil

For the labelling of olive oil Regulation 29/2012¹⁴⁵ refers back to the old labelling Directive 2000/13/EC (see Chapter 8.1.1).

c) Regulation (EU) No 251/2014 supplementing the labelling provisions of Regulation (EC) No 1169/2011 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products

According to Article 5 of Reg. (EU) 251/2014¹⁴⁶, aromatised wine products shall follow the labelling rules laid down in Reg. (EU) 1169/2011 and are allowed to accompany their sales denominations (set out in Annex II) with a customary name as defined in Article 2(2)(o) of Reg. (EU) 1169/2011.

d) Regulation (EU) No 1379/2013 on the common organisation of the markets in fishery and aquaculture products

For the purposes of Regulation (EU) 1379/2013¹⁴⁷ the definitions of Article 2 of Reg. (EU) 1169/2011 shall apply. In addition, Reg. (EU) 1379/2013 clarifies that "pre-packed fishery and aquaculture products" mean fishery and aquaculture products which are "pre-packed food" (as referred to in Article 2 of Reg. (EU) 1169/2011. Moreover, it complements rules on mandatory labelling information (Articles 35-39). Specifically, products referred to in points (a), (b), (c) and (e) of Annex I to this Regulation (e.g. live fish; fish fresh, chilled, frozen; fish fillets and other fish meat; fish dried, smoked, salted or in brine; crustaceans/molluscs whether in shell or not; seaweeds and other algae) may be offered for sale to the final consumer or to a mass caterer with some additional

¹⁴⁵ Commission Implementing Regulation (EU) No 29/2012 on marketing standards for olive oil. Official Journal of the European Union (2012). L. 12/14

¹⁴⁶ Regulation (EU) No 251/2014 of the European Parliament and of the Council on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and repealing Council Regulation (EEC) No 1601/91. Official Journal of the European Union (2014). L. 84/14

¹⁴⁷ Regulation (EU) No 1379/2013 of the European Parliament and of the Council on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000. Official Journal of the European Union (2013). L. 354/1

indications, such as the commercial designation of the species and their scientific name, the area where the product was caught or farmed, the production method, whether the product has been defrosted, date of minimum durability etc. For non-pre-packed fishery and aquaculture products this information may be provided by means of commercial information. For mixed products consisting of the same species but has been derived from different production methods, the method for each batch shall be stated. Products sold directly from fishing vessels to consumers, are exempted from this Regulation. Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007

e) Regulation 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007

Reg. (EU) 1308/2013¹⁴⁸ refers to Reg. (EU) 1169/2011 with regard to: a) Content of marketing standards of agricultural products (Art. 75): they should follow the labelling requirements for the country of origin or place of provenance (Reg. (EU) 1169/2011, Article 26), shall be determined by sector or product basis and based on the characteristics of each sector; b) Additional optional reserved terms for agricultural products (that are not listed in Annex IX) (Art. 87): they shall be eligible only if the conditions and use of the term are in conformity with Reg. (EU) 1169/2011; c) Labelling and presentation in the wine sector (Articles 117-123): in addition to the provisions of Reg. (EU) 1169/2011 specific (mandatory and optional) labelling requirements apply. Mandatory particulars include: designation of the category of the grapevine, the term "protected designation of origin", indication of provenance, alcoholic strength, indication of the bottler and importer, sugar content for sparkling wine; d) Compulsory indication on the label of bovine animals aged less than 12 months (Annex VII, Part I, Point IV): operators shall label the meat with the sales description and the age of the animals on slaughter ("less than 8 months" or "from 8 to less than 12 months"); e) Names that are actually used for milk products (*i.e.* legal name of the food under which the product is legally manufactured and marketed in the Member State, Article 17, Reg. (EU) 1169/2011): they shall also be reserved exclusively for milk products (Annex VII, Part III, 3(b)); f) In relation to milk for human consumption, if the milk has been enriched with milk proteins, mineral salts or vitamins or if the lactose content has been reduced, it also has to be indelibly indicated on the packing of the product so that it can be easily seen and read along with the nutrition labelling laid down by Reg. (EU) 1169/2011 (Annex VII, Part IV, 2).

¹⁴⁸ Regulation (EU) No 1308/2013 of the European Parliament and of the Council establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007. Official Journal of the European Union (2013). L. 347/671

Annex XXXIII: Additional implementing measures for selected Articles of Directive 90/496/EEC and their respective requirements

The following Regulations and Directives lay down additional information necessary for the implementation of the different provisions of Directive 90/496/EEC.

a) Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

Article 7 of Reg. (EC) 1925/2006 contains specific labelling provisions for vitamins and minerals added to foods that shall apply in addition to the requirements of Directive 2000/13. In particular, Nutrition labelling of products to which vitamins and minerals have been added and which are covered by this Regulation shall be compulsory. This information shall consist of that specified in Article 4(1), Group 2 of Dir.90/496/EEC (energy value, amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium) and of the total amounts present of the vitamins and minerals when added to the food. Labelling, presentation and advertising of these products shall not state or imply that a balanced and varied diet cannot provide appropriate quantities of nutrients but may bear a statement indicating such addition under the conditions laid down in Regulation (EC) No 1924/2006 on health and nutrition claims.

b) Regulation (EC) No 1924/2006 on nutrition and health claims made on food

Regulation (EC) No 1924/2006 complements the general principles in Dir. 2000/13/EC and 90/496/EEC and lays down specific provisions concerning the use and labelling of nutrition and health claims concerning food. In particular, the information to be provided shall consist of information in Group 2 as defined in Article 4(1) of Dir. 90/496/EEC (energy value, amounts of protein, carbohydrate, sugars, fat, saturates, fibre and sodium). If a substance(s) to which a nutrition or health claim relates does not appear in the nutrition labelling it shall be stated in the same field of vision as the nutrition information and be expressed in accordance with Article 6 of Dir. 90/496/EEC. Moreover, the Annex of Reg. (EU) 1924/2006 (*i.e.* authorised nutrition claims) refers to Dir. 90/496/EEC for clarifications of the claims: "source of [name of vitamin/s] and/or [name of mineral/s]" and "reduced [name of the nutrient]".

c) Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies and marmalades and sweetened chestnut purée intended for human consumption

According to Article 2, labelling of these products shall also include the total sugar content by the words 'total sugar content ... g per 100 g'. If no nutrition claim is made for sugars on the labelling in accordance with Dir. 90/496/EEC, this indication is not needed.

d) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction

Directive 96/8/EC¹⁴⁹ in Article 5, adopts specific nutrition labelling requirements for foods intended for weight-reduction diets. These products shall bear mandatory particulars that include: the name 'Total diet replacement for weight control' or 'Meal replacement for weight control' accordingly, the energy value and the content of proteins, carbohydrates and fat, the average quantity of each mineral and each vitamin, if a product provides a daily intake of polyols in excess of 20 g per day there shall be a statement that the food may have a laxative effect, a statement on the importance of maintaining an adequate daily fluid intake etc. These rules shall only be valid until the Reg. (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control fully comes into effect, *i.e.* July of 2016.

e) Council Directive 2001/112/EC of 20 December 2001 relating to fruit juices and certain similar products intended for human consumption

This Directive, in particular Article 2, authorises the addition of vitamins and minerals to the products, subject to Directive 90/496/EEC.

f) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements

In accordance with Articles 8 and 9 of Dir. 2002/46/EC, nutrition labelling of certain food supplements must include the names of the categories of the nutrients or substances and the portion of the product recommended for daily consumption. The amount of the nutrients or substances shall be declared on the labelling in numerical form, per portion, as recommended for daily consumption, expressing average values based on the manufacturer's analysis of the product (see also Chapter 8.1.1).

¹⁴⁹ Commission Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction. Official Journal of the European Communities (1996). L 55/22

Annex XXXIV: Additional implementing measures for selected Articles of Regulation (EC) No 1924/2006 and their respective requirements

The following Regulations and Directives lay down additional information necessary for the implementation of the different provisions of Regulation (EC) No 1924/2006.

a) Regulation 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods

As regards the maximum amounts of vitamins and minerals and the conditions restricting their addition, Reg. (EC) 1925/2006 requires (in Article 3) that the nutrient profile of the product established as provided for by Reg. (EC) 1924/2006, shall be also taken into account. Additionally, Article 7 requires that for products to which vitamins and minerals have been added, any statement indicating such addition shall follow the conditions laid down in this Regulation.

b) Directive 2006/141/EC on infant formulae and follow-on formulae

Directive 1925/2006/EC¹⁵⁰ sets out additional specific conditions for the use of nutrition and health claims concerning infant formulae. With this Directive, nutrition and health claims to be used for labelling of infant formulae are allowed only in the cases listed in Annex IV and in accordance with the conditions set out therein. (This Directive has been repealed by Reg. 609/2013 and its validity shall stop when the Commission adopts delegated acts or the latest by the 20/7/2015).

c) Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control

Foods for specific groups shall follow the requirement for health and nutrition claims laid down in Reg. (EC) 1924/2006, unless otherwise specified in Reg. (EC) 609/2013. Reg. (EU) 609/2013 requires that a delegated act should be adopted that transfers the rules that regulate foods presented as 'meal replacement for weight control' (i.e. the conditions of use of such claims) to Reg. (EC) 1924/2006.

d) Commission Directive 2007/29/EC amending Directive 96/8/EC as regards labelling, advertising or presenting foods intended for use in energy-restricted diets for weight reduction

As long as conditions laid down in Article 13, paragraph 1 of Regulation 1924/2006 are fulfilled, then health and nutrition claims are allowed to products for use in energy-restricted diets for weight reduction. (This Directive has also been repealed by Regulation 609/2013 and its validity shall stop when the Commission adopts delegated acts or the latest by the 20/7/2015).

¹⁵⁰ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC. Official Journal of the European Union (2006). L. 401/1

e) Regulations 462/2014 and 563/2014

These two Regulations, after examination carried out by EFSA in accordance with Regulation 1924/2006, approve that the basic substances *Equisetum arvense* L. and *chitosan hydrochloride* (Reg. (EU) 462/2014¹⁵¹ and 569/2014¹⁵² respectively) can be considered as foods as they fulfil the criteria of a foodstuff according to the General Food Law (Article 2 of Reg. (EC) 178/2002).

f) Regulation 907/2013 Commission Regulation (EU) No 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations)

According to Article 1 of Reg. (EU) 907/2013¹⁵³ specific generic descriptors (denominations)(as described in Article 1(4) of Reg. (EU) 1924/2006) which could imply an effect on health and which have traditionally been used in a Member State (e.g. "digestive biscuits") may be exempted from Reg. (EC) 1924/2006 following an application by the food business operators concerned. The procedure is similar to the one followed for health and nutrition claims authorisation (rules set out in the Annex of Reg. (EU) 907/2013).

¹⁵¹ Commission Implementing Regulation (EU) No 462/2014 approving the basic substance *Equisetum arvense* L., in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Implementing Regulation (EU) No 540/2011. Official Journal of the European Union (2014). L. 134/28

¹⁵² Commission Implementing Regulation (EU) No 563/2014 approving the basic substance *chitosan hydrochloride* in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Commission Implementing Regulation (EU) No 540/2011. Official Journal of the European Union (2014). L. 156/5

¹⁵³ Commission Regulation (EU) No 907/2013 setting the rules for applications concerning the use of generic descriptors (denominations). Official Journal of the European Union (2013). L. 251/7

Annex XXXV: Additional legislation related to selected Articles of Directive 2009/39/EC and respective requirements

The following delegated acts are repealed from the date of application of the new delegated acts that shall be adopted by 20 July 2015, as referred to in Article 11 of the new Regulation 609/2013 (FSG) on Food for Specific Groups.

a) Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC

This Directive lays down compositional and labelling requirements for infant formulae and follow-on formulae intended for use by infants in good health. These products shall be manufactured from cows' or goats' milk proteins or soya proteins and other food substances (minerals, vitamins, amino acids, etc.) set out in Annex I. Compositional criteria (energy, proteins, lipids, carbohydrates, minerals, vitamins, nucleotides etc.) for infant formulae are set out in Annex I taking into account the specifications in Annex V, and for follow-on formulae in Annex II. Only the substances listed in Annex III may be used in the manufacture of infant formulae and follow-on formulae. Before placing on the market, the manufacturer (or importer) shall forward a model of the label used for the product to the competent authority of the Member State where the product is to be marketed. Residues of individual pesticides shall be less than 0.01 mg/kg of the product. As for the labelling and advertising of such products, please refer to the relevant part of Chapter 8.1.2.

b) Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children

This Directive lays down standards for the composition (list of authorised products) and labelling of processed cereal-based foods and baby foods which are intended for use by weaning infants and by young children. Annex I sets out the compositional criteria for processed cereal-based foods and Annex II for baby foods. Only the nutritional substances listed in Annex IV may be added in their manufacture and residues of individual pesticides shall be less than 0.01 mg/kg of the product. Moreover, this Directive prohibits the use of certain pesticides in agricultural products intended for baby foods (list in Annex VII). As for the labelling of such products, please refer to the relevant part of Chapter 8.1.2.

c) Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes

This Directive lays down compositional and labelling requirements for dietary foods which are intended for special medical purposes. Such foods are classified in three categories: i) nutritionally complete foods with a standard nutrient formulation and may constitute the sole source of nourishment, ii) nutritionally complete foods with a nutrient-adapted formulation (for a medical condition) and may constitute the sole source of nourishment or as a partial replacement to the patient's diet, and iii) nutritionally incomplete foods with a standard nutrient formulation or a nutrient-adapted formulation which cannot to be used as the sole source of nourishment but only as a partial replacement or as a supplement to the patient's diet. The formulation of such

products shall be based on sound medical and nutritional principles and comply with the compositional criteria specified in the Annex to this Directive. In addition to the general labelling provisions (Directive 79/112/EC but repealed by Directive 2000/13) and as provided for in Article 4 to Directive 1999/21/EC, such products shall bear the following mandatory particulars: energy value, the content of protein, carbohydrate and fat, the average quantity of mineral substances and vitamins present in the product, the content of components of protein, carbohydrate and fat or of other nutrients the declaration of which would be necessary for the appropriate use of the product (all expressed in numerical form per 100 g or per 100 ml of the product as sold or ready for use). Labelling shall also bear i) information on the origin and the nature of the protein and/or protein hydrolysates contained, ii) on the osmolality or the osmolarity of the product, iii) the statement "For the dietary management of...(medical condition)...", iv) a statement on adequate precautions and contra-indications, v) a description of the properties and/or characteristics that make the product useful and the rationale of the use of the product, vi) a warning that the product is not for parenteral use (where appropriate), and vii) instructions for the appropriate preparation, use and storage of the product. The following statements must be preceded by the words "important notice" or their equivalent: i) that the product must be used under medical supervision, ii) suitability to be used as the sole source of nourishment (where appropriate), iii) specific age group (where appropriate), and iv) potential hazardous effects when consumed by persons who do not have the medical conditions for which the product is intended (where appropriate). Before placing on the market, the manufacturer (or importer) shall forward a model of the label used for the product to the competent authority of the Member State where the product is to be marketed.

d) Commission Directive 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction

This Directive lays down compositional and labelling requirements for foods intended for use in energy-restricted diets and are classified in two categories: i) products replacing the whole of the daily diet and ii) products replacing one or more meals of the daily diet. The name under which the product is sold shall be "Total diet replacement for weight control" or "Meal replacement for weight control", accordingly. In addition to the general labelling provisions (Directive 79/112/EC but repealed by Directive 2000/13) and as provided for in Article 5 to Directive 96/8/EC, such products shall bear the following mandatory particulars: energy value, the content of protein, carbohydrate and fat, the average quantity of mineral substances and vitamins present in the product (expressed in numerical form, per specified quantity), instructions for appropriate preparation, a statement that the food may have a laxative effect if it provides a daily intake of polyols more than 20 g per day, a statement that the product should not be used for more than three weeks without medical advice (for products replacing the whole of the daily diet) or a statement to that the products are useful for the intended use only as part of an energy-restricted diet and that other foodstuffs should be a necessary part of such diet (for products replacing one or more meals), a statement on the importance of adequate daily fluid intake. Such products shall not make any reference to the rate or amount of weight loss which may result from their use.

The following Regulations and Directives lay down additional information necessary for the implementation of the different provisions of Directive 2009/39/EC.

a) Commission Regulation (EC) No 1135/2009 of 25 November 2009 imposing special conditions governing the import of certain products originating in or consigned from China

Article 2 of Reg. (EC) 1135/2009¹⁵⁴ prohibits the import into the Community of products containing milk, milk products, soya or soya products intended for the particular nutritional use of infants and young children within the meaning of Directive 2009/39/EC, originating from China. Member States shall withdraw and destroy any such product found on the market.

b) Regulations on the authorisation and conditions of use of food additives, flavourings, and other substances that may be added in foods

Regulation (EC) No 1333/2008 on food additives: According to Annex II, Part A, the carry over principle set out in Article 18(1)(a) of the same regulation, shall not apply and the presence of a food colour shall not be permitted for foods for infants and young children as mentioned in Directive 2009/39/EC, including foods for special medical purposes for infants and young children. Moreover, the use of an additive shall not be permitted for dry pasta, excluding gluten-free and/or pasta intended for hypo-proteic diets, in accordance with Directive 2009/39/EC. Part E, category 13 of the same Annex contains the authorised food additives and conditions of use in foods intended for particular nutritional uses as defined by Directive 2009/39/EC.

Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods¹⁵⁵: Annex I, Part A of Regulation 1334/2008 contains the authorised flavourings and conditions of use in foods (including for those foods intended for particular nutritional uses as defined by Directive 2009/39/EC).

Commission Regulation (EC) No 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses¹⁵⁶: Annex of Regulation 953/2009 lists the substances (vitamins, minerals, amino-acids, nucleotides etc.) that may be added for specific nutritional purposes in foods for particular nutritional uses (excluding infant and follow-on formulae and processed cereal-based foods and baby foods).

¹⁵⁴ Commission Regulation (EC) No 1135/2009 imposing special conditions governing the import of certain products originating in or consigned from China, and repealing Commission Decision 2008/798/EC. Official Journal of the European Union (2009). L. 311/3

¹⁵⁵ Regulation (EC) No 1334/2008 of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. Official Journal of the European Union (2008). L. 354/34

¹⁵⁶ Commission Regulation (EC) No 953/2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses. Official Journal of the European Union (2009). L. 269/9

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