



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

**JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES**  
**One-hundredth meeting (Safety evaluation of certain food additives)**  
**10–19 June 2025**

**SUMMARY AND CONCLUSIONS**

*Issued on 4 July 2025*

The One-hundredth meeting of the Joint FAO/WHO Expert Committee on Food Additives was held in Rome from 10 to 19 June 2025. The purpose of the meeting was to evaluate the safety of certain food additives. The present meeting was the One-hundredth in a series of similar meetings. The tasks before the Committee were to (a) further elaborate principles governing the evaluation of food additives; (b) undertake safety evaluations of certain food additives; and (c) review and prepare specifications for certain food additives.

Dr R. Cantrill served as Chairperson and Dr D. Bedford served as Vice-chairperson. Ms A. Vlachou and Mr K. Petersen served as joint secretaries.

The Committee evaluated the safety of eight food additives and one processing aid and revised the specifications of one food additive and six processing aids.

The report of the meeting will be published as WHO Technical Report Series No. 1058. The report will summarize the main conclusions of the Committee in terms of acceptable daily intakes (ADIs) and other toxicological, dietary exposure and safety recommendations. Information on deliberations and conclusions with regards to the specifications for the identity and purity of certain food additives examined by the Committee will also be included.

The participants are listed in Annex 1. Information of a general nature that the Committee wishes to disseminate quickly is provided in Annex 2. Future work and recommendations arising from the summary report of the One-hundredth meeting are summarized in Annex 3. Finally, Annex 4 includes requests for corrections that were reported to the JECFA Secretariat, evaluated by the Committee and found to be necessary (note that these corrections will only be made in the electronic versions available in the online database).

Toxicological monographs summarizing the data that were considered by the Committee in establishing ADIs will be published as WHO Food Additives Series No. 91. New and revised specifications for the identity and purity of the compounds will be published in FAO JECFA Monographs No. 35.

More information on the work of JECFA is available at: <http://www.fao.org/food-safety/scientific-advice/jecfa/en/> and <https://www.who.int/foodsafety/en/>.

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## Toxicological and dietary exposure information and conclusions

### *Food additives and processing aids evaluated toxicologically, assessed for dietary exposure and specifications revised*

Food additive	Specifications	ADIs and other conclusions on toxicology and dietary exposure
Adipates	No <sup>a</sup>	<p>The Committee noted that the estimates of dietary exposure calculated at the current meeting are overestimated for a number of reasons. The Committee concluded that most of these conservative dietary exposure estimates greatly exceed the current group ADI of 0–5 mg/kg bw. Further, the Committee noted that there is the potential for exceedances of the current group ADI as a result of normal daily consumption amounts of an individual food.</p> <p>The Committee noted that hazard assessment procedures have evolved and additional relevant data may have become available since the numerical ADI was established at its Ninth meeting in 1965, indicating that a re-evaluation of the toxicology of adipic acid is needed.</p>
Amyloglucosidase (JECFA95-4) from <i>Rasamsonia emersonii</i> expressed in <i>Aspergillus niger</i>	R	<p>The Committee concluded that dietary exposure to this enzyme is not anticipated to pose a risk for allergenicity.</p> <p>Based on the absence of any treatment-related adverse effects in a 13-week oral toxicity study in rats, the previous Committee identified a NOAEL of 1500 mg TOS/kg bw per day, the highest dose tested. The previous Committee concluded that the dietary exposure estimate of 9 mg TOS/kg bw per day was appropriate for use in the evaluation. Comparison of the NOAEL of 1500 mg/kg bw per day with the dietary exposure estimate of 9 mg TOS/kg bw per day yields an MOE of more than 160.</p> <p>Based on this MOE and a lack of concern for allergenicity and genotoxicity, the Committee removed the temporary designation of the previous ADI and established an ADI “not specified”<sup>b</sup> for amyloglucosidase (JECFA95-4) from <i>R. emersonii</i> expressed in <i>A. niger</i> when used at the levels specified and in accordance with current GMP.</p>
Ascorbyl palmitate	R	<p>The Committee noted new studies that showed that ascorbyl palmitate was rapidly and extensively hydrolysed pre-systemically to ascorbic acid and palmitic acid. Hydrolysis of ascorbyl palmitate is mediated by carboxylesterases, which are also expressed in neonates and infants, albeit at lower levels than in adults.</p> <p>On that basis, the Committee considered that systemic exposure to ascorbyl palmitate would be low for all population subgroups.</p> <p>The Committee withdrew the previously established ADI of 0–1.25 mg/kg bw for ascorbyl palmitate or ascorbyl stearate, or the sum of both. The Committee noted that the previous ADI for ascorbyl palmitate or ascorbyl stearate, or the sum of both, was based on toxicological data for ascorbyl palmitate, and therefore established a group ADI “not specified”<sup>b</sup> for ascorbyl palmitate or ascorbyl stearate, or the sum of both.</p>
Carob bean gum	No <sup>c</sup>	<p>The Committee previously assigned an ADI “not specified”<sup>b</sup> to carob bean gum. However, an ADI does not apply to infants younger than 12 weeks since they might be at risk at lower levels of exposure compared with older age groups. To complete the evaluation, the Committee therefore requested studies in neonatal animals adequate for the evaluation of the safety of carob bean gum in infant formula. Newly submitted unpublished data obtained from a neonatal pig study evaluated at the present meeting allowed the Committee to identify a NOAEL of 2400 mg/kg bw per day, the highest dose tested.</p> <p>Based on the estimated high dietary exposures for infants, the Committee noted that MOEs calculated for the use of carob bean gum at 1000 mg/L and 6000 mg/L in infant formula were 9 and 1.5, respectively. The MOE for the high exposure calculated for infants from the use of carob bean gum at 10 000 mg/L in infant formula was less than 1.</p> <p>The Committee concluded that the MOEs based on carob bean gum concentrations of 1000 and 6000 mg/L in infant formula indicate a low risk; however, the MOE based on a concentration of 10 000 mg/L indicates a potential risk. Based on the available data and considering the short exposure period involved, the Committee concluded that there is no concern for the disruption of the intestinal microbiota by carob bean gum used as a thickener in infant formula.</p>
Diocetyl sodium sulfosuccinate	No	<p>At its Forty-fourth meeting in 1995, the Committee established an ADI of 0–0.1 mg/kg bw for DSS. The high (P95) dietary exposure estimates of DSS of up to 0.30 mg/kg bw per day for children aged 1–17 years could exceed this ADI. The estimates for adults were all below the ADI.</p> <p>Considering that (i) the dietary exposure estimates are conservative because of the assumptions that all soft drinks that could contain DSS do contain this food additive (although other food additives that perform the same function in foods are available) and, when DSS is used, it will always be present at the maximum and/or average use levels; and (ii) the ranges of exposure estimates based on only maximum use levels were comparable to those based on a combination of maximum and average use levels, the Committee concluded that the use of DSS as a food additive in soft drinks and fruit-flavoured water-based desserts does not pose a safety concern.</p>
Gardenia (Genipin) Blue	N	<p>The Committee identified a NOAEL of 50 mg/kg bw per day for geniposide based on hepatotoxic effects observed at the next higher dose in a 26-week oral toxicity study in rats. The Committee also identified a NOAEL of 50 mg/kg bw per day for genipin based on hepatotoxic effects observed at the highest dose in a 21-day oral toxicity study in mice. No longer-term oral toxicity studies on genipin were available.</p> <p>The Committee selected the NOAEL of 700 mg/kg bw per day for the Gardenia Blue polymer from the carcinogenicity study as a point of departure for the safety evaluation of Gardenia (Genipin) Blue. The Committee established an ADI of 0–7 mg/kg bw per day for the Gardenia (Genipin) Blue, expressed on the basis of the Gardenia Blue polymer, by applying an uncertainty factor of 100 to the NOAEL to account for inter- and intraspecies variabilities.</p> <p>Comparison of the NOAEL of 50 mg/kg bw per day with the theoretical high dietary exposure to geniposide of 1 µg/kg bw per day yields an MOE of 50 000. Based on this MOE and no concern for</p>

		genotoxicity, the Committee concluded that dietary exposure to geniposide as an impurity in Gardenia (Genipin) Blue does not pose a safety concern.
Glycolipids	N	<p>A proportion of the glycolipids is hydrolysed by intestinal microflora to their components, namely glucose, xylose, acetate, isovalerate and long-chain fatty acids, and the remaining unchanged glycolipids are eliminated in the faeces. The Committee further noted that the hydrolysis products are normal components of the human diet. The Committee therefore established an ADI “not specified”<sup>b</sup> for glycolipids.</p> <p>The Committee noted the high dietary exposure estimates of 3.3 mg/kg bw per day for children aged 2–5 years in the USA and 1.3 mg/kg bw per day for adults in Europe. The Committee concluded that these dietary exposure estimates did not raise any safety concerns.</p>
Rosemary extract	No	<p>A BMDL<sub>20</sub> of 97 mg/kg bw per day expressed as carnosic acid plus carnosol was calculated for a new study on thyroid hormone levels in rat pups from dams treated with rosemary extract in the diet during pregnancy and lactation. This BMDL<sub>20</sub> is higher than the NOAEL of 64 mg/kg bw per day, expressed as carnosic acid plus carnosol, on which the current temporary ADI for rosemary extract is based.</p> <p>In the derivation of the temporary ADI of 0–0.3 mg/kg bw per day, an additional uncertainty factor of 2 was incorporated into the overall uncertainty factor of 200 to account for the absence of studies to elucidate the potential developmental and reproductive toxicity of rosemary extract. This factor is no longer necessary. The temporary ADI of 0–0.3 mg/kg bw per day (expressed as carnosic acid and carnosol) was therefore withdrawn and an ADI of 0–0.6 mg/kg bw per day (expressed as carnosic acid and carnosol) was established.</p> <p>Estimated high dietary exposures to rosemary extract (expressed as carnosic acid plus carnosol) based on naturally occurring sources combined with dietary exposures from added sources at typical use levels were up to 0.84 mg/kg bw per day for children and up to 0.32 mg/kg bw per day for adults. The MOE between the BMDL<sub>20</sub> for reduction in T<sub>4</sub> levels in pups and the estimated high dietary exposure for children is greater than 100, and is considered sufficient. The Committee therefore did not consider the slight exceedance of the ADI, which was only by children, as a safety concern.</p>
Thaumatococcus	N	<p>Based on the amino acid sequence similarity of thaumatococcus I, thaumatococcus II and recombinant thaumatococcus II, the Committee revised the ADI “not specified”<sup>b</sup> for thaumatococcus (INS No. 957) to a group ADI “not specified” including thaumatococcus (INS No. 957) and thaumatococcus II produced by recombinant methods in the seeds of the tobacco plant <i>Nicotiana tabacum</i>.</p> <p>The high dietary exposure to thaumatococcus was estimated to be up to 0.33 mg/kg bw per day for children. The Committee concluded that the dietary exposure to thaumatococcus does not present a safety concern.</p>

ADI: acceptable daily intake; BMDL<sub>20</sub>: lower 95% confidence limit on the benchmark dose for a 20% response; DSS: dioctyl sodium sulfosuccinate; GMP: Good Manufacturing Practices; INS: International Numbering System for Food Additives; MOE: margin of exposure; N: new specifications; NOAEL: no-observed-adverse-effect limit; R: revised specifications; TOS: total organic solids; USA: United States of America.

<sup>a</sup> Information is required to complete the specifications.

<sup>b</sup> The reader is referred to the Technical Report of the Eighty-seventh JECFA meeting for clarification of the term ADI “not specified”.

<sup>c</sup> No new toxicological information was available for this evaluation that indicated a need for revision of the ADI “not specified” established previously by the Committee. An errata item was prepared for the existing specifications monographs.

### Food additives and processing aids considered for specifications only

Food additive	Specifications	Details
α-Amylase (JECFA95-1) from <i>Geobacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</i>	R	The specifications monograph was revised and the tentative status was removed. As a result, the temporary designation of ADI “not specified” established at the Ninety-fifth meeting was removed.
α-Amylase (JECFA95-2) from <i>Geobacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</i>	R	The specifications monograph was revised and the tentative status was removed. As a result, the temporary designation of ADI “not specified” established at the Ninety-fifth meeting was removed.
α-Amylase (JECFA95-3) from <i>Rhizomucor pusillus</i> expressed in <i>Aspergillus niger</i>	R	The specifications monograph was revised and the tentative status was removed. As a result, the temporary designation of ADI “not specified” established at the Ninety-fifth meeting was removed.
Asparaginase (JECFA95-5) from <i>Pyrococcus furiosus</i> expressed in <i>Bacillus subtilis</i>	R	The specifications monograph was revised and the tentative status was removed. As a result, the temporary designation of ADI “not specified” established at the Ninety-fifth meeting was removed.
β-Amylase (JECFA95-6) from <i>Bacillus flexus</i> expressed in <i>Bacillus licheniformis</i>	R	The specifications monograph was revised and the tentative status was removed. As a result, the temporary designation of ADI “not specified” established at the Ninety-fifth meeting was removed.
Gellan gum	N, R	The Committee generated new specifications for low-acyl clarified gellan gum (INS No. 418(ii)) and revised the existing specifications monograph for gellan gum (INS No. 418(i)).
Xylanase (JECFA95-9) from <i>Bacillus licheniformis</i> expressed in <i>Bacillus licheniformis</i>	R	The specifications monograph was revised and the tentative status was removed. As a result, the temporary designation of ADI “not specified” established at the Ninety-fifth meeting was removed.

N: new specifications; R: revised specifications.

## Annex 1. List of participants

### Members

- Dr S. Barlow, Brighton, East Sussex, United Kingdom of Great Britain and Northern Ireland (*invited by WHO*)
- Dr D. Benford, Cheddington, Buckinghamshire, United Kingdom (*Vice-Chairperson*) (*invited by WHO*)
- Dr R. Cantrill, Bedford, Nova Scotia, Canada (*Chairperson*) (*invited by FAO*)
- Dr E. Dessipri, General Chemical State Laboratory, Athens, Greece (*invited by FAO*)
- Dr M. DiNovi, Baltimore (MD), United States of America (USA) (*invited by FAO*)
- Dr N. Fletcher, Food Standards Australia New Zealand, Majura Park, Australian Capital Territory, Australia (*invited by WHO*)
- Dr D.E. Folmer, Office of Post-Market Assessment, Office of Food Chemical Safety, Dietary Supplements and Innovation, Human Foods Program, United States Food and Drug Administration, College Park (MD), USA (*Joint Rapporteur*) (*invited by FAO*)
- Ms T. Hambridge, Food Standards Australia New Zealand, Majura Park, Australian Capital Territory, Australia (*invited by FAO*)
- Dr S.M.F. Jeurissen, Department for Chemical Food Safety, Centre for Prevention, Lifestyle and Health, National Institute for Public Health and the Environment, Bilthoven, the Netherlands (*invited by WHO*)
- Ms K. Laurvick, United States Pharmacopeia, Rockville (MD), USA (*invited by FAO*)
- Dr J.-C. Leblanc, Laboratory for Food Safety, French Agency for Food, Environmental and Occupational Health and Safety, Maisons-Alfort, France (*invited by WHO*)
- Dr U. Mueller, Perth, Western Australia, Australia (*Joint Rapporteur*) (*invited by WHO*)
- Dr J. Schlatter, Zurich, Switzerland (*invited by WHO*)
- Dr J.R. Srinivasan, Division of Cosmetics, Office of Cosmetics and Colors, United States Food and Drug Administration, College Park (MD), USA (*invited by FAO*)

### Additional experts invited by FAO and WHO

- Dr F. Aguilar M., Chessy, France (*invited by WHO*)
- Dr P.E. Boon, Department for Chemical Food Safety, Centre for Prevention, Lifestyle and Health, National Institute for Public Health and the Environment, Bilthoven, the Netherlands (*invited by FAO*)
- Ms M.-A. Hammer, Ottawa, Ontario, Canada (*invited by WHO*)
- Dr S.V. Kabadi, Office of Pre-Market Additive Safety, Office of Food Chemical Safety, Dietary Supplements and Innovation, Human Foods Program, United States Food and Drug Administration, College Park (MD), USA (*invited by FAO*)
- Dr F.-Q. Li, China National Center for Food Safety Risk Assessment, Beijing, China (*invited by FAO*)
- Dr A.-K. Lundebye, Institute of Marine Research, Bergen, Norway (*invited by WHO*)
- Dr N. Sugimoto, Division of Food Additives, National Institute of Health Sciences, Kanagawa, Japan (*invited by FAO*)
- Dr S. West-Barnette, Office of Pre-Market Additive Safety, Office of Food Chemical Safety, Dietary Supplements and Innovation, Human Foods Program, United States Food and Drug Administration, College Park (MD), USA (*invited by FAO*)
- Dr H.-J. Yoon, Department of Food Safety and Regulatory Science, Chung-Ang University, Republic of Korea (*invited by WHO*)

### Secretariat

- Dr Y.-X. Fan, China National Center for Food Safety Risk Assessment (CFSA), China (*Codex Chair*)
- Dr V. Fattori, Agrifood Systems and Food Safety Division, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Secretariat*)
- Ms N.Y. Ho, Department of Nutrition and Food Safety, World Health Organization, Geneva, Switzerland (*WHO*)

*Consultant)*

Ms R. Kihara, Food and Agriculture Organization of the United Nations, Rome, Italy (*Codex Secretariat*)

Dr M. Lipp, Food Systems and Food Safety Division, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Secretariat*)

Dr J.-W. Park, Food and Agriculture Organization of the United Nations, Rome, Italy (*Codex Secretariat*)

Mr K. Petersen, Department of Nutrition and Food Safety, World Health Organization, Geneva, Switzerland (*WHO Joint Secretary*)

Dr M. Sanaa, Department of Nutrition and Food Safety, World Health Organization, Geneva, Switzerland (*WHO Secretariat*)

Ms A. Vlachou, Agrifood Systems and Food Safety Division, Food and Agriculture Organization of the United Nations, Rome, Italy (*FAO Joint Secretary*)

Ms L.-P. Zhang, Food and Agriculture Organization of the United Nations, Rome, Italy (*Codex Secretariat*)

## **Annex 2. General considerations**

### **2.1 Requests from Codex Alimentarius for safety assessment**

The Committee noted that to complete an evaluation of the safety of a chemical in food, information to characterize the hazard and estimate the dietary exposure must be available. In some cases, requests from Codex to the Committee to consider only dietary exposure to a food chemical have resulted in the Committee noting that the previous toxicological assessment and specifications are old and may not reflect current scientific knowledge, including the availability of new studies. The Committee therefore considers that requests from Codex should include a consideration of the toxicological data (including any new data available since the previous assessment), and information on chemical and technical considerations as well as dietary exposure necessary to conduct a full safety evaluation.

### **2.2 Mapping food categories of the General Standard for Food Additives (GSFA) to the FoodEx2 classifications**

The Committee is aware of the work that has been undertaken by a group of members of the Codex Committee for Food Additives (CCFA) to map the food categories in the GSFA to the FoodEx2 food classification system of the European Food Safety Authority (EFSA). Such a mapping was requested by the Committee at its Eighty-ninth meeting to enable the dietary exposure assessment for sucrose esters of fatty acids (INS No. 473) and sucrose oligoesters, type I and type II (INS No. 473a) to be undertaken using the FAO/WHO chronic individual food consumption database (CIFOCCoss) (which is classified according to FoodEx2) and use levels provided. The need for the mapping was also noted by the Committee at its Ninety-ninth meeting for the same reason for polyglycerol esters of fatty acids (INS No. 475). The mapping was provided to the JECFA secretariat in January 2025 and was used at the current meeting for the dietary exposure assessment for adipic acid (INS No. 355) and dioctyl sodium sulfosuccinate (INS No. 480).

The Committee noted that the mapping was comprehensive and was presented in several different ways that made it easy to review and use. The Committee also noted that there are some FoodEx2 categories that have multiple GSFA food categories assigned. This is a positive aspect of the mapping, and allows the JECFA dietary exposure experts to determine the particular concentration from which GSFA category to use for the assessment based on the knowledge of use of the food additive. These assumptions or decisions may vary between different assessments or scenarios.

The mapping, together with submitted use level information for food additives, will enable dietary exposures to be estimated for a greater number of food additives in the future and for a broad range of countries. This will inevitably better support the CCFA by providing evidence and conclusions from the safety assessments of food additives for risk management purposes, and will assist in the establishment of its priority list of food additives for evaluation by the Committee.

The Committee concluded that this mapping was very useful and enabled the fast and efficient assignment of concentration data to food consumption data for a large number of foods to enable dietary exposure calculations to be undertaken within the timeframes for the meeting. The Committee noted that the mapping will enable consistent use for its assessments for future meetings. The Committee also noted that the use of the CIFOCCoss data for a dietary exposure assessment will be decided on a case-by-case basis, taking into consideration the availability of other exposure estimates from the sponsor or the literature, the food groups included and the availability of concentration data. The eventual choice of whether to use CIFOCCoss and the mapping can be made by the exposure experts. The Committee recommends that the mapping be publicly available to promote its consistent application internationally, including assisting coding of food consumption databases for submission to FAO/WHO for inclusion in the CIFOCCoss database.

### **2.3 Enzymes**

At its Ninety-fifth meeting, the Committee was only able to assign temporary ADIs and prepare tentative specifications for several enzyme preparations on the agenda (see table below) because of deficiencies in the data packages.

### **Enzymes brought forward for completion of specifications**

JECFA No.	Enzyme name
JECFA95-1	$\alpha$ -Amylase (JECFA95-1) from <i>Geobacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</i>
JECFA95-2	$\alpha$ -Amylase (JECFA95-2) from <i>Geobacillus stearothermophilus</i> expressed in <i>Bacillus licheniformis</i>
JECFA95-3	$\alpha$ -Amylase (JECFA95-3) from <i>Rhizomucor pusillus</i> expressed in <i>Aspergillus niger</i>
JECFA95-4	Amyloglucosidase (JECFA95-4) from <i>Rasamsonia emersonii</i> expressed in <i>Aspergillus niger</i>
JECFA95-5	Asparaginase (JECFA95-5) from <i>Pyrococcus furiosus</i> expressed in <i>Bacillus subtilis</i>
JECFA95-6	$\beta$ -Amylase (JECFA95-6) from <i>Bacillus flexus</i> expressed in <i>Bacillus licheniformis</i>
JECFA95-9	Xylanase (JECFA95-9) from <i>Bacillus licheniformis</i> expressed in <i>Bacillus licheniformis</i>

The Committee at its Ninety-fifth meeting noted that “the details of the assays supplied included the use of an enzyme reference or calibrant, rather than a direct link to an original enzyme assay from which a meaningful unit definition could be derived”. According to the guidance document Environmental health criteria (EHC) 240 chapter 9.1.4.2, each evaluation requires a definition of the unit of enzyme activity and a validated method to measure it directly. These requirements are stated in items 21 and 22 in the checklist found in the appendix to the chapter, and were reproduced as annex 3, table A3.1 of the report of the Ninety-ninth meeting of the Committee.

In the report of the Ninety-fifth meeting and associated toxicological monographs, enzyme activities are expressed in the arbitrary units reported in the submissions. At the present meeting, the Committee received methods measuring activity in traceable units and data from enzyme preparations using these methods. The specifications were revised to include these methods and unit definitions. Enzyme activities in the new units, activity per gram total enzyme concentrate and activity per mg TOS are presented in the relevant report items (sections 3.1 and 3.2). The Committee recommends that a future meeting prepare an addendum for the toxicological monographs for JECFA95-1, JECFA95-2, JECFA95-3, JECFA95-5, JECFA95-6 and JECFA95-9.

#### **2.4 Limits for lead in specifications of food additives for use in infant formula**

The Committee at the present meeting considered three additives for use in infant formula and formula for special medical purposes for infants, namely ascorbyl palmitate, carob bean gum and gellan gum. The Committee noted that the Eighth session of the Codex Committee on Contaminants in Foods (CCCCF) set a maximum level (ML) of 0.01 mg/kg for lead in infant formula (as consumed). The Committee also noted that the use of two of the three additives (gellan gum and carob bean gum) at proposed use levels could result in an exceedance of the ML for lead in infant formula, if lead were present at the specified limit (i.e. 2 mg/kg in carob bean gum and gellan gum). The Committee noted that lower lead limits in the specifications (e.g. 0.5 mg/kg for carob bean gum and 0.5 mg/kg for gellan gum) would result in neither of the additives exceeding the ML for lead in the final infant formula (i.e. 0.01 mg/kg). This was calculated without considering the contribution of other ingredients to the overall lead level in infant formula. The Committee reaffirmed that the responsibility for ensuring that the final infant formula (as consumed) comply with the ML for lead remains with infant formula producers.

Since these food additives are also used in the manufacture of other foods as well as infant formula, lower lead limits should be introduced in the specifications for additives used in infant formula. Specifications monographs already exist for carob bean gum and carob bean gum (clarified). A lower lead limit for infant formula was not added, despite agreement by the Committee at its Eighty-second meeting to do so, and is included in the errata (Chapter 4) considered at the present meeting. The Committee noted that data provided at the present meeting by the sponsors indicate that individual food additives can be produced with lead levels below the specified limits, as listed above. A new specifications monograph for low-acyl clarified gellan gum for applications in infant formula was developed at the current meeting, including a limit of 0.5 mg/kg for lead.

## Annex 3. Recommendations and future work

Report item	Recommendation
3.1.1 Adipates	The Committee requests submission of any updated or additional data on use levels of adipic acid in order to refine the estimates of dietary exposure, including: minimum use levels that achieve the technological function of the additive in the range of relevant foods; any further or more specific information on typical use levels; updated information on proposed maximum levels; an updated list of food categories for which uses are actually required; and national estimates of dietary exposure based on individual dietary records and typical use levels. The Committee recommends that an updated toxicological evaluation, including the reassessment of the current group ADI, be conducted.
3.1.3 Ascorbyl palmitate	The Committee noted that ascorbyl stearate specifications need analogous revision and recommended that the additive be included in a future call for data.
3.1.5 Dioctyl sodium sulfosuccinate	The Committee noted that any further increases in exposure to DSS, for example as a result of higher use levels or an extension of its use in other food categories, would warrant an updated toxicological evaluation, including a reassessment of the current ADI (which was established 30 years ago).
3.1.9 Thaumatin II	The Committee recommended that the specifications for thaumatin (INS No. 957) be updated.

ADI: acceptable daily intake; DSS: dioctyl sodium sulfosuccinate.

## Annex 4. Errata

### A4.1 Maximum permissible lead levels in formula

The Committee noted that at its Eighty-second meeting there was a decision to reduce the maximum permissible lead level in the specifications for carob bean gum and carob bean gum (clarified) when used in infant formula from 2 mg/kg to 0.5 mg/kg. The current specifications were revised to include the following statement: “Not more than 0.5 mg/kg for use in infant formula and formula for special medical purposes intended for infants”.

Substance	Original text	Revised text	Additional information
Carob bean gum	–	Not more than 0.5 mg/kg for use in infant formula and formula for special medical purposes intended for infants	At the Eighty-second meeting there was a decision to reduce the maximum permissible lead level in the specifications for carob bean gum and carob bean gum (clarified) when used in infant formula from 2 mg/kg to 0.5 mg/kg
Carob bean gum (clarified)	–	Not more than 0.5 mg/kg for use in infant formula and formula for special medical purposes intended for infants	At the Eighty-second meeting there was a decision to reduce the maximum permissible lead level in the specifications for carob bean gum and carob bean gum (clarified) when used in infant formula from 2 mg/kg to 0.5 mg/kg

### A4.2 Titanium dioxide authors

The monograph of the Ninety-seventh meeting (FAS 88) was published with the names of several authors of the item on titanium dioxide mistakenly omitted.

The full list of authors should have been: Marc Beal, Polly Boon, Raymond Peter Brinas, Eugenia Dessipri, Valerie Fessard, Nick Fletcher, Mary-Anne Hammer, Dirk Pallapies, Shirley Price, Jannavi Srinivasan, Stephan Walch, Matthew Wheeler, Sue Barlow, Diane Benford, Richard Cantrill, Michael DiNovi, Mark Feeley and Kristie Laurvick.