

EUROPEAN PARLIAMENT

1999



2004

Session document

FINAL
A5-0133/2004

10 March 2004

*****I**

REPORT

on the proposal for a regulation of the European Parliament and of the Council
laying down requirements for feed hygiene
(COM(2003) 180 – C5-0175/2003 – 2003/0071(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Hedwig Keppelhoff-Wiechert

Symbols for procedures

- * Consultation procedure
majority of the votes cast
- **I Cooperation procedure (first reading)
majority of the votes cast
- **II Cooperation procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- *** Assent procedure
*majority of Parliament's component Members except in cases
covered by Articles 105, 107, 161 and 300 of the EC Treaty and
Article 7 of the EU Treaty*
- ***I Codecision procedure (first reading)
majority of the votes cast
- ***II Codecision procedure (second reading)
*majority of the votes cast, to approve the common position
majority of Parliament's component Members, to reject or amend
the common position*
- ***III Codecision procedure (third reading)
majority of the votes cast, to approve the joint text

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

	Page
PROCEDURAL PAGE	4
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	5
EXPLANATORY STATEMENT	18
OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT	21

PROCEDURAL PAGE

By letter of 14 April 2003 the Commission submitted to Parliament, pursuant to Articles 251(2), 37(2) and 152(4) of the EC Treaty, the proposal for a regulation of the European Parliament and of the Council laying down requirements for feed hygiene (COM(2003) 180 – 2003/0071(COD)).

At the sitting of 12 May 2003 the President of Parliament announced that he had referred the proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Agriculture and Rural Development for its opinion (C5-0175/2003).

The Committee on the Environment, Public Health and Consumer Policy appointed Hedwig Keppelhoff-Wiechert rapporteur at its meeting of 4 November 2003.

The committee considered the Commission proposal and draft report at its meetings of 20 January and 8 March 2004.

At the latter meeting it adopted the draft legislative resolution by 35 votes to 3, with 8 abstentions.

The following were present for the vote: Caroline F. Jackson (chairman), Alexander de Roo, Guido Sacconi (vice-chairmen), , Hedwig Keppelhoff-Wiechert (rapporteur) (for María del Pilar Ayuso González), Jean-Louis Bernié, Hans Blokland, David Robert Bowe, John Bowis, Martin Callanan, Chris Davies, Saïd El Khadraoui, Francesco Fiori (for Eija-Riitta Anneli Korhola pursuant to Rule 153(2)), Karl-Heinz Florenz, Robert Goodwill, Jutta D. Haug (for Dorette Corbey), Marie Anne Isler Béguin, Martin Kastler, Christa Klaß, Hans Kronberger, Bernd Lange, Peter Liese, Torben Lund, Albert Jan Maat (for Raquel Cardoso), Minerva Melpomeni Malliori, Erik Meijer (for María Luisa Bergaz Conesa), Rosemarie Müller, Neil Parish (for Raffaele Costa), Marit Paulsen, Encarnación Redondo Jiménez (for Avril Doyle), Dagmar Roth-Behrendt, Jacqueline Rousseaux, Yvonne Sandberg-Fries, Karin Scheele, Ursula Schleicher (for Marialiese Flemming), Inger Schörling, Jonas Sjöstedt, Renate Sommer (for Cristina García-Orcoyen Tormo), María Sornosa Martínez, Catherine Stihler, Robert William Sturdy (for Françoise Grossetête), Charles Tannock (for Cristina Gutiérrez Cortines), Nicole Thomas-Mauro, Antonios Trakatellis, Elena Valenciano Martínez-Orozco, Peder Wachtmeister and Phillip Whitehead.

The opinion of the Committee on Agriculture and Rural Development is attached.

The report was tabled on 10 March 2004.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council laying down requirements for feed hygiene
(COM(2003) 180 – C5-0175/2003 – 2003/0071(COD))

(Codecision procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to the European Parliament and to the Council (COM(2003) 180)¹,
 - having regard to Articles 251(2), 37(2) and 152(4) of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0175/2003),
 - having regard to Rule 67 of its Rules of Procedure,
 - having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinion of the Committee on Agriculture and Rural Development (A5-0133/2004),
1. Approves the Commission proposal as amended;
 2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;
 3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission

Amendments by Parliament

Amendment 1 Recital 12

(12) The application of HACCP principles to primary production of feed ***is not yet generally feasible***. But guides to good practice should ***encourage*** the use of appropriate hygiene requirements.

(12) The application of HACCP principles to primary production of feed is ***the medium-term objective of European hygiene legislation***. But guides to good practice should ***already be encouraging*** the use of appropriate hygiene requirements.

Justification

The medium-term objective of improved food and feed hygiene legislation should be the comprehensive application of the HACCP principles.

¹ OJ C ... / Not yet published in OJ.

Amendment 2
Recital 24

(24) Successive feed crises have shown that failures at any stage in the feed chain can have important economic consequences. Feed production and its complex distribution chain does not make it the withdrawal of feed from the market an easy task. The costs of rectifying the economic damages along the feed and food chain is often borne by public funds. The remedying of this economic consequence at a low cost to society could be improved if the operator, whose activity causes economic damage in the feed sector, is held financially responsible. ***This gives operators an incentive to meet high standards, which might not be met without such a system of financial liability. Operators should provide an appropriate financial guarantee, such as an insurance, in order to cover costs of the withdrawal of products from the market, treatment and/or destruction of feed and food produced therefrom. This can induce operators to adopt measures and develop practices to minimise the risks related to their activities.***

(24) Successive feed crises have shown that failures at any stage in the feed chain can have important economic consequences. Feed production and its complex distribution chain does not make it the withdrawal of feed from the market an easy task. The costs of rectifying the economic damages along the feed and food chain is often borne by public funds. The remedying of this economic consequence at a low cost to society could be improved if the operator, whose activity causes economic damage in the feed sector, is held financially responsible. ***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, with recommendations, within 12 months of the entry into force of this Regulation.***

Justification

Serious concerns have been expressed about the feasibility and appropriateness of this proposal. Establishing risk, cause and liability in feed crises is complex. Requiring mandatory financial guarantees may add significant cost to businesses, some of which are small, that do not in fact pose a significant risk. Insurance practices and products also vary considerably among the Member States: in some member states no insurance market exists in this area.

Amendment 3

Article 5, paragraph 1, subparagraph 1

1. Feed business operators at the level of primary production of feed shall comply with the provisions in Annex I, including the following associated operations:

1. Feed business operators at the level of primary production of feed ***including operators who produce feed on farm from primary products*** shall comply with the provisions in Annex I, including the following associated operations:

Justification

Clarifies the status of farmers mixing primary and compound feed ingredients on the farm.

Amendment 4
Article 5, paragraph 2

2. Feed business operators other than ***at the level of primary production of feed as*** referred to in paragraph 1 shall comply with the provisions in Annex II.

2. Feed business operators other than ***the primary producers*** referred to in paragraph 1 ***but including agricultural holdings which have registered as mixed feed establishments***, shall comply with the provisions in Annex II.

Justification

A clear distinction should be drawn between agricultural primary production, the registered or authorised production of mixed feed on fattening farms and feed processing establishments (most of which operate on a supranational basis).

Amendment 5
Article 8

Financial guarantees

Feed business operators shall ensure that a financial guarantee, such as insurance, is available to cover the cost of risks related to their businesses. This guarantee

Financial guarantees

1. To prepare for an effective system of financial guarantees for feed business operators within the meaning of Article 5(2), the Commission shall submit a

shall provide cover for the total costs of the withdrawal from the market, treatment and/or destruction of any feed and food produced therefrom.

report on financial guarantees in the feed sector, within 12 months after 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 also set out recommendations for such a feasible and practicable guarantee system at EU level.

2. Feed business operators within the meaning of Article 5(2) shall be liable for any infringements of the relevant legislation on feed safety and must submit proof that they are covered by an adequate financial guarantee, established after the feasibility study referred to in paragraph 1 and a period of not more than 12 months.

Justification

It is too early at the present time to introduce a compulsory liability system at European level without having information and basic data concerning existing systems in the EU. The decision whether to introduce a liability system, and which system, should be taken on the basis of a report drawn up by the Commission. There should be a voluntary system of financial guarantees in place while the Commission carry out their report and that practicable mandatory financial guarantees could come into effect following this report.

Amendment 6 *Article 9, paragraph 2*

2. The competent authority shall maintain a register of establishments.

2. The competent authority shall maintain **and publish** a register of establishments.

Justification

Article 20 provides for the establishment of a list of approved feed businesses. There is no equivalent requirement for registered feed businesses. Since traceability is clearly identified as a key objective of this proposal, we think that any feed business operator should have the possibility to check if its supplier is registered, which may only be achieved through an updated published EU list of registered feed business operators.

Amendment 7
Article 9, paragraph 2 a (new)

2a. The requirements of this paragraph shall not apply to feed businesses solely operating at the level of primary production or to livestock farms other than those requiring approval or registration in accordance with Directive 95/69/EC.

Justification

Farms which buy-in and mix certain additives (e.g. vitamins and trace elements) in feeds are currently subject to approval or registration under Directive 95/69/EC. This proposal would extend the registration requirement to hundreds of thousands of other farms in the EU, including arable farms that grow crops and sell them for feeds and livestock farms producing crops for their own animals. The registration requirement would have major implications for enforcement authorities and is not necessary because most farms can be identified by enforcement authorities through their participation in other schemes.

Amendment 8
Article 17

The approval of establishments shall be renewable every five years. The competent authority shall renew the approval of establishments only where an on-site visit has demonstrated that they meet the relevant requirements of this Regulation. ***deleted***

Justification

The imposition of a time limit on approvals offers no obvious advantage. On the one hand, permanent monitoring of the operators is guaranteed by the on-site visits provided for, while, on the other, Articles 14 and 15 provide sufficient opportunities for the competent authorities to withdraw from the register of approved establishments those which do not fulfil the current requirements.

Amendment 9
Article 19, paragraph 2

2. Establishments and intermediaries requiring neither approval nor registration in accordance with Directive 95/69/EC but requiring registration in accordance with this Regulation may continue their activities until **one year** from the day of application of this Regulation, on condition that they submit, to the relevant competent authority in whose area their facilities are located, an application for registration before the **day of application** of this Regulation.

In their application they must declare that the conditions laid down in this Regulation have been met.

2. Establishments and intermediaries requiring neither approval nor registration in accordance with Directive 95/69/EC but requiring registration in accordance with this Regulation may continue their activities until **18 months** from the day of application of this Regulation, on condition that they submit, to the relevant competent authority in whose area their facilities are located, an application for registration before the **date as from which** this Regulation **becomes applicable**.

In their application they must declare that the conditions laid down in this Regulation have been met.

In so doing, the competent authorities shall take account of the systems already existing for the collection of data and, in such cases, shall ask the applicant to provide solely the additional information required to ensure compliance with the conditions laid down in this Regulation. Registration or approval shall become effective upon the expiry of the period laid down. From that date onwards, feed businesses shall meet the requirements of this Regulation.

Justification

An extension to the possible continuation of the activities of businesses which have already submitted an application for registration or approval in accordance with the new Regulation should give the businesses more time in which to make the requisite preparations and adjustments. In the registration and approval procedures, the competent authorities should, as far as possible, use data already available under other data collection systems (for example, those relating to subsidies).

Amendment 10 Article 20

List of approved establishments

1. For each activity, the competent authority shall enter the establishments it has approved in accordance with Article 13

List of **registered and** approved establishments

1. For each activity, the competent authority shall enter **in a national list** the establishments it has **registered in**

in a national list under an individual identifying number.

2. Member States shall update the entries of establishments in the list referred in paragraph 1 in accordance with the decisions referred to in Articles 14, 15 and 16 to suspend, withdraw or amend approval.

3. The list referred to in paragraph 1 must be drawn up in accordance with the model set out in Annex V, Chapter I.

4. The approval number referred to in paragraph 1 shall be in the form set out in Annex V, Chapter II.

5. **Each Member State** shall publish **the list** of the establishments approved in accordance with Article 13 for the first time in [November ...], and thereafter each year, by 30 November at the latest, the consolidated list of amendments made during the year.

accordance with Article 9.

For each activity, **feed businesses** approved **by the competent authority** in accordance with Article 13 **shall be entered** in a national list under an individual identifying number.

2. Member States shall update the entries of establishments in the list referred in paragraph 1 in accordance with the decisions referred to in Articles 14, 15 and 16 to suspend, withdraw or amend **registration or** approval.

3. The list referred to in paragraph 1 must be drawn up in accordance with the model set out in Annex V, Chapter I.

4. The approval number referred to in paragraph 1 shall be in the form set out in Annex V, Chapter II.

5. **The Commission** shall **consolidate and publish that part of the Member States' lists which includes** the establishments approved in accordance with Article 13 for the first time in [November ...], and thereafter each year, by 30 November at the latest, the consolidated list of amendments made during the year.

The Member States shall also guarantee public access to that part of the list which includes the establishments registered in accordance with Article 9.

Justification

As provided for in Directive 95/69/EC, a list is to be kept of the establishments registered and approved. That list is to be constantly updated and, in the case of approvals, is also to be published by the Commission as a list of the establishments authorised to operate on the European market. The making available of the list of registered establishments by the Member States should serve towards the attainment of the key objective of this proposal - traceability - since it will enable feed businesses to ascertain whether their suppliers are registered.

Amendment 11 Article 21, paragraph 1

1. **Member States** shall encourage the

1. **The Commission** shall encourage the

development of ***national*** guides to good practice in the feed sector and for the application of HACCP principles in accordance with Article 22.
Community guides shall be developed in accordance with Article 23.

development of ***Community*** guides to good practice in the feed sector and for the application of HACCP principles in accordance with Article 23.
Where necessary, national guides ***may*** be developed ***by the Member States*** in accordance with Article 22.

Justification

The aim of this amendment is to spell out that - as far as possible - Community guides are to be given preference. Despite their non-binding character, Community-level guides contribute to the avoidance of possible distortions of competition. However, the possibility of national guides being adopted should be retained in order to take due account of the diversity of European feed production.

Amendment 12
Article 24 a (new)

Article 24a

Exports

Feed, including feed for non-food-producing animals, produced in the Community for placing on the market in third countries, must satisfy the provisions of Article 12 of Regulation (EC) No 178/2002.

Justification

This corresponds to similar provisions in the field of food hygiene. Although reference is made to the issue of exports in Recital 27, the operative part of the proposal for a regulation includes no corresponding reference.

National measures adapting the requirements of Annex II ***deleted***

1. Member States may, without compromising feed hygiene objectives, adopt national measures adapting the requirements laid down in Annex II in accordance with paragraphs 2 to 5 of this Article.

2. The national measures adapting the requirements laid down in Annex II shall:

(a) have the aim of accommodating the needs of feed businesses situated in regions suffering from special geographical constraints; or

(b) concern the construction, layout and equipment of establishments.

3. Any Member State wishing to adopt national measures adapting the requirements laid down in Annex II shall notify the Commission and other Member States. The notification shall:

(a) provide a detailed description of the requirements the Member State considers need to be adapted and the nature of the adaptation sought;

(b) describe the feed and establishment concerned;

(c) explain the reasons for the adaptation (including, where relevant, a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise hygiene objectives); and

(d) give any other relevant information.

4. Other Member States shall have three months from the receipt of a notification

referred to in paragraph 3 to send written comments to the Commission.

In the case of adaptations referred to in paragraph 2 (a) of this Article, this period shall, at the request of any Member State, be extended to four months.

The Commission may – and, when it receives written comments from one or more Member States, shall – consult Member States within the committee referred to in Article 31 (1). The Commission may decide, in accordance with the procedure referred to in Article 31 (2), whether the measures envisaged may be implemented subject, where necessary, to appropriate amendments. Where appropriate, the Commission may propose measures of general application in accordance with Articles 27 or 28.

5. A Member State may adopt national measures adapting the requirements of Annex II only:

(a) in compliance with a decision adopted in accordance with paragraph 4; or

(b) where, one month after the expiry of the period referred to in paragraph 4, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision referred to in point (a).

Justification

An amendment or an adjustment of the annexes is possible at any time under Article 31(2). The feed businesses concerned by Annex II operate principally on a cross-border basis in the single market. That being the case, additional adjustment at national level is unnecessary and may rapidly result in distortions of competition.

Amendment 14
Article 29 a (new)

Article 29a

Rapid Alert System

Should a specific feed, including feed for non-food-producing animals, present a serious risk to animal or human health or the environment, the provisions of Article 50 of Regulation (EC) No 178/2002 shall apply, mutatis mutandis.

Justification

Reference needs to be made to the Rapid Alert System laid down in Article 50 of Regulation (EC) No 178/2002 for the notification of a risk deriving from food or feed.

Amendment 15

Annex II, Facilities and Equipment, point 8

8. Windows and other openings must, where necessary, be ***fitted with pest-proof netted screens***. Doors must be close-fitting and ***pest-proof*** when closed.

8. Windows and other openings must, where necessary, be ***proofed against pests***. Doors must be close-fitting and ***proofed against pests*** when closed.

Justification

Facilities and equipment should be 'proofed against pests', not 'pest-proof'. It is virtually impossible to make an opening window or door 'pest-proof'.

Amendment 16

Annex II, Quality Control, paragraph 4

4. Samples of ingredients and of each batch of products placed on the market or of each specific portion of production (in the case of continuous production) must be taken in sufficient quantity using a procedure pre-established by the manufacturer and be retained in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration. They must be

4. Documentation relating to the raw materials used in end products must be kept by the manufacturer in order to ensure traceability. Such documentation must be available to the competent authorities for a period appropriate for the use to which the products are placed on the market.

In addition, samples of ingredients and of each batch of products placed on the market or of each specific portion of production (in the case of continuous production) must be taken in sufficient

kept at the disposal of the competent authorities for a period appropriate for the use to which the feed **are** placed **in** the market.

quantity using a procedure pre-established by the manufacturer and be retained in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration. They must be kept at the disposal of the competent authorities for a period appropriate for the use to which the feed **is** placed **on** the market.

In the case of petfood, no samples of ingredients need be taken.

Justification

The diversity of typically fresh raw materials of vegetable and animal origin used in the manufacture of feed makes it technically and logistically difficult, especially for petfood manufacturers, to retain samples of every raw material used. Accordingly, they should be exempted from the requirement to take and retain samples of ingredients. The storage of samples of the end product and the traceability of the raw materials on the basis of documentation relating to the raw materials used to be retained by the manufacturer may be regarded as adequate for product safety in this field.

Amendment 17

Annex II, Documentation, paragraph 2(b)(i)

(i) Additives:

- the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;
- the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;

(i) Additives:

- the nature and quantity of the additives produced, the respective dates of manufacture and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;
- ***name and address of the establishment to which the additives were delivered***, the nature and quantity of the additives delivered and, where appropriate, the number of the batch or of the specific portion of production, in the case of continuous manufacture;

Justification

Detailed information about the recipients of additives should be required, as is the case for

other products.

EXPLANATORY STATEMENT

Feed quality became the subject of European legislation for the first time in 1970. In that year, Directive 70/524/EEC laid down minimum requirements for the manufacturers of certain additives, premixtures and compound feedingstuffs including those additives. Particularly undesirable substances were restricted to tolerable levels in a 1973 Directive. Over the years, the legislation has been expanded to include approval for certain establishments which manufacture, produce or place on the market certain substances deemed problematical.

This initial attempt to differentiate on the basis of the degree of risk was retained in Directive 95/69/EC which is currently in force. Pursuant to that Directive, approval is a requirement for establishments which manufacture or use products with a high degree of risk (what are known as 'products classified as sensitive'), with the remaining establishments being simply required to register.

Approved or registered establishments are given a specific identifying number and recorded in separate lists kept by the competent authorities. In this way, the authorities may monitor feed manufacturers and, in the event of unlawful conduct, intervene. However, registration and approval of establishments are not watertight. For example, some establishments which are active in the feed chain but are also involved in activities other than those covered by the Directive are exempted. That applies in particular to primary production (agricultural holdings), the food industry, hauliers, feed merchants, etc.

Despite the improved feed hygiene legislation which entered into force in 1996, some incidents have occurred in recent years which have brought feed quality and safety into disrepute. For example, there were cases in Belgium, the Netherlands and Germany where dioxin levels in feed were exceeded, where feed was unlawfully treated with the pesticide Nitrofen, with the MPA hormone or with antibiotics, etc. The BSE crisis also came about because meat-and-bone meal was fed to cattle, hence because of the feed used. To that must be added a new aspect: the issue of genetically modified feed¹. In brief, we must reluctantly admit that food scandals in recent years have all too frequently resulted from feed scandals.

The increase in impurities in foodstuffs resulting from contaminated feed has brought to the surface a latent uncertainty in consumers which must be countered by changes in policy. The Commission has therefore proposed a new way of regulating feed hygiene, which, on the one hand, in connection with the White Paper on Food Safety, forms the keystone of the new version of hygiene legislation and, on the other, by extending and tightening up the legislation, seeks to give a tangible response to consumer uncertainty.

The Commission proposal

The Commission sets out the key objectives of the proposal very concisely: the aim is to guarantee the safety of feed throughout the feed chain, from the primary producers to livestock farmers. To that end, the Commission is proposing harmonised hygiene legislation for all feed businesses as well as stricter provisions to ensure traceability in the event of unlawful treatment of feed.

¹ This aspect was regulated afresh in Regulation (EC) No 1829/2003 which recently entered into force (OJ L 286, 20.10.2003, p. 1).

The elements in the proposal which are new by comparison with the Directive currently in force (Directive 95/69/EC) may be summed up as follows:

- introduction of the **HACCP principles** (establishment of hazard analysis and critical control points), obligatory for feed business operators and via guides to good practice for the primary production sector
- introduction of watertight **traceability** through obligatory registration and, where necessary, approval of all feed businesses
- extension to the entire feed production chain of the principle that **primary responsibility** for compliance with food legislation and food safety lies with the food businesses.

Accordingly, the proposal seeks to extend the scope of hygiene legislation to the entire feed chain, with obligatory registration and approval being extended to cover the activities of feed businesses at all stages, from primary production to the placing of feed on the market (Article 2). Exemption from that obligation is, however, granted to private domestic production of feed for private domestic consumption, the direct supply of small quantities at local level and the retailing of petfood, which are to be covered by national rules and guidance. Those exemptions correspond to the Commission's proposals concerning legislation applying to food hygiene (2000/178(COD)), currently at second reading stage in the European Parliament.

The gradual introduction of the HACCP principles is a logical step, given what is happening in other sectors involved in food safety. Initially, primary production remains exempt from obligatory application, although the guides to be published may be regarded as the first step towards the obligatory adoption of those principles.

The definition of responsibility, which, pursuant to Article 3(b), henceforth lies solely with feed business operators is new to the extent that, hitherto, the issue of responsibility (liability irrespective of culpability) had not been explicitly regulated. In the past, the costs involved in remedying economic damage were frequently borne by the public purse. In that connection, pursuant to Article 8, feed businesses must provide evidence that they are covered by a financial guarantee.

The possibility of national and Community guides being published to ensure good practice is also new. National guides are provided for principally in the area of the exemptions from the scope of the Directive set out in Article 2, especially agricultural primary production. Community guides are to serve the harmonisation of guides.

Finally, the provisions relating to the import of feed from third countries are repeated. The equivalence principle is to continue to apply, with lists being kept of the third countries and the establishments in third countries which comply with the rules.

Your rapporteur's assessment

Your rapporteur expressly welcomes the thrust proposed by the Commission in the revision of the Feed Hygiene Directive currently in force. The extension of hygiene legislation to the entire feed chain, the extension of the approval and registration obligation to cover all businesses active in the feed chain, as well as the gradual introduction of the internationally recognised HACCP principles of the *Codex Alimentarius* and systematic traceability correspond to the modern approach to feed and food hygiene legislation which is likely to

lead to an improvement in consumer confidence. In addition, with a view to uniform application, the decision to draw up the new legal act in the form of a regulation is expressly to be welcomed.

Of course, even the new legislation will not be able to prevent abuse or unlawful conduct. However, traceability and the consequent identification of responsibility will guarantee swift action so that risks to human and animal health and the environment may be countered by the taking of preventive measures.

However, some problematical aspects of the proposed revision need to be addressed. The major such problem, as your rapporteur sees it, is the provision of financial guarantees by the feed businesses. As we saw above, the Commission proposes - in Article 8 - that feed business operators be required to provide financial guarantees. That proposal is the one which has been most hotly contested by the sector concerned. The extension of the definition of 'feed business' to cover the entire feed chain entails the inclusion of every agricultural holding which does not produce exclusively for private domestic consumption. The possible extent of such risk liability might well result in unacceptably high costs for cover against that liability and could not, in any event, be introduced immediately on an obligatory basis without experimental data having first being collected. Accordingly, your rapporteur proposes that, initially, a voluntary system be introduced, since that would, for example, allow the insurance industry to apply to the feed production sector experience with risk cover options acquired from other branches. Should the results of that approach be positive, comprehensive and uniform cover might be established either via the market or as a result of pressure exerted by the legislator.

Your rapporteur is also proposing a number of other amendments seeking, for example, to ensure that, in the medium term, the HACCP principles are applied in the area of primary production, that preference is given to the publication of Community guides, that indefinite approval is given, subject to constant monitoring, and that access to the list of registered and approved establishments is facilitated.

28 January 2004

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on the Environment, Public Health and Consumer Policy

on the proposal for a regulation of the European Parliament and of the Council laying down
requirements for feed hygiene
(COM(2003) 180 – C5-0175/2003 – 2003/0071(COD))

Draftsman: Neil Parish

PROCEDURE

The Committee on Agriculture and Rural Development appointed Neil Parish draftsman at its meeting of 20 May 2003.

It considered the draft opinion at its meeting of 11 September, 24 November, 2 December and 22 January 2003.

At the last meeting it adopted the following amendments unanimously.

The following were present for the vote: Joseph Daul (chairman), Friedrich-Wilhelm Graefe zu Baringdorf, Albert Jan Maat (vice-chairmen), Neil Parish (draftsman), Gordon J. Adam, María del Pilar Ayuso González (for Agnes Schierhuber), Reimer Böge (for Michl Ebner), António Campos, Francesco Fiori, Georges Garot, Lutz Goepel, Willi Görlach, João Gouveia, María Esther Herranz García (for Encarnación Redondo Jiménez), María Izquierdo Rojo, Elisabeth Jeggle, Salvador Jové Peres, Hedwig Keppelhoff-Wiechert, Heinz Kindermann, Christa Klač (for Christos Folias), Xaver Mayer, Jan Mulder (for Giovanni Procacci), James Nicholson (for Robert William Sturdy), Ioannis Patakis (for Dimitrios Koulourianos), Mikko Pesälä, Christa Prets (for María Rodríguez Ramos), Dominique F.C. Souchet and Eurig Wyn (for Danielle Auroi).

SHORT JUSTIFICATION

The proposal fulfils a commitment in the Commission's White Paper on Food Safety of January 2000¹ to strengthen controls on safety throughout the animal feed chain. In particular, following a number of recent feed contamination cases in continental Europe, the Commission wants to improve the rules so that feeds can easily be traced and recalled if appropriate. Avoiding such food scares, and guaranteeing not only food safety, but also consumer confidence in EU food production, is essential for consumers and food producers alike.

It is vital to make sure that the necessary provisions to ensure feed safety are in place and properly enforced. However, the draftsman strongly believes that any system introduced should be as unbureaucratic, as easy to implement and as cheap as possible. Both the industry and farmers throughout the EU are under pressure from strict safety measures and heavy administrative burdens. The draftsman wishes to avoid unnecessary costs and burdens, especially to those who are least able to meet them.

Many of the proposals put forward by the Commission will help to strengthen feed safety, but the proportionality of some provisions needs to be examined more closely. The requirement for Member States to extend registration to all feed businesses brings a wide range of companies within the scope, e.g. importers and traders in feed materials, agricultural merchants selling feed to farmers and food businesses that sell surplus food for animal feed. In addition, the registration requirement would cover both arable farms and most livestock farms, if they sell their crops for feed production. Furthermore, the proposals could require the approval of a large number of establishments including certain primary producers who mix feed ingredients on their farms. Clarity is needed in respect of article 5 to ensure that those mixing primary feed ingredients (other than those listed under Article 10) are not subject to the more onerous requirements of Annex II. These points are of serious concern to the draftsman.

While recognising the need to be able to identify and isolate all those producers and feed businesses involved in the food production chain, the draftsman believes that this should be done without adding a tier of registration. The draftsman recognises the need for a complete identification of all feed business operators (including farms) by adapting existing registration systems, in order to enable the competent authorities to inspect operators. However, national registration systems, which are already in place and functioning for other purposes, should be utilised wherever possible to avoid unnecessary duplication and regulation. Currently the majority of farms can be identified through their participation in other schemes.

Feed businesses, except those involved solely in primary production, will be required to adopt HACCP principles. HACCP is a method of identifying potential hazards and ensuring that proper control strategies are in place. The draftsman welcomes the introduction of HACCP as a means of improving and tightening controls by monitoring hazards and identifying critical control points.

Clear guidance on the implementation of the proposed regulation on the individual farm level

¹ COM(1999) 719 final.

is needed. The draftsman believes that it is important to adopt a more focused approach which takes into account the huge differences between farms in different parts of the European Union to provide for a successful roll-out, and believes that it is important to allow sufficient time for operators to adapt to these more stringent requirements. An extension should be introduced for certain operators in order to fully meet their obligations.

The area of the most serious concern in the Commission proposal is the use of financial guarantees. All feed businesses (including farms) would need to fulfil a new requirement to have financial guarantees in place to cover the cost of withdrawing products in the event of a feed safety incident. This would be restricted to the withdrawal, treatment and possible destruction of products. Having consulted with the farming industry, feed manufacturers and the insurance sector, the draftsman finds that the consequences of introducing financial guarantees have not been sufficiently analysed. The feasibility of financial guarantees or insurance policies has not been properly developed with the industry, and it is unclear whether such guarantees would be available from the insurance sector. The cost implications for feed manufacturers and farmers from such a guarantee scheme are also unclear. The draftsman is not convinced that guarantees would improve feed safety, or promote a change in culture with the operators. It is suggested therefore that the Commission, in full consultation with feed manufacturers, farmers and insurers, should conduct a feasibility study over an 18-month period.

The draftsman has long been concerned over the safety and quality of imports into the EU. He therefore fully supports the provisions on imports from non-EU countries, which would require the same, or equivalent, standards to those in the EU.

The Annexes to the Regulation set out standards that must be complied with and cover criteria on facilities and equipment, personnel, production, quality control, storage and transport and record-keeping. However, these standards would apply to various types of premises, which operate differing systems, e.g., farms, pet food manufacturers, importers of feed materials. The draftsman therefore believes that a more focused approach, as reflected in current legislation¹ should be adopted.

¹ Council Directive 95/69/EC of 22 December 1995, OJ L 332 30.12.1995, pp. 15-32.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission ¹	Amendments by Parliament
<p>Amendment 1 Recital 22</p>	
<p>(22) 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.</p>	<p>(22) A system of registration and approval <i>or other identification</i> by the competent authority of the Member State of all feed businesses is appropriate to ensure traceability from manufacturer to final user.</p>
<p><i>Justification</i></p> <p><i>Consequential to amendments of articles 9 and 19.</i></p>	
<p>Amendment 2 Recital 24</p>	
<p>(24) Successive feed crises have shown that failures at any stage in the feed chain can have important economic consequences. Feed production and its complex distribution chain does not make it the withdrawal of feed from the market an easy task. The costs of rectifying the economic damages along the feed and food chain is often borne by public funds. The remedying of this economic consequence at a low cost to society could be improved if the operator, whose activity causes economic damage in the feed sector, is held financially responsible. <i>This gives operators an incentive to meet high standards, which might not be met without such a system of financial liability. Operators should provide an</i></p>	<p>(24) Successive feed crises have shown that failures at any stage in the feed chain can have important economic consequences. Feed production and its complex distribution chain does not make it the withdrawal of feed from the market an easy task. The costs of rectifying the economic damages along the feed and food chain is often borne by public funds. The remedying of this economic consequence at a low cost to society could be improved if the operator, whose activity causes economic damage in the feed sector, is held financially responsible. <i>However, establishing a general mandatory system of financial liability and financial guarantees, for example through insurance, which applies to all feed</i></p>

¹ OJ C 15.10.2003, p. ...

appropriate financial guarantee, such as an insurance, in order to cover costs of the withdrawal of products from the market, treatment and/or destruction of feed and food produced therefrom. This can induce operators to adopt measures and develop practices to minimise the risks related to their activities.

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, with recommendations, within 18 months of the entry into force of this Regulation.

Justification

Serious concerns have been expressed about the feasibility and appropriateness of this proposal. Establishing risk, cause and liability in feed crises is complex. Requiring mandatory financial guarantees may add significant cost to businesses, some of which are small, that do not in fact pose a significant risk. Insurance practices and products also vary considerably among the Member States: in some member states no insurance market exists in this area.

Amendment 3

Article 5, paragraph 1, subparagraph 1

1. Feed business operators at the level of primary production of feed shall comply with the provisions in Annex I, including the following associated operations:

1. Feed business operators at the level of primary production of feed ***including operators who produce feed on farm from primary products*** shall comply with the provisions in Annex I, including the following associated operations:

Justification

Clarifies the status of farmers mixing primary and compound feed ingredients on the farm.

Amendment 4

Article 5, paragraph 2

2. Feed business operators other than ***at*** the

2. Feed business operators other than the

level of primary production of feed as referred to in paragraph 1 shall comply with the provisions in Annex II.

*primary producers referred to in paragraph 1 **but including those agricultural establishments which have been designated as compound feed businesses,** shall comply with the provisions in Annex II.*

Justification

A clear distinction should be made between primary agricultural production, registered or authorised production of compound feedingstuffs on the fattening establishment and feed processing establishments (mostly operating nation-wide).

Amendment 5 Article 8

Feed business operators shall ensure that a financial guarantee, such as insurance, is available to cover the cost of risks related to their businesses. This guarantee shall provide cover for the total costs of the withdrawal from the market, treatment and/or destruction of any feed and food produced therefrom.

The Commission shall submit a report on financial guarantees in the feed sector, within 18 months after 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 also set out recommendations for a future, feasible and practicable guarantee system at EU level.

Justification

It is too early at the present time to introduce a compulsory liability system at European level without having information and basic data concerning existing systems in the EU. The decision whether to introduce a liability system, and which system, should be taken on the basis of a report drawn up by the Commission.

Amendment 6 Article 9, paragraph 2

2. The competent authority shall maintain a register of establishments.

2. The competent authority shall maintain **and publish** a register of establishments.

Justification

Article 20 provides for the establishment of a list of approved feed businesses. There is no equivalent requirement for registered feed businesses. Since traceability is clearly identified as a key objective of this proposal, we think that any feed business operator should have the possibility to check if its supplier is registered, which may only be achieved through an updated published EU list of registered feed business operators.

Amendment 7

Article 9, paragraph 2 a (new)

2a. The requirements of this paragraph shall not apply to feed businesses solely operating at the level of primary production or to livestock farms other than those requiring approval or registration in accordance with Directive 95/69/EC.

Justification

Farms which buy-in and mix certain additives (e.g. vitamins and trace elements) in feeds are currently subject to approval or registration under Directive 95/69/EC. This proposal would extend the registration requirement to hundreds of thousands of other farms in the EU, including arable farms that grow crops and sell them for feeds and livestock farms producing crops for their own animals. The registration requirement would have major implications for enforcement authorities and is not necessary because most farms can be identified by enforcement authorities through their participation in other schemes.

Amendment 8

Article 17

The approval of establishments shall be renewable every five years. ***deleted***

The competent authority shall renew the approval of establishments only where an on-site visit has demonstrated that they meet the relevant requirements of this Regulation

Justification

Under the existing arrangements for the approval of establishments in Directive 95/69/EC there are no provisions for the renewal of approvals. The frequency of visits to approved establishments to check that they continue to meet the requirements of the Regulation should be based on risk rather than standard time periods. In many cases this may mean inspection visits of less than every five years. Such visits will effectively renew the approval of establishments.

Amendment 9 Article 19, paragraph 1

1. Establishments and intermediaries approved and/or registered in accordance with Directive 95/69/EC may continue their activities ***until one year from the day of application of this Regulation***, on condition that they submit, to the relevant competent authority in whose area their facilities are located, an application for approval before the day of application of this Regulation.

In their application they must declare that the conditions laid down in this Regulation have been met.

1. Establishments and intermediaries approved and/or registered in accordance with Directive 95/69/EC may continue their activities on condition that they submit, to the relevant competent authority in whose area their facilities are located, an application for approval ***or registration*** before the day of application of this Regulation.

Justification

Farms which buy-in and mix certain additives (e.g. vitamins and trace elements) in feeds are currently subject to approval or registration under Directive 95/69/EC. This proposal would extend the registration requirement to hundreds of thousands of other farms in the EU, including arable farms that grow crops and sell them for feeds and livestock farms producing crops for their own animals. The registration requirement would have major implications for enforcement authorities and it is not necessary because most farms can be identified by enforcement authorities through their participation in other schemes.

Amendment 10 Article 19, paragraph 2

2. Establishments and intermediaries requiring neither approval nor registration in accordance with Directive 95/69/EC but requiring registration in accordance with this Regulation may continue their activities ***until one year from the day of application of this Regulation***, on condition that they submit, to the relevant competent authority in whose area their facilities are located, an application for registration before the day of application of this Regulation.

In their application they must declare that the conditions laid down in this Regulation have been met.

2. Establishments and intermediaries requiring neither approval nor registration in accordance with Directive 95/69/EC but requiring registration in accordance with this Regulation may continue their activities on condition that they submit, to the relevant competent authority in whose area their facilities are located, an application for registration before the day of application of this Regulation.

The requirements of this paragraph shall not apply to feed businesses solely operating at the level of primary production or to livestock farms other than those requiring approval or registration under 95/69/EC.

Justification

The proposal would extend the registration requirement to hundreds of thousands of other farms in the EU, including arable farms that grow crops and sell them for feeds and livestock farms producing crops for their own animals. The registration requirement would have major implications for enforcement authorities and it is not necessary because most farms can be identified by enforcement authorities through their participation in other schemes.

Amendment 11 Article 19, paragraph 2 a (new)

2a. The competent authority shall decide:

(a) within one year from the day of application of this regulation on applications submitted in accordance with paragraph 1.

(b) within three years from the day of application of this regulation on applications submitted in accordance with

paragraph 2.

Justification

The proposal places new requirements on many feed businesses (including many small businesses) and they should be given sufficient time (three years) to make the necessary upgrades and adaptations.

Amendment 12
Article 19, paragraph 2 b (new)

2b. Feed businesses solely operating at the level of primary production or livestock farms other than those requiring approval or registration under 95/69/EC shall comply with the requirements of this legislation within 3 years from the day of application of this Regulation.

Justification

The proposal places new requirements on many feed businesses (including many small businesses) and they should be given sufficient time (three years) to make the necessary upgrades and adaptations.

Amendment 13
Annex II, Facilities and Equipment, point 8

8. Windows and other openings must, where necessary, be ***fitted with pest-proof netted screens***. Doors must be close-fitting and ***pest-proof*** when closed.

8. Windows and other openings must, where necessary, be ***proofed against pests***. Doors must be close-fitting and ***proofed against pests*** when closed.

Justification

Facilities and equipment should be ‘proofed against pests’, not ‘pest-proof’. It is virtually impossible to make an opening window or door ‘pest-proof’.

Amendment 14
Annex II, Quality Control, point 4

4. Samples of ingredients and of each batch of products placed on the market or of each specific portion of production (in the case of continuous production) must be taken in sufficient quantity using a procedure pre-established by the manufacturer and be retained in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration. They must be kept at the disposal of the competent authorities for a period appropriate for the use to which the feed are placed in the market.

4. Samples of ingredients and of each batch of products placed on the market or of each specific portion of production (in the case of continuous production), ***or as appropriate records to be kept in a register by the manufacturer for at least two years***, must be taken in sufficient quantity using a procedure pre-established by the manufacturer and be retained in order to ensure traceability (on a regular basis in the case of manufacture solely for the manufacturer's own needs). The samples must be sealed and labelled for ease of identification; they must be stored under conditions which prevent any abnormal change in the composition of the sample or any adulteration. They must be kept at the disposal of the competent authorities for a period appropriate for the use to which the feed are placed in the market.

In the case of feedingstuffs for non-food producing animals, the manufacturer of the feedingstuff intended for direct animal feeding must only keep samples of the finished product.

Justification

Traceability tools, such as sampling, should be proportional and practicable. In the case of feed for non-food producing animals, a broad variety of different and typically fresh animal and vegetable by-products is used, in particular for pet food. Large cold stores to keep samples for typically fresh ingredients would not be practicable and appropriate. Paper records kept for at least two years are also recognised as an appropriate traceability tool for example in Regulation 1774/2002/EC on health rules concerning animal by-products not intended for human consumption (Art. 9, Art. 18 [2] [i], Annex II Chapter IV & V). For feed intended for non-food producing animals the keeping of samples of the finished feedingstuffs intended for direct feeding is regarded as appropriate, proportional and practicable for safety guarantees.