

**L.N. 81 of 2005**

**VETERINARY SERVICES ACT  
(CAP. 437)**

**Undesirable Substances in Animal Feeds Rules, 2005**

IN exercise of the powers conferred by article 10 of the Veterinary Services Act, the Minister for Rural Affairs and the Environment has, after consultation with the Minister of Health, the Elderly and Community Care, made the following rules :

**1.** (1) The title of these rules is the Undesirable Substances in Animal Feeds Rules, 2005. Title, scope and applicability.

(2) These rules deal with undesirable substances in products intended for animal feed.

(3) The scope of these rules is to implement the provisions found under Directive 2002/32 EC of the European Parliament and of the Council of the 7th May 2002 on undesirable substances in animal feeds.

(4) These rules shall apply without prejudice to the provisions in:

- (a) Order (70/524) concerning additives in feedingstuffs;
- (b) Order (96/25) and Order (79/373) on the marketing of compound feedingstuffs;
- (c) Orders relating to the fixing of maximum levels for pesticide residues, where these residues are not listed in Schedule I to this Order;
- (d) Veterinary legislation relating to public health and animal health;
- (e) Order (82/471) concerning certain products used in animal nutrition;
- (f) Order (93/74) on feedingstuffs intended for particular nutritional purposes.

**2.** For the purposes of these rules:

“additives” means additives as defined in Article 2(a) of Council Directive/Order (70/524)/EEC;

“animals” means animals belonging to species normally fed and kept or consumed by man as well as animals living freely in the wild in cases where they are fed with feedingstuffs;

“the competent authority” means the competent authority as mentioned in Article 2 (f) of Order (95/53) fixing the principles governing the organisation of official inspections in the field of animal nutrition;

“the Commission” means the Commission of the European Union;

“complementary feedingstuffs” means mixtures of feedingstuffs which have a high content of certain substances and which, by reason of their composition, are sufficient for a daily ration only if used in combination with other feedingstuffs;

“complete feedingstuffs” means mixtures of feedingstuffs which, by reason of their composition, are sufficient for a daily ration;

“compound feedingstuffs” means mixtures of feed materials, whether or not containing additives, which are intended for oral animal feeding as complete or complementary feedingstuffs;

“the Council” means the Council of the European Union;

“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;

“feedingstuffs” means products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, used singly or in mixtures, whether or not containing additives, for oral animal feeding;

“feed materials” means various products of vegetable or animal origin, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or

inorganic substances, whether or not containing additives, which are intended for use in oral animal feeding either directly as such or, after processing, in the preparation of compound feedingstuffs or as substrates for premixtures;

“Member State” means a member state of the European Union;

“premixtures” means mixtures of additives or mixtures of one or more additives with substances used as carriers, intended for the manufacture of feedingstuffs;

“products intended for animal feed” means feed materials, premixtures, additives, feedingstuffs and all other products intended for use or used in animal feed;

“putting into circulation” or “circulation” means the holding of products intended for animal feed for the purposes of sale, including offering for sale, or any other form of transfer, whether free or not, to third parties, and the sale or other forms of transfer themselves;

“undesirable substance” means 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.

**3.** (1) Products intended for animal feed may enter for use in Malta from third countries, be put into circulation and, or used in Malta only if they are sound, genuine and of merchantable quality. When correctly used such products do not represent any danger to human health, animal health or to the environment or could adversely affect livestock production.

Animal feed products.

(2) In particular, products intended for animal feed shall be deemed not to be in conformity with sub-rule (1) if the level of undesirable substances they contain does not comply with the maximum levels laid down in Schedule I.

**4.** (1) Undesirable substances listed in Schedule I may be tolerated in products intended for animal feed only subject to the conditions laid down therein.

Tolerance of undesirable substances.

(2) In order to reduce or eliminate sources of undesirable substances of products intended for animal feed, the competent authority,

in co-operation with economic operators, shall carry out investigations to identify the sources of undesirable substances, in cases where the maximum levels are exceeded and in cases where increased levels of such substances are detected, taking into account background levels. For a uniform approach in cases of increased levels it may be necessary to set action thresholds to trigger such investigations. These may be laid down in Schedule II.

(3) The competent authority shall transmit to the Commission and to the relevant international organisation and to the other Member States all relevant information and findings of the source and the measures taken to reduce the level or elimination of the undesirable substances. This information shall be transmitted in the frame of the annual report to be transmitted to the Commission and to the relevant international organisation according to the provisions of Article 22 of Directive (95/53)/EC except in those cases where the information is of immediate relevance for the other Member States. In this latter case, the information shall be transmitted immediately.

Products not to be mixed.

**5.** Products intended for animal feed containing levels of an undesirable substance that exceed the maximum level fixed in Schedule I may not be mixed for dilution purposes with the same, or other, products intended for animal feed.

Complementary feedingstuffs.

**6.** In so far as there are no special provisions for complementary feedingstuffs, complementary feedingstuffs may not, taking into account the proportion prescribed for their use in a daily ration, contain levels of the undesirable substances listed in Schedule I that exceed those fixed for complete feedingstuffs.

New information.

**7.** (1) Where the competent authority has grounds, based on new information or a reassessment of existing information made since the provisions in question were adopted, demonstrating that a maximum level fixed in Schedule I, or an undesirable substance not listed therein, present a danger to animal or human health or to the environment, it may provisionally reduce the existing maximum level, fix a maximum level or prohibit the presence of that undesirable substance in products intended for animal feed. It shall immediately inform the other Member States and the Commission and to the relevant international organisation thereof, stating the grounds for its decision.

(2) An immediate decision shall be taken, whether to amend Schedules I and II.

(3) Insofar as neither the Council nor the Commission and the relevant international organisation has taken a decision, the

competent authority may maintain the measures it has implemented. The competent authority must ensure that the decision taken is made public.

**8.** (1) In consideration of developments in scientific and technical knowledge, Schedules I and II shall be adapted in agreement with decisions adopted by the relevant international organisation. Adaptation of Schedules.

(2) Furthermore, in accordance with the procedure laid down in Article 24, the competent authority:

(a) shall periodically adopt consolidated versions of Annexes I and II incorporating any adaptations made pursuant to sub-rule (1);

(b) may define acceptability criteria for detoxification processes as a complement to the criteria provided for products intended for animal feed which have undergone such processes may be defined.

(3) Measures shall be taken to guarantee the correct application of any acceptable processes pursuant to sub-rule (2) and the conformity of the detoxified products intended for animal feed with the provisions of Schedule I.

**9.** Products intended for animal feed which comply with these rules shall not be subject to any other restrictions on circulation as regards the presence of undesirable substances other than those provided for in these rules and Directive (95/53)/EC. No other restrictions applicable.

**10.** Provisions that may have an effect upon public or animal health or on the environment shall be adopted after consultation with the relevant international organisation. Provisions that may be adopted.

**SCHEDULE I**

Undesirable substances	Products intended for animal feed	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
1. Arsenic	<p>Feed materials with the exception of:</p> <ul style="list-style-type: none"> <li>- meal made from grass, from dried lucerne and from dried clover, and dried sugar beet pulp and dried molasses sugar beet pulp</li> <li>- phosphates and feedingstuffs obtained from the processing of fish or other marine animals</li> </ul> <p>Complete feedingstuffs with the exception of:</p> <ul style="list-style-type: none"> <li>- complete feedingstuffs for fish</li> </ul> <p>Complementary feedingstuffs with the exception of:</p> <ul style="list-style-type: none"> <li>- mineral feedingstuffs</li> </ul>	<p>2</p> <p>4</p> <p>10</p> <p>2</p> <p>4</p> <p>4</p> <p>12</p>
2. Lead	<p>Feed materials with the exception of:</p> <ul style="list-style-type: none"> <li>- green fodder</li> <li>- phosphates</li> <li>- yeasts</li> </ul> <p>Complete feedingstuffs</p> <p>Complementary feedingstuffs with the exception of:</p> <ul style="list-style-type: none"> <li>- mineral feedingstuffs</li> </ul>	<p>10</p> <p>40</p> <p>30</p> <p>5</p> <p>5</p> <p>10</p> <p>30</p>

3. Fluorine	<p>Feed materials with the exception of:</p> <ul style="list-style-type: none"> <li>- feedingstuffs of animal origin</li> <li>- phosphates</li> </ul> <p>Complete feedingstuffs with the exception of:</p> <ul style="list-style-type: none"> <li>- complete feedingstuffs for cattle, sheep and goats</li> <li>- in milk</li> <li>- other</li> <li>- complete feedingstuffs for pigs</li> <li>- complete feedingstuffs for poultry</li> <li>- complete feedingstuffs for chicks</li> </ul> <p>Mineral mixtures for cattle, sheep and goats</p> <p>Other complementary feedingstuffs</p>	<p>150</p> <p>500</p> <p>2 000</p> <p>150</p> <p>30</p> <p>50</p> <p>100</p> <p>350</p> <p>250</p> <p>2 000 (1)</p> <p>125 (2)</p>
4. Mercury	<p>Feed materials with the exception of:</p> <ul style="list-style-type: none"> <li>- feedingstuffs produced by the processing of fish or other marine animals</li> </ul> <p>Complete feedingstuffs with the exception of:</p> <ul style="list-style-type: none"> <li>- complete feedingstuffs for dogs and cats</li> </ul> <p>Complementary feedingstuffs except:</p> <ul style="list-style-type: none"> <li>- complementary feedingstuffs for dogs and cats</li> </ul>	<p>0,1</p> <p>0,5</p> <p>0,1</p> <p>0,4</p> <p>0,2</p>
5. Nitrites	<p>Fish meal</p> <p>Complete feedingstuffs excluding:</p> <ul style="list-style-type: none"> <li>- feedingstuffs intended for pets except birds and aquarium fish</li> </ul>	<p>60</p> <p>(expressed as sodium nitrite)</p> <p>15</p> <p>(expressed as sodiumnitrite)</p>

6. Cadmium	<p>Feed materials of vegetable origin</p> <p>Feed materials of animal origin except:</p> <ul style="list-style-type: none"> <li>- feedingstuffs for pets</li> </ul> <p>Phosphates</p> <p>Complete feedingstuffs for cattle, sheep and goats except:</p> <ul style="list-style-type: none"> <li>- complete feedingstuffs for calves, lambs and kids</li> </ul> <p>Other complete feedingstuffs except:</p> <ul style="list-style-type: none"> <li>- feedingstuffs for pets</li> </ul> <p>Mineral feedingstuffs</p> <p>Other complementary feedingstuffs for cattle, sheep and goats</p>	<p>1</p> <p>2</p> <p>10 (3)</p> <p>1</p> <p>0,5</p> <p>5 (4)</p> <p>0,5</p>
7. Aflatoxin B <sub>1</sub>	<p>Feed materials with the exception of:</p> <ul style="list-style-type: none"> <li>- groundnut, copra, palm-kernel, cotton seed, babassu, maize and products derived from the processing thereof</li> </ul> <p>Complete feedingstuffs for cattle, sheep and goats with the exception of:</p> <ul style="list-style-type: none"> <li>- dairy cattle</li> <li>- calves and lambs</li> </ul> <p>Complete feedingstuffs for pigs and poultry (except young animals)</p> <p>Other complete feedingstuffs</p> <p>Complementary feedingstuffs for cattle, sheep and goats (except complementary feedingstuffs for dairy animals, calves and lambs)</p> <p>Complementary feedingstuffs for pigs and poultry (except young animals)</p> <p>Other complementary feedingstuffs</p>	<p>0,05</p> <p>0,02</p> <p>0,05</p> <p>0,005</p> <p>0,01</p> <p>0,02</p> <p>0,01</p> <p>0,05</p> <p>0,03</p> <p>0,005</p>



8. Hydrocyanic acid	Feed materials with the exception of: - linseed - linseed cakes - manioc products and almond cakes Complete feedingstuffs with the exception of: - complete feedingstuffs for chicks	50  250 350 100 50 10
9. Free gossypol	Feed materials with the exception of: - cotton-seed cakes Complete feedingstuffs with the exception of: - complete feedingstuffs for cattle, sheep and goats - complete feedingstuffs for poultry (except laying hens) and calves - complete feedingstuffs for rabbits and pigs (except piglets)	20 1 200 20  500 100 60
10. Theobromine	Complete feedingstuffs with the exception of: - complete feedingstuffs for adult cattle	300 700
11. Volatile mustard oil	Feed materials with the exception of: - rape-seed cakes Complete feedingstuffs with the exception of: - complete feedingstuffs for cattle, sheep and goats (except young animals) - complete feedingstuffs for pigs (except piglets) and poultry	100 4 000 (expressed as allyl isothiocyanate) 150 (expressed as allylisothiocyanate) 1 000 (expressed as allyl isothiocyanate) 500 (expressed as allylisothiocyanate)
12. Vinyl thiooxazolidone (Vinylloxazolidine thione)	Complete feedingstuffs for poultry with the exception of: - complete feedingstuffs for laying hens	1 000 500
13. Rye ergot (Claviceps purpurea)	All feedingstuffs containing unground cereals	1 000

14. Weed seeds and unground and uncrushed fruits containing alkaloids, glucosides or other toxic substances separately or in combination including (a) <i>Lolium temulentum</i> L., (b) <i>Lolium remotum</i> Schrank (c) <i>Datura stramonium</i> L.	All feedingstuffs	3 000  1 000 1 000 1 000
15. Castor oil plant - <i>Ricinus communis</i> L.	All feedingstuffs	10 (expressed in terms of castor-oil plant husks)
16. <i>Crotalaria</i> spp.	All feedingstuffs	100
17. Aldrin } 18. Dieldrin } Singly or combined expressed as dieldrin	All feedingstuffs with the exception of: - fats	0,01 0,2
19. Camphechlor (toxaphene)	All feedingstuffs	0,1
20. Chlordane (sum of cis- and trans-isomers and of oxychlordane, expressed as chlordane)	All feedingstuffs with the exception of: - fats	0,02 0,05
21. DDT (sum of DDT-, TDE- and DDE isomers, expressed as DDT)	All feedingstuffs with the exception of: - fats	0,05 0,5
22. Endosulfan (sum of alpha- and betaisomers and of endosulfansulphate expressed as endo-sulfan)	All feedingstuffs with the exception of: - maize - oilseeds - complete feedingstuffs for fish	0,1 0,2 0,5 0,005
23. Endrin (sum of endrin and of delta-ketoiendrin, expressed as endrin)	All feedingstuffs with the exception of: - fats	0,01 0,05
24. Heptachlor (sum of heptachlor and of heptachlorepoxyde, expressed as heptachlor)	All feedingstuffs with the exception of: - fats	0,01 0,2
25. Hexachlorobenzene (HCB)	All feedingstuffs with the exception of: - fats	0,01 0,2

26. Hexachlorocyclo-hexane (HCH)	All feedingstuffs with the exception of:	0,02
26.1. alpha-isomers	- fats	0,2
26.2. beta-isomers	Compound feedingstuffs with the exception of:	0,01
	- feedingstuffs for dairy cattle	0,005
	Feed materials with the exception of:	0,01
	- fats	0,1
26.3. gamma-isomers	- fats	0,2
	All feedingstuffs with the exception of:	2,0
	- fats	
27. Dioxin (sum of PCDD and PCDF), expressed in international toxic equivalents	Citrus pulp AMENDED BY DIR 2003/57/EC	500 pg I-TEQ/kg (upper bound detection limit)
28. Apricots - <i>Prunus armeniaca</i> L. 29. Bitter almond - <i>Prunus dulcis</i> (Mill.) D.A.m Webb var. <i>amara</i> (DC.) Focke (= <i>Prunus amygdalus</i> Batsch var. <i>amara</i> (DC.) Focke) 30. Unhusked beech mast - <i>Fagus silvatica</i> L. 31. Camelina - <i>Camelina sativa</i> (L.) Crantz 32. Mowrah, Bassia, Madhuca - <i>Madhuca longifolia</i> (L.) Macbr. (= <i>Bassia longifolia</i> L. = <i>Illipe malabrorum</i> Engl.) <i>Madhuca indica</i> Gmelin (= <i>Bassia latifolia</i> Roxb.) = <i>Illipe latifolia</i> (Roscb.) F. Mueller) 33. Purghera - <i>Jatropha curcas</i> L. 34. Croton - <i>Croton tiglium</i> L. 35. Indian mustard - <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>integrifolia</i> (West.) Thell. 36. Sareptian mustard - <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>juncea</i> 37. Chinese mustard - <i>Brassica juncea</i> (L.) Czern. and Coss. ssp. <i>juncea</i> var. <i>lutea</i> Batalin	All feedingstuffs	Seeds and fruit of the plant species listed in the first column hereof, as well as their processed derivatives may only be present in feedingstuffs in trace amounts not quantitatively determinable

38. Black mustard - <i>Brassica nigra</i> (L.) Koch 39. Ethiopian mustard - <i>Brassica carinata</i> A. Braun		
<p>(1) The competent authority may also prescribe a maximum fluorine content of 1,25 % of the phosphate content.</p> <p>(2) Fluorine content per 1 % phosphorus.</p> <p>(3) The competent authority may also prescribe a maximum cadmium content of 0,5 mg per 1 % phosphorus.</p> <p>(4) Member States Competent authority may also prescribe a maximum cadmium content of 0,75 mg per 1 % phosphorus.</p> <p>(5) Upper bound concentrations are calculated assuming that all values of the different congeners less than the limit of detection are equal to the limit of detection.</p>		

**SCHEDULE II**

Undesirable substances	Products intended for animal feed	Action threshold in mg/kg (ppm) relative to a product intended for animal feed with a moisture content of 12 %	Comments and additional information (e.g. the nature of the investigation to be performed)