

EUROPEAN ECONOMIC AREA
EFTA SURVEILLANCE AUTHORITY

RECOMMENDATION OF THE EFTA SURVEILLANCE AUTHORITY

No 65/04/COL

of 31 March 2004

concerning a coordinated programme for the official control of feedingstuffs for 2004

THE EFTA SURVEILLANCE AUTHORITY,

Agreement, and the protection of public and animal health.

Having regard to the Agreement on the European Economic Area, and in particular Article 109 and Protocol 1 thereof,

Having regard to the Agreement between the EFTA States on the establishment of a Surveillance Authority and a Court of Justice, and in particular Article 5(2)(b) and Protocol 1 thereof,

Having regard to the Act referred to at point 31a of Chapter II of Annex I to the EEA Agreement (Council Directive 95/53/EC of 25 October 1995 fixing the principles governing the organisation of official inspections in the field of animal nutrition⁽¹⁾), as amended, and as adapted to the EEA Agreement by Protocol 1 thereto, and in particular Article 22(3) thereof,

Whereas:

(1) It is necessary, with a view to the sound operation of the European Economic Area, to arrange for coordinated feed inspection programmes within the EEA designed to improve the harmonised implementation of the official controls by the EEA States.

(2) Such programmes should place emphasis on complicity with the relevant legislation in force under the EEA

(3) The results from simultaneous implementation of national programmes and coordinated programmes may provide information and experience on which to base future control activities and legislation.

(4) Although the Act referred to at point 33 of Chapter II of Annex I to the EEA Agreement (Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed⁽²⁾) establishes maximum contents of aflatoxin B₁ in feedingstuffs, there is no legislation in force under the EEA Agreement for other mycotoxins, such as ochratoxin A, zearalenone, deoxynivalenol and fumonisins. Gathering information on the presence of those mycotoxins through random sampling could provide useful data for an assessment of the situation with a view to the development of the legislation. Furthermore, certain feed materials such as cereals and oil seeds are particularly exposed to mycotoxin contamination because of harvesting, storage and transport conditions. As mycotoxin concentration varies from year to year, it is appropriate to collect data from consecutive years for all mycotoxins mentioned.

(5) Previous checks for the presence of antibiotics and coccidiostats in certain feedingstuffs where those substances are not authorised indicate that this type of infringement still occurs. The frequency of such findings and the sensitivity of this matter justify the continuation of checks.

⁽¹⁾ OJ L 265, 8.11.1995, p. 17. Directive as last amended by Directive 2001/46/EC of the European Parliament and of the Council (OJ L 234, 1.9.2001, p. 55).

⁽²⁾ OJ L 140, 30.5.2002, p. 10. Directive as last amended by Commission Directive 2005/8/EC (OJ L 27, 29.1.2005, p. 44).

- (6) The participation of Norway and Iceland in the programmes within the scope of Annex II of this Recommendation concerning substances not authorised as feed additives will have to be evaluated with respect to their exemptions from Chapter II of Annex I to the EEA Agreement.
- (7) It is important to ensure that the restrictions on the use of feed materials of animal origin in feedingstuffs, as laid down in the relevant EEA legislation, are effectively enforced.
- (8) The case of contamination of the feed and food chain with medroxyprogesterone acetate (MPA) highlighted the value of the selection of supplies in the safety of feedingstuffs. Some ingredients in feedingstuffs are by-products of agri-food industries, or of other industries, or of mineral extraction. The source of feed materials of industrial origin and the processing methods applied to them may be of particular significance in the safety of the products. Therefore the competent authorities should consider this aspect when carrying out their checks.
- (9) The measures provided for in this Recommendation are in accordance with the opinion of the EFTA Plants and Animal Feedingstuffs Committee assisting the EFTA Surveillance Authority,
- analysis; the method of sampling should comprise both random and targeted sampling; in the case of targeted sampling, the samples should be feed materials suspected of containing higher concentrations of mycotoxins, such as cereal grains, oil seeds, oil fruits, their products and by-products, and feed materials stored for a long time or transported by sea over a long distance; the results of the checks should be reported using the model set out in Annex I;
- (b) certain medicinal substances, whether or not authorised as feed additives for certain animal species and categories, in non-medicated pre-mixtures and compound feedingstuffs in which these medicinal substances are not authorised; the checks should target those medicinal substances in pre-mixtures and compound feedingstuffs if the competent authority considers that there is a greater probability of finding irregularities; the results should be reported using the model set out in Annex II;
- (c) the implementation of restrictions on the production and use of feed materials of animal origin, as set out in Annex III;
- (d) the procedures applied by manufacturers of compound feedingstuffs in order to select and assess their supplies of feed materials of industrial origin and to ensure the quality and safety of such ingredients, as set out in Annex IV.
- HEREBY RECOMMENDS TO THE EFTA STATES:
1. During 2004, to carry out a coordinated inspection programme aimed to check:
- (a) the concentration of mycotoxins (aflatoxin B₁, ochratoxin A, zearalenone, deoxynivalenol and fumonisins) in feedingstuffs, indicating the methods of
2. To include the results of the coordinated inspection programme provided for in paragraph 1 in a separate Chapter in the annual report on inspection activities to be transmitted to the EFTA Surveillance Authority by 1 April 2005 in accordance with Article 22(2) of Directive 95/53/EC and the latest version of the harmonised reporting model.

Done at Brussels, 31 March 2004.

For the EFTA Surveillance Authority

Bernd HAMMERMAN
College Member

Niels FENGER
Director

ANNEX I

Concentration of certain mycotoxins (aflatoxin B₁, ochratoxin A, zearalenone, deoxynivalenol, fumonisins) in feedingstuffs

Individual results of all tested samples; model for reports as referred to in paragraph 1(a)

Feedingstuffs		Sampling (random or targeted)	Type and concentration of mycotoxins (µg/kg relative to a feedingstuff with a moisture content of 12 %)				
Type	Country of origin		Aflatoxin B ₁	Ochratoxin A	Zearalenone	Deoxynivalenol	Fumonisins ⁽⁴⁾

⁽⁴⁾ The concentration of fumonisins comprises the total of fumonisins B₁, B₂ and B₃.

The competent authority should also indicate:

- the action taken when maximum levels for aflatoxin B₁ are exceeded,
- the methods of analysis used,
- the limits of detection.

ANNEX II

Presence of certain substances not authorised as feed additives

Certain antibiotics, coccidiostats and other substances may be legally present as additives in pre-mixtures and compound feedingstuffs for certain species and categories of animals, when authorised under the Act referred to at point 1 of Chapter II of Annex I to the EEA Agreement (Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ⁽¹⁾).

The presence of unauthorised substances in feedingstuffs constitutes an infringement.

The substances to be controlled should be chosen from the following:

1. Substances authorised as feed additives for certain animal species or categories only:

avilamycin	monensin sodium
decoquate	narasin
diclazuril	narasin — nicarbazin
flavophospholipol	robenidine hydrochloride
halofuginone hydrobromide	salinomycin sodium
lasalocid A sodium	semduramicin sodium
maduramicin ammonium alpha	

2. Substances no longer authorised as feed additives:

amprolium	nicarbazin
amprolium/ethopabate	nifursol
arprinocid	olaquinox
avoparcin	ronidazol
carbadox	spiramycin
dimetridazole	tetracyclines
dinitolmid	tylosin phosphate
ipronidazol	virginiamycin
meticlorpindol	zinc bacitracin
meticlorpindol/methylbenzoate	other antimicrobial substances

3. Substances never authorised as feed additives:

other substances

Individual results of all non-compliant samples; model for reports as referred to in paragraph 1(b)

Type of feedingstuff (animal species and category)	Substance detected	Level found	Reason for the infringement ^(e)	Action taken

^(e) Reason leading to the presence of the unauthorised substance in the feedingstuff, as concluded after an investigation carried out by the competent authority.

⁽¹⁾ OJ L 270, 14.12.1970, p. 1.

The competent authority should also indicate:

- the total number of samples tested,
 - the names of the substances which have been investigated,
 - the methods of analysis used,
 - the limits of detection.
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ANNEX III

Restrictions on the production and use of feed materials of animal origin

Without prejudice to Articles 3 to 13 and 15 of Directive 95/53/EC, the EFTA States should during 2004 undertake a coordinated inspection programme to determine whether restrictions on the production and use of feed materials of animal origin have been complied with.

In particular, in order to ensure that the ban on feeding processed animal protein to certain animals, as laid down in the Annex IV of the Act referred to at point 7, 1, 12 of Chapter I of Annex I to the EEA Agreement (Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾), are effectively applied, EFTA States should implement a specific control programme based on targeted controls. In accordance with Article 4 of Directive 95/53/EC, that control programme should be based on a risk-based strategy where all stages of production and all types of premises where feed is produced, handled and administered are included. EFTA States should pay special attention to the definition of criteria that can be related to a risk. The weighting given to each criterion should be proportional to the risk. The inspection frequency and the number of samples analysed in the premises should be in correlation to the sum of weightings allocated to those premises.

The following indicative premises and criteria should be considered when drawing up a control programme:

Premises	Criteria	Weighting
Feed mills	<ul style="list-style-type: none"> — Double-stream feed mills producing ruminant compound feed and non-ruminant compound feed containing derogated processed animal proteins — Feed mills with previous history, or suspicion, of non-compliance — Feed mills with a large amount of imported feedingstuffs with high protein content such as fishmeal, soybean meal, corn gluten meal and protein concentrates — Feed mills with a high production of compound feed — Risk of cross-contamination resulting from internal operational procedures (dedication of silos, control of the effective separation of lines, control of ingredients, internal laboratory, sampling procedures, etc.) 	
Border Inspection Posts and other points of entry into the EEA	<ul style="list-style-type: none"> — Large/small amount of imports of feedingstuffs — Feedingstuffs with high protein content 	
Farms	<ul style="list-style-type: none"> — Home mixers using derogated processed animal proteins — Farms keeping ruminants and other species (risk of cross feeding) — Farms purchasing feedingstuffs in bulk 	
Dealers	<ul style="list-style-type: none"> — Warehouses and intermediate storage of feedingstuffs with high protein content — High volume of bulk feedingstuffs traded — Dealers in compound feedingstuffs produced abroad 	
Mobile mixers	<ul style="list-style-type: none"> — Mixers producing for both ruminants and non-ruminants — Mixers with previous history, or suspicion, of non-compliance — Mixers incorporating feedingstuffs with high protein content — Mixers with high production of feedingstuffs — Large number of farms served including farms which keep ruminants 	
Means of transportation	<ul style="list-style-type: none"> — Vehicles used for the transportation of processed animal proteins and feedingstuffs — Vehicles with previous history, or suspicion, of non-compliance 	

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

As an alternative to these indicative premises and criteria, EFTA States may forward their own risk assessment to the EFTA Surveillance Authority before 30 April 2004.

Sampling should be targeted on batches or events where cross-contamination with prohibited processed proteins is most likely (first batch after the transport of feedingstuffs containing animal protein prohibited in this batch, technical problems or changes in production lines, changes in storage bunkers or silos for bulk material).

The minimum number of inspections per year in an EFTA State should be 10 per 100 000 tonnes of compound feed produced. The minimum number of official samples per year in an EFTA State should be 20 per 100 000 tonnes of compound feed produced. Pending the approval of alternative methods, microscopic identification and estimation as described in Commission Directive 98/88/EC of 13 November 1998 establishing guidelines for the microscopic identification and estimation of constituents of animal origin for the official control of feedingstuffs⁽¹⁾ should be used for analysing samples. Any presence of prohibited constituents of animal origin in feedingstuffs should be considered as a breach of the feed ban.

The results of the inspection programmes should be communicated to the EFTA Surveillance Authority using the following formats:

Summary of checks concerning feeding restrictions for feed of animal origin (feeding of prohibited processed animal proteins)

A. Documented inspections

Stage	Number of inspections comprising checks on the presence of processed animal proteins	Number of breaches based on documentary checks etc. rather than laboratory testing
Import of feed materials		
Storage of feed materials		
Feed mills		
Home mixers/mobile mixers		
Intermediaries of feedingstuffs		
Means of transport		
Farms keeping non-ruminants		
Farms keeping ruminants		
Others:		

B. Sampling and testing of feed materials and compound feedingstuffs for processed animal proteins

Premises	Number of official samples tested for processed animal proteins		Number of non-compliant samples						
			Presence of processed animal protein from terrestrial animals			Presence of processed animal protein from fish			
	Feed materials	Compound feeding-stuffs		Feed materials	Compound feeding-stuffs		Feed materials	Compound feeding-stuffs	
for ruminants		for non-ruminants	for ruminants		for non-ruminants	for ruminants		for non-ruminants	
At import									
Feed mills									
Intermediaries/ storage									
Means of transport									
Home mixers/ mobile mixers									
On farm									
Others:									

⁽¹⁾ OJ L 318, 27.11.1998, p. 45.

C. Summary of prohibited processed animal proteins found in samples of feedingstuffs intended for ruminants

	Month of sampling	Type, degree and origin of contamination	Sanctions (or other measures) applied
1			
2			
3			
4			
5			
...			

In addition, EFTA States should analyse fats and vegetable oils intended for feedingstuffs for the presence of traces of bones and include the results of such analyses in the report referred to in paragraph 2 of this Recommendation.

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ANNEX IV

Procedures for selection and assessment of supplies of feed materials of industrial origin

The competent authorities should identify and shortly describe the procedures followed by manufacturers of compound feedingstuffs in order to select and assess supplies of feed materials of industrial origin. Some procedures may be related to the prior establishment of characteristics or requirements for the products to be supplied, or for the suppliers. Other procedures may be related to own-checks for the verification of compliance with certain parameters, carried out by manufacturers of compound feedingstuffs at the reception of supplies.

For each identified procedure (procedure for selection and assessment of supplies), the competent authorities should indicate the advantages and disadvantages of the application of the procedure in terms of feed safety. Finally they should assess whether, taking into account the potential risks, each procedure is acceptable, insufficient or unacceptable for ensuring the safety of feedingstuffs, stating the reasons leading to that conclusion.

Evaluation of procedures

Procedure (short description, including criteria for acceptance/rejection of feed materials)	Advantages	Disadvantages	Assessment of acceptability of procedures