L.N. 119 of 2007

VETERINARY SERVICES ACT
(CAP 437)

Undesirable Substances in Animal Feeds (Amendment) (No. 2) Rules, 2007

IN exercise of the powers conferred by article 22(c) of the Veterinary Services Act, 2001, the Minister for Rural Affairs and the Environment has made the following rules:-

Title and Scope. L.N 81 of 2005

1. (1) The title of these rules is the Undesirable Substances in Animal Feeds (Amendment No.2)Rules" 2007 and they shall be read and construed as one with as Undesirable Substances in Animal Feeds Rules, 2005, herinafter referred to as "the principal rules.

(2) The scope of these rules is to implement the provisions found under Commission Directive 2006/13/EC of 3rd February 2006 amending Annexes I and II to Directive 2002/32/EC of the European Parliament and of the Council on undesirable substances in animal feed as regards dioxins and dioxin-like PCBs'

Amends Schedule I to the principal rules.

2. For point 27 in Schedule I to the principal rules, there shall be subsituted as follows:-

Undesirable substances	Products intended for animal feed	Maximum content relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
27a. Dioxins (sum of polychlorinated dibenzo*para*-dioxins (PCDDs) and polychlorinateddibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxicequivalency factors, 1997 (*)	(a) Feed materials of plant origin with the exception of vegetable oils and their byproducts	0,75 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(b) Vegetable oils and their by-products	0,75 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(c) Feed materials of mineral origin	1,0 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(d) Animal fat, including milk fat and egg fat	2,0 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(e) Other land animal products including milk and milk products and eggs and egg products	0,75 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(f) Fish oil	6,0 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(g) Fish, other aquatic animals, their products and by-products with the exception of fish oil and fish protein hydrolysates containing more than 20 % fat	1,25 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(h) Fish protein hydrolysates containing more than 20 % fat	2,25 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(i) The additives kaolinitic clay, calcium sulphate dihydrate, vermiculite, natrolitephonolite, synthetic calcium aluminates and clinoptilolite of sedimentary origin belonging to the functional groups of binders and anti-caking agents	0,75 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(j) Additives belonging to the functional group of compounds of trace elements	1,0 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(k) Premixtures	1,0 ng WHO-PCDD/F-TEQ/kg (**) (***)
	(l) Compound feedingstuffs, with the exception of feed for fur animals, pet foods and feed for fish	0,75 ng WHO-PCDD/F-TEQ/kg (**) (***)

	(m) Feed for fish. Pet foods	2,25 ng WHO-PCDD/F-TEQ/kg (**) (***)
27b. Sum of dioxins and dioxin-like PCBs (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997 (*)	(a) Feed materials of plant origin with the exception of vegetable oils and their byproducts	1,25 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(b) Vegetable oils and their by-products	1,5 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(c) Feed materials of mineral origin	1,5 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(d) Animal fat, including milk fat and egg fat	3,0 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(e) Other land animal products including milk and milk products and eggs and egg products	1,25 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(f) Fish oil	24,0 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(g) Fish, other aquatic animals, their products and by-products with the exception of fish oil and fish protein hydrolysates containing more than 20 % fat	4,5 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(h) Fish protein hydrolysates containing more than 20 % fat	11,0 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(i) Additives belonging to the functional groups of binders and anti-caking agents	1,5 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(j) Additives belonging to the functional group of compounds of trace elements	1,5 ng WHO-PCDD/F-PCB-TEQ/kg(**)
	(k) Premixtures	1,5 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(l) Compound feedingstuffs, with the exception of feed for fur animals, pet foods and feed for fish	1,5 ng WHO-PCDD/F-PCB-TEQ/kg (**)
	(m) Feed for fish. Pet foods	7,0 ng WHO-PCDD/F-PCB-TEQ/kg (**)

(*) WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation meeting in Stockholm, Sweden, 15-18 June 1997 (Van den
Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, and PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106(12), 775).

Congener	TEF value	Congener	TEF value
Dibenzo-p-dioxins (PCDSS)		"Dioxin-Like PCBs"	
2-3-7-8 TCDD	1	**Non-ortho**	0.0001
		PCBs+Mono-ortho	0.0001
1,2,3 7 8 PeCDD	1	**Non-ortho PCBs**	0.1
			0.01
1,2,3,4,7, HxCDD	0,1	PCB 77	
1,2,3,7,8 HxCDD	0,1	PCB 81	
1,2,3,4,7,8 HxCDD	0.01	PCB 126	
OCDD	0.0001	PCB 169	
Dibenzofurans (PCDFs)		**Mono-ortho PCBs**	
2,3,7,8-TCDF	0,1	PCB 105	0,0001
1,2,3,7,8-PeCDF	0,05	PCB 114	0,0005
2,3,4,7,8-PeCDF	0,5	PCB 118	0,0001
1,2,3,4,7,8-HxCDF	0,1	PCB 123	0,0001
1,2,3,6,7,8-HxCDF	0,1	PCB 156	0,0005
1,2,3,,7,8,9-HxCDF	0,1	PCB 157	0,0005
2,3,4,6,7,8-HxCDF	0,1	PCB 167	0,00001
1,2,3,4,6,7,8-HpCDF	0,01		
1,2,3,4,7,8,9-HpCDF	0,01	PCB 189	
OCDF	0,0001		0,0001

(**) Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of
quantification are equal to the limit of quantification.
(***) The separate maximum level for dioxins (PCDD/F) remains applicable for a temporary period. The products intended for animal feed mentioned in point 27a have
to comply both with the maximum levels for dioxins and with the maximum levels for the sum of dioxins and dioxin-like PCBs during that temporary period.
(****) Fresh fish directly delivered and used without intermediate processing for the production of feed for fur animals is not subject to the maximum levels, while maximum levels of 4,0 ng WHO-PCDD/F-TEQ/kg product and 8,0 ng WHO-PCDD/F-PCB-TEQ/kg product are applicable to fresh fish used for the direct feeding of pet animals, zoo and circus animals. The products, processed animal proteins produced from these animals (fur animals, pet animals, zoo and circus animals) cannot enter the food chain and cannot be fed to farmed animals which are kept, fattened or bred for the production of food.'

Amendment to Schedule II to the principal rules.

3. For Schedule II to the principal rules, shall be subsituted by the following:

‘SCHEDULE II

‘Undesirable substances	Products intended for animal feed	Action threshold relative to a feedingstuff with a moisture content of 12 %	Comments and additional information (e.g. nature of investigations to be performed)
(1))	(2)	(3	(4)
1. Dioxins (sum of polychlorinated dibenzo-*para*-dioxins (PCDDs), polychlorinated PCDFs) expressed in World Health Organisation (WHO dibenzofurans toxic equivalents, using the WHO-TEFs (toxic equivalency factors, 1997 (*)	a) Feed materials of plant() (origin with the exception of vegetable oils and their byproducts	0,5 ng WHO-PCDD/F-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	(b) Vegetable oils and their byproducts	0,5 ng WHO-PCDD/F-TEQ	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	(c) Feed materials of mineral origin	0,5 ng WHO-PCDD/F-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	(d) Animal fat, including milk fat and egg fat	1,0 ng WHO-PCDD/F-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	(e) Other land animal products including milk and milk products and eggs and egg products	0,5 ng WHO-PCDD/F-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	(f) Fish oil /	5,0 ng WHO-PCDD/F-TEQ	In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded all information , such as sampling

			period, geographical origin, fish species etc., should be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.
. ,	(g) Fish, other aquatic animals, their products and byproducts with the exception of fish oil and fish protein hydrolysates containing more than 20 % fat	0,5 ng WHO-PCDD/F-TEQ/ kg	In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded all information, such as sampling period, geographical origin, fish species etc., should be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.
	h) Fish protein hydrolysates containing more than 20 % fat	1,75 ng WHO-PCDD/F-TEQ/ kg	In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded all information, such as sampling period, geographical origin, fish species etc., should be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.
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	i) Additives belonging to the functional groups of binders and anti-caking agents	0,5 ng WHO-PCDD/F-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination

	j) Additives belonging to the functional group of compounds of trace elements	0,5 ng WHO-PCDD/F-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	(k) Premixtures .	0,5 ng WHO-PCDD/F-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	(l) Compound feedingstuffs, with the exception of feedingstuffs for fur animals, pet foods and feedingstuffs for fish	0,5 ng WHO-PCDD/F-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	(m) Feedingstuffs for fish. Pet foods (***)	1,75 ng WHO-PCDD/F-TEQ/kg	In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded, all information, such as sampling period, geographical origin, fish species etc., must be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition. (.

2. Dioxin like PCBs (sum of polychlorinated biphenyls (PCBs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHOTEFs (toxic equivalency factors, 1997 (*)	(a) Feed materials of plant origin with the exception of vegetable oils and their byproducts	0,35 ng WHO-PCB-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination.
	b) Vegetable oils and their byproducts source of contamination.	0,5 ng WHO-PCB-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate
	(c) Feed materials of mineral origin	0,35 ng WHO-PCB-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	(d) Animal fat, including milk fat and egg fat	0,75 ng WHO-PCB-TEQ/ kg (**) (***)	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	e) Other land animal products including milk and milk products and eggs and egg products	0,35 ng WHO-PCB-TEQ/ kg (**) (***)	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination
	f) Fish oil kg (**) (***)	14,0 ng WHO-PCB-TEQ/	In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded, all information, such as sampling period, geographical origin, fish species etc., must be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.

	(g) Fish, other aquatic animals, their products and byproducts with the exception of fish oil and fish protein hydrolysates containing more than 20 % fat	2,5 ng WHO-PCB-TEQ/ kg	In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded, all information, such as sampling period, geographical origin, fish species etc., must be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.
	(h) Fish protein hydrolysates containing more than 20 % fat	7,0 ng WHO-PCB-TEQ/ kg (**) (***)	In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded, all information, such as sampling period, geographical origin, fish species etc., must be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.
	(i) Additives belonging to the functional groups of binders and anti-caking agents	0,5 ng WHO-PCB-TEQ/ kg	Identification of source of contamination. Once source is identified,take appropriate measures, where possible, to reduce or eliminate source of contamination
	(j) Additives belonging to the functional group of compounds of trace elements	0,35 ng WHO-PCB-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination.
	(k) Premixtures	0,35 ng WHO-PCB-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminate source of contamination

	(l) Compound feedingstuffs, with the exception of feedingstuffs for fur animals, pet foods and feedingstuffs for fish	0,5 ng WHO-PCB-TEQ/ kg	Identification of source of contamination. Once source is identified, take appropriate measures, where possible, to reduce or eliminatesource of contamination
	(m) Feedingstuffs for fish. Pet foods	3,5 ng WHO-PCB-TEQ/ kg	In many cases it might not be necessary to perform an investigation into the source of contamination as the background level in some areas is close to or above the action level. However, in cases where the action level is exceeded, all information, such as sampling period, geographical origin, fish species etc., must be recorded with a view to future measures to manage the presence of dioxins and dioxin-like compounds in these materials for animal nutrition.

(*) WHO-TEFs for human risk assessment based on the conclusions of the World Health Organisation meeting in Stockholm, Sweden, 15-18 June 1997 (Van den Berg et al., (1998) Toxic Equivalency Factors (TEFs) for PCBs, PCDDs, PCDFs for Humans and for Wildlife. Environmental Health Perspectives, 106(12), 775).

Congener	TEF value	Congener	TEF value
Dibenzo-p-dioxins (PCDSS)		**"Dioxin-Like PCBs"**	
2-3-7-8 TCDD	1	**Non-ortho PCBs+Mono0ortho**	
1,2,3 7 8 PeCDD	1	**Non-ortho PCBs**	
1,2,3,4,7, HxCDD	0,1	PCB 77	0.0001
1,2,3,7,8 HxCDD	0,1	PCB 81	0.1
1,2,3,4,7,8 HxCDD	0.01	PCB 126	0.01
OCDD	0.0001	PCB 169	0.0001
Dibenzofurans (PCDFs)		**Mono-ortho PCBs**	
2,3,7,8-TCDF	0,1	PCB 105	0,0001
1,2,3,7,8-PeCDF	0,05	PCB 114	0,0005
2,3,4,7,8-PeCDF	0,5	PCB 118	0,0001
1,2,3,4,7,8-HxCDF	0,1	PCB 123	0,0001
1,2,3,6,7,8-HxCDF	0,1	PCB 156	0,0005
1,2,3,,7,8,9-HxCDF	0,1	PCB 157	0,0005
2,3,4,6,7,8-HxCDF	0,1	PCB 167	0,00001
1,2,3,4,6,7,8-HpCDF	0,01		
1,2,3,4,7,8,9-HpCDF	0,01	PCB 189	
OCDF	0,0001		0,0001

(**) Upper-bound concentrations; upper-bound concentrations are calculated on the assumption that all values of the different congeners below the limit of quantification are equal to the limit of quantification.
(***) The Commission will review these action levels by 31 December 2008 at the latest at the same time as it reviews the maximum levels the sum of dioxins and dioxin-like PCBs.'

Ippubblikat mid-Dipartiment ta' l-Informazzjoni (doi.gov.mt) — Valletta — *Published by the Department of Information (doi.gov.mt) — Valletta*
Mitbugh fl-Istamperija tal-Gvern — *Printed at the Government Printing Press*

Prezz/*Price*
Lm0.44c (€1.02)