



FOOD — SCIENCE AND TECHNIQUES

# Reports of the Scientific Committee for Food

(Thirty-second series)



EUROPEAN COMMISSION



European Commission

# **food science and techniques**

**Reports of  
the Scientific Committee for Food**

**(32nd series)**

**Opinions of the Scientific Committee for Food on:**

*An activated lactoperoxidase system*  
*Re-evaluation of five modified celluloses*  
*Addendum concerning enzymatically hydrolysed carboxymethylcellulose*  
*The potential risk to health presented by lead in food and drink*  
*The evaluation of sucrose acetate isobutyrate (SAIB)*  
*The acceptability of wines treated with certain ion-exchange resins*  
*Certain additives for use in infant formulas, follow-on formulas and weaning foods*  
*Carrageenan*

**Revisions of previous opinions on:**

*Alginates*  
*Modified starches – starch sodium octenyl succinate*  
*Extraction solvents – dichlormethane*  
*Glycerol esters of wood resin*  
*Food irradiation: use in relation to Camembert cheeses*

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## OPINION ON AN ACTIVATED LACTOPEROXIDASE SYSTEM

EXPRESSED ON 19 JUNE 1992

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### 1. Terms of reference

The Committee was asked to evaluate the safety in use of an activated lactoperoxidase system for the control of micro-organisms in milk intended for cheese production.

### 2. Background

The activated lactoperoxidase system concerned relies for its anti-microbial action on the interaction between three components:

- bovine lactoperoxidase
- sodium thiocyanate
- and
- hydrogen peroxide.

The hydrogen peroxide may be generated either by a secondary enzymatic system consisting of glucose oxidase and its substrate glucose, or by lactic acid bacteria such as those of the lactobacillus group.

### 3. Discussion and conclusions

The Committee noted that:

- a) the system proposed is intended to combat the microbial contamination of milk used in the manufacture of different types of cheeses. The committee insists that, if such a system were to be employed, it should not have the effect of encouraging practices which would lead to a failure to use all hygiene measures aimed at improving the microbiological quality of milk intended for the manufacture of cheese and of the conditions under which the manufacture takes place;
- b) the level of each component of the complex system proposed varied according to the conditions of assay. It does not seem to the Committee that the practical circumstances of use in different situations are as yet well defined, nor that the microbiological efficacy of the system (in particular against *Listeria monocytogenes*, *Staphylococcus aureus*, *Salmonella typhimurium*, *Escherichia coli* etc.) has been rigorously demonstrated;
- c) the dossier submitted does not follow the guidelines of the Committee concerning the presentation of data on food enzymes (Twenty-seventh Series of Reports of the Scientific Committee for Food, 1992 EUR14181) in relation to the two enzymes constituting the system: lactoperoxidase and glucose oxidase.

**The Committee is unable to reach a judgement on the dossier without further information on the following points:**

- full dossiers on lactoperoxidase and glucose oxidase presented according to the committee's guidelines;
- information on the precise composition of the system under the different conditions of use for which approval is sought and evidence of the system's microbiological efficacy;
- for the different conditions under which the system would be used, information on the kinetics of the formation of oxythiocyanate ion and the disappearance of thiocyanate ion, and the kinetics of the formation, disappearance and/or accumulation of hydrogen peroxide

(the Committee noted that for identical proportions of each of the constituents of the system, the accumulation of hydrogen peroxide appeared to depend on the concentration of the system in the solution employed).

The Committee considers these data to be necessary to demonstrate that the system can be used in a well controlled manner.

**The committee is unable to come to any judgement on the toxicological data supplied in the absence of the detailed information requested above.**

In effect, the Committee must have at its disposal data concerning the potential toxicity of the system functioning under rigorously identical stoichiometric conditions to those which would occur in practice and which would therefore produce intermediate and end products in the same quantities and proportions.

Finally the Committee wishes to have at its disposal a detailed account of the results of the utilisation of the activated lactoperoxidase system in milk, in the countries where the system has already been employed.

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## OPINION ON RE-EVALUATION OF FIVE MODIFIED CELLULOSES

EXPRESSED ON 13 MARCH 1992

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### 1. Terms of reference

The Committee was asked to re-evaluate in the light of the most recent information on technology and toxicology, the modified celluloses permitted by the Council Directive relating to emulsifiers, stabilisers, thickeners and gelling agents for use in foodstuffs (74/329/EEC, as amended).

### 2. Background

Five modified celluloses are permitted in the EEC under the Directive on Emulsifiers, Stabilizers and Thickening Agents (74/329/EEC). These comprise methylcellulose (E 461), hydroxypropylcellulose (E 463), hydroxypropylmethylcellulose (E 464), ethylmethylcellulose (E 465) and sodiumcarboxymethylcellulose (E 466). Specifications for these five substances have been published in the Directive 78/663/EEC. Of these compounds only E 466 has been evaluated by the SCF in the 7th Series of Reports in 1978, when a group ADI of 25 mg/kg b.w. (previously established by JECFA in 1973) was endorsed together with the rider, that specifying a limit to the molecular weight was considered unnecessary. The Committee had not been asked at that time to evaluate the other permitted modified celluloses.

### 3. Discussion

JECFA has evaluated seven modified celluloses, the five substances in the EEC Directive as well as ethylcellulose and ethylhydroxyethylcellulose. That committee initially established a group ADI of 25 mg/kg b.w., based on the traditional procedure of using the highest NEL obtainable in lifespan studies without causing any nutritional effects and a safety factor of 100. It was realised subsequently that food additives which are poorly, if at all, absorbed and practically non-toxic when tested extensively in animals, do not produce adverse effects in feeding studies, even at the maximum levels of dietary incorporation consistent with mild adverse nutrition of the test animals. The observed gastro-intestinal effects were clearly produced by the physical effects of the bulk and the hydrophilic properties of the ingested materials. It was therefore illogical to persist with the traditional evaluation procedures for these substances.

If, in addition, information on the chemical structure, absorption, tissue distribution, excretion, metabolism and human exposure together with appropriate clinical observations suggested, that no true toxic effects could be expected even after high intakes, then a numerical limitation of the ADI becomes unnecessary. JECFA therefore allocated, on the basis of these arguments, in 1990 a group ADI "not specified", as had been done with other bulking food additives, to the seven modified celluloses evaluated in its 35th session. The committee made, however, a general comment on the need to consider the possible laxative effect of an excessive total dietary consumption of all bulking agents, particularly in view of the additivity of this effect. It therefore suggested that some controls to limit consumption should be introduced.

A review of the available data, summarized in the attached table, on the five modified celluloses listed in the Directive 74/329/EEC, which covered chemical structure, biochemical behaviour, toxicological properties and clinical observations in man, demonstrates that modified celluloses are practically non-absorbed by mice, rats rabbits and man, are of low toxicity and do not possess carcinogenic properties. Only E 461 and E 466 have been tested for mutagenic properties, both substances yielding no evidence of any mutagenic potential. The three modified celluloses E 461, E 463 and E 466 have been shown to cause no embryotoxic or teratogenic effects. The human data, covering ingestion of amounts up to 30 g/day/person, suggest the usual effects of undigestible fibre on the bulk, the physical consistency, and the frequency of faeces without however causing clinically significant diarrhoea at this level of ingestion. Information available to the Committee indicates that average daily intakes from present uses are well within this range.

#### **4. Conclusions**

Consistent with its evaluation of bulking agents with similar biological properties, the Committee allocated an ADI "not specified" to the five modified celluloses listed in Directive 74/329/EEC.

This evaluation relates to present food additive uses only, where levels of addition are commonly in the range 0.2 - 3.0 % of the foodstuff. Provided uses remain as at present and levels of addition are within the limits of those necessary for strictly technological purposes, true clinical laxative effects are unlikely to occur. However, the contribution of other dietary constituents with potential laxative effects to the overall dietary load of substances with this biological property should be kept under review.

#### **Selected references**

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Wyatt, G.M., Horn, N., Gee, J.M. & Johnson, I.T. (1988) *Brit. J. Nutr.*, 60, 197-207.

modified cellulose	biochemistry	acute toxicity	irritation - sensitization	subacute toxicity	subchronic toxicity	chronic toxicity carcinogenicity	reproductive toxicity	teratogenicity	genotoxicity	human observations
Ethylcellulose	-	+	-	-	+	-	-	-	-	-
Ethylhydroxy ethylcellulose	-	+	+	-	+	-	-	-	-	+
E 461	+	+	+	+	+	+	-	+	+	+
E 463	+	+	+	-	+	-	-	+	-	-
E 464	+	+	+	+	+	+	-	-	-	+
E 465	+	-	-	+	-	+	-	-	-	-
E 466	+/*	+	+	+	+	+	-	+	+	+

\* caecal microflora investigated as well

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**ADDENDUM TO OPINION ON MODIFIED CELLULOSES**  
**OPINION ON ENZYMATICALLY HYDROLYSED CARBOXYMETHYLCELLULOSE**  
**EXPRESSED ON 11 DECEMBER 1992**

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Subsequent to the request to re-evaluate the five modified celluloses permitted by Council directive 74/329/EEC, the Committee was asked to evaluate the safety in use of an enzymatically hydrolysed form of carboxymethylcellulose. The enzyme concerned is a cellulase derived from *Trichoderma longibrachiatum* (*T. reesei*) and its use results in a significant reduction of the average molecular weight of the carboxymethylcellulose and hence in changes in its technological properties. The Committee was provided with a 90-day feeding study on the material carried out in rats and a radiolabel metabolic balance study comparing hydrolysed carboxymethylcellulose with conventional carboxymethylcellulose, also in rats.

The Committee concluded that the enzymatically modified carboxymethylcellulose in question is acceptable and included it in the group ADI "not specified" previously allocated to the five currently permitted modified celluloses. The group ADI is subject to the limitation of the celluloses concerned to the levels of addition strictly necessary for technological purposes and is subject to the need to keep under review the overall dietary load of substances with a potential for laxation.

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**OPINION ON THE POTENTIAL RISK TO HEALTH PRESENTED BY LEAD IN FOOD AND  
DRINK**

EXPRESSED ON 19 JUNE 1992

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## **1. Terms of reference**

The Committee was asked to evaluate the potential risk to health presented by lead in food and drink. This evaluation took into account a report prepared at the request of the Commission of the European Communities by the National Food Agency of Denmark (Levnedsmiddelstyrelsen). It addressed essentially two aspects:

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## **2. Discussion**

### **2.1 Toxicity of lead**

A large number of data concerning the toxicity of low doses of lead in man have become available in the course of the last 10 to 15 years. The key questions today seem to be those concerning the effects of lead on the central nervous system of the foetus and of the young child, and its action on arterial blood pressure in the adult. These effects are apparent with circulating blood-lead levels of the order of around 15 µg/dl.

Whilst in 1990 the Committee endorsed the provisional tolerable weekly intake (PTWI) of 25 µg of lead per kg bodyweight for children proposed by the WHO in 1986, it considers it must now undertake a comprehensive re-examination of the toxicity of lead in order to arrive at a new evaluation of the PTWI for children and for adults in the light of the most recent data.

The Committee wishes to pursue this work in concertation with other organisations who have also undertaken the re-evaluation of the toxicology of lead (the WHO International Programme on Chemical Safety; the United States Food and Drug Administration and Environmental Protection Agency).

### **2.2 Dietary sources of lead**

The three major dietary sources of lead, responsible for at least 70% of exposure, are:

- fruits and vegetables;
- cereals;
- drinks.

Their respective contributions, variable with country according to dietary habits, are essentially identical. Amongst drinks, wine is a non-negligible source of lead.

Where, as for certain countries, comparative data exist, it is apparent that dietary contributions of lead have diminished in the course of recent years. This diminution can be attributed:

- to the use of lead-free petrol for automobiles in the case of fruits and vegetables;
- to a progressive reduction in the use of lead solders for cans used to conserve fruits, vegetables and fruit juices etc.

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### **3. Conclusion**

The mean level of contamination of foodstuffs does not seem to be a cause for alarm. However, the high values which have been observed in extreme cases must be considered as anomalies due to errors during production and processing which it is necessary to identify.

Recent data obtained in the European Community on the initiative of the European Commission show that this is also the case for wine produced in the Community. For this reason the Committee encourages the Commission to undertake studies designed to establish the cause of the rare anomalies observed, enabling measures to be taken to eliminate progressively the production of wines with lead contents grossly in excess of the mean.

Efforts should equally be made towards the elimination of lead solders in cans for food-use within the Community and on the surveillance of imported cans.

The "seeking out" of anomalies could be the means of a rapid improvement in the situation. Longer term action should follow with the objective of further lowering the mean lead level of foodstuffs in general.

The Committee wishes to undertake a re-examination of the toxicity of lead in concertation with other organisations which are presently considering the issue.



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## OPINION ON THE EVALUATION OF SUCROSE ACETATE ISOBUTYRATE (SAIB)

EXPRESSED ON 9 OCTOBER 1992

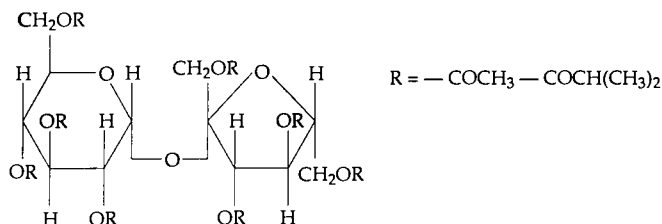
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### 1. Terms of reference

The Committee was asked to evaluate the safety use of Sucrose Acetate Isobutyrate (SAIB) as a stabilizer in soft drinks.

### 2. Background

SAIB is a mixed acetyl and isobutyryl ester of sucrose.



Use levels may vary from 50 - 400 mg/l, being most commonly 300 mg/l, of beverage.

### 3. Evaluation and conclusion

Metabolic studies in rats, dogs and man have shown, that the rat and man eliminate about 50% of SAIB as expired CO<sub>2</sub>, while the dog eliminates only 25% by this route. Rat and man excrete about 20 - 30 % of the administered dose as metabolites in their urine and 10 - 20 % as intact SAIB and metabolites in the faeces. The dog, on the other hand, excretes about 7% metabolites in the urine and about 50% of SAIB and metabolites in the faeces. Dogs appear to excrete highly acetylated sucrose in the urine while the rat and man excrete less highly acetylated partial sucrose esters. Although rats, dogs, monkeys and man absorb SAIB easily, the dog, in contrast to rat, monkey and man, appears to be unable to degrade the highly acetylated sucrose.

With regard to hepatobiliary function the dog appears to be a particularly sensitive species. Short and long-term studies in the mouse and rat as well as a one year study in monkeys produced no adverse hepatic effects and showed no evidence of interference with hepatobiliary function. Studies in human volunteers similarly produced no indications of any adverse effects on hepatobiliary function. In the light of the above studies taken in conjunction with the reassuring evidence from the study in a primate species, it would not be unreasonable to consider the hepatic effects, noted in the dog, as having little relevance to the evaluation of the safety of SAIB in man. The chronic studies in the rat, the species relevant for evaluating the safety in man, can therefore be used for establishing a no-adverse effect level and consequently of an ADI.

This no-adverse effect level is based on the results of long-term studies which have shown that at the highest dose levels used, there is some evidence of an effect on bodyweight and food consumption in both sexes. At the 1g/kg b.w. dose level, no consistent adverse effects were noted.

Using a safety factor of 100 in view of the adequacy of the data base now available, the Committee allocated an acceptable daily intake (ADI) of 10 mg/kg b.w. calculated as SAIB.

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# OPINION ON THE ACCEPTABILITY OF WINES TREATED WITH CERTAIN ION-EXCHANGE

## RESINS

EXPRESSED ON 11 DECEMBER 1992

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### 1. Terms of reference

To advise on the acceptability of wines treated with certain ion-exchange resins (IXR) from the point of view of safety to health or the consumer.

### 2. Background

The use of IXRs in oenological practice has been under consideration since 1945 and is being practised particularly in the USA and Australia. The primary objective of this process is the prevention of further precipitation of K-bitartrate in wine, bottled after the usual bulk cold storage, by the reduction in the pH of the wine or grape juice. The technology involves the treatment of a portion, varying from an average 5 % to a maximum of 20% of the total wine stored before bottling, by a bypass operation with continuous refeeding into the bulk wine. The actual portion eventually passed through the IXR column depends on the analysis of the wine before treatment, particularly for K<sup>+</sup>, pH and tartrate. It is known that the K<sup>+</sup> concentration in the grape berry is the most important indicator for the pH, the titratable acidity and the K-bitartrate content of grape juice and wine. In a good quality product there should be no excess of K<sup>+</sup>, and thus a lower pH and smaller K-bitartrate content.

Cold storage for a considerable period and the addition of tartaric acid have been, in the European Community, the traditional means of stabilising stored wine, largely preventing sediment formation after bottling. In the USA there is an absolute consumer requirement for bottled wine to be perfectly clear without any evidence of haze or deposit. The US wineries claim that, because of the often extreme variations in temperature encountered across the country during transport and storage on business premises, the traditional methods will not guarantee a stable and absolutely clear bottled wine when marketed. They are therefore dependent on using essentially cationic IXRs to exchange the K<sup>+</sup> for H<sup>+</sup> in a portion of the stored bulk wine, thereby avoiding the unstable supersaturation with K-bitartrate. In rare circumstances, for special regional products already having initially a very low pH, K<sup>+</sup> may be exchanged for Na<sup>+</sup> with a maximum limit of 200 mg Na/l for nutritional reasons. It should also be borne in mind, that it is current practice in the European Community to treat portions, between 10%-40%, of clarified grape juice with IXRs and then to blend these back with the untreated portion.

The preferred treatment is by cationic IXRs but anionic IXRs are also used, though far less frequently, in the production of dessert wines. Anionic IXRs are not used for general treatment because even small changes in the anion content are likely to affect the taste and quality characteristics of the wine to a recognisable extent. Mixed cationic and anionic IXRs are never used. Any treatment with cationic and anionic or non-ionic IXRs is always carried out consecutively in separate IXR towers.

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### 3. Discussion

#### 3.1 Nature of IXRS

In the USA the use of IXRs for treating potable water and in food processing is generally permitted under FDA Regulations 21 CFR 173.25. These regulations list 19 different IXRs (see annex), setting out their approximate chemical type, physical form, functions and conditions of use. They also lay down strict limits for purity and global but not specific migration of IXR constituents under prescribed conditions of testing. Of these 19 listed IXRs some 4 (a12, a13, a16, a18) are excluded from use in the treatment of wine. Of the remaining 15 IXRs only 5 (a1, a3, a4, a5, a7) are claimed to be in actual use by wineries. Of these the IXR a1 is the most widely employed cationic IXR in the production of table wines. The IXRs a4 and a7 (anionic) are used far less frequently and then only in the production of dessert wines. No information on the use of IXRs a3 and a5 was available. The BATF (= US Bureau of Alcohol, Tobacco and Firearms) is, however, anxious to maintain the other 10 IXRs as possible candidates for reasons of flexibility. Neither the BATF nor the US wine industry are able to state at present, which of the 10 potential candidate IXRs were still being manufactured today and were specifically suitable for the treatment of wine.

The monomers permitted for producing the resin matrix include styrene, divinylbenzene, phenolformaldehyde, methacrylic acid and methacrylate, epichlorhydrin and acrylonitrile. All of these are also presently permitted in the Community for the production of packaging and materials in contact with food. The permitted additives include  $\text{NH}_3$ ,  $\text{H}_2\text{O}_2$ , acetone, methylchloride, chloromethylating agents, trimethylamine, dimethylamine, diethylenetriamine, dimethylethanolamine, triethylenetetramine, and tetraethylenepentamine. Almost all of these are also in use in the Community for the production of plastic food packaging. The overall global extraction limit set the FDA is 1 mg/l organic extractives in either distilled water, 15% aqueous alcohol or 5% acetic acid. In the  $\text{H}_2\text{O}_2$ -modified resins up to 7 ppm nitrogenous extractives are permitted. The Australian wine industry apparently uses the same IXRs that are permitted in the USA.

The Council of Europe (CoE) has published a Resolution AP(89)2 which aims at regulating the use of IXRs in general food processing but excludes cellulosic and inorganic matrix IXRs. One appendix lists the acceptable monomers and other starting substances, chemical modifiers, and polymerisation aids. Another appendix lists the provisionally acceptable substances falling into the same three categories. The limits for migration of the IXR constituents and the simulants to be used in the determination of the migration characteristics are identical with those set by the FDA in 21 CFR 173.25. In addition, a large number of specific migration limits for many of the permitted components of the IXRs is laid down, the "not detectable" limitation being set at 0.1 mg/l extractant. The CoE list does not indicate which substances are to be permitted specifically for the treatment of alcoholic beverages and wine. In this respect the CoE lists are less useful for assessing the safety aspects of the IXRs used in the treatment of wine.

### 3.2 Safety to health considerations

The FDA Regulations 21 CFR 173.25 permit the use of 19 IXRs for treating potable water and in food processing. Of these 5 IXRs are used in practice for the treatment of wine since the early 1960s. The remainder is used for the treatment of potable water and in the processing of food.

The basis for FDA approval was

- a) some IXRs were already in use before the 1958 Food and Drug Act;
- b) the monomers and additives used in these IXRs have been approved already for years as components of food contact materials without apparently having caused any health problems;
- c) these IXRs have been tested for compliance with the migration limits set out in 21 CFR 173.25 and the data, including some studies with radio labelled materials, are held by the FDA;
- d) none of the monomers are known carcinogens and only a few may be regarded as probable carcinogens;
- e) exposure of the consumer from migration into food was considered infinitesimal taking into account the ratio between the very large mass of food or liquid processed and the weight of IXR used in the treatment columns.

Migration from the aforementioned 15 IXRs is limited in the FDA Regulations to 1 ppm of organic extractives obtained with each of the solvents, distilled water, 15% ethyl alcohol and 5% aqueous acetic acid, when prepared ready for use with food. Because of the chemical nature of the IXRs certain modifications of the procedure for determining migration are specified in the Regulations. It is thus clear that the residues from migration are strictly limited particularly when IXRs are used for the treatment of wine.

The cationic IXRs, once loaded into an exchange tower, remain in constant use from 10-20 years. About 2% of IXR per year requires replacement with fresh resin because of losses as a result of purely physical break-up of the resin particles during the regeneration, washing and nitrogen blowing cycles required at regular intervals to maintain the activity of the column. The resulting fine powder of broken up IXR is removed every time the column is used after regeneration and before a new treatment cycle. Because anionic IXRs are slightly less stable, about 4% IXRs have to be replaced per year giving an average column life of about 10 years.

Between 75% -100% of bottled US table wine on the market contains wine treated with IXRs. The quantity of wine treated in any by-pass operation varies, depending on the analysis of the bulk wine, between 10%-15%, as a maximum, of the total stored bulk wine before bottling. The actual quantity of wine passing through an exchange column is about 75-150 million gallons in 10 years for cationic IXRs and slightly smaller for anionic IXRs. Thus, in both cases, any migrant from the IXR would be enormously diluted even before it reaches the main bulk of the wine stored before bottling.

Taking into account the vast dilution of any migrant from the IXRs the exposure of the consumer can be regarded as infinitesimal, whichever of the 5 IXRs is being employed. In addition the toxicological information available on these IXRs suggests that the monomers are not carcinogenic and have not given rise to toxicological problems.

In view of the infinitesimal actual exposure of the consumer to any migrating component from the IXRs a detailed knowledge of the SMLs of all monomers and additives is superfluous. Furthermore, because IXRs are never mixed in any given single column and these columns are used in series, there is also no need to consider combination effects of IXRs. It would also be inappropriate to demand general screening tests of IXRs with solvents other than those legally stipulated in 21 CFR 173.25, which are incidentally similar to those listed in the COE Regulation.

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#### **4. Conclusion**

On the basis of the information received on the technology, on the general nature of the IXRs, and on the likely exposure of the consumer to any migrating constituents of these IXRs, which might conceivably be present in wine bottled after treatment with the IXRs a1, a4 and a7, the only IXRs claimed to be used in the USA and in Australia, the Committee is of the opinion, that the consumption of imported wines treated with the aforementioned IXRs does not constitute any health hazard to the consumer.

Before the Committee can consider extending the advice on acceptability to wines treated with other IXRs, the Committee would require, as a minimum, information similar to that furnished for the 3 IXRs mentioned above as well as any other relevant information which might be needed for an appropriate risk assessment, in particular, more details on the actual quantities of wine passing through the exchange columns for each IXR used and their replacement frequencies.

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**List of ion-exchange resins permitted in the USA for wine treatment**


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Resin code	Chemical name
a(1)	Sulfonated copolymer of styrene + divinylbenzene
a(2)	Sulfonated anthracite coal
a(3)	sulfite modified crosslinked phenol-formaldehyde w/sulfonic acid groups on side chains
a(4)	Methacrylic acid-divinylbenzene copolymers
a(5)	Crosslinked polystyrene chloromethylated + aminated w/trimethylamine, dimethylamine, diethylenetriamine, or dimethylethanolamine
a(6)	Diethylenetriamine, triethylenetetramine, tetraethylenepentamine crosslinked w/epichlorohydrin
a(7)	Crosslinked phenol-formaldehyde activated w/triethylene tetramine and/or tetraethylenepentamine
a(8)	Reaction resin of formaldehyde, acetone, and tetraethylenepentamine
a(9)	Completely hydrolyzed copolymers of methyl acrylate and divinylbenzene
a(10)	Completely hydrolyzed terpolymer of methyl acrylate, divinylbenzene and acrylonitrile
a(11)	Sulfonated terpolymers of styrene, divinylbenzene and acrylonitrile or methyl acrylate
a(12)	Methyl acrylate - divinylbenzene copolymer w/ $\geq 2\%$ divinylbenzene, aminolyzed w/dimethylaminopropylamine
a(13)	Methyl acrylate - divinylbenzene copolymer w/ $\geq 3.6\%$ divinylbenzene, aminolyzed w/dimethylaminopropylamine
a(14)	Epichlorohydrin crosslinked w/ammonia
a(15)	Sulfonated tetrapolymer of styrene, divinylbenzene, acrylonitrile, and methylacrylate from mixture of monomers w/ $\leq 2\%$ acrylonitrile + methyl acrylate
a(16)	Methyl acrylate - divinylbenzene - diethylene glycol divinyl ether terpolymer w/ $\geq 3.5\%$ divinylbenzene and $\leq 0.6\%$ diethylene glycol divinyl ether, aminolyzed w/dimethylaminopropylamine
a(17)	Styrene-divinylbenzene crosslinked copolymer, chloromethylated + aminated w/dimethylamine and oxidized w/hydrogen peroxide w/ $\leq 15\%$ vinyl N,N-dimethylbenzylamine-N-oxide and $\leq 6.5\%$ nitrogen
a(18)	Methyl acrylate - divinylbenzene - diethylene glycol divinyl ether terpolymer w/ $7\%$ divinylbenzene and $\leq 2.3\%$ of diethylene glycol divinyl ether, aminolyzed w/dimethylaminopropylamine and quaternized w/methyl chloride
a(19)	Epichlorohydrin crosslinked w/ammonia and quaternized w/methyl chloride to contain $\leq 18\%$ strong base capacity





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# OPINION ON CERTAIN ADDITIVES FOR USE IN INFANT FORMULAE, FOLLOW-ON

## FORMULAE AND WEANING FOODS

EXPRESSED ON 11 DECEMBER 1992

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### 1. Terms of reference

To advise on the safety of a series of additives for use in infant formulae, follow-on formulae and weaning foods not included in the European Commission Proposal for a Council Directive on Food Additives Other Than Colours and Sweeteners (1).

### 2. Background

The European Commission Proposal for a Council Directive on Food Additives Other Than Colours and Sweeteners (1) includes at Annex VI a list of the food additives which should be permitted in infant formula, in follow-on formula and in weaning foods. The Committee has given an opinion on the use of these technological additives in earlier reports on **Infant Formulae and Follow-Up Milks** (27/4/83) (Fourteenth Series) (2) and on **Weaning Foods** (27/10/89;30/3/90) (Twenty-fourth Series)(3). Industry has now submitted a request for the addition of a new set of additives to Annex VI of the Council Proposal.

### 3. Discussion and conclusions

#### 3.1 Principles used in the evaluation

The consideration of the safety of additives for use in infant formulae, follow-on formulae and weaning foods is a special case. The immaturity of the organs of absorption, metabolism or excretion may mean that the distribution of an additive in the body is different in the infant or young child than in the adult. In addition, developing organs and tissues may show greater sensitivity to the effects of an additive than mature organs and tissues. The Committee notes that infant formulae milks can constitute virtually the entire infant diet and therefore patterns of exposure to additives used in such formulae is very different to the normal situation of additives approved for general food use.

For all these reasons the Committee considers it prudent that the number and amounts of additives used in foods for infants and young children should be kept to the minimum necessary. The Committee confirms its long standing view that additives should not be permitted in foods specially prepared for infants. Rarely, exceptional technological circumstances may justify the use of an additive. In such cases submissions should be accompanied by a full justification, including evidence of safety, for the use requested. Where the requests concern additives falling into functional classes represented by substances approved already, the justification should explain why the existing additives are not sufficient for the use in question

This is especially so for additives in infant formulae. As part of the evaluation of the acceptability of additives in this class of foods it is necessary to have detailed information about the function of the additive, the minimum concentration of it required to have the desired effect, and the benefits arising from the use of the additive. It should also be noted that an additive with an ADI 'not specified' for general food use may not be acceptable for use in infant formulae or other foods specially prepared for infants and young children.

### 3.2 Additives for use in infant formulae

#### *E338 Phosphoric acid*

The Committee considered phosphoric acid as an additive for general food use in its Report on a First Series of Food Additives of Various Technological Functions (Twenty-fifth Series, 1991)(4). The possible concern arising from calcium, magnesium and phosphate imbalances in the diet was noted and the Committee endorsed the JECFA estimate of an MTDI of 70 mg/kg bodyweight, calculated as P, for the sum of phosphates naturally present in food and derived from additives in diets nutritionally adequate in calcium. Provided this requirement was met a group ADI 'not specified' was allocated to the phosphates.

The Committee also considered the optimum phosphorus content of infant formulae in its Report on Infant Formulae (2). A maximum limit for phosphorus of 22mg/100kJ in infant formulae was recommended in addition to a calcium/phosphorus ratio between 1.2 and 2. These recommendations are now incorporated into the European Commission Directive on Infant Formulae and Follow-on Formulae (5). Since infant formulae containing phosphoric acid as an additive will have to comply with these limits, the Committee considers that the use of phosphoric acid in infant formulae is acceptable.

#### *Thickening agents/stabilisers*

E407	Carrageenan
E410	Carob bean gum
E412	Guar gum
E440	Pectins
E1412	Distarch phosphate
E1414	Acetylated distarch phosphate
E1422	Acetylated distarch adipate

The remaining new additives requested for use in infant formulae are all stabilisers used to keep liquid ready-to-feed formulae in a homogenous condition. Liquid ready-to-feed infant formulae are convenient and hygienic and have the advantage that it is easier to incorporate long chain polyunsaturated fatty acids, such as linoleic and alpha-linolenic acid, into the formula.

The Committee in its Report on Infant Formulae (2) did not recommend the use of thickening agents other than pre-cooked or gelatinised starch. This view was based in part on the recommendations published in 1977 by the European Society for Paediatric Gastroenterology and Nutrition (ESPGAN) (6).

The Committee notes that thickening agents have been extensively tested in animals in order to be permitted for general food use. Data on effects in young animals can be derived from reproduction or multigeneration studies where exposure of the offspring to thickening agents continues through lactation and weaning. The Committee considers that a lack of toxicological data on thickening agents is not a general problem but could apply in certain cases.

On the other hand, in accordance with the general principles formulated above the Committee wishes to have more information about the technological function of each of these additives before it can be convinced that each new thickening agent/stabiliser requested is essential in liquid ready-to-feed formulae. In addition to this general requirement the Committee has specific concerns about the use of the following thickening agents.

#### *E407 Carrageenan*

The general food use of carrageenan is currently under reevaluation by the Committee. During this review, the Committee noted the uptake of small amounts of carrageenan in certain species (7-10), the effects on the immune system in animals (11-14) and the increased intestinal permeability found in very young infants (15). Although there is no direct evidence of harm from carrageenan in human infants and no toxicologically significant effects were seen in infant baboons fed carrageenan in commercial infant formulae for 16 weeks (16), high levels of reassurance are needed to permit additives in infant formulae. The Committee could not exclude the possibility of absorption of carrageenan by the immature gut or the possibility that the absorbed material might affect the immune system in the infant. The Committee does not therefore consider carrageenan acceptable for use in infant formulae.

#### *E412 Guar gum*

The Committee notes the lack of a multigeneration study or a reproduction study in which exposure to guar gum continued through lactation and weaning.

#### *E1412 Distarch phosphate/E1414 Acetylated distarch phosphate/E1422 Acetylated distarch adipate*

Pancreatic alpha-amylase activity is virtually zero at birth but several studies have demonstrated that neonates and young infants can digest a certain amount of starch (17,18). Indeed, in the absence of pancreatic amylase, salivary amylase and mucosal glucoamylase are thought to be sufficient to digest long-chain glucose polymers in many 1 month old infants (19). Salivary amylase activity in infants has been shown to be low at birth but, although variable, to increase rapidly to two-thirds of adult values by 3 months (20).

The amount of glucoamylase in the intestinal mucosa of infants under 6 months has been shown to be similar to that in older children (21) and it has been shown that digestion of starch is as rapid as in adults by 1 year of age (25). It is for these reasons that the Committee considers that pre-cooked or gelatinized starch can be added to infant formulae up to a concentration of 2g/100ml (2%) but not exceeding 30% of the total carbohydrate content (2). These recommendations are now incorporated into the European Commission Directive on Infant Formulae and Follow-on Formulae (5).

The Committee notes that most enzymatic hydrolysis studies have demonstrated little or no difference between the digestibility of chemically modified and native starches and that greater differences were seen between different native starches (22). The *in vitro* hydrolysis studies relevant to the modified starches under consideration (22) used pancreatin (a pancreatic extract including alpha-amylase) and the *in vivo* hydrolysis studies used animals after weaning (22,23). These studies may not be relevant to infants where pancreatic amylase is low although salivary amylase has a similar spectrum of activity to pancreatic amylase (20). The Committee would prefer to see direct evidence indicating that infants can tolerate the levels of modified starches requested (2.5%) since it is concerned about the possibility of fermentive diarrhoea and/or modification of intestinal flora in very young infants fed formulae containing modified starches. The Committee also wishes to see detailed justification for the use of modified starches rather than pre-cooked or gelatinised starch where there is direct evidence that they can be tolerated in infants (17,18).

The modified starches listed above were considered by the Committee for general food use in 1981 (24). They were considered acceptable but, because they also contributed to the energy balance of the diet, no individual ADIs were set. In the same report, the Committee recommended that these (and most other modified starches) could be used in infant foods and foods for young children subject to a limit of 5%. The Committee wishes to make clear that this recommendation does not apply to infant formulae. The Committee considered the use of several modified starches in its Report on Weaning Foods (3) and concluded that this use was acceptable up to a combined limit of 5g/100g.

#### *Packaging gases - nitrogen and carbon dioxide*

The Committee considered the use of these compounds as acceptable for use as packaging gases for general food use in 1990 (4). The establishment of an ADI was not considered necessary. The Committee considers the use of these packaging gases acceptable for infant formulae.

## SUMMARY TABLE OF ADDITIVES REQUESTED FOR USE IN INFANT FORMULAE

ADDITIVE	MAX USE LEVEL READY TO EAT	PRODUCT	OPINION
E338 Phosphoric acid	q.s.	Infant formula	Acceptable if phosphorus <22mg/100kj and calcium/phosphorus ratio 1.2-2.0
E407 Carrageenan	(0.3 g/l)		Not acceptable
E410 Carib bean gum (locust bean gum)	1.0g/l alone or together		Await confirmation of essential need
E412 Guar gum	1.0g/l alone or together		Await confirmation of essential need. No multigeneration study.
E440 Pectins	1.0g/l alone or together	Liquid ready to eat infant formula	Await confirmation of essential need
E1412 Distarch phosphate (max SO <sub>2</sub> 10ppm)	25g/l alone or together		Await confirmation of essential need; evidence that each is tolerated by infants at levels requested is desirable
E1414 Acetylated distarch phosphate (max SO <sub>2</sub> 10ppm)	25g/l alone or together		Await confirmation of essential need; evidence that each is tolerated by infants at levels requested is desirable
E1422 Acetylated distarch adipate (max SO <sub>2</sub> 10ppm)	25g/l alone or together		Await confirmation of essential need; evidence that each is tolerated by infants at levels requested is desirable
Packaging gases - Nitrogen, Carbon dioxide	q.s.	Infant formula	Acceptable

### 3.3 Additives for use in follow-on formulae

#### *E338 Phosphoric acid*

The Committee's evaluation of phosphoric acid for general food use is described above. The Committee's report on composition of follow-on formulae (2) states that mineral levels should be similar to those in cows milk and again the calcium/phosphorus ratio should not exceed 2. These recommendations are now incorporated into the European Commission Directive on Infant Formulae and Follow-on Formulae (5). Since follow-on formulae containing phosphoric acid as an additive will have to comply with these limits, the Committee considers that the use of phosphoric acid in follow-on formulae is acceptable.

#### *E440 Pectins*

In its First Report on Emulsifiers and Stabilizers, the Committee endorsed the JECFA ADI 'not specified' for pectins (26). More recently (27), JECFA have considered further data on pectins including a three-generation reproduction study using 2% or 5% non-amidated pectin but no controls. There were no clear adverse toxicological effects. Pectin, at up to 1% in all weaning foods or up to 2% in gluten free weaning foods, was considered acceptable in the Committee's Report on Weaning Foods (3). The Committee considers the use of pectins in acidified follow-on formulae acceptable at the requested level of 5g/l (0.5%).

#### *Packaging gases - nitrogen and carbon dioxide*

The Committee considers the use of these packaging gases acceptable for follow-on formulae as well as infant formulae (section 3.2).

#### SUMMARY TABLE OF ADDITIVES REQUESTED FOR USE IN FOLLOW—ON FORMULAE

ADDITIVE	MAX USE LEVEL READY TO EAT	PRODUCT	OPINION
Packaging gases - Nitrogen, Carbon dioxide	q.s.	Follow-on formula	Acceptable
E338 Phosphoric acid	q.s.	Follow-on formula	Acceptable if phosphorus level similar to cow's milk and calcium/phosphorus ratio < 2.0
E440 Pectins	5.0 g/l	Acidified follow-on formula	Acceptable

### 3.4 Additives for use in weaning foods

#### *E407 Carrageenan*

The Committee's concerns about the use of carrageenan in very young infants are described above. By the age of 4-6 months the infants' gut is more fully developed but nevertheless the Committee is not completely satisfied that its use in weaning foods is acceptable. A decision on this point is deferred until the Committee has completed its re-evaluation of the general food use of Carrageenan. At that time the Committee will also decide whether there is any need to revise its previous opinion on the acceptability of Carrageenan in follow-on formulae (2).

#### *E354 L(+) Calcium tartrate*

The Committee endorsed the JECFA group ADI for tartrates of 30 mg/kg bodyweight in its Report on a First Series of Food Additives of Various Technological Functions (4). The JECFA evaluation did not report any multigeneration studies but tartrates are normal constituents of foods. The Committee's Report on Weaning Foods (3) lists L(+)-tartaric acid, sodium L(+)-tartrate and potassium L(+)-tartrate as acceptable in weaning foods. The Committee considers that calcium L(+)-tartrate is also acceptable in weaning foods.

#### *E472e Mono- and diacetyl-tartaric esters of mono and di-glycerides of fatty acids (DATEM)*

DATEM was considered to be acceptable by the Committee in 1977 (26) and the JECFA ADI of 50 mg/kg bodyweight was endorsed. JECFA acknowledged (28) that some absorption of unhydrolysed compound could occur and based the ADI on a long term study published in 1950. The Committee is aware of some *in vitro* and *in vivo* hydrolysis studies on DATEM (29) which have been reported (30) to show that hydrolysis was incomplete. The Committee wishes to see this data before accepting this additive for use in weaning foods.

#### *E466 Carboxymethylcellulose*

The Committee has recently allocated an ADI not specified to a group of modified celluloses including E466. No multigeneration studies were included in the data package. The Committee wishes to complete its work on persorption of macromolecular food additives (see 1.2 (ii) above) before coming to a final view. Otherwise, the toxicological data does not indicate any effect likely to be of concern for infants and young children over weaning age.

## SUMMARY TABLE OF ADDITIVES REQUESTED FOR USE IN WEANING FOODS

ADDITIVE	MAX USE LEVEL READY TO EAT	PRODUCT	OPINION
E407 Carrageenan	500 mg/kg	Desserts and puddings	Decision deferred until completion of general review
E354 L(+) Calcium tartrate	Residue from raising agents 5g/kg	Substitute for sodium containing agents	Acceptable
E472e Mono- and diacetyl tartaric esters of mono- and di-glycerides of fatty acids (DATEM)	5g/kg	Gluten-free bakery products	Await further hydrolysis data
E466 Carboxymethylcellulose	10g/kg	Toddler meals, chocolate flavour milks	Await view expert group on persorption of macromolecular additives

### 3.5 Additives for use in nutrient preparations

Industry have requested new or amended uses of various additives in nutrient preparations intended for addition to foods specially prepared for infants and young children. In accordance with the general principles outlined in the opening section of this opinion, the Committee needs more information about the functions of and justification for the use of these additives before coming to a final conclusion. It also requires quantitative estimates of the levels of carry-over into the final food if these additives are used at the concentrations requested.



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## RE-EVALUATION OF CARRAGEENAN

OPINION EXPRESSED ON 11 DECEMBER 1992

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### 1. Terms of reference

The Committee last considered carrageenan in its 7th Series Report in 1978 when it endorsed the acceptable daily intake of 0 - 75 mg/kg bw previously established by JECFA. The Committee was asked to re-evaluate Carrageenan in the light of more recent data.

### 2. Discussion

The Committee notes that since the re-evaluation of carrageenan by JECFA in 1984 new elements, complementary to the then available data base and thus essential for the present reassessment by the SCF, have become available. These relate in the first instance to new information on the influence of processing technology on the degradation of carrageenan in food, from the FDA, when processed at a pH similar to that found in the human stomach. Secondly, a discussion of the study by Ekstrom on the hydrolysis of carrageenan by artificial gastric juice highlighted the need for further experimental evidence on the possible protective effect of the gel form of carrageenan, under these conditions. Thirdly, information was supplied to the Committee that research was in progress, both on behalf of MAFF in the UK and the FDA in the USA, to clarify the effect of food processing on the molecular weight distribution of carrageenan in the food matrix. Fourthly, the original data of the long-term monkey study on carrageenan have only very recently become available for study by national authorities and the SCF. Finally, in-vitro models are now available to investigate the effects of carrageenan and of partially degraded carrageenan on the functional capacities of the immune system.

### 3. Conclusion

The Committee concluded, that it would be premature to arrive at a final conclusion on the proposals to adjust the present ADI until the results of the relevant studies now under way are available, particularly as there appears to be no immediate urgency in the present situation of use.

The Committee also recommends that the use of carrageenan should not be permitted in infant formulas which would constitute almost the entire food supply for the infant at that age period.



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## REVISIONS OF PREVIOUS OPINIONS

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### I. ALGINATES

(opinion expressed on 19th October 1990)

The Committee previously evaluated alginic acid, its salts and its propylene glycol ester in 1978 (5th series of reports) when it endorsed the then current ADI's allocated by JECFA of 50 mg/kg b.w. for alginic acid and its salts (group ADI) and 25 mg/kg b.w. for propylene glycol alginate.

On the basis of newly presented data together with existing data the Committee has now allocated an ADI "not specified" for alginic acid and its sodium, potassium and calcium salts. It stressed that the evaluation only covered the substances when used as food additives according to GMP and not special dietary or medical uses.

For propylenglycol alginate an ADI of 25 mg/kg b.w. expressed as propylenglycol was allocated. The committee expressed the wish to re-evaluate the ADI of propylenglycol at a future stage and reiterated the request, as expressed in the 11th report series, that the intake from all sources of this solvent should be reviewed in relation to the ADI.

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### II. MODIFIED STARCHES – STARCH SODIUM OCTENYL SUCCINATE

(opinion expressed on 19th October 1990)

The Committee has previously considered a number of chemically modified starches (Reports of the Scientific Committee for Food, 2nd Series 1976 and 13th Series - EUR 7982, 1982). It has categorised them into three groups, designated A, B and C, according to their toxicological acceptability. Starches falling into Group A are considered acceptable for use in food without specific restrictions; those in Group B are considered acceptable for use in foods in general but with restrictions on their use in infant foods; and those remaining in Group C after the review of 1982 (those modified by the use of epichlorhydrin) are considered not acceptable for use in foods.

The Committee was asked to evaluate an additional modified starch, starch sodium octenyl succinate. The extent of the data available on this modified starch includes the results of short-term, 90-day and long-term feeding studies in rats. Data on caloric utilisation in rats and from mutagenicity studies and in vitro enzyme digestibility studies are also available. The Committee found this product acceptable for use in food and placed it with the other previously evaluated modified starches in Group B, that is starches which are acceptable for use in foods in general without specific restrictions but which should be subject to a maximum limit of 5 % in foods specially prepared for infants and young children.

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### **III. EXTRACTION SOLVENTS - DICHLOROMETHANE**

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(opinion expressed on 10th April 1992)

In its opinion of 21 June 1991 concerning extraction solvents (Reports of the Scientific Committee for Food, 29th Series EUR 14482, 1992), the Committee found the use of dichloromethane acceptable for the limited use of the decaffeination of tea and coffee providing that levels in the beverage as consumed are subject to a limit of not more than 50 µg/litre. The Committee was subsequently informed that this solvent is also presently used as an extraction solvent in the production of flavourings, notably those prepared from certain herbs and spices, and was asked to consider the acceptability of its continued use for this purpose.

The Committee was provided with information indicating that residues of dichloromethane in those foods where the flavourings concerned are used, do not exceed 20 µg/kg and are in practice usually less than 1.25 µ/kg. It concluded that the additional exposure which would result from these uses is small and that, taken together, the residues resulting from the decaffeination of tea and coffee and from current uses as an extractant for flavourings constitute no hazard to health. The Committee agrees that the use of dichloromethane for both of these purposes is acceptable.

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### **IV. GLYCEROL ESTERS OF WOOD ROSIN**

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(opinion expressed on 19th June 1992)

Glycerol esters of wood rosin were previously evaluated by the Committee in 1990 (26th series of reports, EUR 13913) when a temporary ADI of 0,5 mg/kg b.w. was allocated pending the results of a new 90-day rat study using well specified commercial product.

The results of a recent 90-day rat study have now been provided to the Committee and indicate a NOEL of 2500 mg/kg b.w. Assurances have been given that the material tested was the same as that used in previous studies. Although the study was not of long-term duration, when taken together with the previous studies it was adequate for the purpose of establishing a full ADI. Taking into account the 90 day duration, the Committee applied a safety factor of 200 and allocated to glycerol esters of wood rosin a full ADI of 12.5 mg/kg b.w.



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## V. FOOD IRRADIATION: USE IN RELATION TO CEMBERT

(opinion expressed on 19th June 1992)

The Committee has previously expressed its views on the irradiation of food in its 18th series of reports (EUR 10840, 1989). The Committee was asked to consider whether Camembert cheese could be added to the food classes listed in that report for which irradiation was considered acceptable. It was informed that the use of gamma-irradiation at doses up to 2.5 kGy had been requested as a means of controlling the micro-flora of Camembert cheese manufactured from raw milk.

The information provided in support of the request indicated that the efficacy of 2.5 kGy gamma-radiation as a control for *Listeria* had been adequately demonstrated, that there were no indications of the induction of radio-resistant strains of micro-organisms, and that such depletion of nutrients (vitamins) as occurred could not be considered significant because Camembert cheese was not a significant dietary source of the vitamins concerned. The Committee noted that the dossier included the results of taste panel evaluations of treated cheeses of an appropriate age and reported the absence of organoleptic effects.

The Committee agreed that the treatment of Camembert cheeses manufactured from raw milk with gamma-radiation at doses up to 2.5 kGy was acceptable from a health point of view.







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The Scientific Committee for Food was established by Commission Decision 74/234/EEC of 16 April 1974 (OJ L 136, 20.5.1974, p. 1) to advise the Commission on any problem relating to the protection of the health and safety of persons arising from the consumption of food, and in particular the composition of food, processes which are liable to modify food, the use of food additives and other processing aids as well as the presence of contaminants.

The members are independent persons, highly qualified in the fields associated with medicine, nutrition, toxicology, biology, chemistry, or other similar disciplines.

The secretariat of the committee is provided by the Directorate-General for Industry of the Commission, Division III-E-1. Recent Council directives require the Commission to consult the committee on provisions which may have an effect on public health falling within the scope of these directives.

The present report deals with opinions on:

an activated lactoperoxidase system;

re-evaluation of five modified celluloses;

addendum concerning enzymatically hydrolysed carboxymethylcellulose;

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