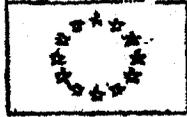


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EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Director-General

SANCO

Brussels, 24.05.2003
D/G - G/Prise - 62005/2003

Dear Mrs Jackson,

During the discussion and vote of the Committee on the Environment, Public Health and Consumer Policy of the European Parliament (ENVI) on the proposal of the Commission for a European Parliament and Council Directive amending Directive 95/2/EC on food additives other than colours and sweeteners (COM (2002)622 - 2002/0274 (COD)) on 11 June 2003, you asked for the views of the Commission on two proposed amendments:

- (1) To authorise carbon monoxide (CO) as a food additive.
- (2) To withdraw authorisations for nisin and natamycin

Mr Dymc has asked me to give you the following explanations:

1. Carbon monoxide

The Commission received the request from Norway to authorize CO as a packaging gas. Norway had authorised temporarily the use of carbon monoxide as a food additive under Article 5 of Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption. The authorisation came to an end on 1 October 2000.

On 13 December 2001, the Scientific Committee on Food adopted an opinion on the use of carbon monoxide as a packaging gas for fresh meat. The Committee concluded that *"there is no health concern associated with the use of carbon monoxide in a gas mixture of carbon dioxide and nitrogen as a modified atmosphere packaging gas for fresh meat provided temperature during the storage and transport does not exceed 4°C. However, the Committee wishes to point out that, should products be stored under inappropriate conditions, the presence of CO may mask visual evidence of spoilage."*

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The main technological function of CO is to provide a stable red colour in fresh meat. It is our opinion that to maintain the red colour of fresh meat would mislead the consumer as regards the freshness of the product. Therefore, we consider that this general criterion for the authorisation of a food additive as listed in Annex II of Directive 85/376/EEC, namely the use of an additive shall not mislead the consumer, is not fulfilled. As a secondary effect, the use of CO may also present a hazard to the health of consumers if the treated meat product is not stored under appropriate conditions (below 4°C) as it may mask spoilage. This is of particular relevance in Member States which have a warm climate. In the ENVI Committee the oral proposal was made to inform the consumer by labelling that the colour of the meat does not necessarily reflect its freshness. It is our opinion that even such extensive labelling would not solve the problem, as part of the consumers base their decisions on the general appearance of a meat product rather than on the written information given on the label.

2 a) Nisin

Nisin is an antimicrobial peptide secreted in fermented milk by a lactic acid bacterium. It is authorized as a preservative for cheese and other products. The main uses of nisin are to control food spoilage bacteria. Nisin is effective against *Listeria* and spore-forming heat-resistant bacteria such as those that cause botulism. It is not used in medicine and there seems to be no resistance problems. If the authorization of nisin would be withdrawn, alternative preservatives would need to be used. The Commission agrees with the principle that anti-microbial agents should not be used in the food production chain. However, in this particular case, the Commission will ask the European Food Safety Authority (EFSA) for an opinion on the effectiveness of nisin as an agent to prevent botulism and on possible alternative substances, before deciding whether it is appropriate to propose changes to the existing authorisations.

2 b) Natamycin

Natamycin is a fungicide and authorized for the surface treatment of cheese and catseges. In 2002, the WHO/FAO expert committee (JELFA) evaluated natamycin with a specific request to assess the issue of antimicrobial resistance. The Committee concluded that resistance would not be "an issue". The Commission will ask EFSA for an opinion whether by applying good manufacturing practice (GMP) the use of the substance could be avoided, before deciding whether it is appropriate to propose changes to the existing authorisations.

I take the opportunity to comment on other amendments endorsed by the ENVI Committee on 11 June 2003:

A number of amendments request the Commission to review existing authorisations. One amendment asks even to review all authorisations for additives by end of 2006. These amendments duplicate the requirements of the framework Directive on additives 89/107/EEC which requests in its Annex II that all additives are kept under continuous observation and must be re-evaluated whenever necessary. To this end, the Commission has submitted to the European Parliament and the Council an intake report on additives and identified a number of additives for which more refined intake estimates should be carried out. The Commission requested the Member States to submit actual food consumption data combined with the actual usage levels for these additives. On the basis of these data the Commission will decide whether the current authorisations have to be modified. To meet the concerns expressed in the respective amendments, the

Commission could agree to the inclusion of an Article in the present Directive which requests the Commission to forward to the European Parliament a progress report on these re-evaluations within 2 years.

On nitrates and nitrites, I would like to inform you that we have already asked EFSA to advise the Commission with high priority on the minimum levels of nitrates and nitrites required to still exert a sufficient preservative effect to avoid botulism. The levels must be suitable to protect the consumers from microbial risks in the whole Community, including the Southern Member States which have a warm climate.

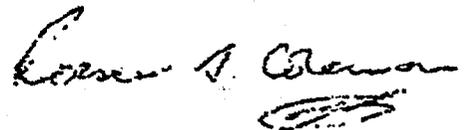
For the new additive hydrogenated poly-1-decene, one amendment requests a review within 2 years. This additive has been evaluated by the Scientific Committee on Food (SCF) in July 2001 and an acceptable daily intake of 6 mg/kg bodyweight has been set. The proposed authorisations ensure that the ADI is not exceeded. Thus, we cannot agree to allocate resources for the priority evaluation of this recently evaluated additive. In addition, it would be far too early to review the authorisation for this new additive within 2 years, since the substance needs to be authorised and used for a few years before realistic intake estimations can be carried out.

On the three additives E 230, E 231 and E 232, which are used for post-harvest treatment of citrus fruit, the intention of the Commission is to cover them in the future by the pesticide legislation. Therefore, we propose to delete them from Directive 94/7/EC. In order to meet the concerns about a possible legal gap on authorisation and labelling obligations, the Commission could accept the inclusion of an Article which keeps these substances as food additives until relevant provisions are included in the pesticide legislation. However, this provision can only apply to E 231 and E 232 since the pesticide industry does not support E 230 in the evaluation programme of pesticides according to Directive 91/414/EEC, meaning that the industry did not commit itself to submit the data necessary for evaluation. Thus, the authorisation for this additive should be withdrawn.

The Commission proposed to amend the definition of stabilisers in order to apply the requirements for food additives to cross-link proteins used in the preparation of meat products. Currently, such substances are used under national rules. By widening the definition of stabilisers and thus including such substances into the scope of Directive 75/2/EC, they have to undergo a safety evaluation which certainly would improve the current situation in respect to the protection of consumers' health. Also, consumers would be informed about their use by labelling.

The rapporteur together with the shadow rapporteur, the Council representatives and the Commission are currently negotiating in order to achieve adoption of this proposal in the first reading. I sincerely hope that these explanations will help to find agreement between the three institutions.

Yours sincerely,



Robert J. Coleman