

ОБЗОРИ

**EUROPEAN AND NATIONAL LEGISLATION OF BULGARIA AND GREECE FOR THE “SAFETY AND QUALITY OF ANIMAL FEED”:
A REVIEW**

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Европейското и националните законодателства на България и Гърция по отношение „Безопасност и качество на фуражите“: преглед

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РЕЗЮМЕ

Проучени са европейското и националните законодателства на България и Гърция във връзка с „Безопасност на храните и фуражите за животни“. В проучването е включено законодателството, регулиращо наличието на микотоксини, алкалоиди от растителен произход, неорганични замърсители, съдържащи се в храните, както и генномодифицираните растения, използвани като фуражи, и наредбите за техния контрол.

Ключови думи: Европейски регламент, национално законодателство на България и Гърция, НАССР система на контрол

Bulgaria and Greece, as EU Member States coordinate and implement the applicable laws in all countries. On this base are established law of Bulgaria and Greece in the sector of Animal Nutrition and the laws on the use of feed and additives. The main legal instrument of the EU to the safety of food and feed introduced by Regulation (EO) №178 / 2002 with that regulate food safety. It is necessary to follow all aspects of the food chain to be viewed as a continuous process starting from primary production and feed production to the sale or supply of food to consumers. This approach is called from “Farm to fork”, which indicates the feed as an important factor in the safety and quality of animal production at the beginning of the chain (Tasseva, 2010).

The Bulgarian and Greek legislation for animal fodder and nutrition is based on European laws, rules, decisions, and directives. This legislation on animal feed is harmonized at European Union (EU) level. It applies principally to

feed for farmed livestock, but also covers feed for horses, pets, farmed fish, zoo and circus animals, and creatures living freely in the wild. On 6 May 2013, the European Commission has adopted a proposal for a single, comprehensive animal health law to replace the complicated animal health rules currently in place.

In the next the following points regarding the Bulgarian, Greek and European legislation for fodder and nutrition will be explained: Undesirable substances, Genetically Modified Organisms, Feed approvals, Feed controls, Feed Labeling, Community Catalogue of additives, Processed Animal Proteins and Feed penalties.

**1. UNDESIRABLE SUBSTANCES
(DIRECTIVE 2002/32/EC)**

The following substances are marked as undesirable:

- Inorganic Contaminants and Nitrogenous Compounds (Arsenic, Cadmium, Fluorine, Lead, Mercury, Nitrite, Melamine);
- Mycotoxins (Aflatoxin B1, Rye Ergot);
- Inherent Plant Toxins (Free Gossypol, Hydrocyanic Acid, Theobromine, 5-vinylthiopyridine-2-thione, Volatile Mustard Acid);
- Organochlorine Compounds (Aldrin, Dieldrin, Camphechlor, Chlordane, DDT, Endosulfan, Endrin, Heptachlor, Hexachlorobenzene, Hexachlorocyclohexane (HCH) – (Alpha-isomers, Beta-isomers, Gamma-isomers);
- Dioxins and PCBs (Dioxins, Sum of Dioxins and Dioxin-like PCBs);
- Harmful Botanical Impurities (Datura Sp., Crotalaria Sp., Unhusked beech mast, Purghera, Indian Mustard, Sareptian Mustard, Chinese Mustard, Black Mustard, Ethiopian Mustard, Ambrosia Seeds);
- Authorized feed additives in non-target feed following unavoidable carry-over (Decoquinat, Diclazuril, Halofuginone hydrobromide, Lasalocid Sodium, Maduramicin ammonium alpha, Monensin Sodium, Nasarin, Nicarbazin, Robenidine hydrochloride, Salinomycin Sodium, Semduramicin Sodium);

Regulations of the Undesirable Substances

EU legislation on the above mentioned in animal feed from the 1970s on was consolidated by Council Directive 2002/32/EC. The Directive has been subsequently regularly amended in the light of developments in scientific and technical knowledge.

- Directive 2002/32/EC; introduced several major amendments. The most important prohibits the dilution of contaminated feed materials. This Directive includes maximum limits for heavy metals such as arsenic, lead, mercury and cadmium as well as for dioxin, aflatoxin, certain pesticides, and botanical impurities in certain feed materials, feed additives and feeding stuffs. In Bulgaria this Directive is included in regulation № 10.

- Regulation 1831/2003/EC; about supplements in animal feeds.

- Regulation 882/2004/EC; about the official control for accordance with the law for feeding

products and the rules of animal health and welfare.

- Commission Recommendation 2006/583/EC of 17 August 2006 on the prevention and reduction of Fusarium toxins in cereals and cereal products.

- Commission Recommendation 2006/576/EC of 17 August 2006 on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding as amended by Commission Recommendation 2013/637/EU of 4 November 2014 as regards T-2 and HT-2 toxin in compound feed for cats.

- Commission Recommendation 2013/165/EU of 27 March 2013 on the presence of T-2 and HT-2 toxin in cereals and cereal products.

In the national legislation of Bulgaria several regulations are made based on those recommendations: (Regulation № 4); about feeds which are mentioned in directives 82/471 and 96/25. (Regulation № 10); about feeds with special purpose, mentioned in directives 93/74 and 94/39. (Regulation № 21); about maximum concentrations of unsuitable substances and products in forages. (Regulation № 101); for feed supplements and the dates of prohibition of some in different species.

The Greek legislation completely covers the European directives related with the unsuitable substances in feed.

2. GENETICALLY MODIFIED ORGANISMS

GMOs (or “genetically modified organisms”) are living organisms whose genetic material has been artificially manipulated in a laboratory through genetic engineering, or GE. This relatively new science creates unstable combinations of plant, animal, bacterial and viral genes that do not occur in nature or through traditional cross-breeding methods.

Virtually all commercial GMOs are engineered to withstand direct application of herbicide and/or to produce an insecticide. Despite biotech industry promises, none of the GMO

traits currently on the market offer increased yield, drought tolerance, enhanced nutrition, or any other consumer benefit.

Meanwhile, a growing body of evidence connects GMOs with health problems, environmental damage and violation of farmers' and consumers' rights.

Genetically Modified Organisms Regulations

The European Union has established a legal framework to ensure that the development of modern biotechnology, and more specifically of GMOs, takes place in safe conditions.

The legal framework aims to:

Protect human and animal health and the environment by introducing a safety assessment of the highest possible standards at EU level before any GMO is placed on the market.

Put in place harmonized procedures for risk assessment and authorization of GMOs that are efficient, time-limited and transparent.

Ensure clear labeling of GMOs placed on the market in order to enable consumers as well as professionals (e.g. farmers, and food feed chain operators) to make an informed choice.

Ensure the traceability of GMOs placed on the market.

The GMO legislation is:

- Directive 2001/18/EC on the deliberate release of GMOs into the environment.

- Regulation (EC) 1829/2003 on genetically modified food and feed.

- Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

- Regulation (EC) 1830/2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

- Directive 2009/41/EC on contained use of genetically modified micro-organisms.

- Regulation (EC) 1946/2003 on transboundary movements of GMOs.

- Regulation (EC) 298/2008 change regulation 1829/2003.

These main pieces of legislation are supplemented by a number of implementing rules or by recommendations and guidelines on more specific aspects. The Bulgarian and Greek legislation regarding genetically Modified Organisms is based on the European legislation.

In Bulgaria there is national law about GMO (Law of GMO – enter in use 01.06.2005, with last change 16.10.2009). Regulation of working with GMO in controlled environment (last changed 11.10.2005). Regulation about release of GMO in the environment and marketing of GMO products (last changed 11.10.2005).

The legislation of Greece follows the main directives about GMO, but loudly oppose it's use.

3. FEED APPROVALS

European Commission (EC) Regulation 183/2005 on Feed Hygiene requires feed businesses that manufacture, market or use certain additives and products for animal feed to be approved and/or registered.

Feed Approvals Regulations

The following rules govern the feed approval:

- Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene.

- Commission Regulation (EC) No 141/2007 of 14 February 2007 concerning a requirement for approval in accordance with Regulation (EC) No 183/2005 of the European Parliament and of the Council for feed business establishments manufacturing or placing on the market feed additives of the category coccidiostats and histomonostats.

- Commission Regulation (EU) No 225/2012 of 15 March 2012 amending Annex II to Regulation (EC) N 183/2005 of the European Parliament and of the Council as regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fats and as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof.

- Commission Implementing Regulation (EU) No 226/2012 of 15 March 2012 amending Regulation (EC) No 1730/2006 as regards the conditions of use of benzoic acid.

- Commission Implementing Regulation (EU) No 227/2012 of 15 March 2012 concerning the authorization of *Lactococcus lactis* (NCIMB 30117) as a feed additive for all animal species.

- Commission Implementing Regulation (EU) No 228/2012 of 15 March 2012 establishing the standard import values for determining the entry price of certain fruit and vegetables.

- Commission Implementing Regulation (EU) No 229/2012 of 15 March 2012 fixing the import duties in the cereals sector applicable from 16 March 2012.

- Commission Implementing Regulation (EU) No 230/2012 of 15 March 2012 amending the representative prices and additional import duties for certain products in the sugar sector fixed by Implementing Regulation (EU) No 971/2011 for the 2011/12 marketing year.

- Commission Recommendation of 15 March 2012 on the monitoring of the presence of ergot alkaloids in feed and food.

In Bulgaria and Greece there is list and register of manufacturers of fodders, and register of representatives which import feeds from third countries.

(http://www.nszf.bg/new/main.php?module=info&object=info&action=view&inf_id=67)

4. FEED CONTROLS

EU Regulation 882/2004 on official controls for feed and food law (and animal health and animal welfare) sets out the approach that competent authorities of member states must adopt for official controls. Essentially, how they should monitor and enforce businesses' compliance with feed and food law (and with animal health and welfare rules).

The European Commission believes that the legislation has been broadly successful in setting out a framework for feed and food controls throughout Europe, but has identified opportunities to strengthen 882/2004. The Commission

published proposals to change the current legislation on 6 May 2013.

Systems used in feed control

ISO (International Organization for Standardization) – a quality management system standard that is designed to ensure that the needs of the customers are met.

HACCP (Hazard Analysis & Critical Control Points) – a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

Feed Controls Regulations

Reg. (EC) 178/2002 (28/01/2002). Definition of the general principles and requirements of food law, food safety issues.

Reg. (EC) 882/2004 (29.04.2004). Performance of official controls to verify compliance with feed and food law and rules on the welfare of animals.

Reg. (EC) 152/2009 (27.01.2009). On sampling and analysis for the official control of feed.

Reg. (EC) 51/2013 (01.16.2013). Amending Regulation (EC) No 152/2009 on analytical methods for the determination of constituents of animal origin for the official control of foodstuffs.

Reg. (EC) 691/2013 (07/19/2013) amending Regulation (EC) No 152/2009 as regards the sampling and analysis methods.

Reg. (EC) 709/2014 (06/20/2014) amending Regulation (EC) No 152/2009 regarding the determination of levels of dioxins and polychlorinated biphenyls.

Reg. (EC) 669/2009 (24.07.2009). Regarding the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504 / EC.

Reg. (EC) 525/2015 (27/03/2015) amending Annex I to Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as It regards the increased level of official controls on imports of certain feed and food of non-animal origin.

Reg. (EC) 884/2014 (08/13/2014) imposing special conditions governing the importation of feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009 .

Reg. (EC) 1135/2009 (25.11.2009). Imposing special conditions governing the import of certain products originating in or consigned from China and repealing Decision 2008/798 / EC.

Reg. (EC) 258/2010 (25.03.2010). Imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, and repealing Decision 2008/352 / EC (valid until 02.25.2015).

Reg. (EC) 175/2015 (06/02/2015). Lay down special conditions applicable to imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins (effective from 26.02.2015).

Reg. (EC) 322/2014 (03/28/2014) 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.

All mentioned European directives are considered in the Bulgarian main law for feed and many other sub law regulations (Regulation No 44).

In Greece the main law is also pursuant with the EU laws. (CMD 323306/2007). Determination of necessary additional measures for the implementation of Regulations (EC) no. 178/2002 and no. 882/2004 of the European Parliament and the Council on the general principles of safety and official controls on feed (Decision 196386). Details application of Nos 323 306 / 2007KYA (V1881).

5. FEED LABELING

The packaging and labeling of food is subject to regulation in most jurisdictions, both to prevent false advertising and to promote food safety. Issues include the following:

Ingredients list (in descending order): Food additives, Nutrition facts label;

Safety information: Refrigerate after opening, Shelf life dates (“Use by” and “Best before”), Food allergy and food intolerance risks;

Preparation instructions: Shake well;

Geographical indication: Country of origin, Protected Geographical Status (European Union);

Labeling of genetically modified food.

Feed Labeling Regulations

Reg. (EC) 767/2009 (13.07.2009). Placing on the market and use of feed, amending Regulation (EC) No. 1831/2003 of the European Parliament and the Council.

Reg. (EC) 68/2013 (01.16.2013). For a list of feed materials.

Directive 2008/38 / EC (05.03.2008) for the purpose of drawing up a list of animal feeding stuffs intended for particular nutritional purposes.

Directive 82/475 / EC (23.06.1982). Determination of categories M2 feed materials which may be used for the labeling of compound feeding stuffs for pet animals.

There is also a code of proper labeling for pet foods stating how labeling must be made.

Bulgarian **Regulation No 44** for marketing with combined feed; in which it is written the proper way of packaging, labeling and content of fodder.

Greek legislation gave some law regulation as follows: **CMD 155 344 (26.05.2001)**. Additional necessary measures for the implementation of Council Regulation (EC) no. 767/2009 on the placing on the market and use of feed (L. 229/1) and amendment of PD 296/1997 (A 212). **Circular 172 651 / 20.07.2011** Send clarifications for implementing JMD No. 155344/2011 (Government Gazette 985 / vol. B / 26.05.2011) – additional implementing Regulation (EC) no. 767/2009. Reg. (EC) 68/2013 (01.16.2013).

6. COMMUNITY CATALOGUE OF ADDITIVES

In accordance with Article 17 of **Regulation (EC) No 1831/2003** on additives for use in ani-

mal nutrition, the Commission has established the European Union Register of Feed Additives

The Register was published for the first time in November 2005. It is composed of 2 parts. The first contains the list of modifications to the Register and the current authorizations in Annex I. The second file contains Annex II, the Additives Subject to the provisions of Art. 10 § 2 of Reg. (EC) No 1831/2003 for which no application for reevaluation was submitted before the deadline of 8 November 2010. Some of the additives in this Annex II are already withdrawn but subject to transitional measures.

Until the entry into force of Regulation (EC) No 1831/2003 on feed hygiene on 1st of January 2006, the establishments and the intermediaries producing or putting into circulation certain categories of additives must be registered or approved following Council Directive 95/69/EC of 22 December 1995 laying down the conditions and arrangements for approving and registering certain establishments and intermediaries operating in the animal feed sector.

Ministry of agriculture and food of republic of Bulgaria has a “**List of authorized feed additives**” which is made 2002. Till now all the points inside are revising to be proper with the EU directives and regulations.

7. PROCESSED ANIMAL PROTEINS

Derived from the processing of mammalian by-products, they are primarily used as an additive for animal feed.

Processed Animal Proteins Regulations

Reg. (EC) 999/2001 (22/05/2001) laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathy.

Reg. (EC) 56/2013 (01.16.2013) to amend Annexes I and IV to Regulation (EC) No. 999/2001 of the European Parliament and of the Council.

Reg. (EC) 1292/2005 (05.08.2005). Amending Annex IV to Regulation (EC) No. 999/2001 of the European Parliament and of the Council as regards animal nutrition.

Greek legislation gave their specific governing laws about this point. **JMD 275751 (20.08.2004)**. Implementation measures for Regulation (EC) Art. 1234/2003 amending Annexes I and .IV XI of Regulation 999/2001 of the European Parliament and Council Regulation (EC) No 1326/2001 as regards transmissible spongiform encephalopathy and animal nutrition. **JMD 290 710 (07.06.2007)**. Amending Nos. 275751/2004 (Government Gazette 1276 / B / 20.8.2004) Decision “On measures for the implementation of Council Regulation (EC) no. 1234/2003 amending Annexes I, IV, and XI to Regulation (EC) no. 999/2001 of the European Parliament and of the Council and of Council Regulation (EC) no. 1326/2001 of the Commission with regard to transmissible spongiform encephalopathy and animal nutrition.

Bulgaria as country in EU follows the law which regulate specific Animal Proteins (**EC 1069/2009 (21/10/2009)**). The main legislation of Bulgaria is based on that regulation.

8. FEED PENALTIES IN EU LEGISLATION

The basic principles related to responsibilities of the Member States' authorities are already laid down in the **Regulation (EC) No 178/2002**, which lays down the general principles of food law. The present regulation describes in more detail how these principles must be interpreted and implemented.

The official controls carried out by the Member States must enable them to verify and ensure compliance with national and Community rules on feed and food. To this end, official controls must in principle be carried out at any stage of production, processing and distribution of feed and food. These controls are defined as a function of the identified risks, the experience and knowledge gained from previous controls, the reliability of the controls already carried out by the business operators concerned, and a suspicion of possible non-compliance.

The most common penalties are given when there is not proper or insufficient labeling. Apart from the fine itself there is a high possibility that

the fodder will be returned to the producer and due to EU regulations the latter is obligated to demand the return of the false labeled fodder.

These Regulations are designed to fill in the loopholes in the existing legislation concerning the official control of food and feed thanks to a harmonised Community approach to the design and implementation of national control systems.

The purpose of this Regulation is:

To prevent or eliminate risks which may arise, either directly or via the environment, for human beings and animals, or reduce these risks to an acceptable level;

To guarantee fair practices as regards trade in food and feed and the protection of consumers' interests, including labeling of food and feed and any other form of information intended for consumers.

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 does not apply to official controls for the verification of compliance with the rules on common market organizations agricultural products.

The following two rules govern the feed penalty policies in Greece:

- **Law 4235/2014 (02.11.2014)**. Administrative measures, procedures and sanctions in the implementation of EU and national legislation in the fields of food, feed and health and animal welfare and other provisions by the Ministry of Rural Development and Food.

- **Judgment 2158-121168 (10/02/2014)**. Calculating the rate of measurement criteria for imposing administrative sanctions Article 23 of Law. 4235/2014 (A32) in the feed sector.

In Bulgaria the penalties are regulated in the **Low of forages**. If there is violation of the low the proper institution gave most of the time financial penalty which varies due to the type of violation and its turn.

As it is seen by the above mentioned, legislation is needed for the animal fodder and nutrition, in order to get both better and healthier products by animals.

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Council Directive 2002/32/EC – about controlled unusable substances

Regulation No 4; about feeds.

Regulation No 10; about feeds with special purpose.

Regulation No 21; about maximum concentrations of unsuitable substances and products in forages.

Regulation No 101; for feed supplements and the dates of prohibition of some in different species.

Regulation (EC) 1829/2003 – about genetically modified food and feed.

Low of GMO – (01.06.2005). Main law about GMO in Bulgaria.

Regulation 183/2005 – for Feed Hygiene requires, feed businesses that manufacture, market or use certain additives and products for animal feed approved and/or registered.

Regulation 882/2004 – performing the official control about to verify compliance with feed and food law and rules on the welfare of animals.

CMD 323306/2007 – Determination of necessary additional measures for the implementation of Regulations (EC) no. 178/2002 and no. 882/2004 of the European Parliament and the Council on the general principles of safety and official controls on feed.

CMD 155 344 (26.05.2001). About measures for the placing on the market and use of feed.

Circular 172 651 / 20.07.2011 – Clarifications for additional implementing about list of feed materials.

Regulation (EC) No 1831/2003 - for additives for use in animal nutrition.

JMD 275751 (20.08.2004) – for transmissible spongiform encephalopathy and animal nutrition.

JMD 275751 (20.08.2004). – amending JMD 275751 (20.08.2004) for transmissible spongiform encephalopathy and animal nutrition

(EC) 1069/2009 (21/10/2009). About health rules concerning animal by-products not intended for human consumption.

Law 4235/2014 (02.11.2014). Administrative measures, procedures and sanctions in the implementation of EU and national legislation in the fields of food, feed and health and animal welfare and other provisions by the Ministry of Rural Development and Food.

Judgment 2158-121168 (10/02/2014). Calculating the rate of measurement criteria for imposing administrative sanctions Article 23 of Law. 4235/2014 (A32) in the feed sector.

Low of forages – entered into use 07.07.2006 (last changed 13.02.2015).

http://www.nszf.bg/new/main.php?module=info&object=info&action=view&inf_id=67

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ABSTRACT

Study of European and national legislation of Bulgaria and Greece related to “Food safety and animal feed” is held. The study included legislation regulating the presence of mycotoxins, alkaloids of plant origin, inorganic contaminants in foodstuffs and genetically modified plants used as feed, as well as regulations for their control.

Key words: European regulation, national regulation of Bulgaria and Greece, HACCP system of control