EUROPEAN COMMISSION
DIRECTORATE-GENERAL XXIV
CONSUMER POLICY AND CONSUMER HEALTH PROTECTION
Directorate B - Scientific Health Opinions
**Unit B3 - Management of scientific committees II**

# Report of the Scientific Committee for Animal Nutrition on the use of Formaldehyde as a preserving agent for animal feedingstuff (Opinion: October 1995, updated 11 June 1999)

## TERMS OF REFERENCE (October 1994)

1. Is the incorporation of formaldehyde into the feedingstuffs under the conditions requested (Table 1) likely to affect their characteristics or livestock production?

2. Under the conditions of use requested (Table 1) are the conditions of Article 7 of Council Directive 70/524/CEE fulfilled?

## BACKGROUND

The precepts governing the admission of additives in the animal feedingstuffs within the Community are set by Council Directive 70/524/EEC[1] and the rules for the marketing of compound feedingstuffs are fixed by Directive 79/373/EEC[2]. According to Article 1 and to Article 2 of Directive 70/524/EEC and 79/373/EEC respectively the following definitions shall apply:

Additives: substances, or preparations containing substances, other than premixtures referred to in (h) which, when incorporated in feedingstuffs, are likely to affect their characteristics or livestock production;

Feedingstuffs: 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;

Complete feedingstuffs: mixtures of feedingstuffs that, by reason of their composition, are sufficient for a daily ration;

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

Ingredients (raw materials): 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

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1 O.J. No. L270 (14.12.70) p.1. as amended by Council Directive 84/587/EEC (O.J. No. L319 (08.12.84) p.13)

2 (O.J. No. L86, 06.04.79 p. 30) As last amended by Council Directive 93/74/EEC of 13 September 1993 on feedingstuffs intended for particular nutritional purposes (O.J. No. L237, 22.09.93 p.23)

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inorganic substances, whether or not containing additives, which are intended to be entered for circulation as straight feedingstuffs or for the preparation of compound feedingstuffs or as carriers of premixtures.'

According to Article 7 (2) of Directive 70/254/EEC when amendments are made to Annex I or Annex II, an additive shall be included in Annex I only if:

(a) It has a favourable effect on the characteristics of those feedingstuffs or on livestock production when incorporated in such feedingstuffs;

(b) At the level permitted in feedingstuffs, it does not adversely affect human or animal health or the environment, nor harm the consumer by altering the characteristics of livestock products;

(c) Its presence in feedingstuffs can be controlled;

(d) At the level permitted in feedingstuffs, treatment or prevention of animal disease is excluded; this condition does not apply to substances of the kind listed in Annex I (D);

(e) For serious reasons concerning human or animal health its use must not be restricted to medical or veterinary purposes.

Products listed in Council Directive 64/54/EEC[3] are also generally authorised for feed. Article 5 (a) of this directive establishes, by way of derogation from Article 1, that Member States may maintain in force the provisions of their national laws relating to the use in foodstuffs of formic acid and its salts, and in regard to formaldehyde, Council Directive 74/62/EEC[4] amending for the ninth time Directive 64/54/EEC[5], permits Member States to maintain the provisions of their national laws relating to the use of formaldehyde in Grana Padano cheese[6]. This derogation is maintained for a further period of three years by Directive 78/145/EEC[7]; the derogation has been maintained thereafter, but more recently in 1990, the SCF has expressed its negative opinion of the use of Formaldehyde as a food preservative, therefore it will not be retained in a future amendment of this Directive.

A request for the inclusion of Formaldehyde ($CH_2O$; EEC Number E-240), under the conditions described in Table 1 has been addressed to the Commission.

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3 On the approximation of the laws of the Member States concerning the preservatives authorised for use in foodstuffs intended for human consumption, (O.J. No. 12, 27.01.64 p.161)

4 O.J. No. L 38 11.02.74 p.29

5 O.J. No. L 38, 11.02.74, p. 29. 5

6 Since 1992 the Consorzio per la Tutela del Formaggio Grana Padano has prohibited the use of formaldehyde in Grana Padano production

7 O.J. No. L 44, 15.02.78 p. 23

Table 1. Annex I. G. Preservatives

| Species or category of animals | Maximum age | Minimum content mg/kg of complete feedingstuffs | Maximum content mg/kg of complete feedingstuffs | Other Provisions |
|---|---|---|---|---|
| All species or categories of animals | - | - | 660 | All feedingstuffs except skimmed milk and silage, when applied as an aqueous spray using air atomization apparatus in a purpose designed application-system equipped with suitable facilities for containing any possible emissions and venting those emissions to a safe place. |

It should be noted that under heading G of the Annex I to Council Directive 70/524/CEE formaldehyde (E 240) is already authorised under the conditions described in Table 2.

Table 2. Annex I. G. Preservatives

| Species or category of animals | Maximum age | Minimum content mg/kg of complete feedingstuffs | Maximum content mg/kg of complete feedingstuffs | Other Provisions |
|---|---|---|---|---|
| Pigs | 6 months | - | 660 | Skim dried milk only. Maximum content: 600 mg/kg |
| All species or categories of animals | - | - | - | (for silage only) |

Formaldehyde handling may present some hazards to the user, in effect, in Council Directive 67/548/EEC[8] last amended by Commission Directive 98/98/EEC[9], formaldehyde in solution in concentrations

- equal to or superior to 25% was classified as toxic, corrosive, irritant and suspect of being carcinogenic (category 3),
- between 5% and 25% was classified as harmful, irritant and suspected of being carcinogenic (category 3) and,
- between 1% and 5% was classified as irritant and suspected of being carcinogenic (category 3).

The Commission will encourage the scientific work required on formaldehyde and, where necessary, will amend these classifications.

In regard to the use of formaldehyde in the work environment, the European Parliament at it own-initiative, produced a resolution[10] addressed to the Council, the Commission and the Member States Governments calling on the Commission to submit to it a report specifying the legal rules laid down to regulate concentrations of formaldehyde in enclosed spaces. An overall strategy for controlling dangerous substances was adopted in Council Directive

8 O.J. No. L351 , 07.12.81 p.5

9 Commission Directive 98/98/EC of 15 December 1998 adapting to technical progress for the 25th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (O.J. No L355 of 30.12.1998, p. 1)

10 Resolution Schleicher (O.J. No. C274 of 15.10.84, p. 38)

80/1101/EEC[11] that make it possible to set limits values for working environment to such agents at Community level.

A Commission recommendation 90/326/EEC[12] to the member States concerning the adoption of a European schedule of occupational diseases, advocates that the diseases mentioned in this schedule must be linked directly to the occupation. One of these originates from formaldehyde exposure. The evaluation of the risks involving existing substances appears in the European Inventory of Existing Commercial Substances (EINECS)[13]. These are in effect or in preparation in the Member States in so far as they concern health, safety, environmental and consumer protection in accordance Council Regulation (EEC) No 793/93[14] which aims to diminish the disparities between the laws, regulations and administrative provisions relating evaluation of EINECS.

The SCAN expressed its opinion on the use of formaldehyde in feedingstuffs for Piglets, on the 20 April 1983[15].

## OPINION OF THE COMMITTEE

### 1. General remarks

Formaldehyde is very widely used in industry and a large number of toxicological studies have been conducted. Most of these are on formaldehyde as a gas, in aqueous solution or mixed with methanol and water (formalin). Typically, toxic effects are confined to contact sites (e.g. mucosal membranes) at high level of exposure. Thus it is demonstrated that formaldehyde is genotoxic, irritant and a local carcinogen at these high exposure levels. In feed some of the formaldehyde will bind to the protein. A sensitive analytical technique is required to identify in treated feed (both freshly treated and stored feed) the proportions of free formaldehyde, reversibly bound formaldehyde or irreversibly bound formaldehyde.

There are no published literature studies which allow the toxicity of formaldehyde incorporated in feed to be adequately assessed, although there are a number of studies on formalin, paraformaldehyde and formaldehyde vapour.

### 2. Efficacy

2.1. *Antimicrobial effects of formaldehyde.*

Formaldehyde has been used as a means of microbial decontamination and formaldehyde fumigation is used, for example, to eliminate *Salmonella* from animal production facilities. However, there appears to be relatively few

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11 On the protection of workers from the risks related to chemical, physical and biological agents at work, (O.J. No. L327, 03.12.80, p. 8) amended by 88/642/EEC (O.J. No. L356, 24.12.88 p.74)

12 O.J. No. L160, 26.06.90; p.39

13 O.J. No C 146, 15.06.90, p. 1

14 On the evaluation and control of the risks of existing substances ( O.J. No. L84, 05.04.93 p. 1)

15 Report of the Scientific Committee for Animal Nutrition on the use of Formaldehyde in feedingstuffs for Piglets. Opinion expressed: 20 April 1983. (Fourth Series, 1984. Report EUR 8769. Catalogue Nº CD-NK-83-010-EN-C, p.111)

recent studies on the effective anti-microbial concentrations of formaldehyde in different applications. There is a body of experience of using formaldehyde in ensiling. At the dose range of 500 – 600 mg per kg the results have been unsatisfactory with aerobic deterioration becoming a problem. This indicates that, at least in an environment with high water activity, the formaldehyde, probably due to being inactivated by silage components, soon looses its anti-microbial efficacy.

2.2. *Summary of the efficacy data provided by the company.*

The company reports that, having analysed since 1992 13,000 samples of treated feedingstuffs, application of 660 mg formaldehyde / kg feed is effective in eradicating microbial (*Salmonella*) contamination. However it would appear that no assessment was made of the degree of microbial contamination before treatment and so these results provide only presumptive support for the claims made by the Company. Better evidence of effect is shown by the examination of samples of European broilers feed where 16/111 untreated feeds proved positive for *Salmonella* compared to 46/540 after treatment with 330 mg/kg and 0/109 with 667 mg/kg.

Using samples of various feed ingredients (wheat bran, barley, wheat, palm kernel, rape meal and copra) which had failed an official *Salmonella* test, the Company was able to show that subsequent treatment with 660 mg formaldehyde / kg feed eradicated the *Salmonella* (MPN method). However, the ingredients examined are not the major sources of protein in animal feeds. Also, it is not apparent from the data supplied, whether the results represent a single time point immediately after the treatment, or whether several samplings were performed spanning the average storage periods of the feedingstuffs in question.

In artificial contamination experiments with *Salmonella senftenberg* (1500 - 2000 CFU per gram), *Salmonella* was still detectable in contaminated fishmeal at two days after the treatment with 667 mg of formaldehyde per kg.

Table 3: Recontamination of formaldehyde treated fishmeal with *Salmonella senftenberg* at various time points after the treatment. Results of the *Salmonella* assays at 1, 5 and 9 days after the recontamination.

| | **Day of the recontamination** | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | | | 15 | | | 21 | | | 30 | | |
| | **Day of analysis** | | | **Day of analysis** | | | **Day of analysis** | | | **Day of analysis** | | |
| | 1 | 5 | 9 | 1 | 5 | 9 | 1 | 5 | 9 | 1 | 5 | 9 |
| **Dose (mg/kg)** | | | | | | | | | | | | |
| **0** | + | + | + | + | + | + | + | + | + | + | + | + |
| **333** | + | + | + | + | + | + | + | + | + | + | + | + |
| **667** | + | + | - | + | + | - | + | + | - | + | + | + |
| **999** | - | - | - | + | - | - | + | - | - | + | + | - |
| **1332** | - | - | - | + | - | - | + | - | - | + | - | - |
| **1665** | - | - | - | - | - | - | - | - | - | + | - | - |

+ : *Salmonella* detected

The ability of formaldehyde to prevent recontamination of feeds was also examined. In these experiments, fishmeal was artificially inoculated with *Salmonella senftenberg* at various intervals (1-60 days) after formaldehyde treatment (see table 3).

It is evident from the studies cited above that:

- Formaldehyde is weakly bacteriocidal at the concentration claimed (667 mg/kg feed), taking at least 2 days in artificial contamination experiments and 5 days in recontamination experiments (see table 3) to eradicate the *Salmonella*.

- The ability to resist recontamination at the concentration claimed decreases with time

- Only the highest doses tested (1332 and 1665 mg/kg) appeared to protect fishmeal from recontamination for 21 days or more after the initial treatment.

*2.3. Conclusion*

SCAN concludes that :

(1) At the proposed incorporation rate, the Company has provided some evidence that formaldehyde is able to eradicate or substantially reduce the numbers of pathogenic bacteria such as *Salmonella* in animal feedingstuffs.

(2) The proposed dose, however, does not provide sufficient protection against recontamination

(3) The proposed use of a single concentration of formaldehyde does not take account of the considerable variations in the composition of feeds or feed ingredients. The extent to which formaldehyde becomes irreversibly bound to the feed will influence its antimicrobial capacity.

SCAN also notes that formaldehyde is very reactive forming easily Schiff bases by linking to terminal amino-groups of proteins. This reaction can limit the availability of amino-acids and thus reduce the nutritional value of proteins.

The suggested level of formaldehyde is low compared to the FDA-approved level of 2.5 kg per ton or 2.5 gram of formaldehyde per kg feed in feeds and feed ingredients needed to keep them *Salmonella* negative for 21 days.

To ensure the absence of pathogenic bacteria, SCAN considers that much higher incorporation rates of formaldehyde into the feed are likely to be required. There is an additional risk at greatly increased incorporation rates of corrosion of metal surfaces creating surface pitting, which may facilitate multiplication of such bacteria.

## 3. Safety of use of formaldehyde

### *3.1. Target animal safety*

No specific investigations have been instigated by the company to assess target animal safety. Instead reference is made to a number of published works in which pigs, poultry and various ruminant species have been fed feed or feed ingredients treated with various amounts of formaldehyde. In virtually all cases, the purpose of these studies was to assess performance on the treated feed and only performance-related parameters were measured. In these studies the actual level of formaldehyde in the feed is not always provided or, when available, is sometimes lower than that presently claimed. In addition, in the case of ruminants, several studies deal with the use of formaldehyde applied to protein or protein-rich feed to increase resistance to microbial degradation in the rumen. These studies are not relevant to the issue of safety. Only in the case of two studies made with poultry, in which the feed was treated with concentrations of formaldehyde substantially greater than 660 mg/kg, macroscopic and histopathological checks were performed. No adverse effects related to feed treatment were found in either case.

Thus, with the exception of broilers, the evidence supplied by the company is inadequate to allow an assessment of safety for target animals to be made.

In an earlier opinion, SCAN concluded that the addition of formaldehyde to skimmed milk at the level of 600 mg/kg for feeding piglets was acceptable in terms of safety.

### 3.2. *User's safety*

Worker (farmers) exposure is of importance with respect to inhalation of formaldehyde, inhalation of formaldehyde containing dust and dermal contact (irritation, sensitisation).

There is wide experience of the use of formaldehyde in industry in many countries. Both short term exposure limit (STEL) and 8 hr air workplace standards have been established.

*3.2.1.* Inhalatory exposure was measured by personal monitoring during handling (15 minutes) at the farm. Feedstuffs were treated with formaldehyde 37% (1kg/ton, i.e. 330 ppm), 4h and 24h before the monitoring. Concentrations were between 0.09 and 0.26 ppm with the feedingstuff treated 4h before, while no formaldehyde could be detected when feed was treated 24 h before. No experimental details, only a summary of these studies was available. These figures fall within the EU short term occupational exposure limits of 0.4-3 $mg/m^3$. However data on the claimed level of use have not been provided.

3.2.2. Exposure through dust is another potential risk. No actual figures were given for dust levels, but an estimation of formaldehyde risk through dust particles, using a Maximum Exposure Limit of 10mg

dust/$m^3$, yields a maximum intake of 1 µg/kg/day under worst case conditions, which represents an adequate level of safety.

3.2.3. The risk for sensitisation is not specifically considered in the dossier. However, in regard of the widespread application of formaldehyde, the use of formaldehyde as feed preservative is not likely to pose a significant additional risk factor at these low levels of incorporation.

Conclusion

The user's safety has not been demonstrated with data according to the claimed level of use of formaldehyde.

3.3. *Environmental safety*

Formaldehyde is known to occur naturally in the environment and to be rapidly broken down. Similarly, any residual formaldehyde, if excreted, will also be promptly degraded. It is therefore unlikely that use of formaldehyde treated feed will constitute an environmental risk. To confirm this, data would be required on levels of formaldehyde from treated feed excreted by livestock. However, no directly relevant data is provided on environmental safety in the dossier submitted for authorisation.

3.4. *Consumer safety*

As data has not been provided on residual levels of formaldehyde or formaldehyde related products in animal produce, the safety for consumers of additional formaldehyde introduced by treated feed cannot be considered as demonstrated by the company.

## General Conclusion

Under the conditions of use requested (Table1), the conditions of Article 7 of Council Directive 70/524/EEC are not fulfilled.

## Documents supplied to SCAN

Document of Anitox LTD on Formaldehyde

Technical dossier provided by the Ministry of Agriculture, Fisheries and Food (UK) : Assessment of formaldehyde as an additive in feedingstuffs

Supplementary dossier on formaldehyde in animal feedingstuffs (Anitox Ltd) provided by the Ministry of Agriculture, Fisheries and Food (UK), 1994

Anitox Ltd Response dossiers

Review of the toxicological implications of formaldehyde treatment of feeding stuffs. Report no. RI96/TOX/005. Robens Institute, Guildford, Surrey. UK

Federal Register, October 6, 1998, number 193, p. 53579-53580, Food Additives Permitted in Feed and Drinking Water of Animals; Formaldehyde

Feedstuffs, November 9, 1998 (AFIA asks FDA to clarify formaldehyde rule)

Guideline for Utility Studies for Anti-*Salmonella* Chemical Food Additives in Animal Feeds (Draft), Center for Veterinary Medicine, 1994

21 Code of Federal Regulations Part 573 Food additives permitted in food and drinking water of animals : formaldehyde. Federal register, vol.61 n° 69, p.15703, 1996.

Document of the Scientific Committee for Food : summary of new toxicological data relevant to the use of formaldehyde in cheese production

Observations on disinfection regimes used on *Salmonella enteritidis* infected poultry units, Dawies, R.H. and Wray, C. Poultry Science 1995, 74: 638-647.

Report of the Scientific Committee for Food on Formaldehyde in “Grana Padano” cheese (1977)

Report of the Scientific Committee on Animal Nutrition on the use of formaldehyde in feeding piglets.

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