

ADVISORY COMMITTEE ON ANIMAL FEEDINGSTUFFS

47th Meeting of ACAF on 23 September 2009

Information Paper

EC DEVELOPMENTS

**Secretariat
September 2009**

EC DEVELOPMENTS

1. This paper outlines the main developments in relation to EC legislation and related matters since the ACAF meeting held on 5 June 2009.

Official feed and food controls - Regulation (EC) No 882/2004

Implementing rules for import controls for 'high-risk' feed and food of non-animal origin

2. European Commission Regulation (EC) 669/2009 implementing the above rules was published in the Official Journal on 25 July 2009 and will apply from 25 January 2010. The Regulation is available at:

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:194:0011:0021:EN:PDF>

3. The Agency is currently developing the measures that are needed to give effect to the Commission Regulation at national level and will be consulting stakeholders on these in due course.
4. The Commission has started discussion with Member States on the development at EU level, of guidelines on the principles and criteria for deciding which products should be subject to the provisions in the Regulation and on the technical application of the Regulation. Stakeholders' views have been sought on the issues arising from these discussions and have been kept up-to-date on developments via the FSA's website at:

<http://www.food.gov.uk/foodindustry/regulation/europeleg/euupdates/>.

Review of fees and charges for official controls

5. The Commission will start discussions with Member States in September 2009 on possible future options for changes to the provisions on fees and charges for official controls in Regulation 882/2004. This is in response to the findings of an external study carried out in 2008 which, in particular, considered the scope of existing arrangements and whether the system of mandatory fees should be extended.

Genetically Modified Organisms (GMOs)

6. Three GM maize varieties which had received a favourable opinion from EFSA were tabled for a vote in the Standing Committee on 22 July -- 50122 x NK603, MON 89034 and MON 88017. None obtained a qualified majority, and in line with established procedures will be referred for further consideration by the Council of Ministers.

7. EFSA recently delivered a favourable opinion on a GM cotton variety, 281-24-236 x 3006-210-23 x MON88913.
8. There has been no progress towards a technical solution for the presence of low levels of unauthorised GM varieties in imports from non-EU countries, which had first been proposed by the Commission in the Spring of 2008.
9. The Commission has advised that it expects to undertake an evaluation of the operation in practice of EC Regulation 1829/2003 on genetically modified food and feed in 2010. This will include the circulation to stakeholders of a questionnaire prepared by consultants appointed by the Commission.

Adoption of the Regulation on the Marketing and Use of Feed

10. The draft Regulation on the placing on the market and the use of feed was adopted by the Council of Ministers on 22 June 2009 and was published in the Official Journal of the European Union as Regulation 767/2009 on 1 September 2009. It will come into effect on 1 September 2010.
11. The Food Standards Agency has drawn up a descriptive note summarising, on an Article-by-Article basis, the provisions of the Regulation. The descriptive note can be viewed using the link below:

<http://www.food.gov.uk/foodindustry/farmingfood/animalfeed/ecmarketinganduseregulation>

European Food Safety Authority (EFSA)

12. The following Opinions have been published by the EFSA Scientific Panels FEEDAP and CONTAM since the Committee was updated in June 2009:

Additive / contaminant	Additive category and functional group	EFSA Opinion
Chromium methionine	Nutritional – trace element	Unable to conclude on safety or efficacy. There is no evidence that Chromium (Cr) is an essential trace element. Cr can have beneficial zootechnical effects when animals are not healthy – but response is highly inconsistent. The toxicology of Cr is not fully understood yet.
3-phytase produced by GMM	Zootechnical –	Positive conclusion on the

Additive / contaminant	Additive category and functional group	EFSA Opinion
<i>Aspergillus niger</i> (CBS 101.672)	digestibility enhancer	reduction of minimum recommended dose for pigs for fattening.
6-phytase (IUB No 3.1.3.26) produced by GMM <i>Aspergillus oryzae</i> (DSM 17594)	Zootechnical – digestibility enhancer / substance which favourably affects the environment	Positive conclusion on safety and efficacy for use in feed for poultry, weaned piglets and pigs for fattening.
Endo-1,4- β -glucanase (EC 3.2.1.6) and endo-1,3(4)- β -xylanase (EC 3.2.1.8) produced by two strains of <i>Trichoderma reesei</i>	Zootechnical – digestibility enhancer	Positive conclusion on safety and efficacy for use in feed for chickens for fattening.
<i>Bacillus subtilis</i> DSM 17299	Zootechnical – gut flora stabiliser	Unable to conclude on compatibility with maduramicin ammonium, monensin sodium, narasin, salinomycin sodium and semduramicin sodium.
Endo-1,4- β -xylanase, endo-1,3(4)- β -glucanase and pectinase (polygalacturonase)	Zootechnical – group not indicated	Positive conclusion on safety, but unable to conclude on efficacy as not provided with three studies (conducted according to the guidelines) that demonstrated efficacy.
Endo-1,4- β -xylanase (EC 3.2.1.8) produced by <i>Aspergillus niger</i> (CBS 109.713)	Zootechnical – digestibility enhancer	Positive conclusion on safety and efficacy for use in feed for chickens for fattening and ducks.
Endo-1,4- β -xylanase (EC 3.2.1.8) produced by GMM <i>Trichoderma reesei</i> (ATCC PTA 5588), α -amylase produced by GMM <i>Bacillus amyloliquefaciens</i> (ATCC 3978) and subtilisin produced by GMM <i>Bacillus subtilis</i> (ATCC 2107)	Zootechnical – digestibility enhancer	Positive conclusion on safety and efficacy for use in feed for chickens and ducks for fattening. Positive conclusion on safety and efficacy for turkeys for fattening. However, the methods of analysis for this additive are not considered suitable for official control methods by the CRL.
Serine protease (EC 3.4.21) produced by a GMM <i>Bacillus licheniformis</i>	Zootechnical – digestibility enhancer	Positive conclusion on safety and efficacy for use in feed for chickens for fattening.
Paromomycin sulphate	Histomonostat for the treatment of blackhead in turkeys	The EFSA Opinion was presented to the Standing Committee and Member States and the

Additive / contaminant	Additive category and functional group	EFSA Opinion
	As there are currently no products authorised for histomoniasis this was an urgent application submitted under Article 15 of Regulation 1831/2003 for turkeys for fattening and turkeys reared for breeding.	Commission agreed that the data provided were not sufficient to grant authorisation. However, the dossier could be discussed again when more data are available.

Opinions relating to the safety of use of colouring agents in animal nutrition

13. EFSA has recently published the third part of its Opinion relating to the safety of colouring agents in animal nutrition. Previous parts of this opinion examined general principles and a range of carotenoids/xanthophylls. These were summarised in the EC Developments papers from the ACAF meetings of 7 February 2006 and 28 November 2006 (EC/06/07 and EC/06/31 – see Annex).

14. The latest document looks at the safety of β -apo-8'-carotenal, ethyl ester of β -apo-8'-carotenoic acid, lutein and zeaxanthin. None of these colourants raised any particular safety concerns. However, EFSA recommended the introduction of specifications for each carotenoid/xanthophylls, or to adjust or supplement existing specifications. Specifically, EFSA has recommended maximum contents for each carotenoid/xanthophyll (accounting for the combined use of red and yellow carotenoids) and recommended to exclude β -carotene from the list of colouring carotenoids/xanthophylls.

Standing Committee on the Food Chain and Animal Health (SCoFCAH): Animal Nutrition Section

Votes

15. Votes in favour were obtained for the authorisation of 11 feed additives at the June and July 2009 meetings of SCoFCAH. These are summarised below.

Additive	Additive type	Vote in favour achieved for
25-hydroxycholecalciferol	Nutritional -	An extension of the authorisation to use in

	vitamin	feed for all poultry and pigs.
Selenomethionine produced by <i>Saccharomyces cerevisiae</i> CNCM I-3399	Nutritional – trace element	Authorisation as a feed additive for all species.
Zinc chelate of hydroxyl analogue of methionine	Nutritional – compound of trace element	Authorisation as a feed additive for chickens for fattening.
<i>Aspergillus oryzae</i> (NRRL 458)	Zootechnical – digestibility enhancer	An administrative amendment terms of authorisation (change of trade name of product).
Endo-1,4- β -xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> (CBS 114044)	Zootechnical – digestibility enhancer	Authorisation for use in feed for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and weaned piglets.
<i>Clostridium butyricum</i> CBM588 (FERM-P 1467)	Zootechnical – gut flora stabiliser	Authorisation for use in chickens for fattening.
Guanidinoacetic acid	Nutritional additive – Amino acids, their salts and derivatives.	Authorisation as a feed additive for chickens for fattening.
<i>Lactobacillus rhamnosus</i> CNCM-I-3698 and <i>Lactobacillus farciminis</i> CNCM-I-3699	Zootechnical – gut flora stabiliser	Administrative amendment terms of authorisation (change of trade name of product).
<i>Pediococcus acidilactici</i> CNCM MA 18/5M	Zootechnical – other zootechnical additive (favourably affects animal growth)	Authorisation for use in salmonids and shrimp.
<i>Saccharomyces cerevisiae</i> CNCM I-1077	Zootechnical – digestibility enhancer	Authorisation for use in horses.
<i>Saccharomyces cerevisiae</i> CBS 493.94	Zootechnical – digestibility enhancer	An extension of the authorisation to use in feed for all horses.

Discussions

Proposed changes to limits for certain contaminants in animal feed

16. Following the EFSA Opinions on mercury and gossypol as undesirable substances in animal feed, the Commission is to propose further amendments to the Undesirable Substances Directive 2002/32. These are summarised in the table below.

Undesirable substance	Products intended for animal feed	Previous Maximum Permitted Level in mg/kg		New Maximum Permitted Level in mg/kg
Mercury ^a	Feed materials with the exception of: - feedingstuffs produced by the processing of fish or other marine animals - calcium carbonate	0.1 0.5 0.3		0.1 0.5 0.3
	Compound feed with the exception of: - compound feed for fish - compound feed for dogs, cats and fur animals	0.1 ^b 0.1 ^b 0.4 ^b	0.2 ^c 0.2 ^c - ^c	0.1 0.2 0.3
Nitrites	Fish meal	60 ^d		-
	Feed materials with the exception of: - silage	-		15 ^d
	Complete feedingstuffs excluding: - feedingstuffs for dogs and cats with a moisture content exceeding 20% feedingstuffs intended for pets except birds and aquarium fish	15 ^d		15 ^d
Free gossypol	Feed materials with the exception of: - cottonseed - cottonseed cakes and cottonseed meal	20 5000 1200		20 5000 1200
	Complete feedingstuffs with the exception of:	20		20
	- complete feedingstuffs for adult cattle; sheep and goats	500		500
	- complete feedingstuffs for poultry (except laying hens), goats (except kids) and calves - complete feedingstuffs for rabbits, sheep (except lambs) and pigs (except piglets)	100 60		100 60
Mowrah, Bassia, Madhuca —Madhuca longifolia (L.) Macbr. (= Bassia longifolia L. = Illipe malabrorum Engl.), Madhuca indica Gmelin (= Bassia latifolia Roxb.) = Illipe latifolia (Roseb.) F. Mueller)	All feedingstuffs	^e		-

Amendments shown in **bold** Deletions shown in ~~strikethrough~~

^a maximum levels refer to total mercury

^b levels for complete feedingstuffs

^c levels for complementary feedingstuffs

^d expressed as sodium nitrite

^e Seeds and fruit of the plant species as well as their processed derivatives may only be present in feedingstuffs in trace amounts not quantitatively determinable.

Grey area products

17. Discussions have continued on the development of guidelines to clarify the distinction between feed materials, feed additives and other products such as veterinary drugs. Member States are considering the general approach and criteria for categorisation and will consider producing a list to indicate which 'grey area' substances can be considered to be feed materials. The legal status of such a list has yet to be addressed. The Commission has drafted a paper to provide guidance on the categorisation of feed products. The paper contains current definitions for feed products (e.g. feed materials, additives and processing aids), a set of criteria to help in case by case assessments (e.g. no 'dual listing') and a list of 'grey area' substances that SCoFCAH has already agreed are feed materials. The paper will be revised and a working group will be held to discuss the issue in further detail.

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ANNEX

Excerpt from ACAF/06/7 EC developments paper from the meeting held on 7 February 2006 regarding the EFSA Opinion on the safety of use of colouring agents (part I).

- '30. FEEDAP, the Panel on additives and products or substances used in animal nutrition has published an Opinion on astaxanthin, a natural colourant.
- 31. The Panel could not establish a 'no observed effect level' (NOEL) nor an 'acceptable daily intake' (ADI), as chronic studies and full toxicological data were not available.
- 32. FEEDAP has suggested that supplementing salmonid feed with astaxanthin does not increase flesh astaxanthin levels of farmed fish greatly compared to wild fish. It is therefore considered by the Panel, that the use of astaxanthin at up to the maximum permitted level in feed presents no significant risks to the consumer.

Excerpt from ACAF/06/31 EC developments paper from the meeting held on 28 November 2006 regarding the EFSA Opinion on the safety of use of colouring agents (part II).

'Three red carotenoids, capsanthin, citranaxanthin and cryptoxanthin were also reviewed with no safety issues raised. The Panel considered discontinuation for the approval of beta-cryptoxanthin as a sensory additive, due to its low absorption in poultry and minimal effect in pigmenting eggs and tissues.'

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