

REVIEW

EU legislation on feed related issues: an update

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Abstract

This review aims at providing an update of the current European Union (EU) legislation on feed-related issues. Regulations and Directives were classified into the following categories: general food law, placing on the market and use of feed, official controls, sampling and analysis, hygiene, undesirable substances, additives, animal by-products, OGMs, feed intended for particular nutritional purposes, and organic production. An overview of all laws related to the above-mentioned topics is given, and the main points of each law, cited in conjunction with its effect on previous laws (replacement, modification, amendments, and main related acts), are reported in tables.

Introduction

The issue of food safety plays a role of primary importance for producers and consumers. As to market conditions, European Union (EU) countries, on average, import approximately 50% of their total food supply from other EU countries or from outside the EU. Food import shares vary strongly across EU members. Although food in Europe has probably never been safer, a number of issues has weakened the public's confidence on the quality and safety of foods of animal origin, and the methods of food production (Report Special Eurobarometer 354 of 2010, http://www.efsa. europa.eu/en/factsheet/ docs/reporten.pdf). Therefore, researchers, industry, and governments have been forced to pay serious attention to animal feedstuff production processes. In a review paper, Sapkota et al. (2007) emphasize that the ingredients used in animal feed are fundamentally important in terms of both the quality of the resulting food products and for the

potential human health impacts associated with the animal-based food-production chain.

Food legislation is vital to ensuring a fair act of authority, and is the guideline to address the food safety risks. The current food safety policy is centred on a set of principles identified in the White Paper on Food Safety January 2000, http://ec.europa.eu /dgs/health_consumer/library/pub/pub06_en.p df) and set out in Regulation (EC) 178/2002 (European Commission, 2002d), entered into force 10 years ago. The responsibility of the decisions on food safety is of the European Commission, the European Parliament, the Council of the European Union, and the competent national authorities of each Member State. In this context, the European Food Safety Authority (EFSA) is not responsible for the laws regarding food safety or their application, but helps to ensure the safety of food and feed products. The role of EFSA is to assess the risks providing independent scientific advice on risks related to food and feed safety and to support the EU risk managers to make their final decisions. In recent years, beside health and consumer protection issues, food legislation has acquired a fundamental role in the context of legal matters with a high economic and trade impact and implications. To meet the regulatory requirements, industry, food/feed official control professionals, and researchers in the field have to be increasingly faced with the continuous evolution of the regulatory aspects at EU and national level.

The aim of the paper is to address some aspects concerning feed-related issues, providing an update of the current EU Regulations and Directives. EU Regulations and Directives were classified into general food law, placing on the market and use of feed, official controls, sampling and analysis, hygiene, undesirable substances, additives, animal by-products, OGMs, feed intended for particular nutritional purposes, and organic production. To give the reader a rapid first approach to the topic of his interest, a synoptic presentation of all laws related to the above-mentioned topics is given, and the main points of each law, cited in conjunction with its effect on previous laws (replacement, modification, amendments, and main related acts), are reported in tables. In the reference list, amendments to main Regulations/ Directives are not reported, as they all can be found on the website of the main Regulations/Directives, where the consolidated versions are also reported.

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Food/Feed law: general principles and requirements

The integrated EU strategy aims to ensure a high level of food safety, animal health and welfare, and plant health within the EU, through coherent measures and adequate monitoring, while ensuring at the same time the effective functioning of the internal market. In order to ensure the safety of food, all aspects of the food production chain must be considered, from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer. This approach involves the development of legislative and other actions in order to assure effective control systems, evaluate compliance with EU standards in the food chain within the EU and in third countries in relation to their exports to the EU, manage international relations with third countries and international organisations, manage relations with the EFSA, and ensure science-based risk management (Arvanitoyannis et al., 2005). At EU level, on 28th of January 2002, the European Parliament and the Council adopted the Regulation (EC) 178/2002 (European Commission, 2002d) 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, with an integrated feed to food approach. The aim is to provide a framework to ensure a coherent approach in the development of food legislation. At the same time, the Regulation (EC) 178/2002 (European Commission, 2002d), that is the milestone of the legislative structure in the field of feed and





food legislation, provides the general framework for those areas not covered by specific harmonised rules but where the functioning of the Internal Market is ensured by mutual recognition. A summary of the EU Regulations and Decisions related to general principles and food law and of the related acts is given in Table 1.

Feed: placing on the market and use

Pinotti and Dell'Orto (2011) presented a synthetic description of the European feed sector sustaining the European livestock production, indicating that about 500 million tons of feedingstuffs are required each year within the EU-27. Approximately 50% of this volume is roughages produced on-farm, 10% are grains produced on-farm, 10% are purchased feed materials and 30% are industrial compound feeds. The EU-27 produces 152 million tons of compound feed per year, which is the second largest single share of the world compound feed market (Best, 2010; European Feed Manufacturers' Federation, 2011). Clearly, ensuring that such high volumes of traded products are conformed to adequate quality standards is a major undertaking of EU legislation in this area.

The placing on the market and the use of feed is regulated by Regulation (EC) 767/2009 (European Commission, 2009e). The objective of this Regulation, in accordance with the general principles laid down in Regulation (EC) 178/2002 (European Commission, 2002d), is to harmonise the conditions for the use of feed, in order to ensure a high level of feed safety and thus a high level of protection of public health. It lays down rules on the placing on the market and use of feed for both food-producing and non food-producing animals within the Community, including requirements for labelling, packaging and presentation. This Regulation shall apply without prejudice to other Community provisions applicable in the field of animal nutrition. The Regulation establishes the creation of a Community Catalogue of feed materials, to be used by feed business operators on a voluntary basis, as a tool to improve the labelling of feed materials and compound feed. The Catalogue shall facilitate the exchange of information on the product properties and list feed materials in a nonexhaustive manner. Regarding this topic, the Commission Regulation (EU) 68/2013 (European Commission, 2013) is of particular importance, as it updated the Community Catalogue of feed materials. In according to Commission Regulation (EU) 68/2013 (European Commission, 2013), all entries in the list of feed materials in Part C shall comply with the restrictions on the use of feed materials in accordance with the relevant legislation of the Union. Feed business operators using a feed material entered in the Catalogue shall ensure that it complies with Article 4 of 767/2009 Regulation (EC) (European Commission, 2009e). A register of feed materials is available at http://www.feedmaterialsregister.eu. Therefore, operators must regularly check that their feed materials comply with the requirements set for the Community Catalogue of feed Materials and the register.

A summary of the EU Regulations related to placing on the market and use of feed and of the related acts is given in Table 2.

Feed: official controls

The official controls of feeds are regulated by the Regulation (EC) 882/2004 (European Commission, 2004k). Official controls are defined as: any form of control performed by the competent authority or by the Community for the verification of compliance with feed and food law, as well as animal health and animal welfare rules. This Regulation describes in more details how the general principles, laid down in the Regulation (EC) 178/2002 (European Commission, 2002d), must be interpreted and implemented, and defines the European Union's duties as regards the organisation of these controls, as well as the rules which must be respected by the national authorities responsible for carrying out the official controls, including coercive measures adopted in the event of failure to comply with Community law. This Regulation re-organises official controls of food and feed so as to integrate controls at all stages of production and in all sectors, in the context of the review of food hygiene legislation (hygiene package). The main purposes of the Regulation (EC) 882/2004 (European Commission, 2004k) are to prevent or eliminate risks which may arise, either directly or via the environment, for human beings and animals, or to reduce these risks to an acceptable level, and to guarantee fair practices as regards trade in food and feed and the protection of consumers' interests, including labelling of food and feed and any other form of information intended for consumers. This Regulation does not apply to official controls for the verification of compliance

with the rules on common market organisations agricultural products. The topic of the official control of feed is a critical point, therefore the legislative context is particularly complex. Therefore, there are several related acts to the Regulation (EC) 882/2004 (European Commission, 2004k) (Table 3).

Feed sampling and analysis

Sampling is the critical step in obtaining reliable results regarding feed composition, and evaluation of the presence of undesirable substances. A sampling plan may be defined as a test procedure combined with specific analytical procedures, and, in the case of undesirable substances, combined with a sample acceptance limit (Cheli *et al.*, 2009). To plan a sampling procedure, the substance to be tested, the analytical method, the numbers of replicates samples, the numbers of replicate measurements per samples, and the sampling technique have to be selected.

Feed sampling and analysis topic is covered by the Commission Regulation (EC) 152/2009 (European Commission, 2009b) laying down the methods of sampling and analysis for the official control of feed. It is foreseen to update the sampling provisions in due time to take into account the recent developments in feed production, storing, transport, and marketing procedures. Methods of analysis for the official control of feed (control of the composition of feed materials and compound feed, control of the level of authorised additives, control of undesirable substances in feed, and determination of constituents of animal origin in feed) are described with specific references to the expression of the results. The specific topic regarding the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material is covered by existing regulations, such as Commission Recommendation 2004/787/EC (European Commission, 2004b) Commission Regulation (EU) 619/2011 (European Commission, 2011d).

A summary of the EU Regulations related to feed sampling and analysis is given in Table 4.

Feed hygiene

Livestock production plays a very important role in the agricultural sector of the Community. Satisfactory results of this activity depend to a large extent on the use of safe and





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Main documents	Main points	Relationship between documents
Regulation (EC) 178/2002 (European Commission, 2002d)	General principles and requirements of food law Common principles and responsibilities to provide a strong science base, efficient organizational arrangements and procedures to underpin decision-making in matters of food and feed safety General obligation of food trade Establishment of the European Food Safety Authority Establishment of a rapid alert system for the notification of a direct or indirect risk to human health deriving from food or feed (RASFF) Emergency measures for food and feed of Community origin or imported from a third country, and other emergency measures	Amendments Commission Regulation (EC) 1642/2003; 575/2006; 202/2008. Regulation (EC) 596/2009
Related Acts	Main points	Relationship between documents
Commission Decision 2004478/CE (European Commission, 2004a) Commission Regulation (EC) 2230/2004 (European Commission, 2004g) Regulation (EC) 854/2004 (European Commission, 2004j)	Establishment of the general plan for food/feed crisis management Definition of practical procedures for the management of a crisis involving a serious direct or indirect risk to human Definition of detailed rules for the implementation of the Regulation (EC) 178/2002 (European Commission, 2002d) with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission Establishment of specific rules for the organisation of official controls on products of animal origin	
Table 2. Main EU Regulations related to placing on the market	to placing on the market and use of feed and main related acts.	
Main documents	Main points	Relationship between documents
Regulation (EC) 767/2009 (European Commission, 2009e)	General rules on the placing on the market and use of feed for both food-producing and non food- producing animals within the Community General requirements in term of safety and marketing Responsibilities and obligations of feed businesses General and specific requirements for labelling, packaging and presentation Definition of a Community Catalogue of feed materials	Amending: Regulation (EC) 1831/2003 Regulation (EC) 1831/2003 Repealing: Council Directives 79/373/EEC; 82/471/EEC; 83/228/EEC; 93/47EEC, 93/113/EC; 96/25/EC. Commission Directive 80/511/EEC; 70/542/EEC. Amendments: Amendments: Commission Regulation (EU) 45/4/2010; 568/2010.
Related Acts	Main points	Relationship between documents
Commission Regulation (EU) 892/2010 (European Commission, 2010b) Commission Recommendation 2011/25/EU (European Commission, 2011a) Commission Regulation (EU) 68/2013 (European Commission, 2013)	Definition of the status of certain products with regard to feed additives within the scope of Regulation (EC) 1831/2003 (European Commission, 2003e) Establishment of guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products Establishment of the Catalogue of feed materials Glossary of feed processes List of feed materials	





good quality feed.

Feed hygiene topic is covered by Regulation (EC) 183/2005 (European Commission, 2005d) laying down requirements for feed hygiene. The principal aim of this Regulation is to set out new hygiene rules in an integrated approach necessary to ensure: i) a higher level of consumer protection with regard to food and feed safety; ii) safety throughout the food chain, starting with primary production of feed up to and including the feeding of food-producing animals; iii) that all feed businesses, including aquaculture, operate in conformity with harmonised safety requirements. The general implementation of procedures is based on the principles of hazard analysis and critical control points (HACCP), that, together with the application of good hygiene practice, represents a valuable instrument to help feed business operators and should reinforce their responsibility. A complete application of a registration of feed business operators and approval system of establishments may guarantee full traceability.

The rules governing feed hygiene controls must consider certain zoonoses and zoonotic agents, for which specific requirements for controls have been laid down by the Regulation (EC) 2160/2003 (European Commission, 2003f) on the control of salmonella and other specified food-borne zoonotic agents, and the Directive 2003/99/EC (European Commission, 2003b) on the monitoring of zoonoses and zoonotic agents. The purpose of the Regulation (EC) No 2160/2003 (European Commission, 2003f) is to ensure that proper and effective measures are taken to detect and to control salmonella and other zoonotic agents at all relevant stages of production, processing and distribution, particularly at the level of primary production, including feed, in order to reduce their prevalence and the risk they pose to public health. The purpose of the Directive 2003/99/EC (European Commission, 2003b) is to ensure that zoonoses, zoonotic agents and related antimicrobial resistance are properly monitored, and that food-borne outbreaks receive proper epidemiological investigation, to enable the collection in the Community of the information necessary to evaluate relevant trends and sources. This Directive covers the monitoring of zoonoses and zoonotic agents, related antimicrobial resistance, the epidemiological investigation of food-borne outbreaks, and the exchange of information related to zoonoses and zoonotic agents.

A summary of the EU Regulation related to feed hygiene is given in Table 5.

Undesirable substances in animal feed

Livestock production is an important topic for the Community and satisfactory results in terms of public and animal health, animal welfare, environment and livestock producers' finances depend to a large extent on the use of appropriate good quality feedingstuffs. Rules on feedingstuffs are needed to ensure agricultural productivity and sustainability. Comprehensive regulations on undesirable substances have been set up in order to guarantee good quality and safety of feedingstuffs at farm level, if they are not commercially produced, or at commercial levels.

As it is impossible to fully eliminate the presence of undesirable substances, it is important to fix maximum limits, considering the substances' acute and chronic toxicity, bioaccumulation and degradability, in order to prevent undesirable and harmful effects. The undesirable substance presence in animal feed is covered by the Directive 2002/32/EC (European Commission, 2002c). In particular, this Directive, considering the continuous amending acts, fixes the maximum levels of undesirable substances in products intended for animal feed as regard to: inorganic contaminants and nitrogenous compounds, mycotoxins, inherent plant toxins, organochlorine compounds and dioxins and PCBs, harmful botanical impurities, authorised feed additives in non-target feed following unavoidable carryover. This Directive must apply to products intended for animal feed as soon as they enter the Community. When a Member State has grounds, based on new information or a reassessment of existing information, suggesting that a maximum level might present a danger to animal or human health or to environment, that Member State may provisionally reduce the existing maximum level in its territory, fix a maximum level or prohibit the presence of that undesirable substance in products. In that case, it shall immediately notify the other Member States and the Commission of the measures taken with a statement of the reasons thereof. An immediate decision shall be taken, in accordance with the procedure laid down in the Directive for adapting the technical provisions in the Annexes to this Directive in the light of developments in scientific and technical knowledge. For a uniform approach in cases of increased levels it may be necessary to set action thresholds to trigger such investigations. These may be laid down in Annex II. So long as neither the Council nor the Commission has taken a decision, the Member State may maintain the measures it has implemented.

As a concrete result of European integration, in terms of ensuring the highest possible level of safety of the food chain and compliances with EU food and feed legislation, the Rapid Alert System for Food and Feed (RASFF) (http://ec.europa.eu/food/food/rapidalert/index en.htm) was launched in 1979. The legal basis of the RASFF is Regulation (EC) 178/2002 (European Commission, 2002d) which established RASFF as a network involving the Member States, the Commission, as member and manager of the system, and EFSA. RASFF is a tool to exchange information between competent authorities on consignments of food and feed in cases where a risk to human and animal health has been identified and measures have been taken. In 2011, out of the 3730 original notifications transmitted in RASFF, 361 concerned feed, about 10 % of the total. Notifications concerning feed have been increasing for only a few specific categories. In decreasing order of importance these are: mycotoxins, non-pathogenic micro-organisms, industrial contaminants, heavy metals and fraud.

A summary of the EU Directives and Regulations related to undesirable substances in animal feed is given in Table 6. The specific topic regarding the methods of sampling and analysis for the official control of undesirable substances in feed has been previously presented (Table 4).

Additives for use in animal nutrition

Experience with the application of Council Directive 70/524/EEC (European Commission, 1970) concerning additives in feedingstuffs has shown that it is necessary to review all the rules on additives in order to take into account the need to ensure a greater degree of protection of animal and human health, and of the environment. It is also necessary to take into account the fact that the technological progress and the scientific developments have made available new types of additives, such as those to be used on silage or in water. The ban, from 1st January 2006, of the use of antibiotics as growth promoter feed additives within the European Union, resulted in a huge progress in the development of alternative and effective products. From a safety point of view, in order to protect human health, animal health and the environment, feed additives should undergo a





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Main documents	Main points	Relationship between documents
Regulation (EC) 882/2004 (European Commission, 2004k)	Description of obligations relating to official controls Definition of the operational criteria that the competent authorities of each Member State for performing official controls and of their obligations and requirements Definition of the criteria for the methods of sampling and analysis used within the context of official controls Definition of the criteria for the methods of sampling and analysis used within the context of official controls Indications for preparing an integrated multi-annual national control plan, and intervention plans in the event of an emergency Specific indications for the controls on products from Non-EU Member Countries (Commission experts may carry out controls in Non-EU Member Countries) Establishment of a number of Community Reference Laboratories assistance to the Commission. Definition of administrative measures	Repealing: Council Directive 70/373/ECC; 85/73/ECC; 85/59/IECC; 89/39/ECC; 93/383/ECC; 95/99/ECC; 95/53/EC. Council Decision 98/383/ECC; 98/728/EC; 1999/313/EC. Amending: Council Directive 96/23/EC; 97/78/EC; 2000/29/EC. Regulation (EC) No 85/4/2004. Amendments Commission Regulation (EC) 776/2006; 180/2008; 737/2008; 1029/2008; 116/2009; 87/2011; 208/2011; 563/2012. Council Regulation (EC) 1791/2006; 301/2008.
Related Acts	Main points	Relationship between documents
Commission Recommendation 2003/91/EC (European Commission, 2003a)	Recommendation on the coordinated inspection programme for the year 2003 in the field of animal nutrition	
Commission Regulation (EC) 136/2004 (European Commission, 2004e)	Definition of the procedures for veterinary checks at Community border inspection posts on products imported from third countries	
Regulation (EC) 852/2004 (European Commission, 2004h)	General rules for food business operators on the hygiene of foodstuffs	
Regulation (EC) 853/2004 (European Commission, 2004i)	General and specific hygiene rules for food of animal origin (unprocessed and processed)	
Regulation (EC) 854/2004 (European Commission, 2004j)	General and specific rules for the organisation of official controls on products of animal origin intended for human consumption	
Commission Recommendation 2005/925/EC (European Commission, 2005b)	Commission Recommendation 2005/925/EC Recommendation on the coordinated inspection programme for the year 2006 in the field of animal nutrition (European Commission, 2005b)	
Regulation (EC) No 183/2005 (European Commission, 2005d)	Definition of requirements for feed hygiene See Table 5	
Commission Decision 2006/677/EC (European Commission, 2006a)	Guidelines for competent authorities' audit systems for the conduct of audits under Regulation (EC) 882/2004 (European Commission, 2004k) on official controls to verify compliance with feed and food law, animal health and animal welfare rules	
Commission Regulation (EC) 829/2007 (European Commission, 2007c)	Definition of rules regarding the placing on the market of certain animal by-products	Amending Regulation (EC) 1774/2002
Commission Decision 2008/798/EC (European Commission, 2008b)	Imposition of special conditions governing the import of products containing milk or milk products originating in or consigned from China	Repealing Commission Decision 2008/798/EC



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kmending Commission Decision 2006/504/EC Relationship between documents Repealing Commission Implementing Regulation (EU) 284/2012; 5 mplementation Regulation (EC) 882/2004 Imposition of 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. Definition of transitional measures for the implementation of Regulations, regarding hygiene rules for food of animal origin, Definition of detailed rules for the inspections carried out by Commission veterinary experts at border inspection Definition of rules concerning the increased level of official controls on imports of certain feed and food and official controls for the verification of compliance with feed and food law, animal health organisation of official controls on products of animal origin intended for the points of entry into the territories posts and at certain other points of entry into the Community Definition of a list of veterinary units in Traces Definition of a list of border inspection posts of non-animal origin at Main points Commission Regulation (EC) 1162/2009 (European Commission, 2009d) Commission Implementing Regulation (EU) 996/2012 (European Commission, 2012) Commission Regulation (EC) 669/2009 Commission Decision 2009/821/EC European Commission, 2009a) European Commission, 2009c)

safety assessment through a Community procedure before being placed on the market, used or processed. This topic is covered by the Regulation (EC) 1831/2003 (European Commission, 2003e) on additives for use in animal nutrition. The purpose of this Regulation is to establish a Community procedure for authorising the placing on the market and use of feed additives and to lay down rules for the supervision and labelling of feed additives and premixtures in order to provide the basis for the assurance of a high level of protection of human health, animal health and welfare, environment and users' and consumers' interests in relation to feed additives, whilst ensuring the effective functioning of the internal market. In order to ensure a harmonised scientific assessment of feed additives, such assessment is carried out by the EFSA. Strict conditions for authorization are reported: no feed additive shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that, when used in accordance with conditions set out in the Regulation authorising the use of the additive, it does not have an adverse effect on animal health, human health or the environment, and it is presented in a manner which may mislead the user. Moreover, each additive must be allocated within a specific category and one or more of the functional groups reported in the Regulation. An European Union Register of Feed Additives pursuant to Regulation (EC) 1831/2003 (European Commission, 2003e) (http://ec.europa.eu/food/food/animalnutrition/feedadditives/comm register feed additives 1831-03.pdf) is available and it is updated every time, when a new authorization is given, obtained, modified, suspended, expired, revoked or extended. A summary of the EU Regulations related to additives in animal nutrition is given in Table 7.

Animal by-products: prevention, control, eradication of certain transmissible spongiform encephalopathies, and use in animal nutrition

Animal by-products not intended for human consumption may be a potential source of risks to public and animal health. Past crises related to outbreaks of foot-and-mouth disease, the of transmissible spongiform encephalopathies, such as bovine spongiform

encephalopathy (BSE), and the occurrence of dioxins in feedingstuffs have shown the consequences of the improper use of certain animal by-products for the public and animal health, the safety of the food and feed chain, and the consumer confidence. In addition, such crises may also have a wider adverse impact on society with a high impact on the socioeconomic situation of the farmers and of the industrial sectors. Since 1990, the Community has adopted a series of measures to protect human and animal health from the risk of BSE. By now, this topic is covered by the Regulation (EC) 999/2001 (European Commission, 2001b) laving down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies. This Regulation has been extensively amended by a huge number of Regulations, according to the new scientific information becoming available in the years, the changing of the epidemiological picture, and the availability of alternative and rapid tests. A complete list of the amending Regulations is available at http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri= CELEX:32001R0999:EN:NOT.

The topic of animal by-product use in animal nutrition is covered by the Regulation (EC) 1069/2009 (European Commission, 2009f), laying down health rules as regards animal byproducts and derived products not intended for human consumption, and its corresponding implementing Commission Regulation (EC) 142/2011 (European Commission, 2011c), revoking and replacing the Regulation (EC) No 1774/2002 (European Commission, 2002e). It is the consequence of a long and comprehensive review carried out by the EU Commission to assess the operation of EU-wide controls on animal by-products. This Regulation defines community health rules for collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use or disposal of animal by-products. The Regulations covers all animal products including meat, fish, milk and eggs when they are not intended for human consumption and other products of animal origin including hides, feathers, wool, bones, horns, and hoofs. It also covers carcasses of fallen stock on farms, pet animals, and wild animals where they are suspected of being diseased. It regulates the use of animal by-products for example as feed (including pet food), fertiliser or for technical products and lays down rules for their transformation through composting and biogas and their disposal via rendering and

A summary of the EU Regulations regarding animal by-product topic is given in Table 8. The



Related Acts

Table 3. Continued from previous page.



Table 4. EU regulations related to feed sampling and analysis and related acts.

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Main documents	Main points	Relationship between documents
Commission Regulation (EC) 152/2009 (European Commission, 2009b)	General principles and definitions regarding sampling for the official control of feed, as regards the determination of constituents, additives and undesirable substances, with the exception of residues of pesticides and microorganisms Definition of the procedures for the preparation of samples for analysis and expression of results in accordance with the methods reported in this Regulation Methods of analysis for the official control of feed (composition of feed materials and compound feed; level of authorised additives; undesirable substances; determination of constituents of animal origin) Methods of analysis to control illegal presence of no longer authorised additives in feed Methods of analysis to control illegal presence of no longer authorised additives in feed	Repealing First Commission Directive 71/250/EEC Second Commission Directive 71/393/EEC Third Commission Directive 71/393/EEC Third Commission Directive 72/49/EEC Fourth Commission Directive 763/71/EEC Seventh Commission Directive 763/71/EEC Eighth Commission Directive 81/715/EEC First Commission Directive 81/715/EEC Tenth Commission Directive 81/715/EEC Commission Directive 88/71/EEC Commission Directive 83/70/EEC Fleventh Commission Directive 83/70/EEC Commission Directive 98/64/EC, 1999/76/EC, 2002/70/EC; 2002/70/E
Related Acts	Main points	
Commission Recommendation 2004/787/EC (European Commission, 2004b)	Technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) 1830/2003 (European Commission, 2003d). Definitions and general principles for sampling protocols Laboratory requirements Testing methods, expression and interpretation of the results of the analyses This guidance covers products that have received authorisations for their placing on the market	
Commission Regulation (EC) 401/2006 (European Commission, 2006c)	General principles and definitions Description of the methods of sampling for official control of the levels of mycotoxins in foodstuffs, specifications for different commodities Criteria for sample preparation and for methods of analysis used for the official control of the levels of mycotoxins in foodstuffs Performance criteria for mycotoxin method of analysis to be used by the laboratory and laboratory control requirements Criteria for acceptance of a lot or sublot	
Commission Regulation (EU) 619/2011 (European Commission, 2011d)	Definition of the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired	





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Table 5. EU regulations and Directives related to feed hygiene an	ves related to feed hygiene and main related acts.	
Main documents	Main points	Relationship between documents
Regulation (EC) 183/2005 (European Commission, 2005d)	General principles and requirements for feed hygiene General and specific obligations for feed business operators Conditions and arrangements ensuring traceability of feed Rules for feed operators in order to put in place, implement and maintain a permanent written procedure or procedures based on the Hazard analysis and critical control points (HACCP) principles. Conditions and arrangements for registration and approval of establishments and record in a national list or lists Rules for import and export	Repealing Council Directive 95/69/EC Commission Directive 98/51/EC Amendments Regulation (EC) 219/2009 Commission Regulation (EC) 225/2012
Regulation (EC) 2160/2003 (European Commission, 2003f)	Definition of the Competent authorities Adoption of targets for the reduction of the prevalence of specified zoonoses in animal populations at the level of primary production, and where appropriate for the zoonosis or zoonotic agent concerned, at other stages of the food chain, including in food and feed Approval of specific control programmes established by Member States and food and feed business operators Adoption of specific rules concerning certain control methods applied in the reduction of the prevalence of zoonoses and zoonotic agents Adoption of rules concerning intra-Community trade and imports from third countries of certain animals and products Approval of laboratories, quality requirements and approved testing methods This Regulation shall not apply to primary production for private domestic use, or leading to the direct supply, by the producer, of small quantities of primary products	Amendments Commission Regulation (EC) 1237/2007; 199/2009; 213/2009; 517/2011; 1086/2011. Council Regulation (EC) 1791/2006 Regulation (EC) 596/2009
Directive 2003.99/EC (European Commission, 2003b)	General and specific rules for the monitoring of zoonoses and zoonotic agents, related antimicrobial resistance, the epidemiological investigation of food-borne outbreaks, and the exchange of information related to zoonoses and zoonotic agent Definition of a list of zoonoses and zoonotic agents to be included in monitoring, and to be monitored according to the epidemiological situation Rules for each Member State to designate a competent authority or competent authorities for the purposes of this Directive Rules for establishing coordinated monitoring programmes, especially when specific needs are identified Rules information Rules for exchange information Rules and procedures for the designation of Community and national reference laboratories	Repealing Council Directive 92/117/EEC Amending Council Decision 90/424/EEC Amendments Council Directive 2006/104/EC Council Directive 2009/470/EC Regulation (EC) 219/2009
Related Acts	Main points	Relationship between documents
Report from the Commission to the European Parliament and the Council (European Commission, 2007e) Commission Regulation (EC) 2073/2005 (European Commission, 2005c)	Report from the Commission On existing legal provisions, systems and practices in the Member States and at Community level relating to liability in the food and feed to the European Parliament sectors and on feasible systems for financial guarantees in the feed sector at Community level in accordance with Article 8 and the Council of Regulation (EC) No 183/2005 laying down requirements for feed hygiene (European Commission, 2007e) Commission, 2005c) (European Commission, 2005c)	Repealing Commission Decision 93/51/ECC Amendments Commission Regulation (EC) 1441/2007; 365/2010; 1086/2011.





Table 6. EU Directives and Regulations focused on undesirable substances in animal fee	÷
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Directive 2002/32/EC (European Commission, 2002c)	General principles and definitions Indications of relationships between Member States and the Commission in order to take immediate decision for adapting the technical provisions in the Annexes to this Directive, in the light of developments in scientific and technical knowledge. Setting of maximum admissible limits of undesirable substances in products intended for animal feed. Setting of maximum levels of each undesirable substances are reported for different type of products intended for animal feed. Annex I: maximum levels of each undesirable substances are reported for different plant toxins, organochlorine compounds and dioxins and PCBs; (inorganic contaminants and nitrogenous compounds; inhorated feed following unavoidable carry-over) Annex II: for dioxin and dioxin like PCB, action threshold relative to feedingstuffs, and comments and additional information (e.g. nature of investigations to be performed) are reported.	Repealing Council Directive 1999/29/EC Amendments Commission Directive 2003/57/EC; 2003/100/EC; 2005/8/EC; 2005/8/EC; 2005/87/EC; 2006/13/EC; 2006/17/EC; 2008/16/EC; 2009/12/4/EC; 2009/14/EC; 2010/ECC. Regulation (EC) 219/2009 Commission Regulation (EU) 574/2011; 277/2012; 744/2012; 107/2013.
Related Acts	Main points	Relationship between documents
Commission Recommendation 2004/704/EC (European Commission, 2004c) Regulation (EC) 882/2004 (European Commission, 2004k) Regulation (EC) 396/2005 (European Commission, 2005e) Commission Recommendation 2011/516/EU (European Commission, 2011b) Commission Recommendation 2006/576/EC (European Commission, 2010b)	On the monitoring of background levels of dioxins and dioxin-like PCBs in feedingstuffs On official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare On maximum residue levels of pesticides in or on food and feed of plant and animal origin On the reduction of the presence of dioxins, furans and PCBs in feed and food On the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding	Amending Council Directive 91/414/EEC Repealing Commission Recommendation 2006/88/EC
Commission Regulation (EC) 1881/2006 (European Commission, 2006d)	Setting maximum levels for certain contaminants in foodstuffs	

specific topic regarding the methods of sampling and analysis for the official control of feed as regards presence of animal by-products has been previously presented (Table 4).

Genetically modified feed: placing on the market

The use of genetically modified (GM) plants in agriculture and their use as food and feed is a topic controversially discussed in academic. institutional and public debates. Many discussion forums, studies and publications have been devoted to evaluate if the release of GM crops is beneficial or harmful for the environment, and to assess the safety of GM food and feed. Other potential risks are: spread of pest resistance or herbicide tolerance to wild plants, inadvertent toxicity to benign wildlife, and increasing control of agriculture by biotechnology corporations. Perceptions of unnaturalness, ethical concerns, the failure to implement an efficacious traceability policy, and disparity between developing and developed countries (in terms of economics and sovereignty over decisions) have also been associated with a negative societal response and great differences in the perception of benefits and risks of GM Organisms (GMOs).

Since the 90', specific measures at the European level have been adopted with the aim to provide a legal framework for the control of GM crops and food: the Council Directive 90/219/EEC (European Commission, 1990a) on the contained use of genetically modified micro-organisms, and the Council Directive 90/220/EEC (European Commission, 1990b) on the deliberate release into the environment of genetically modified organisms. More recently, the European Union adopted a comprehensive and implemented legal framework regarding the authorization and the placing on the market of products consisting of or derived from GMOs. The authorisation procedure covers the use of GMOs and their derived products for food and feed, industrial processing and cultivation. The placing on the market of GMOs and foodstuffs containing GMOs, whether they are intended for consumption by humans or animals, is regulated by a specific authorisation procedure. Any GM food and feed intended for sale in the EU is subject to a rigorous safety assessment, which is the responsibility of EFSA. All these topics are covered by the Regulation (EC) 1829/2003 (European Commission, 2003c), and the Regulation (EC) No 1830/2003 (European Commission, 2003d).





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Regulation (EC) 1831/2003 (European Commission, 2003f)	Definition and establishment of a Community procedure for authorising the placing on the market, use and placing on the market of feed additives Definition of a category list and additive functional groups within the categories General and specific rules for the supervision and labelling of feed additives and premixtures Definition of duties and tasks of the Community reference laboratory	Repealing Council Directive 70/524/EEC; 87/153/EEC. Amending Council Directive 82/471/EEC Amendments Commission Regulation (EC) 378/2005; 386/2009.
		Regulation (EC) 596/2009; 767/2009.
Related Acts	Main points	Relationship between documents
Commission Regulation (EC) 429/2008 (European Commission, 2008d)	On detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and the authorisation of feed additives and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives	
Commission Regulation (EU) 892/2010 (European Commission, 2010b)	On the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council (European Commission, 2003e)	

These Regulations apply to three types of product: i) GMOs for food and feed use; ii) food and feed containing GMOs; iii) food and feed produced from or containing ingredients produced from GMOs. Food and feed consisting of, containing or produced from GMOs should undergo a safety assessment through a Community procedure before being placed on the market within the Community. Aspects and rules related to the authorisation procedures and supervision of GM food and feed are mainly covered by the Regulation (EC) 1829/2003 (European Commission, 2003c), while a framework for the traceability of OGMs at all stages of placing on the market, including the possibility of establishing thresholds, and labelling of GM products is covered by the Regulation (EC) 1830/2003 (European Commission, 2003d). A list of authorised GMOs is available at the website of the Directorate-General for Health Consumers: http://ec.europa.eu/food/dyna/gm _register/index_en.cfm. This search covers the EU GMOs register, pursuant to Regulation (EC) 1829/2003 (European Commission, 2003c), and the products subject to EC decisions on withdrawal from the market.

A summary of the EU Regulations related to placing on the market to genetically modified food and feed is given in Table 9. The specific topic regarding the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material has been previously presented (Table 4).

Feed intended for particular nutritional purposes

It is well-known that feed may have biological activities that are beyond their nutritional value. Recently, this aspect has gained increasing attention mainly in animal nutrition and feed industry, and so-called nutraceuticals are offered for feed applications. From a regulatory point of view, if a feed is brought onto the market with nutritional and health claims, these claims must be objective, supported by scientific evidences, and verifiable by the competent authorities. Therefore, several information are required to bring evidence that these products have a specific composition, have been designed to meet particular nutritional needs of animal categories, have a beneficial effect on the animals, and/or are manufactured using special methods. Such feedingstuffs must be clearly distinguished in their characteristics and purpose from ordinary feedingstuffs. This



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Main documents	Main points	Relationship between documents
Regulation (EC) 999/2001 (European Commission, 2001b)	General, specific rules and requirements for the production and placing on the market of live animals and products of animal origin (not for cosmetic or medicinal products or medical devices; products not intended for use in food, feed or fertilizers; products of animal origin for exhibition, teaching, scientific research) Criteria for the determination of BSE status of each Member state Definition and establishment of the measures for TSE prevention: monitoring system, rules for breeding programmes, prohibitions concerning animal feeding, education programmes Definition of rules and procedures for the control and eradication of TSEs: notification, measures with respect to suspect animals and confirmed presence of TSE, contingency plan Establishment of reference laboratories and sampling, testing and controls procedures	Amendments Complete list at http://eurlex.europa.eu/LexUriServ/ LexUriServdo?uri=CELEX: 32001R0999:EN:NOT
Regulation (EC) 1069/2009 (European Commission, 2009f)	Establishment of community health rules for collection, transport, handling, treatment, transformation, processing, storage, placing on the market, distribution, use or disposal of animal by-products not intended for human consumption. Definition of obligations from the starting point to end point in the manufacturing chain. General animal health restrictions Categorisation and definition of three categories of animal by-products and derived products Establishment of general rules for collection, transport, disposal, placing on the market, and use of animal by-products astablishment of restrictions on use of the 3 category products Establishment of restrictions on use of the 3 category products General obligations, registration and approval procedures for operators as regard collection, transport and traceability Establishment of a list for each Member State of approved or registered establishments, plants and operators	Repealing Regulation (EC) 1774/2002 Amendments Council Directive 2010/63/EU
Related Acts	Main points	
Commission Decision 2002/248/EC (European Commission, 2002a)	Regard to transmissible spongiform encephalopathies and the feeding of animal proteins	Amending Council Decision 2000/766/EC Commission Decision 2001/9/EC
Commission Decision 2002/1003/EC (European Commission, 2002b)	Laying down minimum requirements for a survey of prion protein genotypes of sheep breeds	
Communication from the Commission (European Commission, 2005a)	TSE Road map	
Commission Decision 2007/453/EC (European Commission, 2007b)	Establishing the BSE status of Member States or third countries or regions thereof according to their BSE risk	
Communication from the Commission (European Commission, 2010c)	The TSE Road map 2: a strategy paper on Transmissible Spongiform Encephalopathies for 2010-2015	
Commission Regulation (EC) 142/2011 (European Commission, 2011c)	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	





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Main documents	Main points	Relationship between documents
Regulation (EC) 1829/2003 (European Commission, 2003c)	Definition of Community procedures for the authorisation and supervision of genetically modified food and feed (GMOs for food use; food containing or consisting of GMOs, food produced from or containing ingredients produced from GMOs) Provisions and requirements for labelling of genetically modified food and feed. Rules and requirements for application of authorizations, and renewal of authorizations Rules for modification, suspension, revocation of authorizations, and renewal of authorizations Establishment of a Community register of genetically modified food and feed Duties and tasks of the Community reference laboratories Rules for establishment of National reference laboratories	Repealing Council Regulation (EC) 1139/98 Commission Regulation (EC) 49/2000; 50/2000. Amending Council Directive 68/193/EEC; 82/471/EEC Regulation (EC) 258/97 Council Directive 2002/53/EC; 2002/55/EC Amendments Commission Regulation (EC) 1981/2006 Poorthing (EC) 308/9008
Regulation (EC) 1830/2003 (European Commission, 2003d)	Definition of a framework for the traceability of products consisting of or containing GMOs, and food and feed produced from GMOs Specific rules for the placing on the market of GMOs Traceability and labelling requirements for products consisting of or containing GMOs Traceability requirements for products for food and feed produced from GMOs Definition of inspection and control measures	Regulation (EC) 230/2000 Repealing Directive 2001/18/EC Amendments Regulation (EC) 1137/2008
Related Acts	Main points	Relationship between documents
Regulation (EC) 258/97 (European Commission, 1997)	Concerning novel food and novel food ingredients	
Regulation (EC) 1139/98 (European Commission, 1998) Directive 2001/18/EC (European Commission, 2001a)	Concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified in Directive 79/112/EEC organisms of particulars other than those provided for On the deliberate release into the environment of genetically modified organisms	Repealing Council Directive 90/220/EEC
Commission Regulation (EC) 8892008 (European Commission, 2008e)	Laying down detailed rules for the implementation of Council Regulation (EC) 834/2007 (European Commission, 2007) on organic production and labelling of organic products with regard to organic production, labelling and control	Amendments Complete list at: http://eurlex.europa.eu/Lex UriServ/LexUriServ.do?uri=CELEX: 32008R0889:EN:NOT
Commission Regulation (EC) 65/2004 (European Commission, 2004d)	Establishing a system for the development and assignment of unique identifiers for genetically modified organisms	
Commission Regulation (EC) 641/2004 (European Commission, 2004f)	On detailed rules for the implementation of Regulation (EC) 1829/2003 of the European Parliament and of the Council (European Commission, 2003) as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluations	
Commission Decision 2007/157/EC (European Commission, 2007a)	On emergency measures regarding the non-authorised genetically modified organism Bt10 in maize products	Repealing Commission Decision 2005/317/EC
Commission Decision 2010/315/EC (European Commission, 2010a)	On emergency measures regarding the non-authorised genetically modified organism "LL RICE 601" in rice products	Repealing Commission Decision 2006/601/EC
Commission Decision 2008/289/EC (European Commission, 2008a)	On emergency measures regarding the unauthorised genetically modified organism Bt 63 in rice products	
Commission Regulation (EU) 619/2011 (European Commission, 2011d)	Laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired	



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Main documents	Main points	Relationship between documents
Commission Directive 2008/38/EC (European Commission, 2008c)	Provision of a list of intended uses of animal feedingstuffs for particular nutritional purposes ANNEX I: list of particular nutritional purposes. For each purpose, requirements regarding the essential nutritional characteristics, species or category of animals, labelling declarations, recommended length of time, and other provisions are reported	Repealing Commission Directive 94/39/EC; 95/9/EC; 2002/1/EC; 2008/4/EC Amendments
		Commission Directive 2008/82/CE Commission Regulation (EU) 1070/2010
Regulation (EC) 767/2009 (European Commission, 2009e)	See Table 2	See Table 2

Table 11. EU Regulations focused on organic production.

table 11. EU Regulations focused on organic production.	on organic production.	
Main documents	Main points	Relationship between documents
Council Regulation (EC) 834/2007 (European Commission, 2007d)	General and specific rules for the production and placing on the market of products originating from agriculture (live or unprocessed agricultural products, processed agricultural products and yeasts used use as food and feed, vegetative propagating material and seeds for cultivation), including aquaculture Provision of overall principles and general requirements of organic production (banned products, restriction of the use of external inputs) Establishment of general requirements and specific principles applicable to farming, processing of organic food and feed General rules for production of processed feed, food, and organic yeast Criteria for the use and authorization of products and substances Definition of rules for the use of terms referring to organic production: labelling, compulsory indications, organic logo, specific labelling requirements Set up of a control system Set up of rules for trade with third countries	Repealing Council Regulation (EEC) 2092/91 Amendments Council Regulation (EC) 967/2008 feed
Related Acts	Main points	Relationship between documents
Commission Regulation (EC) 889/2008 (European Commission, 2008e)	Laying down detailed rules for the implementation of Council Regulation (EC) 834/2007 (European Commission, 2007) on organic production and labelling of organic products with regard to organic production, labelling and control	Amendments Complete list at: http://eurlex.europa.eu/Lex UriServ/LexUriServ.do?uri=CELEX: 32008R0889:EN:NOT





topic is covered by the Commission Directive 2008/38/EC (European Commission, 2008c) establishing a list of intended uses of animal feedingstuffs for particular nutritional purposes. This is a positive list indicating, for each nutritional purpose, the essential nutritional characteristics, the labelling declarations and, where appropriate, the special labelling requirements of each feed. The established list may be modified and implemented, where appropriate, following developments in scientific and technical knowledge, and the availability of new Community methods of control. Feeds intended for particular nutritional purposes can be marketed only if their intended uses are included in the list, according to the general principles and requirements reported in Regulation (EC) 767/2009 (European Commission, 2009e), establishing the general principles and requirements regarding the placing on the market and use of feed (Table 2).

A summary of the EU Regulations related to animal feedstuffs intended for particular nutritional purposes is given in Table 10.

Organic production

Organic production is an overall system of farm management and feed and food production that combines best environmental practices, a high level of biodiversity, the preservation of natural resources, the application of high animal welfare standards, and a production method in line with the preference of certain consumers for products produced using natural substances and processes. The share of the organic agricultural sector is increasing, providing products for a specific market and consumer, and delivering public goods contributing to the protection of the environment and animal welfare, as well as to rural development. An agricultural policy and a legislative framework on organic production are fundamental. This topic is covered by the Council (EC) 834/2007 Regulation (European Commission, 2007d), on organic production and labelling of organic products and repealing (European Regulation (EEC) 2092/91 Commission, 1991). This Regulation defines the objectives, principles and rules applicable to organic production, in order to contribute to transparency and consumer confidence as well as to a harmonised perception of the concept of organic production. Detailed rules for the implementation of Council Regulation (EC) 834/2007 (European Commission, 2007d), on organic production and labelling of organic products are reported in the Commission Regulation (EC) 889/2008 (European Commission, 2008e). The general Community framework provides a basis for the sustainable development of organic production, ensuring the effective functioning of the internal market and guaranteeing fair competition. The framework applies to both crop and animal production and all stages of production, preparation, and distribution of organic products.

A summary of the EU Regulations related to organic production is given in Table 11.

Conclusions

This review presented an update of the EU legislation regarding feed related topics in order to provide a general frame of the EU feed legislation and give the reader a useful source of information. Over the last 10-15 years several food safety crises occurred within the framework of the EU and weakened the public's confidence on the quality and wholesomeness of foods of animal origin. As a result, EU Commission, governments, industry, researchers, and farmers have been forced to pay serious attention to animal feedstuff production processes, thereby acknowledging that animal feed safety is an essential prerequisite for human food safety. The EU Commission enhanced the food safety level by either introducing new stricter Regulations/Directives or modifying the already existing ones. Since the adoption of Regulation (EC) 178/2002 (European Commission, 2002d) 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, the target of the Community policies, in the development of food law, was to assure a high level of protection of human life and health. So a common EU framework basis for measures governing food and feed was developed in a non-discriminatory manner whether food or feed is traded on the internal market or internationally. The legislation in the field of feed/food chain is continuously evolving prompted by different factors, such as the availability of new scientific information becoming available in the years, the activity of the EFSA's scientific committees, the changing of the epidemiological picture, and the availability of new analytical approaches. Globalisation and the increased global trade associated with feed and food production pose the need for EU legislation to face with the different legislative framework of other countries. A lack of legislative harmonization is an important point to consider in a worldwide discussion regarding the risk management and regulations in food security and safety governance.

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