


# Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2003/0071(COD) Procedure completed
Animal feed: hygiene requirements and traceability of feed Amended by <a href="#">2014/0255(COD)</a>	
Subject 3.10.08.01 Feedingstuffs, animal nutrition 4.60.04.04 Food safety	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	<b>ENVI</b> Environment, Public Health, Consumer Policy		04/11/2003
		PPE-DE <a href="#">KEPPELHOFF-WIECHERT Hedwig</a>	
	Committee for opinion	Rapporteur for opinion	Appointed
	<b>AGRI</b> Agriculture and Rural Development		20/05/2003
		PPE-DE <a href="#">PARISH Neil</a>	
Council of the European Union	Council configuration	Meeting	Date
	<a href="#">Agriculture and Fisheries</a>	<a href="#">2633</a>	21/12/2004
	<a href="#">Agriculture and Fisheries</a>	<a href="#">2578</a>	26/04/2004
	<a href="#">Agriculture and Fisheries</a>	<a href="#">2555</a>	18/12/2003
European Commission	Commission DG	Commissioner	
	<a href="#">Health and Food Safety</a>		

Key events			
14/04/2003	Legislative proposal published	<a href="#">COM(2003)0180</a>	Summary
12/05/2003	Committee referral announced in Parliament, 1st reading		
18/12/2003	Debate in Council	<a href="#">2555</a>	
08/03/2004	Vote in committee, 1st reading		Summary
08/03/2004	Committee report tabled for plenary, 1st reading	<a href="#">A5-0133/2004</a>	
30/03/2004	Debate in Parliament		
31/03/2004	Decision by Parliament, 1st reading	<a href="#">T5-0234/2004</a>	Summary
21/12/2004	Act adopted by Council after Parliament's 1st reading		
12/01/2005	Final act signed		
12/01/2005	End of procedure in Parliament		

08/02/2005

Final act published in Official Journal

### Technical information

Procedure reference	2003/0071(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amended by <a href="#">2014/0255(COD)</a>
Legal basis	EC Treaty (after Amsterdam) EC 152-p4; EC Treaty (after Amsterdam) EC 037-p2
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/5/19471

### Documentation gateway

Legislative proposal		<a href="#">COM(2003)0180</a>	14/04/2003	EC	Summary
Economic and Social Committee: opinion, report		<a href="#">CES1404/2003</a> <a href="#">OJ C 032 05.02.2004, p. 0097-0100</a>	29/10/2003	ESC	
Committee draft report		PE337.057	13/01/2004	EP	
Committee opinion	<b>AGRI</b>	PE329.816/DEF	22/01/2004	EP	
Amendments tabled in committee		PE337.057/AM	12/02/2004	EP	
Committee report tabled for plenary, 1st reading/single reading		<a href="#">A5-0133/2004</a>	08/03/2004	EP	
Text adopted by Parliament, 1st reading/single reading		<a href="#">T5-0234/2004</a> <a href="#">OJ C 103 29.04.2004, p. 0449-0555 E</a>	31/03/2004	EP	Summary
Follow-up document		<a href="#">COM(2007)0469</a>	14/08/2007	EC	Summary
Follow-up document		<a href="#">SEC(2007)1066</a>	14/08/2007	EC	

### Final act

[Regulation 2005/183](#)

[OJ L 035 08.02.2005, p. 0001-0022](#) Summary

Final legislative act with provisions for delegated acts

## Animal feed: hygiene requirements and traceability of feed

**PURPOSE** : to lay down general rules on feed hygiene and the conditions and arrangements ensuring full traceability of feed. **CONTENT** : this proposal concerns a new Regulation on hygiene requirements for animal feed. Directive 95/69/EC ensures that certain establishments and intermediaries that manufacture and circulate certain additives, premixtures and products covered by Directive 82/471/EEC are approved by the competent authorities verifying compliance with technical specifications. Therefore, rules already exist for aspects of animal feed, such as feed additives, controls and labelling. However, rules on the production, transport, storage and handling of feed as proposed today were missing. Feed businesses operating in the feed chain and carrying out activities other than those described in Directive 95/69/EC are exempt from the registration or approval requirement. Following the BSE crisis, the two serious occurrences of serious dioxin contamination and other concerns such as the contamination of feed materials and feedingstuffs with nitrofen or hormones, this draft regulation proposes: - to ensure the safety of all kinds of feed; - to ensure that all feed businesses operate in accordance with harmonised hygiene requirements; - to improve traceability. Also of particular importance is the obligation for feed operators to provide financial guarantees to cover the costs if something is wrong with their feed. The following main elements are included in the proposed Regulation: - It applies to the production of feed at all stages,

including the primary (on farm) production of feed. It will therefore provide improved traceability throughout the food chain. This last point is of particular importance to enable the swift and accurate identification of feed (and food derived from feed), should a problem be detected. This is essential for the effective protection of public health. - It repeats the requirement that only safe feed be placed on the market by businesses. This obligation on business is already enshrined in the EU Food Law Regulation for the food producing industry. Under current hygiene legislation, the primary responsibility for ensuring compliance with food law, and in particular the safety of food, rests with the food business. This proposal will extend the principle to the entire feed chain. Operators must respect hygiene requirements defined in the Regulation. For example, measures to control the contamination arising from air, soil, and water or plant protection products. Staff must demonstrate adequate training. - Feed business operators other than at the level of primary production must implement the HACCP (Hazard Analysis and Critical Control Points) system to identify where control is critical to ensure feed safety. This is a self-checking system by industry where each establishment will have to design a specific monitoring programme in which all potential hazards must be identified. Proper control procedures for each feed business must be set up individually and documents and records of whatever checks are carried out have to be kept. - The proposal introduces the compulsory registration of all feed businesses by the competent authority. The current obligation to approve after an on-the-spot check by the competent authorities certain types of feed producers who deal with particular substances such as antimicrobial substances will be maintained. - The development of guides of good practices for the production of feed is foreseen under the proposed Regulation. This will particularly affect the primary production on farm level. Hazards in feed may originate at farm level. This Regulation will provide Community legislation with an instrument that covers the entire feed chain and the food chain from farm to table. Codes of good practice will control possible hazards. Some countries or sectors do have such codes of good practice already. - Feed operators will be obliged to ensure a financial guarantee, such as insurance, to cover the cost of risks related to their businesses. This includes the costs arising from withdrawing products from the market, and the treatment or destruction of feed or affected food. - Provisions are made for equivalent standards for imported feed into the EU, particularly the requirement that feed only originates in establishments from which imports of feed are permitted. The following are excluded from the Regulation: - the private production of feed and the feeding of animals for home consumption; - the feeding of non-food-producing animals; - the retailing of pet food; - trade between farmers of small quantities of feed at local level. Member States will be allowed to establish, at national level, rules governing this exclusion. ?

## Animal feed: hygiene requirements and traceability of feed

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The committee adopted the report by Hedwig KEPPELHOFF-WIECHERT (EPP-ED, D) broadly approving the proposal (codecision procedure, 1st reading), subject to a number of amendments. The committee's main focus of concern was the provision of financial guarantees by feed businesses. It felt that it was too early at the present time to introduce a compulsory liability system at European level without having information and basic data on existing systems in the EU. MEPs therefore called for the decision on whether to introduce a liability system to be taken on the basis of a report drawn up by the Commission 12 months after the regulation enters into force. In the meantime, a voluntary system of financial guarantees should be put in place. The committee pointed out that, although the regulation provided for the relevant authorities to maintain a register of establishments, there was no requirement for this list to be published. As traceability was one of the proposal's key objectives, MEPs argued that any feed business operator should be able to consult a published EU list to check if its supplier is registered and that the public should be given access to the list of registered and approved establishments. Other amendments sought to ensure that preference was given to developing Community - rather than national - guides to good practice, and that indefinite approval should be given to establishments, subject to constant monitoring (the Commission had proposed that approval be renewed every 5 years). Lastly, the committee introduced an explicit provision into the body of the regulation stipulating that exports of feed to non-EU countries must satisfy the provisions of the 2002 regulation on the traceability of feed and feed ingredients.?

## Animal feed: hygiene requirements and traceability of feed

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The European Parliament adopted the report by Hedwig KEPPELHOFF-WIECHERT (EPP-ED, D) broadly approving the proposal subject to a number of amendments. The Parliament has included the following amendments: - experience has also shown that it is necessary to ensure that all feed businesses including aquaculture operate in conformity with harmonised safety requirements and that it is necessary to conduct a general review to take into account the need to ensure a higher level of protection of animal and human health, and of the environment; - in order to ensure the complete application of the registration and approval system to all the feed business operators and, consequently, to guarantee full traceability it is appropriate to ensure that feed business operators only source and use feed from establishments which are registered and/or approved in accordance with this Regulation; - the primary production of feed includes products which only undergo simple physical treatment such as cleaning, packaging, storage, natural drying or ensiling; - it is necessary to take into consideration the fact that the risk is less if feed is produced and used for animals only used for domestic consumption or for animals which are not used at all in food production. The trade of small quantities of feed products at local level and the retailing of petfood shall have particular treatment in the framework of this Regulation; - it is appropriate to ensure that operations carried out by a feed business at the level of primary production of feed, including associated operations as well as the mixing of feed with complementary feedingstuffs for the exclusive requirements of its own holding are not obliged to follow the HACCP; - a system of registration and approval by the competent authority of the Member State of all feed businesses is appropriate to ensure traceability from manufacturer to final user and to facilitate the implementation of effective official controls. The existing systems for collection of data concerning feed businesses may be used by the competent authority of the Member States to start up and implement the system provided for in this Regulation. Provision should be made for these conditions to be varied to ensure that they are appropriate to the various types of feed business. It is appropriate to allow Member States to grant conditional approval of establishments if it appears from the on-site visit that the establishment meets all the infrastructures and equipment requirements. However it is also appropriate to set a maximum length of time for such conditional approval. However, establishing a general mandatory system of financial liability and financial guarantees, for example through insurance, which applies to all feed business operators, may not be feasible or appropriate. The Commission should therefore consider this issue in greater depth, taking into account provisions in existing legislation with regard to liability in other spheres, as well as existing systems and practices amongst the Member States. To this end, the Commission should present a report, accompanied, where appropriate by legislative proposals. In order to avoid trade disruptions it is appropriate that, pending the completion of the implementing measures, imports shall continue to be authorised under the conditions laid down in Directive 98/51/EC; - it is appropriate to broaden the scope of the Rapid Alert System for Food and Feed laid down by Regulation 178/2002/EC to include risks to animal health or the environment from feed used for non food producing animals; - to prepare for an effective system of financial guarantees for feed business operators, the Commission shall submit a report on financial guarantees in the feed sector, within 12 months of the entry into force of this Regulation, which, in addition to examining the existing national legal provisions, systems and practices relating to liability in the feed sector and related sectors, shall be accompanied, where appropriate, by legislative proposals for such a feasible and practicable

guarantee system at EU level. These guarantees should provide cover for the total costs for which operators could be held liable as a direct consequence of the withdrawal from the market, treatment and/or destruction of any feed, animals and food produced therefrom. The competent authority may grant conditional approval if it appears from the on-site visit that the establishment meets all the infrastructure and equipment requirements. It shall grant full approval only if it appears from a new on-site visit carried out within three months of granting conditional approval that the establishment meets the other requirements referred to in the previous paragraph. If clear progress has been made but the establishment still does not meet all of these requirements, the competent authority may prolong conditional approval. However, conditional approval shall not exceed a total of six months.?

## Animal feed: hygiene requirements and traceability of feed

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PURPOSE: To lay down requirements for feed hygiene.

LEGISLATIVE ACT: Regulation 183/2005/EC of the European Parliament and of the Council.

CONTENT: Following the BSE crisis, the two serious occurrences of serious dioxin contamination and other concerns such as the contamination of feed materials and feedingstuffs with nitrofen or hormones, this regulation seeks:

- to ensure the safety of all kinds of feed;
- to ensure that all feed businesses operate in accordance with harmonised hygiene requirements;
- to improve traceability.

The principal objective of the new hygiene rules set out in this Regulation is to ensure a high level of consumer protection with regard to food and feed safety, taking particular account of the following principles:

- that primary responsibility for feed safety rests with the feed business operator; the need to ensure feed safety throughout the food chain, starting with primary production of feed, up to and including, the feeding of food-producing animals;
- the general implementation of procedures based on the principles of hazard analysis and critical control points (HACCP), which, together with the application of good hygiene practice, should reinforce feed business operators' responsibility;
- that guides to good practice are a valuable instrument to help feed business operators at all levels of the feed chain comply with feed hygiene rules and with the application of HACCP principles;
- the establishment of microbiological criteria based on scientific risk criteria;
- the need to ensure that imported feed attains a standard that is at least equivalent to that of feed produced in the Community.

ENTRY INTO FORCE: 08/02/2005.

DATE OF APPLICATION: 01/01/2006.

## Animal feed: hygiene requirements and traceability of feed

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The Commission presents a report on existing legal provisions and practices in the Member States and at Community level relating to liability in the food and feed sectors and on feasible systems for financial guarantees in the feed sector at Community level in accordance with Article 8 of Regulation (EC) No 183/2005.

The principle that feed business operators are liable for any infringements of the relevant legislation on feed safety and for the direct consequences of the withdrawal from the market, treatment and/or destruction of any feed, animals and food produced is laid down in Regulation (EC) No 183/2005. However, there is no provision in the Regulation with regard to financial guarantees in the feed sector. The purpose of the report is to set the scene for an effective system of financial guarantees for feed business operators.

Firstly, the report examines the existing legal provisions, systems and practices relating to liability and to financial guarantees in the feed and other sectors. Secondly, it proposes a feasible and practicable system of financial guarantees at Community level. The report analyses various options for financial guarantees.

Food and feed business operators at all stages of production, processing and distribution within the business under their control must ensure that food or feed products satisfy the requirements of food law which are relevant to their activities and must verify that such requirements are met. Although liability rules concerning food law in general must be adopted at national level, feed business operators are liable under Community legislation for any infringements of the relevant legislation on feed safety. However, they are not required to submit proof of a financial guarantee to ensure that they can pay the costs in case of liability. Except for expenses arising from additional official controls, Community legislation does not specifically govern liability in the food sector, instead requiring the Member States to lay down measures themselves. With regard to the feed sector, there are Community-specific grounds for liability in the field of feed hygiene, but the practicability of this depends on national legislation, which determines the legal relationships and obligations that constitute liability as well as the facts, circumstances and conditions under which such relationships and obligations arise. The national systems surveyed are characterised by certain differences as regards liability. Moreover, withdrawals ordered by the competent authorities generally depend on the legislation of the Member State, risk assessment and administrative discretion.

Consequently this means that the financial risk of a feed business operator related to liability claims for possible feed withdrawals and disposal may differ by country.

Financial guarantees in the feed sector ? such as in the form of insurance, bank guarantees, savings, pooling and funds ? are in principle a technically feasible option. However, the degree to which it would in practice be possible for feed business operators to obtain cover depends on the design of any system of financial guarantees. There is a risk that a system of financial guarantees, not appropriately designed and not taking into account criteria for insurability, could lead to a situation where cover could be almost unobtainable on the private market or only for prohibitively high premiums. Limits of coverage and trigger of financial guarantees should be clearly established.

Although product liability insurance exists in some Member States, little practical experience exists especially with recall insurance in the feed sector. At present there is no accurate knowledge on where the premium level would be set on such insurance, for example when it would cover events of large-scale feed withdrawal and disposal. The deductible would be set to a considerably high level. Some schemes are nevertheless either already operational or under preparation in the compound feed sector. Most insurers are at present very reluctant to enter this market, although some seem to be willing to take this risk under very strict underwriting conditions. The main question therefore is not whether such insurance cover for feed withdrawals and disposal is available (it is in some countries), but how, when and under what conditions would major European insurers be willing to enter this market.

The insurance sector is opposed to a compulsory system of financial guarantees in the feed sector - in general, introduction of any compulsory insurance would be strongly opposed by the insurance sector due to obvious problems related to such solutions. The national insurance associations cautioned against any developments in product recall insurance for the feed sector. Moreover, they doubt that such a system would enable feed business operators to fulfil the requirements as regards financial guarantees or meet the policy objectives of transferring withdrawal and disposal costs from the public to the private sector. Nevertheless, product liability insurances already exist in some Member States and their structure and scope is not far from the coverage sought here.

A large number of representatives of feed business operators are also opposed to a system of financial guarantees and, if such a system were to be set up, they would prefer it to be voluntary. One advantage of a voluntary system is the possibility of concluding contracts according to the specific needs and conditions of individual operators, without pushing out of business operators that are not willing or able to participate. The main disadvantages of this option are that the premium would be likely to be high, and if not mandatory, there might be a low percentage of covered operators, even more so due to the high level of the premium. If that were the case, liable operators affected by an incident but not covered by financial guarantees would have to find the means to afford the withdrawal and disposal costs. If they could not afford them or did not pay, this would ultimately compromise the objective of avoiding the spending of public funds for feed safety incidents. Therefore it is unlikely that such a system would reduce the financial burden on public authorities in large-scale crises, and the pressure on governments to support affected businesses would remain.

Some competent authorities support a system of financial guarantees, but are divided over whether such a system should be compulsory or not.

The measures laid down in the Regulation on feed hygiene, such as provisions for the sourcing of feed, traceability, hygiene, HACCP principles and registration, together with other food safety legislation, are important steps taken to reduce the risks and prevent the occurrence of accidents. The full implementation of all those measures by feed business operators should help to reduce the likelihood of major feed and food incidents similar to those witnessed in recent years. The new official controls framework, which is currently being implemented by the competent authorities for verifying business operators' compliance with the law, could become another efficient tool for strengthening feed and food safety.

The Commission states that, due to the complexity of the issue, it proposes to launch a broad public debate about the different options within two years of the publication of this report, followed by further analysis of the costs of financial guarantees and the assessment of the possible outcome of such measure.