TO: Codex Contact Points
    Contact Points of international organizations having observer status with Codex

FROM: Secretariat, Joint FAO/WHO Food Standards Programme,
       Codex Alimentarius Commission,
       Viale delle Terme di Caracalla,
       00153 Rome, Italy

SUBJECT: Request for information and comments on the priority list of substances proposed for evaluation by JECFA

DEADLINE: 15 January 2020

REQUEST FOR INFORMATION AND COMMENTS

1. Members and observers are invited to: i) provide comments on substances already included in the priority list of substances proposed for evaluation by JECFA, ii) submit information on new substances for inclusion in the priority list; and/or iii) confirm previous requests and data availability.

2. Information and comments should be submitted on the basis of the following attached Annexes to this Circular Letter:

   2.1 For submitting information on new substances, refer to:
       - Annex 1 - Criteria for the inclusion of substances in the priority list;
       - Annex 2 - Form for the submission of substances to be evaluated by JECFA.

   2.2 For information of the priority list, to which comments may be made, refer to:
       - Annex 3 - Priority list of substances proposed for evaluation by JECFA, forwarded to FAO and WHO for their follow-up;

   2.3 To confirm previous requests, refer to:
       - Annex 4 - Confirmation of previous requests and data availability.

3. Information and comments, submitted in response to this Circular Letter, will be considered at the 52nd Session of the Codex Committee on Food Additives.
CRITERIA FOR THE INCLUSION OF SUBSTANCES IN THE PRIORITY LIST
(Codex Procedural Manual – Risk Analysis Principles applied by the Codex Committee on Food Additives)

The Codex Committee on Food Additives (CCFA) shall consider the following when preparing its priority list of substances for JECFA review:

- Consumer protection from the point of view of health and prevention of unfair trade practices;
- CCFA’s Terms of Reference;
- JECFA’s Terms of Reference;
- The Codex Alimentarius Commission’s Strategic Plan, its relevant plans of work and Criteria for the Establishment of Work Priorities;
- The quality, quantity, adequacy, and availability of data pertinent to performing a risk assessment, including data from developing countries;
- The prospect of completing the work in a reasonable period of time;
- The diversity of national legislation and any apparent impediments to international trade;
- The impact on international trade (i.e. magnitude of the problem in international trade);
- The needs and concerns of developing countries; and,
- Work already undertaken by other international organizations.
FORM FOR THE SUBMISSION OF SUBSTANCES TO BE EVALUATED BY JECFA

In completing this form, only brief information is required. The form may be retyped if more space is needed under any one heading provided that the general format is maintained.

<table>
<thead>
<tr>
<th>Name of Substance(s):</th>
<th>Question(s) to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)</th>
</tr>
</thead>
</table>

1. Proposal for inclusion submitted by:
2. Name of substance; trade name(s); chemical name(s), IUPAC name, C.A.S number (as applicable):
3. Names and addresses of basic producers:
4. Identification of the manufacturer that will be providing data (Please indicate contact person):
5. Justification for use:
6. Food products and food categories within the GSFA in which the substance is used as a food additive or as an ingredient, including use level(s):
7. Is the substance currently used in food that is legally traded in more than one country? (please identify the countries); or, has the substance been approved for use in food in one or more country? (please identify the country(ies))
8. Are you aware of any current impediments in international trade due to lack of a JECFA evaluation and/or Codex standard? If so, please provide details.
9. Are you aware of risk assessments, either on-going or completed within the last 10 years, at a national or regional level for this additive? If so, please provide the name, address and contact details of the organization having performed the risk assessment.
10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries
11. Please indicate the type of data that are available in the table below.

Ensure that the available data are directly relevant to the substance of interest in this request. In particular, for substances obtained from natural resources, characterization of the products in commerce and a relevant set of biochemical and toxicological data on such products are essential for JECFA to develop a specifications monograph and the related safety. Such data/information typically include: components of interest; all components of the final products; detailed manufacturing process; possible carryover of substances; etc.
### Toxicological data

(i) Metabolic and pharmacokinetic studies (please specify)

(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)

(iii) Epidemiological and/or clinical studies and special considerations (please specify)

(iv) Other data (please specify)

### Technological data

(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)

(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance

### Dietary exposure assessment data

(i) Levels of the listed substance used in food or expected to be used in food based on technological function and the range of foods in which they are used

(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.

### Other information: (please specify)

12. Specify earliest date when data can be made available to JECFA. (Data shall only be submitted in response to a JECFA call for data; **do NOT include any data intended for JECFA to this form**.)
### PRIORITY LIST OF SUBSTANCES PROPOSED FOR EVALUATION BY JECFA

#### TABLE 1 LIST OF SUBSTANCES USED AS FOOD ADDITIVES PROPOSED FOR EVALUATION BY JECFA

<table>
<thead>
<tr>
<th>Substance(s)</th>
<th>General information</th>
<th>Comments about the request</th>
<th>Priority*</th>
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</table>
| 1. Anionic methacrylate copolymer (AMC) (INS 1207) | **Type of request**: Data pending to finalize safety evaluation  
**Proposed by**: JECFA  
**Supported by**: N/A  
**Year requested**: 2019 (CCFA51)  
**Data availability**: Data provider | **Basis for request**: (see JECFA86 report or Table 1 of CX/FA 19/51/3)  
Additional data is required to clarify the in vivo carcinogenic potential of the residual monomer methyl acrylate.  
**Possible issues for trade**: currently unidentified | 2 |
| Neutral methacrylate copolymer (NMC) (INS 1206) | **Type of request**: Data pending – suitable method of assay  
**Proposed by**: JECFA  
**Supported by**: N/A  
**Year requested**: 2019 (CCFA51)  
**Data availability**: Data provider | **Basis for request**: (see JECFA86 report or Table 1 of CX/FA 19/51/3)  
A suitable validated method for its assay is required to remove the tentative status of the specifications developed by JECFA.  
**Possible issues for trade**: currently unidentified | 3 |
| 2. Azodicarbonamide (INS 927a) | **Type of request**: safety assessment and establishment of specifications  
**Proposed by**: CCFA 51  
**Year requested**: 2019 (CCFA51)  
**Data availability**: To be confirmed at CCFA52  
**Data provider**: To be confirmed at CCFA52 | **Basis for request**: The Physical Working Group on Alignment noted the safety concern on this food additive and request the re-evaluation of this food additive. | 1 |
| 3. Benzoic acid and its salts (INS 210-212) | **Type of request**: Data pending – safety assessment  
**Proposed by**: CCFA49  
**Year requested**: 2018 (CCFA50)  
**Data availability**: December 2020  
**Data provider**: International Council of Beverages Associations (ICBA)  
Ms. Katherine Loatman (Kate@icba-net.org) | **Basis for request**: To confirm ICBA’s commitment to provide new toxicological evaluation of benzoates. The studies include extended one-generational reproductive toxicity testing (EOGRT Study, OECD 443) and findings relative to benzoate’s chemical-specific adjustment factor, default uncertainty factors and intake assessment assumptions.  
**Possible issues for trade**: Identified: | 1 |
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| **4.** Carob bean gum (INS 410)     | **Type of request:** Data pending – toxicological data from studies on neonatal animals, adequate to evaluate the safety for use in infant formulas  
**Proposed by:** JECFA  
**Year requested:** 2016 (CCFA48)  
**Data availability:** ongoing discussion with JECFA  
**Data provider:** ongoing discussion with JECFA | **Basis for request:** Although no confirmation was provided for carob bean gum (INS 410), JECFA indicated that there was ongoing discussion with industry and that the deadline for the submission of data could be extended and therefore carob bean gum was retained on the JECFA priority list subject to confirmation of provision of data by CCFA50.  
**Possible issues for trade:** currently unidentified | 1         |
| **5.** Citric and fatty acid esters of glycerol (INS 472c) | **Type of request:** Data pending to designate specifications as FULL  
**Proposed by:** JECFA  
**Supported by:** N/A  
**Year requested:** 2019 (CCFA51)  
**Data availability:** December 2019  
**Data provider:** Japan and EFEMA  
<code>codex@mext.go.jp</code>  
<code>ema@ecco-eu.com</code> | **Basis for request:** (see JECFA86 report or Annex 2 of CX/FA 19/51/4)  
To remove the tentative designation from the specifications, the following information is requested by December 2019:  
- Validated analytical method to replace the obsolete packed column gas chromatographic method for the determination of total citric acid;  
- Validated analytical method that eliminates the use of chloroform for the determination of total glycerol.  
- Amendment to the specification based on the compositions/characteristics of the product commercially available  
**Possible issues for trade:** currently unidentified | 2         |
| **6.** Dioctyl sodium sulfosuccinate(INS 480) | **Type of request:** Exposure assessment  
**Proposed by:** CCFA51  
**Year requested:** 2019 (CCFA51)  
**Data availability:** to be confirmed at CCFA52  
**Data provider:** to be confirmed at CCFA52 | **Basis for request:** The Physical Working Group on GSFA discussed exposure to this food additive, some members noted that exposure of a small child could exceed the ADI. One observer noted that they had performed a budget calculation and that the calculation could be made available upon | 1         |
<table>
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<tr>
<td>7. Flavouring substances (45 new + 1 for re-evaluation + 14 for updates = 60 total)</td>
<td><strong>Type of request:</strong> Safety assessment and establishment of specifications  <strong>Proposed by:</strong> International Organization of the Flavour Industry (IOFI)  <strong>Supported by:</strong> the United States of America  <strong>Year requested:</strong> 2019 (CCFA51)  <strong>Data availability:</strong> December 2019  <strong>Data provider:</strong> IOFI Sean V. Taylor, Ph.D. <a href="mailto:staylor@vertosolutions.net">staylor@vertosolutions.net</a></td>
<td><strong>Basis for request:</strong> Safety assessment or re-assessment, and establishment of specifications or revision of specifications, as applicable  <strong>Possible issues for trade:</strong> currently unidentified</td>
<td>Not applicable</td>
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<td>Flavouring agents: (+)Carvone (no. 380.1) and (-)-Carvone (No. 380.2)</td>
<td><strong>Type of request:</strong> Data pending to finalize exposure assessment and revise the JECFA specifications  <strong>Proposed by:</strong> JECFA  <strong>Supported by:</strong> Japan  <strong>Year requested:</strong> 2019 (CCFA51)  <strong>Data availability:</strong> December 2019  <strong>Data provider:</strong> Japan and IOFI <a href="mailto:codex@mext.go.jp">codex@mext.go.jp</a> <a href="mailto:staylor@vertosolutions.net">staylor@vertosolutions.net</a></td>
<td><strong>Basis for request:</strong> (see JECFA86 report or Table 2 of CX/FA 19/51/3)  Additional data are required to complete the exposure assessment:  - (+)-carvone: data on the oral exposure from all sources;  - (-)-carvone: data on the oral exposure from all sources and toxicological data.  <strong>Possible issues for trade:</strong> currently unidentified</td>
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<td>Flavouring agents: (Ethyl 2-methyl pentanoate (No.214), cis-3-Hexen-1-ol (No.315), Menthol (No.427), l-Menthyl l-lactate (No.433), Myrcene (No.1327), Maltol (No.1480), 2-pentylfuran (No.1491), 3-(2-Furyl)acrolein (No.1497), 3-(5-Methyl-2-furyl)-butanal (No.1500), 2-Furyl methyl ketone (No.1503), 3-Acetyl-2,5-dimethylfuran)</td>
<td><strong>Type of request:</strong> revise the JECFA specifications  <strong>Proposed by:</strong> CCFA 51  <strong>Supported by:</strong> Japan  <strong>Year requested:</strong> 2019 (CCFA51)  <strong>Data availability:</strong> April 2019  <strong>Data provider:</strong> Japan <a href="mailto:codex@mext.go.jp">codex@mext.go.jp</a></td>
<td><strong>Basis for request:</strong> (see CX/FA 19/51/4 add.2)  Requests reconsideration of the specifications for 16 flavouring agents that considered at the 86th JECFA meeting (listed in either Annex 1 or Annex 2 of CX/FA 19/51/4), because the reorganization some gaps between the JECFA specification (some items therein) and the commercially available products for each compound.</td>
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| (No.1506), (2-Furyl)-2-propanone (No.1508), 4-(2-furyl)-3-buten-2-one (No.1511), and Furfuryl methyl ether (No.1520)) | **Type of request**: Safety assessment and establishment of specifications  
**Proposed by**: South Africa  
**Year requested**: 2019 (CCFA51)  
**Data availability**: already available  
**Data provider**: Fulvimed SA  
Stefan Coetzee  
(stefan@fulvimed.co.za) | **Basis for request**: Carbohydrate-Derived Fulvic Acid (CHD-FA®) is described as a novel, pure, biologically-active organic acids embedded in a supramolecular structure, free from heavy metals and safe for human and animal consumption. CHD-FA® liquid would be a suitable preservative for acidic foods such as jams, salad dressings, fruit and vegetable juices, pickles and carbonated drinks. Fulvate (CHD-FA® powder) would be a suitable preservative in dry products, such as cereals, maize, soup powders and meal replacements.  
**Possible issues for trade**: currently unidentified | 2 |
| Fulvic acid | **Type of request**: safety assessment and establishment of specifications  
**Proposed by**: CCFA 51  
**Year requested**: 2019 (CCFA51)  
**Data availability**: To be confirmed at CCFA52  
**Data provider**: To be confirmed at CCFA52 | **Basis for request**: During the discussions on the alignment of the food-additive provision in CXS 152-1985 with the relevant provisions of the GSFA, CCFA51 agreed to include the substance as flour treatment agent to the list. | 2 |
| Fungal amylase from *Aspergillus niger* | **Type of request**: Data pending to finalize safety evaluation and establishment of specifications – Evaluation by JECFA84  
**Proposed by**: CCFA50  
**Year requested**: 2018 (CCFA50)  
**Data availability**: December 2019  
**Data provider**: Colombia  
bolarte@minsalud.gov.co | **Basis for request**: (see JECFA84 report)  
Additional biochemical and toxicological data. Information of characterization of food additive is needed on:  
- Characterization of the low molecular weight components of the “blue polymer”;  
- A validated method for the determination of dimers; and  
- Data on concentrations of dimers from five batches of the commercial products  
**Possible issues for trade**: currently unidentified | 2 |
| Jagua (Genipin-Glycine) Blue | **Type of request**: Data pending to finalize safety evaluation and establishment of specifications – Evaluation by JECFA84  
**Proposed by**: CCFA50  
**Year requested**: 2018 (CCFA50)  
**Data availability**: December 2019  
**Data provider**: Colombia  
bolarte@minsalud.gov.co | **Basis for request**: (see JECFA84 report)  
Additional biochemical and toxicological data. Information of characterization of food additive is needed on:  
- Characterization of the low molecular weight components of the “blue polymer”;  
- A validated method for the determination of dimers; and  
- Data on concentrations of dimers from five batches of the commercial products  
**Possible issues for trade**: currently unidentified | 2 |
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| 11 Magnesium stearate (INS 470(iii)) | **Type of request:** Amendment of JECFA monograph with regards to method of assay  
**Proposed by:** APAG – the European Oleochemicals & Allied Products group, a sector group of CEFIC  
**Supported by:** European Union  
**Year requested:** 2019 (CCFA51)  
**Data availability:** December 2019  
**Data provider:** CEFIC - The European Chemical Industry Council  
Sofia Serafim  
(sse@cefic.be) | **Basis for request:** The method of assay for magnesium (an ICP-AES technique) referred to in the monograph for INS 470(iii), prepared by JECFA80, is considered inappropriate for determination of magnesium content and should be replaced by the titration method reported in the Food Chemical Codex monograph or other pharmacopoeia monographs.  
**Possible issues for trade:** currently unidentified | 3         |
| 12 Natamycin (INS 235) | **Type of request:** Re-evaluation of safety and revision of specifications  
**Proposed by:** Russian Federation  
**Year requested:** 2017 (CCFA49)  
**Data availability:** December 2018  
**Data provider:** Russian Federation Codex Contact Point  
(codex@gsen.ru) | **Basis for request:** The appropriateness of retaining natamycin in the GSFA should be re-evaluated, due to to emerging data on natamycin's role in: (i) promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens; and (ii) unbalancing the immunity and other bodily functions due to effects on gastrointestinal microflora.  
It is suggested that previous evaluations were specific to chemical toxicology and did not adequately take into account antimicrobial effects.  
Comments in opposition to the request note that the antimicrobial effects against a variety of Gram-positive bacteria and their spores are important in maintaining product shelf-life and ensuring food safety.  
**Possible issues for trade:** currently unidentified | 1         |
| Nisin (INS 234)     | **Type of request:** Re-evaluation of safety and revision of specifications  
**Proposed by:** Russian Federation  
**Year requested:** 2017 (CCFA49)  
**Data availability:** December 2018  
**Data provider:** Russian Federation Codex Contact Point | **Basis for request:** The appropriateness of retaining nisin in the GSFA should be re-evaluated, due to to emerging data on nisin role in: (i) promoting antimicrobial resistance, as well as speeding up virulence and pathogenic potential of food-borne human pathogens; and (ii) unbalancing the immunity | 1         |
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| 13 ortho-Phenylphenol (INS 231) and sodium ortho-phenylphenol (INS 232) | **Type of request:** Re-evaluation of ADI  
**Proposed by:** JECFA  
**Supported by:** N/A  
**Year requested:** 2019 (CCFA51)  
**Data availability:** To be confirmed at CCFA52  
**Data provider:** To be confirmed at CCFA52 | and other bodily functions due to effects on gastrointestinal microflora.  
It is suggested that previous evaluations were specific to chemical toxicology and did not adequately take into account antimicrobial effects.  
Comments in opposition to the request note that the antimicrobial effects against a variety of Gram-positive bacteria and their spores are important in maintaining product shelf-life and ensuring food safety.  
**Possible issues for trade:** currently unidentified | 1 |
| 14 Polyglycerol esters of fatty acids (INS 475) | **Type of request:** The completeness of the information for safety assessment  
**Proposed by:** CCFA51  
**Year requested:** 2019 (CCFA51)  
**Data availability:** to be confirmed at CCFA52  
**Data provider:** to be confirmed at CCFA52 | **Basis for request:** (see Appendix 1 of CX/FA 19/51/2 Add. 1)  
Analysis of all group food additives in the GSFA: The Codex Secretariat, in consultation with the JECFA Secretariats, undertake a review of all group food additives in the GSFA and prepare a more comprehensive document for consideration at CCFA51 including proposals on how to deal with the issue. It was noted that a re-evaluation of INS 231 and INS 232 may be needed as some studies indicate that the salt might be more toxic for human health than previously estimated.  
**Possible issues for trade:** currently unidentified | 3 |
<p>| 15 Polyvinyl alcohol (INS 1203) | <strong>Type of request</strong> Revise JECFA specification with regards to solubility of polyvinyl alcohol | <strong>Basis for request:</strong> This is to request a change of the JECFA monograph with | 3 |</p>
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<td><strong>Proposed by:</strong> European Union</td>
<td><strong>Supported by:</strong> IFAC</td>
<td>regards to the solubility of polyvinyl alcohol (PVOH) in ethanol from &quot;sparingly soluble in ethanol&quot; to &quot;practically insoluble or insoluble in ethanol&quot;. In 2011, a solubility testing for PVOH was carried out by Nippon and the test results were interpreted as PVOH being &quot;practically insoluble or insoluble in ethanol&quot;. Possible issues for trade: currently unidentified.</td>
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<td><strong>Year requested:</strong> 2019 (CCFA51)</td>
<td><strong>Data availability:</strong> already available</td>
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<td><strong>Data provider:</strong> Ales Bartl</td>
<td>Tel: 0032 2 645 1452 (<a href="mailto:abartl@jonesday.com">abartl@jonesday.com</a>)</td>
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<td><strong>Type of request:</strong> safety assessment and establishment of specifications</td>
<td><strong>Proposed by:</strong> CCFA 51</td>
<td>Basis for request: During the discussions on the alignment of the food-additive provision in CXS 152-1985 with the relevant provisions of the GSFA, CCFA51 agreed to include the substance as flour treatment agent to the list.</td>
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<td><strong>Year requested:</strong> 2019 (CCFA51)</td>
<td><strong>Data availability:</strong> To be confirmed at CCFA52</td>
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<td><strong>Data provider:</strong> To be confirmed at CCFA52</td>
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<td><strong>Type of request:</strong> Safety assessment and establishment of specifications</td>
<td><strong>Proposed by:</strong> EU Specialty Food Ingredients</td>
<td>Basis for request: Alternative source of riboflavin for colouring purposes and as nutrient source. Possible issues for trade: currently unidentified.</td>
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<td><strong>Supported by:</strong> European Union</td>
<td><strong>Year requested:</strong> 2019 (CCFA51)</td>
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<td></td>
<td><strong>Data availability:</strong> December 2019</td>
<td><strong>Data provider:</strong> BASF SE Nicola Leinwetter (<a href="mailto:nicola.leinwetter@basf.com">nicola.leinwetter@basf.com</a>)</td>
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<td><strong>Type of request:</strong> Revision of specifications with regards to the congealing range identification method</td>
<td><strong>Proposed by:</strong> European Food Emulsifier Manufacturers' Association (EFEMA)</td>
<td>Basis for request: The congealing range identification method as reported in the JECFA monographs for INS 491, 492 and 495 is obsolete, difficult to work with due to poor reproducibility, and irrelevant. This identification parameter should be replaced by the identification test &quot;acid value, iodine value, gas chromatography&quot;. Possible issues for trade: currently unidentified.</td>
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<td><strong>Supported by:</strong> European Union</td>
<td><strong>Year requested:</strong> 2019 (CCFA51)</td>
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<tr>
<td></td>
<td><strong>Data availability:</strong> Immediately</td>
<td><strong>Data provider:</strong> EFEMA Caroline Rey (<a href="mailto:efema@ecco-eu.com">efema@ecco-eu.com</a>)</td>
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<td><strong>Type of request:</strong> Data pending – analytical data</td>
<td><strong>Proposed by:</strong> JECFA</td>
<td>Basis for request: (see JECFA86 report or Table 1 of CX/FA 19/51/3)</td>
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<td><strong>Proposed by:</strong> JECFA</td>
<td><strong>Supported by:</strong> European Union</td>
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| **Supported by:** N/A  
**Year requested:** 2019 (CCFA51)  
**Data availability:** December 2019  
**Data provider:** IACM  
scodrea@vertosolutions.net | JECFA86 received limited analytical data on spirulina extract. To remove the tentative designation from the specifications, the following information on the products of commerce is requested by December 2019:  
- Full compositional characterization of commercial products in both liquid and powder forms.  
- Full compositional characterization of the aqueous extract before formulation/standardization.  
- Validated analytical methods for identification of the substance with a suitable specificity (including validation data and representative batch data).  
- Validated analytical methods for the determination of the purity of the substance with a suitable specificity (including validation data and representative batch data).  
**Possible issues for trade:** currently unidentified |  |  |
| 20 Sucroglycerides (INS 474) | **Type of request:** exposure assessment  
**Proposed by:** CCFA 51  
**Year requested:** 2019 (CCFA51)  
**Data availability:** To be confirmed at CCFA52  
**Data provider:** To be confirmed at CCFA52 | **Basis for request:** During the discussion on the use of this food additive in FC 05.1.4, one member country concern that the proposed use would result in exposures which exceed the ADI, the physical Working Group on GSFA of CCFA51 to request for exposure assessment. | 1 |
| 21 Sucrose esters of fatty acids (INS 473) | **Type of request:** exposure assessment  
**Proposed by:** CCFA 51  
**Year requested:** 2019 (CCFA51)  
**Data availability:** December 2019  
**Data provider:** Japan  
codex@mext.go.jp | **Basis for request:** During the discussion on the use of this food additive in FC 05.1.4, one member country concern that the proposed use would result in exposures which exceed the ADI, the physical Working Group on GSFA of CCFA51 to request for exposure assessment. | 1 |
| 22 Sucrose oligoesters ,type I | **Type of request:** exposure assessment  
**Proposed by:** CCFA 51 | **Basis for request:** During the discussion on the use of this food additive in FC 05.1.4, one member country concern that the proposed use would result in exposures which exceed the ADI, the physical Working Group on GSFA of CCFA51 to request for exposure assessment. | 1 |
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| and type II (INS 473a) | **Year requested:** 2019 (CCFA51)  
**Data availability:** December 2019  
**Data provider:** Japan codex@mext.go.jp | member country concern that the proposed use would result in exposures which exceed the ADI, the physical Working Group on GSFA of CCFA51 to request for exposure assessment. | 1 |
| 23 Tannins (oenological tannins) | **Type of request:** Data pending to complete evaluation – Evaluation by JECFA84  
**Proposed by:** CCFA50  
**Year requested:** 2018 (CCFA50)  
**Data availability:** To be confirmed at CCFA52  
**Data provider:** To be confirmed at CCFA52 | **Basis for request:** In order to complete its evaluation, JECFA requires information on:  
- Composition of tannins derived from the full range of raw materials as well as the processes used in their manufacture;  
- Validated analytical method(s) and relevant quality control data;  
- Analytical data from five batches of each commercial product including information related to impurities such as gums, resinous substances, residual solvents, sulfur dioxide content and metallic impurities (arsenic, lead, iron, cadmium and mercury);  
- Solubility of the products in commerce, according to JECFA terminology; and  
- Use levels, natural occurrence and food products in which tannins are used.  
**Possible issues for trade:** currently unidentified | 2 |
| 24 L-cysteine hydrochloride (INS 920) | **Type of request:** safety evaluation and establishment of specifications  
**Proposed by:** CCFA51  
**Supported by:** to be confirmed  
**Year requested:** 2019 (CCFA51)  
**Data availability:** To be confirmed at CCFA52  
**Data provider:** to be confirmed at CCFA52 | **Basis for request:** (see CX/FA 19/51/6)  
It notes that two food additives, listed as flour treatment agents in CXS 152-1985 have not been added to the GSFA provisions as part of the alignment work. These are L-cysteine hydrochloride (INS 920) and potassium ascorbate (INS 303). It agrees that both cannot be added to the GSFA since they do not have a JECFA specification.  
**Possible issues for trade:** currently unidentified | 3 |
Priority list of 46 flavours proposed for inclusion on the JECFA Priority List to be considered at the 51st session of the Codex Committee on Food Additives

<table>
<thead>
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### Priority list of 14 compounds proposed for specifications modification by JECFA

**Priority List to be considered at the 51st session of the Codex Committee on Food Additives**

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<td>65545-81-5</td>
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<td>Updated Physical appearance and melting point range</td>
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| 1. | 5'-Deaminase from *Streptomyces murinus* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** Japan  
**Year requested:** 2017 (CCFA49)  
**Data availability:** December 2018  
**Data provider:** Amano Enzyme Inc.  
Mr. Tomonari Ogawa  
(tomonari_ogawa@amano-enzyme.com) | **Basis for request:** The enzyme is used in the processing of yeast and like products to promote the conversion of adenosine monophosphate (generally tasteless) to inosine monophosphate (“umami” flavour), thereby enhancing the flavour of the products.  
**Possible issues for trade:** currently unidentified |
| 2. | Acid prolyl endopeptidase from *Aspergillus niger* expressing a gene from *Aspergillus niger* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** DSM Food Specialties  
Dr. Jack Reuvers  
(jack.reuvers@dsm.com) | **Basis for request:** The enzyme is used in the processes of: brewing beer to reduce the amount gluten/gliadins; potable alcohol production to optimize fermentation; protein processing to produce protein hydrolysates without bitter flavour; starch processing to degrade peptides which would negatively affect the production process and reduce the amount of gluten/gliadins.  
**Possible issues for trade:** currently unidentified |
| 3. | Adenosine-5'-monophosphate deaminase from *Aspergillus oryzae* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** Japan  
**Year requested:** 2018 (CCFA50)  
**Data availability:** December 2018  
**Data provider:** Shin Nihon Chemical Co., Ltd.  
Dr. Ashley Roberts  
(ashley.roberts@intertek.com) | **Basis for request:** AMP deaminase from *Aspergillus oryzae* is intended for use during food and beverage processing to increase the content of 5'-monophosphate (5'-IMP) in food, beverages or food ingredients to impart or enhance flavour.  
**Possible issues for trade:** currently unidentified |
| 4. | D-Allulose 3-epimerase from *Arthrobacter globiformis* expressed in *Escherichia coli* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** United States of America  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** Matsutani Chemical Industry Co. Ltd.  
Mr. Yuma Tani | **Basis for request:** The enzyme is used in the production of D-allulose or ketose sugars from D-fructose.  
**Possible issues for trade:** currently unidentified  
**NOTE:** Confirmation of data was provided in response to CL 2018/28-FA. |
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<th>Substance(s)</th>
<th>General information</th>
<th>Comments about the request</th>
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| 5. | Alpha-amylase from *Bacillus licheniformis* expressing a modified alpha-amylase gene from *Geobacillus stearothermophilus* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** Danisco US Inc  
Ms. Lisa Jensen  
(lisa.jensen@dupont.com) | **Basis for request:** The enzyme is a thermostable starch hydrolysing alpha-amylase, which quickly reduced viscosity of gelatinized starch, allowing for processing of materials with high solid levels.  
**Possible issues for trade:** currently unidentified |
| 6. | Alpha-amylase from *Bacillus stearothermophilus* expressed in *Bacillus licheniformis* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2015 (CCFA47)  
**Data availability:** December 2018  
**Data provider:** Novozymes A/S  
Tine Vitved Jensen  
(tvit@novozymes.com) | **Basis for request:** The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.  
**Possible issues for trade:** currently unidentified |
| 7. | Alpha-amylase from *Rhizomucor pusillus* expressed in *Aspergillus niger* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2015 (CCFA47)  
**Data availability:** December 2018  
**Data provider:** Novozymes A/S  
Tine Vitved Jensen  
(tvit@novozymes.com) | **Basis for request:** The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.  
**Possible issues for trade:** currently unidentified |
| 8. | Amyloglucosidase from *Talaromyces emersonii* expressed in *Aspergillus niger* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** Novozymes A/S  
Mr. Peter Hvass  
(phva@novozymes.com) | **Basis for request:** The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.  
**Possible issues for trade:** currently unidentified |
| 9. | Asparaginase from *Aspergillus niger* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union | **Basis for request:** The enzyme is used in cereal- and potato-based products to convert asparagine to aspartic acid, to reduce |
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|    | expressing a modified gene from *Aspergillus niger* | **Year requested:** 2014 (CCFA46)  
**Data availability:** December 2018  
**Data provider:** DSM Food Specialties  
Dr. Mariella Kuilman  
(mariella.kuilman@dsm.com) | acrylamide formation during processing.  
**Possible issues for trade:** currently unidentified |
| 10. | Asparaginase from *Pyrococcus furiosus* expressed in *Bacillus subtilis* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2015 (CCFA47)  
**Data availability:** December 2018  
**Data provider:** Novozymes A/S  
Tine Vitved Jensen  
(tvil@novozymes.com) | **Basis for request:** The enzyme is indicated as a thermostolerant enzyme used to convert asparagine to aspartic acid to reduce acrylamide formation in the course of baking processes, cereal-based processes, fruit and vegetable processing, and coffee and cocoa processing.  
**Possible issues for trade:** currently unidentified |
| 11. | Beta-amylase from *Bacillus flexus* expressed in *Bacillus licheniformis* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** Novozymes A/S  
Mr. Peter Hvass  
(phva@novozymes.com) | **Basis for request:** The enzyme is used for the hydrolysis of starch during the processing of starch-containing foods.  
**Possible issues for trade:** currently unidentified |
| 12. | Beta-glucanase from *Streptomyces violaceoruber* expressed in *S. violaceoruber* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** Japan  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** Nagase ChemteX Corporation  
Mr. Kensaku Uzura  
(kensaku.uzura@ncx.nagase.co.jp) | **Basis for request:** The enzyme is used in the production of yeast extract products. It is indicated that by disrupting cell walls, an increased yield of yeast extract can be obtained, and bacterial contamination during manufacturing is reduced.  
**Possible issues for trade:** currently unidentified |
| 13. | Collagenase from *Streptomyces violaceoruber* expressed in *S. violaceoruber* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** Japan  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** Nagase ChemteX Corporation  
Mr. Kensaku Uzura  
(kensaku.uzura@ncx.nagase.co.jp) | **Basis for request:** The enzymes is used in meat and sausage casing processing to hydrolyze collagen, thereby reducing connective tissue toughness and improving meat tenderness. |
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| 14 | Endo-1,4-ß-xylanase from *Bacillus subtilis* produced by *B. subtilis* LMG S-28356 | **Type of request**: Safety assessment and establishment of specifications  
**Proposed by**: European Union  
**Year requested**: 2016 (CCFA48)  
**Data availability**: December 2018  
**Data provider**: Puratos NV  
Mr. Bas Verhagen  
(bverhagen@puratos.com) | **Possible issues for trade**: currently unidentified  
**Basis for request**: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. |
| 15 | Endo-1,4-ß-xylanase from *Pseudoalteromonas haloplanktis* produced by *B. subtilis*, strain LMG S-24584 | **Type of request**: Safety assessment and establishment of specifications  
**Proposed by**: European Union  
**Year requested**: 2017 (CCFA49)  
**Data availability**: December 2018  
**Data provider**: Puratos NV  
Mr. Bas Verhagen  
(bverhagen@puratos.com) | **Possible issues for trade**: currently unidentified  
**Basis for request**: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. |
| 16 | Endo-1,4-ß-xylanase from *Thermotoga maritima* produced by *B. subtilis*, strain LMG S-27588 | **Type of request**: Safety assessment and establishment of specifications  
**Proposed by**: European Union  
**Year requested**: 2017 (CCFA49)  
**Data availability**: December 2018  
**Data provider**: Puratos NV  
Mr. Bas Verhagen  
(bverhagen@puratos.com) | **Possible issues for trade**: currently unidentified  
**Basis for request**: The enzyme catalyzes the conversion of arabinoxylan into arabinoxylan oligosaccharides, providing technological benefits in baking. |
| 17 | Glucose oxidase from *Penicillium chrysogenum* expressed in *Aspergillus niger* | **Type of request**: Safety assessment and establishment of specifications  
**Proposed by**: European Union  
**Year requested**: 2014 (CCFA46) | **Basis for request**: The enzyme is used in baking, as it forms inter-protein bonds in dough, strengthening the dough and increasing its gas-retaining capacity and |
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| 18. | Inulinase from *Aspergillus ficuum* produced by *Aspergillus oryzae*, strain MUCL 44346 | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2017 (CCFA49)  
**Data availability:** December 2018  
**Data provider:** Puratos NV, Bas Verhagen (bverhagen@puratos.com) | **Basis for request:** The enzyme catalyzes the hydrolysis of inulin to produce fructo-oligosaccharides, theoretically from all food materials that naturally contain inulin.  
**Possible issues for trade:** currently unidentified |
| 19. | Lactase from *Bifidobacterium bifidum* expressed in *Bacillus licheniformis* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2017 (CCFA49)  
**Data availability:** December 2018  
**Data provider:** Puratos NV, Bas Verhagen (bverhagen@puratos.com) | **Basis for request:** The lactase enzyme preparation is used as a processing aid during food manufacture for hydrolysis of lactose during processing of milk and other lactose containing dairy products, e.g. in order to obtain lactose-reduced milk products for lactose-intolerant individuals as well as dairy products with better consistency and increased sweetness due hydrolysis of lactose to form glucose and galactose.  
**Possible issues for trade:** currently unidentified |
| 20. | Lipase from *Aspergillus oryzae* expressing a modified gene from *Thermomyces lanuginosus* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** Puratos NV, Bas Verhagen (bverhagen@puratos.com) | **Basis for request:** The enzyme is used as a processing aid during food manufacture for hydrolysis of lipids during processing of lipid-containing foods, e.g., in order to improve dough strength and stability in baking and other cereal based processes.  
**Possible issues for trade:** currently unidentified |
| 21. | Lipase from *Mucor javanicus* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** Japan  
**Year requested:** 2017 (CCFA49)  
**Data availability:** December 2018 | **Basis for request:** The enzyme catalyzes the hydrolysis of mono-, di- and triglycerides containing short-, medium-, and long-chain fatty acid moieties, providing various sensory benefits in processed dairy products. |
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| 22 | Phosphatidyl inositol-specific phospholipase C from a genetically modified strain of *Pseudomonas fluorescens* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** Amano Enzyme Inc.  
Mr. Tomonari Ogawa  
(tomonari_ogawa@amano-enzyme.com) | **Possible issues for trade:** currently unidentified  
Basis for request: The enzyme hydrolyzes phosphatidylinositol present in vegetable oil, thereby reducing its concentration. PI negatively impacts taste, colour, and stability of vegetable oil, while the hydrolytic products do not. |
| 23 | Phosphodiesterase from *Penicillium citrinum*                                | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** Japan  
**Year requested:** 2017 (CCFA49)  
**Data availability:** December 2018  
**Data provider:** Amano Enzyme Inc.  
Mr. Tomonari Ogawa  
(tomonari_ogawa@amano-enzyme.com) | **Possible issues for trade:** currently unidentified  
Basis for request: The enzyme is used in processing yeast products by hydrolysing RNA, thereby increasing ribonucleotide levels and improving umami flavour. |
| 24 | Phospholipase A2 from pig pancreas expressed in *Aspergillus niger*           | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2014 (CCFA46)  
**Data availability:** December 2018  
**Data provider:** DSM Food Specialties  
Dr. Mariella Kuilman  
(mariella.kuilman@dsm.com) | **Possible issues for trade:** currently unidentified  
Basis for request: The enzyme hydrolyzes natural phospholipids present in foodstuffs resulting in the formation of lyso-phospholipids that have emulsifying properties. This may be of benefit in baking and in egg processing for superior emulsifying properties (e.g. useful in dressings, spreads, sauces). In addition, the enzyme preparation is used during degumming of vegetable oils, where phospholipids can be separated more effectively from the oil. |
| 25 | Phospholipase A2 from *Streptomyces violaceoruber* expressed                 | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** Japan  
**Year requested:** 2016 (CCFA48) | **Possible issues for trade:** currently unidentified  
Basis for request: The enzyme preparation helps to improve emulsification properties of modified lipids increasing yield and texture of the final food in dairy and bakery. The processed baking products, and processed egg products. |
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|    | in S. violaceoruber | **Data availability:** December 2018  
**Data provider:** Nagase ChemteX Corporation  
Mr. Kensaku Uzura  
(kensaku.uzura@ncx.nagase.co.jp) | enzyme preparation can also be used for degumming of vegetable oil. In general, the phospholipase A2 does not exert any enzymatic activity in the final food.  
**Possible issues for trade:** currently unidentified |
| 26. | Protease Aqualysin 1 from *Thermus aquaticus* produced by *B. subtilis*, strain LMGS 25520 | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2017 (CCFA49)  
**Data availability:** December 2018  
**Data provider:** Puratos NV  
Bas Verhagen  
(bverhagen@puratos.com) | **Basis for request:** The enzyme preparation is used as a processing aid during production of bakery products. The food enzyme catalyses hydrolyzes of the peptide bonds. The addition of enzyme provides several benefits during the production of bakery products:  
- Faster dough development upon mixing;  
- Better dough machinability;  
- Reduced dough rigidity;  
- Improved dough's structure and extensibility during the shaping or moulding step;  
- Uniform shape of the bakery product;  
- Regular batter viscosity, and  
- Improved short-bite of certain products like hamburger breads  
**Possible issues for trade:** currently unidentified |
| 27. | Transglucosidase/alpha-glucosidase from *Trichoderma reesei* expressing an Alpha-glucosidase gene from *Aspergillus niger* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2016 (CCFA48)  
**Data availability:** December 2018  
**Data provider:** Danisco US Inc  
Dr. Vincent J. Sewalt  
(vincent.sewalt@dupont.com) | **Basis for request:** The food enzyme catalyzes both hydrolytic and transfer reactions on incubation with α-D-glucose-oligosaccharides. In molasses, non-fermentable sugars including raffinose and stachyose are converted to sucrose, galactose, glucose and fructose, which can then be fermented into alcohol. The enzyme preparation is intended for use in the production of isomalto-oligosaccharides and in the manufacture of potable alcohol, lysine, lactic acid and MSG.  
**Possible issues for trade:** currently unidentified |
<p>| 28. | Xylanase from <em>Bacillus</em> | <strong>Type of request:</strong> Safety assessment and establishment of specifications | <strong>Basis for request:</strong> The enzyme catalyzes the endo-hydrolysis of 1,4-beta-D-xylosidic bonds. |</p>
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|    | *licheniformis* expressed in *B. licheniformis* | **Proposed by:** European Union  
**Year requested:** 2015 (CCFA47)  
**Data availability:** December 2018  
**Data provider:** Novozymes A/S  
Tine Vitved Jensen  
(tvit@novozymes.com) | Linkages in xylans, including arabinoxylans in various plant materials including the cell walls and endosperm of cereals, such as wheat, barley, oats and malt. It is used in baking processes and other cereal based processes where it improves characteristics and handling of the dough.  
**Possible issues for trade:** currently unidentified |
| 29. | Xylanase from *Talaromyces emersonii* expressed in *Aspergillus niger* | **Type of request:** Safety assessment and establishment of specifications  
**Proposed by:** European Union  
**Year requested:** 2014 (CCFA46)  
**Data availability:** December 2018  
**Data provider:** DSM Food Specialties  
Dr. Jack Reuvers  
(jack.reuvers@dsm.com) | **Basis for request:** The enzyme is used in brewing processes to hydrolyze arabinoxylans in cereal cell walls, to reduce wort viscosity and improve filtration. The enzyme is also used in baking processes to improve dough characteristics and handling.  
**Possible issues for trade:** currently unidentified |
CONFIRMATION OF PREVIOUS REQUESTS AND DATA AVAILABILITY

In completing this form, the sponsor, data provider, or supporting Member of a request set out in Annex 3 can indicate if the request is still in effect, and if the data to support the request are currently available. The opportunity to later confirm or discontinue the requests will still be available at the in-session working group of the JECFA Priority List. In case any of the sponsor, data provider, or supporting Member cannot physically attend the meeting, please complete the form and please note one form per request.

And indication of “no” to any of the questions will result in the deletion of the request at the following session of the CCFA. In response to the circular letter, separate tables should be prepared for separate requests.

<table>
<thead>
<tr>
<th>Confirmation of previous request and data availability</th>
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<tbody>
<tr>
<td>Name of Substance (as it appears in Annex 3):</td>
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<tr>
<td>Is the request still in effect? (yes / no)</td>
</tr>
<tr>
<td>Are the data available? (yes / no) &lt;If yes, specify the earliest date on which the data can be made available&gt;</td>
</tr>
<tr>
<td>Change to data provider? (yes/no) &lt;If yes, specify the new data provider including contact person&gt;</td>
</tr>
</tbody>
</table>

(Data shall only be submitted in response to a JECFA call for data; do NOT add data intended for JECFA to this form)