



Federal Ministry
of Food, Agriculture and
Consumer Protection

Legislation on undesirable substances in feed in the European Union

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Directive 2002/32/EC

Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed

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The latest consolidated version (26.2.2013)

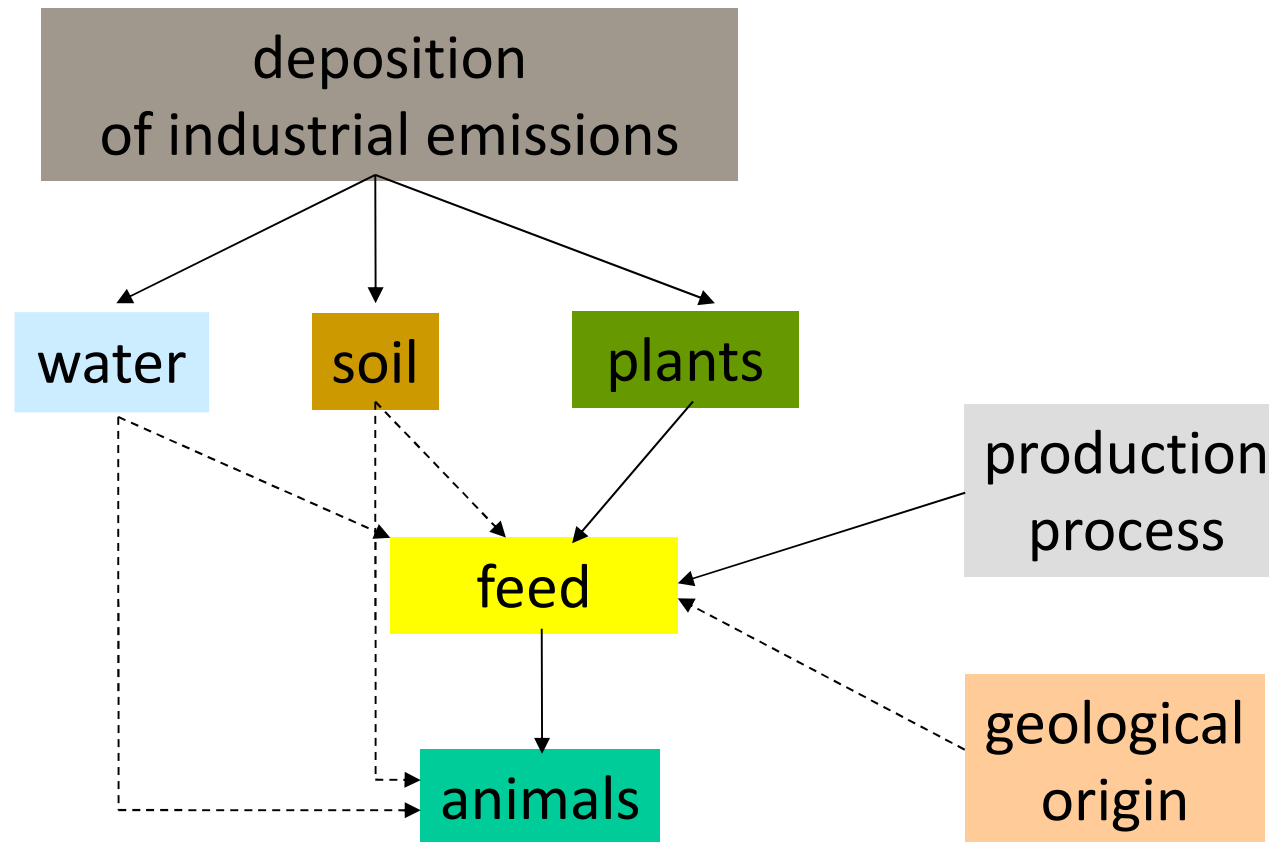
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002L0032:20130226:EN:HTML>

Directive 2002/32/EC

- Animal feed can be a significant **source of contaminants** entering the food chain and the environment.

Transfer of undesirable substances from feed into edible products of food producing animals, including **biotransformation**.

Sources of undesirable substances in feed



Directive 2002/32/EC

- The measures of the Directive help to eliminate or reduce the contamination of feed and contribute to protect:
 - consumer health
 - animal health
 - productivity of livestock
 - environment.
- Products intended for animal feed

‘...must be sound, genuine and of merchantable quality...’

Undesirable substance

*‘ .. **any substance or product**, with the exception of pathogenic agents, which is present in and/or on the product intended for animal feed and which presents a potential **danger to animal or human health** or to the **environment** or could adversely affect livestock production.’*



The definition of undesirable substances includes all substances irrespective whether they are listed in the Annexes of the Directive or not.

Feed

The Directive covers all types of feed:

- **Feed materials**, including roughage, pasture, minerals, feed materials of animal origin,
- **Compound feed**, including complementary feed and complete feed
- **Additives**,
- **Premixtures** and
- **Drinking water for animals** (based on national law)

Animals

The Directive covers feed for **all animals**, who are fed:

- Livestock (e.g. cattle, pigs)
- Poultry
- Fish
- Horses
- Fur animals
- Pets
- Zoo/circus animals
- Game and other wild animals.

Substances

Substances with maximum limits in Annex I :

- **Heavy metals** (e.g. Hg, Pb, As, Cd);
- Other toxic elements (e.g. F, nitrate);
- **Mycotoxins** (e.g. aflatoxin B1);
- **Organochlorides** (e.g. Dioxins, dl and ndl PCBs, aldrin, dielrin, DDT, HCB, HCH);
- **Plant toxins** (e.g. gossypol, theobromin);
- **Harmful botanical impurities** (e.g. *Ricinus communis*, *Ambrosia* spp.)
- Authorised feed additives in feed for non-target animals from **unavoidable carry-over** (coccidiostats e.g. diclazuril, monensin, narasin)

Eexample from Annex I of Directive 2002/32

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▼ M14

SECTION VII: AUTHORISED FEED ADDITIVES IN NON-TARGET FEED FOLLOWING UNAVOIDABLE CARRY-OVER

Coccidiostat	Products intended for animal feed ⁽¹⁾	Maximum content in mg/kg (ppm) relative to a feed with a moisture content of 12 %
1. Decoquinate	Feed materials	0,4
	Compound feed for	
	— laying birds and chickens reared for laying (> 16 weeks),	0,4
	— chickens for fattening for the period before slaughter in which the use of decoquinate is prohibited (withdrawal feed),	0,4
	— other animal species.	1,2
	Premixtures for use in feed in which the use of decoquinate is not authorised.	(²)

Substances

Other substances **controlled** by Directive 2002/32/EC

- ✓ Cross contamination of feed additives
- ✓ Cross contamination of veterinary medicines
- ✓ Cross contamination of pesticides
- ✓ Cross contamination of biocides
- ✓ **any other harmful substances** in feed not authorised for use in feed

Measures should be taken based on a single case
risk assessment.

Substances

Substances **not controlled** by Directive 2002/32/EC

- Pathogenic micro-organisms (e.g. *Salmonella spp*);
- Non-authorised GMO –material
- Processed animal proteins (PAP)



Covered by other EU legislation

Risk assessment

- The risk assessments of undesirable substances in feed are performed by **EFSA's CONTAM Panel**.
- The opinions are published on the EFSA website.
- Recent opinions have included feed and food (e.g. ergot alkaloids, "new" mycotoxins (citrinin, phomopsins), T-2 and HT-2-toxin).
- Also national risk assessment authorities are involved in the risk assessment via EFSA-net (e.g. German Institute of Risk Assessment)

Risk management

- Risk management is generally performed at the Standing Committee under voting procedures in Directive 2002/32.
- The main options considered are whether or not **maximum limits** (Annex I) and/or action thresholds (Annex II) should be set.
- Also **recommendations** can be set.
- In case of emergency also Member States can take preliminary measures and notify to the European Commission.
- The European Commission ask the EFSA for risk assessment and take appropriate measures.

Member States are responsible for implementation and enforcement.

Safety Concept of Directive 2002/32/EC

- The provisions apply for **all types of feed**, including additives, premixtures.
- The **maximum limit** for complete feed applies for the **daily ration**.
- The content of undesirable substances in **feed materials and complementary feed** shall not exceed the maximum limit for the daily ration, taking into account the intended use of the feed material and complementary feed (labelling provision for complementary feed, which exceed the level for complete feed).

Daily ration means the average total quantity of feedingstuffs, calculated on a moisture content of 12 %, required daily by an animal of a given species, age class and yield, to satisfy all its needs.

Safety Concept of Directive 2002/32/EC

- Feed exceeding the maximum limits established in Annex I shall **not be placed on the market or diluted** with the same or other feed.
- In case of exceeding the maximum limits the feed business operator and the competent authority are obligated to **detect the source** of undesirable substances and **measures should be taken** to reduce or eliminate the undesirable substances.
- **Action levels** can be established to trigger actions, taking into account the background level when continued effort is still needed to restrict the presence of some specific undesirable substances to the lowest possible level.

Exceeding maximum levels

- It is prohibited to **use or feed feed exceeding a maximum limit**.
- Valid options for dealing with such consignments include **decontamination processes**, but not 'blending down' or dilution.
- Products that exceed a limit should be notified *via* the **rapid alert system for food and feed** (RASFF), if the feed, when correctly used, represent any danger to human health, animal health or the environment or could adversely affect livestock production..

Action thresholds

- **Action threshold** can be set where further initiatives are being taken to reduce further the levels of certain undesirable substances in feed.
- They would be set **below the corresponding maximum level**.
- Only for **dioxins and dioxin-like PCBs** action thresholds are established.
- Where an action threshold is exceeded, **investigations must be undertaken and the sources of contamination should be identified**. These sources should then be **reduced or eliminated**.
- The action threshold is not a maximum level in law. No offence has been committed, provided that the 'official' maximum limit is not exceeded.

Guidance values

- **Guidance values** are established with Commission Recommendations
 - ✓ DON, ZEA, OTA and Fumonisin B1+B2 in feed (2006/576/EC)
 - ✓ T-2 and HT-2 mycotoxins in cereals and cereal products (2013/165/EU).
- EFSA considered that these pose significant risks to animal health.
- However, the risk to the consumers is generally low.
- These risks should be controlled by good manufacturing practice.

Decontamination

“The Commissionmay define acceptability criteria for detoxification processes as a complement to the criteria provided for products intended for animal feed which have undergone such processes.

Still under discussion

AGENDA ITEM A.4

Discussion on legislation related to the establishment at EU level of criteria for decontamination processes

A) BACKGROUND

- (1) Directive 2002/32/EC provides that the use of products intended for animal feed which contain levels of undesirable substances exceeding the maximum levels laid down in Annex I to that Directive is prohibited.
- (2) The Directive provides that Member States shall ensure that measures are taken to guarantee the correct application of any acceptable process and the conformity of the detoxified products intended for animal feed with the provisions of Annex I of that Directive. In order to ensure a uniform assessment across the European Union of the acceptability of detoxification processes, it is appropriate that acceptability criteria for detoxification processes are established at European Union level.
- (3) Detoxification or decontamination of a contaminated batch of feed can be performed by a physical, chemical or (macro-) biological decontamination process.
- (4) The application of the acceptability criteria should ensure that the detoxified or decontaminated feed should not endanger animal and public health and the environment and the characteristics of the feed should not be adversely altered by the detoxification process. The detoxification process has to be performed in an establishment approved for that purpose. The detoxification process has to be approved by the competent authority, which may require an independent expert advice to be made available for that purpose.
- (5) The requirements do not apply to the use of detoxification processes whereby the contamination by an undesirable substance is reduced or eliminated solely by cleaning, sorting or mechanical removal of certain parts as these processes are in many cases part of the usual production process.
- (6) A functional group of additives which suppress or reduce the absorption, promote the excretion of mycotoxins or modify their mode of action and thereby mitigate possible adverse effects of mycotoxins on animal and public health has been added in the category of technological additives in the Annex I to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition¹. As these additives do not change the level of the undesirable substance in the feed, the feed is not detoxified by the use of these additives and consequently, the use of these additives does not fall in the scope of this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health and neither the European Parliament nor the Council has opposed them.

¹ OJ L 268, 18.10.2003, p. 29

Commission Recommendation

- Differentiation between cleaning and decontamination
- Authorization of establishments for decontamination
- Criteria for decontamination processes

Regulation of Decontamination in Germany

Establishments which **clean feed using mechanical methods** (e.g. sieving, brushing, washing, heating) **must be registered as feed business**.

Establishments which **decontaminate feed using chemical methods** (e.g filtering, treatment with chemical substances) **must be approved** by the competent authority.

Requirements for approval:

- ➔ The feed business operator shall prove by an **expertise from an official approved expert** that the technical **process used for decontamination is suitable** for the decontamination of the specific feed and the specific undesirable substance.

The expertise shall also demonstrate that the feed is safe and suitable for animal nutrition after the decontamination process.

Labelling provisions

Feed that not satisfy the Community requirements for safety and marketing must be labelled

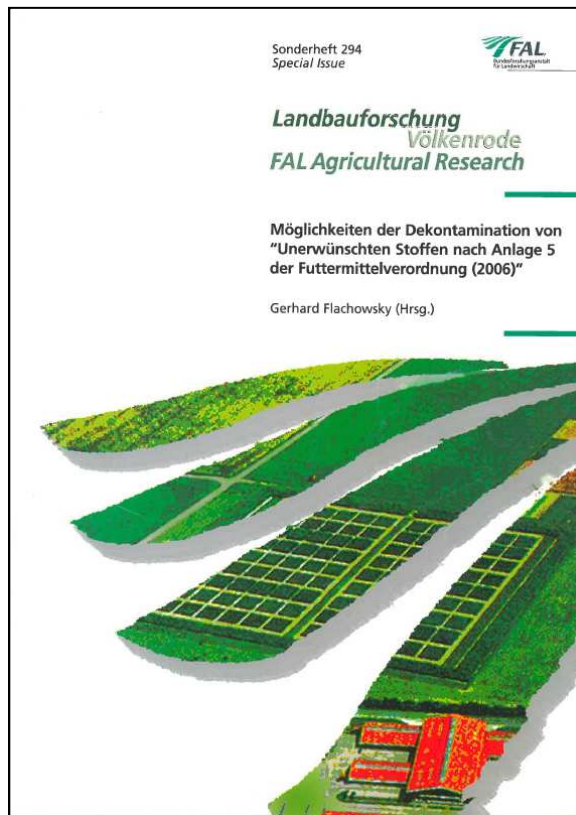
- ✓ if the contamination is to be removed by **detoxification**

“Feed with excessive concentration of ... (designation of the undesirable substance(s) in accordance with Directive 2002/32/EC); only to be used as feed after detoxification by an approved company.”

- ✓ if the contamination is to be removed by **cleaning**

“Feed with excessive concentration of ... (designation of the undesirable substance(s) in accordance with directive 2002/32/EC); only to be used as feed after sufficient cleaning by an registered company.”

Possibilities for Decontamination of Feed



In this study experts of the Agriculture Research Centre characterized the possibilities for decontamination of feed with higher contents of undesirable substances.