EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: production and distribution chain
D1 – Animal nutrition

SCFCAH-SAN/04-2003 / 8 / 001

PART I : List of documents

A. Basic documents

* **Opinion of the Scientific Committee on Animal Nutrition on undesirable substances in Feed (adopted on 20 February 2003, updated on 28 March 2003) (SCFCAH-SAN/04-2003/8/002)**

* **Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. (SCFCAH-SAN/04-2003/8/003)**

B. Documents containing information on heavy metals in general

* **EMFEMA proposal on maximum levels of heavy metals (As, Pb, F, Hg and Cd) in mineral feed materials, mineral feed additives and information on background levels of dioxins in mineral feed materials and additives (SCFCAH-SAN/04-2003/8/004)**

* **Summarised analytical results on the presence of Pb, Cd, As, Hg, F and dioxins in minerals (feed materials) and trace elements (SCFCAH-SAN/04-2003/8/005)**

* **Details of analytical results on the presence of Pb, Cd, As, Hg, F and dioxins in minerals (feed materials) and trace elements (SCFCAH-SAN/04-2003/8/005-bis)**

* **Information from the Norwegian delegation on the presence of**
  - Arsenic in fish
  - Fluorine in fish
  - Cadmium and lead in fish
  - Mercury in fish
  (SCFCAH-SAN/04-2003/8/006)

C. Documents containing information on the presence of ARSENIC (in particular with regard to its presence in seaweed)

* **Arsenic in seaweed: information provided by the Irish delegation (SCFCAH-SAN/04-2003/8/007)**

* **Arsenic in feedingstuffs of marine origin: information provided by the Norwegian delegation (SCFCAH-SAN/04-2003/8/008)**

* **Arsenic in feedingstuffs of marine origin: information provided by the Icelandic delegation (SCFCAH-SAN/04-2003/8/009)**

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* **Bio-availability of Arsenic – sepiolite (SCFCAH-SAN/04-2003/8/010)**

* **Arsenic exposure levels by mineral supplementation for milking cows and laying hen (SCFCAH-SAN/04-2003/8/011)**

D. Documents containing information on the presence of FLUORINE (in particular with regard to its presence in sepiolite)

* **Fluorine presence and availability in sepiolite (SCFCAH-SAN/04-2003/8/012)**

E. Documents containing information on the presence of NITRITES

* **Information on the former use of nitrite as preservative in fish for the production of fish meal (SCFCAH-SAN/04-2003/8/013)**

E. Documents containing information on the presence of heavy metals in MgO

* **Presence of heavy metals in MgO: Information from the delegation of France (SCFCAH-SAN/04-2003/8/014)**

* **Presence of heavy metals (As and F) in MgO: Information from the delegation of Austria (SCFCAH-SAN/04-2003/8/015)**

* **Presence of heavy metals in MgO: Information from EMFEMA (SCFCAH-SAN/04-2003/8/016)**

F. Documents containing information on the presence of heavy metals in $CaCO_3$

* **Presence of heavy metals in $CaCO_3$: Information from CCA-Europe (SCFCAH-SAN/04-2003/8/017)**

* **Presence of heavy metals in $CaCO_3$: Additional information from CCA-Europe (SCFCAH-SAN/04-2003/8/017-bis)**

PART II : Discussion

A. SCAN opinion

These are some summarised extracts from the SCAN opinion on heavy metals. For more information it is appropriate to consult the SCAN opinion itself

1. Lead

* animal health: lead at the limit fixed in current legislation (5 ppm for complete feed) problem may affect the health for sheep and possibly other ruminants
* public health: carry over of lead into edible tissues, egg and milk is low – products of animal contribute to a limited extent to the human exposure

2. Mercury

* inorganic – organic form: organic form (methyl mercury) most toxic
* currently total mercury measured
* methyl mercury mainly in fish and fish products
* animal feed derived from products of plant origin contain mercury levels between 0.001 and 0.03 mg/kg dry matter
* no particular animal health problems with current levels
* current feed legislation ensures a limited mercury load in animal products

3. Cadmium

* animal health: cadmium at the limit fixed in current legislation (0.5 ppm for complete feed for pigs) may affect the health of pigs
* transfer from feed to milk and eggs is very limited / meat products, fish, milk and eggs contain low levels of cadmium
* animal products contribute to a limited extent to the human exposure
* accumulation of cadmium occurs in horse meat and edible offal

4. Arsenic

* inorganic – organic form: inorganic form most toxic
* total arsenic is measured /for the time being no method of analysis available which can be used on a routine basis for official control to distinguish inorganic and organic arsenic.
* feed of terrestrial origin contain low levels of arsenic (mainly < 0.3 mg/kg, rarely exceed 1mg/kg), whereas marine algae contain high levels of organic arsenic (40-50 mg/dry matter)
* seafood (including marine algae): mainly organic arsenic (arsenobetaine – 95 % of total arsenic)
* foodstuffs of animal origin with the exception of seafood contributes only to a limited extent of the human exposure
* no particular problems with animal health
* current feed legislation ensures a limited (inorganic) arsenic load in animal products

5) Fluorine

- principal source of fluorine in feedingstuffs are fluoride rich (rock) phosphate supplements. Can be injurious to livestock when used over long periods and needs therefore to be defluorinated (what is usually done).
– animal health problems : fluorine at the limit fixed in current legislation for complete feedingstuffs are above the tolerance for poultry (ML: 250-350 ppm / Tolerance: 150 – 200 ppm), horse (ML 150 ppm / tolerance : 40 ppm) and rabbit (ML 150 ppm / tolerance 40 ppm)
– public health: contribution of animal products to the total human exposure is low

6) Nitrites

- their natural levels in feedingstuffs have not been reported to cause intoxication of farm animals
- human exposure mainly from the use of preservatives in products of animal origin

7) Aluminium and Chromium

SCAN does not consider both elements to be an undesirable substance in feed.

B. Reported problems of background levels regularly exceeding the current maximum levels (Annex to Directive 2002/32)

Only the problems cited with feed materials and feedingstuffs will be taken up in this document at this stage. The presence of undesirable substances in additives such as trace elements, sepiolite, … will be taken up in the discussion at a later stage. This exercise is only a first step. A complete revision of the annex will require without doubt additional requests to EFSA (Scientific Panel on contaminants) for detailed risk assessments or specific questions to EFSA (Scientific Panel on Contaminants)

1. Background

Declaration of the Commission at the Council in June 2001

Amended proposal for a directive of the European Parliament and the Council on undesirable substances and products in animal nutrition.

Declaration of the Commission ad Article 15:

"The Commission will undertake a review of the provisions laid down in Annex I on the basis of updated scientific risk assessments and taking into account the prohibition of any dilution of contaminated non-complying products intended for animal feed. The Commission has therefore without delay requested the appropriate Scientific Committees to provide these updated scientific risk assessments in order to enable the Commission to finalise this review as soon as possible and with the objective of being available before this Directive shall apply"

Extract from the report of the Standing Committee on 13-14 November 2002, agenda item 8

"8) Information from the Commission services on the progress with regard to the revision of the Annex to Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed

The Scientific Committee on Animal Nutrition is currently discussing an opinion on undesirable substances in feed. The opinion, expected to become available the coming months, will provide a general assessment of the risks for animal and public health and environment of the undesirable substances listed in the Annex of the above-mentioned Directive. The opinion will also provide a general assessment of the risks for animal and public health and environment of substances, not yet included in the Annex, but which should be considered for inclusion.

From 1 August 2003 the dilution of non-complying feed materials is prohibited.

A point of attention for the Standing Committee will be the identification of the feed materials of which normal background levels for a certain undesirable substance regularly exceed the maximum levels established in the Annex I. Such cases like e.g. arsenic in seaweed meal, heavy metals in some minerals, have been already brought to the attention of the services of the Commission

The Commission representative invited the Member States to identify already at this stage such situations and to provide the data for justification and to inform the Commission services thereof."

2. Arsenic

a) Seaweed meal: total arsenic levels range from 33-46 mg /kg, but present as organic arsenic (current maximum level (ML): 2 mg/kg) (Doc 006/007/008/009)

b) Problems with occurrence of arsenic in fish meal and fish feed. (current ML: 10 ppm for fish meal // 4 ppm for fish feed). Control program Norway has shown that a majority of compound fish feed will exceed the maximum level

c) feed materials of mineral origin :

- current ML 2 ppm with the exception of phosphates: 10 ppm

- levels proposed by EMFEMA : MgO 20 ppm // Calcium Carbonate 12 // Oyster shells 0.5 ppm // dolomite: 5 ppm (EMFEMA – document 004)
* data provided for the presence of Arsenic in phosphates support the current ML of 10 ppm
* data provided for the presence of Arsenic in MgO indicate that the current ML of 2 ppm is not achievable and that a higher ML is appropriate (documents 014/015/016)

- level proposed by CCA-Europe for Arsenic in CalciumCarbonate: 10 ppm (current ML = 2 ppm) – Data to support this proposal are provided (document 017)

- of importance is the method of analysis used (total arsenic content // bioavailable arsenic content)

d) palm kernel expeller

Current ML is 2 ppm. On the basis of monitoring data a level of 4 ppm is proposed by Cefetra (Netherlands) (mean level: 0.47 ppm / 99 percentile: 2.9 ppm) (document to follow)

e) conclusion with regard to Arsenic

issues to be considered (issues reported and data provided):
presence of Arsenic in

- seaweed meal
- fish feed / fish meal
- magnesium oxide
- calcium carbonate
- palm kernel expeller

3. Lead

a) To be considered revision (reduction) of ML for green fodder and phosphates (cf available data and SCAN opinion) and possibly complete feed for sheep (SCAN opinion)

b) feed materials of mineral origin :

- current ML 10 ppm with the exception of phosphates: 30 ppm

- proposed level by EMFEMA for dolomite: 150 ppm but no data (EMFEMA – doc. 004)

- data submitted support lowering the level for phosphates from 30 ppm to 10 ppm (doc. 005/016)

- no problems for fish feed with current levels (doc. 006)

- Calcium carbonate: data submitted by CCA- Europe (doc. 017) – proposed by CCA-Europe is 30 ppm supported by data (to be noted that EMFEMA is proposing 10 ppm for Calcium carbonate but no data submitted by EMFEMA)

– Cefetra proposes a level of 30 ppm of lead in all lime products (lime, limestone, chalk, Calcium carbonate) (data are submitted – document to follow)

c) conclusion with regard to lead

issues to be considered (issues reported and data provided)

presence of lead in

- green fodder and phosphates (complete feed for sheep) – reduction of level
- Calcium carbonate (lime products in general)

4. Fluorine

a) Feedingstuffs derived from fish/of marine origin

marine krill / krill meal contain levels of 3000 mg Fluorine /kg (doc. 006), whereas current ML is 500 ppm

b) feed materials of mineral origin :

- current ML for fluorine in feed materials of mineral origin is 150 ppm with the exception of phosphates: 2000 ppm

- proposed levels by EMFEMA: MgO 700 ppm // Calcium Carbonate 500// Oyster shells 50 ppm // dolomite: 50 ppm (EMFEMA – document 004)
* data provided for the presence of fluorine in phosphates support the current ML of 2000 ppm (doc. 005)
* data provided for the presence of fluorine in MgO indicate that the current ML of 150 ppm is not achievable and that a higher ML is appropriate (a level of 700 ppm is suggested) (documents 005/014/015/016)

- Calcium carbonate - proposed level by CCA-Europe: 500 ppm – data submitted by CCA-Europe (doc. 017) (note: data support a level of 400 ppm)

– Cefetra proposes a level of 200 ppm of fluorine in all lime products (lime, limestone, chalk, Calcium carbonate) (no data submitted)

c) conclusion with regard to fluorine

issues to be considered (issues reported and data provided):
presence of fluorine in
- complete feed for poultry, horses and rabbits (SCAN opinion)
– feedingstuffs of marine origin in particular marine krill
– Magnesium oxide
- Calcium carbonate (lime products in general)

5) Mercury

a) Feedingstuffs derived from fish/of marine origin

- current ML for mercury in fish meal is 0.5 ppm and for fish feed 0.1 ppm.

- the ML for complete fish feed is regularly exceeded based on data 1997-1999. In 2000 ML was not exceeded (information provided by Norway – doc. 006)

b) feed materials of mineral origin

- current ML 0.1 ppm

- level proposed by EMFEMA for Calcium carbonate : 0.3 ppm (doc. 004). No data are provided to support this proposal
CCA – Europe proposes a level of 1 ppm for mercury in calcium carbonate; Data are provided but data do not support the level of 1 ppm. Methods of analysis used have too high limits of detection. (document 017)

c) conclusion with regard to mercury

issues to be considered (issues reported and data provided):
presence of mercury in
- fish feed
– calcium carbonate

6. Cadmium

a) Feedingstuffs derived from fish/of marine origin

- Current ML for cadmium in fish meal is 2 ppm and in fish feed 0.5 ppm

- No problem with current EU levels (only low frequency of non-compliance (2 %) with the presence of cadmium in fish feed with levels just above the ML) (document 006)

b) feed materials of mineral origin

- Legislation: maximum level for cadmium in phosphates 10 ppm /no ML for cadmium for other feed materials of mineral origin / ML for cadmium in mineral feedingstuffs: 5 ppm

- proposed levels by EMFEMA: phosphates: 10 ppm// MgO: 2 ppm, CaCarbonate: 2 ppm, oystershells: 1 ppm, dolomite 1 ppm (document 004).
* data provided by EMFEMA for the presence of cadmium in phosphates support the current ML of 10 ppm (doc. 005)
* data provided EMFEMA for the presence of cadmium in MgO indicate that the proposed level is 2 ppm is probably too high (data less than 2 ppm// data less than 0.5 ppm (doc 016)

- level proposed by CCA-Europe for cadmium in calcium carbonate : 1 ppm. Data provided by CCA-Europe support the level proposed by CCA-Europe (document 017)

c) conclusion with regard to cadmium

issues to be considered (issues reported and data provided):
presence of cadmium in
- pig feed (SCAN opinion)
(– calcium carbonate)
(- Magnesium oxide)

7. Mycotoxins

– Cefetra proposes a level of 50 ppb of aflatoxine B1 in copra (current maximum level: 20 ppb). No data have been provided

8. Overview of issues to be considered

presence of **arsenic** in

- seaweed meal
- fish feed / fish meal
- magnesium oxide
- calcium carbonate
- palm kernel expeller

presence of **lead** in

- green fodder and phosphates (complete feed for sheep) – reduction of level (SCAN opinion)
- Calcium carbonate (lime products in general)

presence of **fluorine** in

- complete feed for poultry, horses and rabbits (SCAN opinion)
– feedingstuffs of marine origin in particular marine krill
– Magnesium oxide
- Calcium carbonate (lime products in general)

presence of **mercury** in

- fish feed
– calcium carbonate

presence of **cadmium** in

- pig feed (SCAN opinion)
(– calcium carbonate)
(- Magnesium oxide)