



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fifty-sixth Session

PROPOSALS FOR ADDITIONS AND CHANGES TO THE PRIORITY LIST OF SUBSTANCES
PROPOSED FOR EVALUATION BY JECFA (REPLIES TO CL 2025/32-FA)

(Submitted by Japan, Paraguay, Republic of Korea, FoodDrinkEurope, International Association of Color Manufacturers (IACM), International Food Additives Council (IFAC), International Organization of the Flavor Industry (IOFI) and International Sweeteners Association (ISA))

Part A: Replies to CL 2025/32-FA, Annex 2 - Form for the submission of substances to be evaluated by JECFA

Republic of Korea

Name of Substance(s):	Ammonia
Question(s) to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)	Safety evaluation as a processing aid

- Proposal for inclusion submitted by: [The Republic of Korea](#)
- Name of substance; trade name(s); chemical name(s), IUPAC name, C.A.S number (as applicable):

Name of substance	Trade name(s)	Chemical name(s)	IUPAC	CAS No.
Ammonia	Anhydrous ammonia, Ammonia gas	Ammonia	Azane	7664-41-7

- Names and addresses of basic producers:

Name of Factory/Company	PT. Kaltim Parna Industri
Address of Factory/Company	Kaltim Industrial Estate, Bontang, Kalimantan Timur
Post code	75711
Country	Indonesia

- Identification of the manufacturer that will be providing data (Please indicate contact person):

[CJ CheilJedang](#)

[CJ BLOSSOM PARK, 55, Gwanggyo-ro 42beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16495](#)

[The Republic of Korea](#)

* [Contact Person](#): Suyoung Lim (e-mail: suyoung.lim@cj.net, Tel.: +82-31-8099-2525)

- Justification for use:

Nitrogen derived from ammonia(NH_3) is utilized as a nutrient source(nitrogen source) for microbial fermentation. Ammonia represents the most readily assimilable inorganic form of nitrogen for microorganisms. In aqueous solutions, ammonia is converted to the ammonium ion(NH_4^+), which can be directly taken up by microbial cells.

Following uptake, ammonium is assimilated into microbial biomass primarily via enzymatic pathways such as glutamate dehydrogenase (GDH) and glutamine synthetase (GS). These pathways are essential for the

incorporation of nitrogen into amino acids, which is a fundamental requirement for microbial growth and protein synthesis.

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):

Ammonia (gas) is not directly added to the final food products and is used only indirectly during the microbial fermentation process. Specifically, ammonia (gas) is applied during fermentation for technical purposes, including the provision of a nitrogen source required for microbial growth and the control of pH during the process. Ammonia (gas) is introduced into the fermentation medium as a nutrient for microorganisms used in the manufacture of food additives, flavourings or food ingredients derived from microbial fermentation, at a typical use level of approximately 26,000 mg/kg of fermentation medium. Following completion of the fermentation process, the substance is removed or neutralized, and it does not perform any technological function in the final foods.

The food additives, flavourings or food ingredients produced using ammonia (gas) are intended to be used in food category 12.0 (Salts, spices, soups, sauces, salads, protein products), including spices, sauces, and soups. Ammonia (gas) dissolves in water and is converted to the ammonium ion. In the case of ammonium hydroxide (ammonia solution), a safety evaluation was completed by the 9th session of JECFA in 1965, concluding that there were no safety concerns related to dietary intake. Accordingly, for ammonia (gas), the application of GMP levels is proposed.

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))

[Table 1] Regulatory Status of 'Ammonia'

No.	Country/Organization	Food Category	Maximum Limit (mg/kg)	Reference
1	Republic of Korea/ Ministry of Food and Drug Safety	All food category	GMP	Standards and specification of Food Additives (MFDS Notification)
2	Japan/ Ministry of Health, Labour and Welfare	All food category	GMP	List of Designated Food Additives (JFRF Regulation)
3	Europe/ European Commission	All food category	GMP	(EC) No 872-2012
4	China/ National Health Commission of the People's Republic of China	All food category	GMP	GB 2760-2024

[Table 2] Regulatory Status of 'Ammonium hydroxide'

No.	Country/Organization	Food Category	Maximum Limit (mg/kg)	Reference
1	Republic of Korea/ Ministry of Food and Drug Safety	All food category	GMP	Standards and specification of Food Additives (MFDS Notification)
2	The United States/ Food and Drug Administration	All food category	GMP	21CFR184.1139
3	Europe/ European Commission	All food category	GMP	(EC) No 1333/2008

4	China/ National Health Commission of the People's Republic of China	All food category	GMP	GB 2760-2024
5	CODEX	All food category	GMP	CXS 192-1995

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.

Ammonia (gas) is an essential substance in the food industry for the manufacture of products based on microbial fermentation. However, in the absence of a safety evaluation by JECFA, several developed countries have permitted its use based on their own national safety assessments concluding that ammonia (gas) is safe under the intended conditions of use. For example, according to the *List of Designated Food Additives* published by the Japan Food Chemical Research Foundation referring to an English reference translation of the Enforcement Regulations of the Japanese Food Sanitation Act, ammonia is designated as a permitted food additive in Japan (see Attachment 2).

In contrast, many developing countries face difficulties in conducting independent safety evaluations, and as a result, ammonia has not been listed as a permitted processing aid or food additive for use in foods. This has led to discrepancies in the regulatory status of ammonia between developed and developing countries, creating challenges for the food industry engaged in international trade. For instance, while ammonia(gas) is authorized in regions such as Europe, as well as in countries including the Republic of Korea, China, and Japan, it is not listed in several Asia-Pacific (APAC) countries, including Indonesia. Consequently, special permits have been required to enable its use in such jurisdictions (as of 22 December 2025). To address these regulatory inconsistencies and facilitate international food trade, it is therefore requested that JECFA conduct a safety evaluation of ammonia as a processing aid and establish an internationally recognized conclusion supporting its safe use in food manufacturing.

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.

The 9th JECFA(1965) completed a safety evaluation of 'ammonium hydroxide' and concluded that there were no safety concerns related to its dietary intake.

For reference, in 2011, the European Food Safety Authority (EFSA) completed a safety evaluation of 'ammonia' as a flavouring substance. The relevant scientific opinion is available at the following DOI link: <https://doi.org/10.2903/j.efsa.2011.1925>

- European Food Safety Authority (EFSA)
- Address: Via Carlo Magno 1A, 43126 Parma, ITALY
- Contact: +39 0521 036 111

10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries.

Ammonia is listed as a substance permitted for safe use in foods in major developed countries, including Europe, the United States, Japan, the Republic of Korea, and China, based on their respective national safety evaluations. However, in many developing countries, where the capacity to conduct independent safety assessments is limited, ammonia is not authorized for use in foods, as it is regarded as a substance lacking a JECFA safety evaluation and is not listed in Codex standards.

Ammonia is a key microbial nutrient required during microbial fermentation, particularly in precision fermentation, which is emerging as a core technology in the future food industry. Consequently, the absence of an international safety evaluation may further widen the gap between developed and developing countries in the development and adoption of future food technologies.

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.

Data	Data available? (Y / N)
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify) - Acute toxicity (single-dose) - Reproductive and developmental toxicity / Genotoxicity and mutagenicity - Animal carcinogenicity studies	Y
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	N
(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)	Y
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Y
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	Y
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Y
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.)

The data supporting this request are available for submission by Dec 2026.

International Association of Color Manufacturers (IACM)

Name of Substance(s):	Beet Red from <i>S. cerevisiae</i> strain P0
Question(s) to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)	Safety assessment and establishment of new production method for Beet red.

1. Proposal for inclusion submitted by:

International Association of Color Manufacturers (IACM) on behalf of Phytolon

2. Name of substance; trade name(s); chemical name(s), IUPAC name, C.A.S number (as applicable):

Name of the substance: Beet Red from *S. cerevisiae* strain P0

Trade name: Beetroot Red, Phytolon® Beetroot Red, PhytoPurple

IUPAC name: Betanin (the principal coloring compound) - 1-[2-(2,6-dicarboxy-1,2,3,4-tetrahydro-4-pyridine)ethylidene]-5-beta-D-glucopyranosyloxy-6-hydroxyindolium-2-carboxylate

CAS number: 7659-95-2 (Betanin)

3. Names and addresses of basic producers:

Phytolon Ltd.

Ha-Tsmikha 1 st,

Yokne'am Illit, Industrial park, Israel

4. Identification of the manufacturer that will be providing data (Please indicate contact person):

IACM or its member company can provide the available published data in a submission dossier.

IACM contact is Sarah Codrea, Executive Director,
1101 17th St, NW, Suite 700,
Washington, DC, 20036,
email scodrea@iacmcolor.org.

Phytolon Ltd. Contact is Dr. Tal Zeltzer, co-founder & CTO;
Ha-Tsmikha 1 st,
Yokne'am Illit, Industrial park, Israel
Email: tal@phytolon.com

5. Justification for use: Use as a food color

Traditional agricultural production of Beetroot Red by cultivation and extraction of red beets (*Beta vulgaris* L.) is land-intensive, water consuming, and highly vulnerable to seasonal volatility, climate-related crop failures, and supply chain disruptions. In addition, the peels, leaves and pomace (approximately 40% of the root's weight) remaining upon completion of the extraction are considered waste and present a high risk for land and water contamination. Therefore, there is a critical need for scalable, cost effective, sustainable, non-polluting and climate-resilient alternatives to fill the global demand for naturally derived colors. Fermentation-derived production provides a reliable, year-round supply that can meet the massive volume requirements of the global food industry.

Fermentation-derived betanin is identical to plant-derived betanin, meets JECFA specifications, and offers improved safety by eliminating agricultural contaminants, requiring only recognition of the production method.

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):

Beet Red from *S. cerevisiae* strain P0 is not currently listed in the GSFA but will be proposed for use in the same food categories and use level currently permitted for Beet Red (INS 162).

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))

Extraction of red beets containing betanin as the predominant coloring constituent has been traded globally as a food color for decades under INS. 162 (Codex), E162 (EU), 21 CFR 73.40 and 21 CFR 73.250 (U.S.), Beet Red (B.1) (Canada) and more.

The US FDA has provided Phytolon with a draft codified proposed rule indicating that it will be approved under the common name Beetroot Red (designated 21 CFR 73.39) (CAP 4C0326, Beetroot Red).

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.

The use of a greater number of globally approved naturally derived color additives is in significant demand globally. Therefore, a JECFA evaluation will positively impact trade moving forward, and the lack of JECFA recognition for fermentation-derived Beetroot Red will create a significant technical barrier to trade once approved in the United States. Many Codex member states, particularly in developing regions, rely on JECFA safety assessments to authorize ingredients.

Harmonizing fermentation-derived Beet Red is essential to stabilize supply and prices of natural red colorings, ensuring equitable access, especially for developing countries, while reducing reliance on synthetic alternatives. It also removes trade barriers by enabling global export compliance with JECFA-recognized, clean-label standards.

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.

- A petition (CAP 4C0326) for the approval of Beetroot Red (Beet Red from *S. cerevisiae*) has completed a risk assessment and the codification process by the US FDA (designated 21 CFR 73.39, *Beetroot Red*) and is currently in external clearance prior to publication.
- An application to amend the Food Additive specification of E 162 Beetroot Red, Betanin to Include Betanin from *Saccharomyces cerevisiae* was submitted to the European Commission. Application reference number FAD-2025-36096; question number EFSA-Q-2026-00001.
- An application for the approval of Phytolon's Beet Red as a color additive in Canada has been submitted to Health Canada. The application reference number is Case 2025-168301.

10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries.

In many developing countries, risk management decisions relating to food colors under the Codex General Standard for Food Additives (GSFA) are influenced by documented challenges in ensuring compliance with permitted uses, maximum levels, and specifications. Various national authorities have reported instances of the use of non-permitted red industrial dyes, including Sudan dyes, Rhodamine B, and Auramine O, particularly in beverages, confectionery, spices, seasonings, and sauces. Although these incidents reflect limitations in enforcement rather than deficiencies in Codex standards themselves, these situations are in part a reflection of the high cost of food colorings. With developing nations moving away from synthetic colorings, the long-term consequences will be unavailability of affordable sources of natural color additives in the global marketplace, increasing incentives for misuse, substitution or adulteration of color additives in the developing world. Fermentation-based production supports a stable supply and affordability of color additives, contributing to food security, food safety and supporting small and medium food enterprises in developing regions with access to affordable natural coloring alternatives to synthetic dyes.

11. Please indicate the type of data that are available in the table below.

	Data available? (Y / N)
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y (ADME data on betanin is available in the literature)
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y Genotoxicity: *Bacterial reverse mutation assays (OECD 471), <i>In vitro</i> chromosome aberration study (OECD 473), <i>In vitro</i> micronucleus study (OECD 487), <i>In vivo</i> pig-a mutation study (OECD 470) and <i>in vivo</i> duplex-sequencing mutagenesis study. Sub-chronic: Sub-chronic toxicity (90-day study) in rats (OECD 408).
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	Y (human studies involving betanin preparations are available in the literature)
(iv) Other data (please specify)	N
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Y
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Y
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	Y
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Y
Other information: (please specify)	Detailed information on the production strain, stability of substance (as bulk and in food applications), comparison to INS 162 (identity, functionality, efficacy, stability, fate in food).

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.**)

The data supporting this request is available for submission immediately and will be available to submit to JECFA by December 2026. While the application focuses on amending the existing specifications for INS 162 to include an additional source for Beet Red (*S. cerevisiae* fermentation), a complete dossier, including full compositional, chemical and toxicological characterization of the color additive, has been prepared and is available for review.

The International Organization of the Flavor Industry (IOFI)

Name of Substance(s):	See Appendix IIa 2026CCFA56 , to be evaluated by the Procedure for the Safety Evaluation of Flavouring Agents. See Appendix IIc 2026CCFA56 for substances that have updates to the online edition of "Specifications for Flavourings"
Question(s) to be answered by JECFA (Provide a brief justification of the request in case of re-evaluations)	1. Are the substances in Appendix IIa and IIb of no safety concern at the current levels of exposure? 2. Do the published specifications for the flavouring agents as listed in Appendix IIc and Appendix IId represent what is in global commerce?

1. Proposal for inclusion submitted by:

International Organization of the Flavor Industry

2. Name of substance; trade name(s); chemical name(s), IUPAC name, C.A.S number (as applicable):

See [Appendix IIa 2026CCFA56](#) for substances to be evaluated by the Revised Procedure for the Safety Evaluation of Flavouring Agents.

3. Names and addresses of basic producers:

International Organization of the Flavor Industry (IOFI). Flavor producers are members of the International Organization of the Flavor Industry (IOFI). All contacts can be made through IOFI.

4. Identification of the manufacturer that will be providing data (Please indicate contact person):

Sean V. Taylor, Ph.D. (staylor@iofi.org)

5. Justification for use:

The listed flavouring ingredients are used to improve the quality and enjoyment of food for human consumption.

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):

Food Categories and Use Levels will be submitted for all new flavouring agents and candidates.

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))

Yes (United States, European Union, Latin America and Japan)

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.

We are unaware of any current specific impediments to international trade due to a lack of JECFA evaluation and/or Codex standard for the ingredients listed.

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.

We are currently unaware of ongoing risk assessments at a national or regional level for these flavourings. For some of these flavorings, the European Food Safety Authority has conducted risk assessments within the last 10 years. We would be happy to provide the details of such assessments. The contact address is European Food Safety Authority (EFSA), Via Carlo Magno 1A, 43126 Parma Italy.

10. Please provide details if this food additive is of particular relevance to the livelihood and food safety in developing countries.

We are currently unaware if these food additives are 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.

Data	Data available? (Y / N)
Toxicological data	
(i) Metabolic and pharmacokinetic studies (please specify)	Y
(ii) Short-term toxicity, long-term toxicity/carcinogenicity, reproductive toxicity, and developmental toxicity studies in animals and genotoxicity studies (please specify)	Y
(iii) Epidemiological and/or clinical studies and special considerations (please specify)	N
(iv) Other data (please specify)	N
Technological data	
(i) Specifications for the identity and purity of the listed substances (specifications applied during development and toxicological studies; proposed specifications for commerce)	Y
(ii) Technological and nutritional considerations relating to the manufacture and use of the listed substance	Y
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	Y
(ii) Estimation of dietary exposures based on food consumption data for foods in which the substance may be used.	Y
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.**)

The earliest date that the data can be made available to JECFA is December 15, 2026.

Appendix IIa. Seven (7) flavourings newly proposed for inclusion on the JECFA Priority List to be considered at the 56th session of the Codex Committee on Food Additives.

CCFA History	FEMA	CAS	PRINCIPAL NAME	Structural class
New 56 th	5002	2294887-29-7	(E)-3-(1,3-benzodioxol-5-yl)-n-phenyl-n-tetrahydrofuran-3-yl-prop-2-enamide	III
New 56 th	5030	1928720-93-7	4-(l -Menthoxoy)-2-methyl-2-butanol	III
New 56 th	5038	2379651-17-7	Hexahydro-6a,7-dimethyl-2,5-methano-2H -cyclopenta[b]furan	III
New 56 th	5050	2910770-74-8	1-(tert-Butyl)-N -(4-methoxyphenyl)cyclohexane-1-carboxamide	III
New 56 th	5066	2771072-99-0	4-(4-Methylpent-3-en-1-yl)thiophen-2(5H)-one	III
New 56 th	5067	17627-44-0	<i>alpha</i> -Bisabolene	I

New 56 th	5077	6753-98-6	<i>alpha</i> -Humulene	I
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Appendix IIc – JECFA Priority List additions/changes for fourteen (14) compounds proposed for specifications modification to be considered at the 56th session of the Codex Committee on Food Additives.

History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation	Status	Update
Old	4018	1049	638-17-5	2,4,6-Trimethyldihydro-4 <i>H</i> -1,3,5-dithiazine	2002 (Session 59)	Full	The Assay Minimum % does not reflect the material currently in commerce.
Old	3144	1333	1195-32-0	<i>p</i> - <i>alpha</i> -Dimethylstyrene	2004 (Session 63)	Full	The Refractive Index and Specific Gravity do not reflect the material currently in commerce.
Old	3410	1400	1211-29-6	Methyl jasmonate	2004 (Session 63)	Full	The Assay Minimum % does not reflect the material currently in commerce and should be expressed as the sum of stereoisomers.
Old	2454	1576	121-39-1	Ethyl 3-phenylglycidate	2005 (Session 65)	Full	The Refractive Index and Assay Minimum % do not reflect the material currently in commerce.
Old	4246	1611	121-44-8	Triethylamine	2008 (Session 69)	Full	The Refractive Index and Specific Gravity do not reflect the material currently in commerce.
Old	4446	1998	502-26-1	<i>gamma</i> -Octadecalactone	2010 (Session 73)	Full	The Melting Point does not reflect the material currently in commerce.
Old	4447	1999	1227-51-6	<i>delta</i> -Octadecalactone	2010 (Session 73)	Full	The Melting Point does not reflect the material currently in commerce.
Old	2055	0043	123-92-2	Isoamyl acetate	1996 (Session 46)	Full	Add requirement on minimum assay to include the sum of both isomers.
Old	2060	0045	106-27-4	Isoamyl butyrate	1996 (Session 46)	Full	Add requirement on minimum assay to include the sum of both isomers.
Old	2075	0046	2198-61-0	Isoamyl hexanoate	1996 (Session 46)	Full	Add requirement on minimum assay to include the sum of both isomers.
Old	2082	0044	105-68-0	Isoamyl propionate	1996 (Session 46)	Full	Add requirement on minimum assay to include the sum of both isomers.
Old	3544	0963	3289-28-9	Ethyl cyclohexane-carboxylate	2008 (Session 69)	Full	The Refractive Index and Specific Gravity do not reflect the material currently in commerce.
Old	2451	0039	628-97-7	Ethyl palmitate	1996 (Session 46)	Full	The Assay Minimum % and Acid Value Max do not reflect the material currently in commerce.
Old	3524	0269	5435-64-3	3,5,5-Trimethyl hexanal	1997 (Session 49)	Full	Add requirement on minimum assay to include the sum of both isomers.

Part B: Replies to CL 2025/32-FA, Annex 3 - Priority list of substances proposed for evaluation by JECFA

Japan

Japan would like to withdraw No13 in PART B, because we were unable to confirm that the sponsor's submission materials were ready.

Other items proposed from Japan have no change.

PART B: LIST OF SUBSTANCES USED AS PROCESSING AIDS PROPOSED FOR EVALUATION BY JECFA

13.	Acylglycerol lipase from <i>Penicillium crustosum</i> expressed in <i>Penicillium crustosum</i>	Type of request: Safety assessment and establishment of specifications Proposed by: Japan Year requested: 2024 (CCFA54) Data availability: December 2025 Data provider: Amano Enzyme Inc. Mr. Hidetaka Sugimoto aejregulatory@amano-enzyme.com	Basis for request: The enzyme is used in milk processing to hydrolyze ester bond between fatty acid and glycerol in monoglycerides and diglycerides to release fatty acids and glycerol. This results to enzyme modified cheese (EMC), enzyme modified dairy products (EMD) and enhanced flavour. The enzyme is also used in fats and oil processing to hence improve the relative purity of triglyceride in oil. Possible issues for trade: currently unidentified
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Paraguay

Paraguay is pleased to submit its comment on the information requested in Annex 3.

Annex 3 - Priority list of substances proposed for evaluation by JECFA.

In the context of Circular Letter CL 2025/32-FA, and regarding the information requested in point 2.2 of Annex 3, Paraguay submits the following observation:

Paraguay considers it appropriate that Transglutaminase (EC 2.3.2.13), derived from *Streptomyces mobaraensis* strain M2020197, be considered by JECFA for safety assessment and establishment of specifications, in order to have an international scientific reference to support national and regional regulatory decisions, according to the information contained in Annex 3, Part B: list of substances used as processing aids proposed for evaluation by JECFA of Circular Letter CL 2025/32-FA.

Part C: Replies to CL 2025/32-FA, Annex 4 - Confirmation of previous requests and data availability

FoodDrinkEurope

Name of Substance (as it appears in Annex 3):	Polyglycerol Esters of Interesterified Ricinoleic Acid (INS 476)
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	Yes, basis for re-evaluation subject to available data evaluated in EFSA 2017 re-evaluation
Change to data provider? (yes/no)	No

The International Food Additives Council (IFAC)

The International Food Additives Council (IFAC) is responding to the Circular Letter published in April 2025 requesting information and comments on the priority list of substances proposed for evaluation by JECFA (JECFA priority list). IFAC is a global association representing manufacturers and end-users of food additives. IFAC has NGO Observer status before Codex Alimentarius and appreciates the opportunity to provide the following information.

IFAC is requesting the deprioritization of silicon dioxide, amorphous (INS 551) on the JECFA priority list as it is currently listed as priority 1 for food additive evaluation. Our rationale includes:

- Silicon dioxide, amorphous has been used for many years and does not raise any health concerns;
- There has been no change in the specifications or the manufacturing process;
- The European Food Safety Authority has confirmed that the use of silicon dioxide, amorphous in foods (E 551), including those for infants and children, is safe;
- JECFA guidelines on how to evaluate nanoparticles have not been developed yet.

It is for these reasons we respectfully request that INS 551 be given a lower priority and that its safety evaluation be postponed until after 2028 or until JECFA guidance on nanomaterials is available. The updated form "Confirmation of Previous Requests and Data Availability" is included as an annex to this letter.

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Silicon Dioxide, Amorphous (INS 551)
Is the request still in effect? (yes/no)	Yes
Are the data available? (yes/no)	<If yes, specify the earliest date on which the data can be made available> 2028 (if JECFA guidance on nanomaterials is available in time)
Change to data provider? (yes/no)	<If yes, specify the new data provider including contact person> No Data provider: IFAC Contact persons: Sabrina Migliorini, Manager, Association of Synthetic Amorphous Silica Producers (ASASP), a Sector Group of Cefic smi@cefic.be Joel F. Carpenter, Executive Director, Synthetic Amorphous Silica and Silicate Industry Association (SASSI) jcarpenter@sassiassociation.org Berit Dockter, Senior Manager, Scientific & Regulatory Affairs International Food Additives Council (IFAC) bdockter@foodingredientfacts.org

The International Organization of the Flavor Industry (IOFI)

Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	See Appendix IIb 2026CCFA56 , to be evaluated by the Procedure for the Safety Evaluation of Flavouring Agents. See Appendix IId)2026CCFA56 , for Flavouring Agents for consideration of revision of existing specifications.

Is the request still in effect? (yes/no)	Yes
Are the data available? (yes/no)	December 15, 2026
Change to data provider? (yes/no)	No
Name of Substance (as it appears in Annex 3):	See Appendix IIb 2025CCFA55 , to be evaluated by the Procedure for the Safety Evaluation of Flavouring Agents.
Is the request still in effect? (yes / no)	Yes
Are the data available? (yes / no)	December 15, 2025
Change to data provider? (yes/no)	No

Appendix IIb. One-hundred twenty-four (124) flavourings previously submitted to the Codex Committee on Food Additives for inclusion on the JECFA Priority list.

CCFA History (submitted at)	FEMA	CAS	PRINCIPAL NAME	Structural class
CCFA51	3557 (JECFA 973)	2111-75-3	<i>p</i> -Mentha-1,8-dien-7-al (Perillaldehyde)	
CCFA43	4074	6321-45-5	Allyl valerate	II
CCFA43	4072	20474-93-5	Allyl crotonate	II
CCFA45	4685	7370-92-5	(±)-6-Octahyltetrahydro-2H-pyran-2-one	I
CCFA45	4673	7370-44-7	<i>delta</i> -Hexadecalactone	I
CCFA45	4682	23333-91-7	Octahydro-4,8a-dimethyl-4a(2 <i>H</i>)-naphthol	I
CCFA45	4742	917750-72-2	1-(2-Hydroxy-4-methylcyclohexyl)ethanone	III
CCFA45	4687	544409-58-7	(±)-3-Hydroxy-3-methyl-2,4-nonanedione	II
CCFA51	4836	137363-86-1	10% solution of 3,4-dimethyl-2,3-dihydrothiophene-2-thiol	III
CCFA51	4842	911212-28-7	2,4,5-Trithiaoctane	III
CCFA51	4817	38634-59-2	S-[(methylthio)methyl]thioacetate	I
CCFA51	4870	17564-27-1	2-Ethyl-4-methyl-1,3-dithiolane	II
CCFA51	4828	729602-98-6	1,1-Propanedithioacetate	III
CCFA51	4824	1658479-63-0	2-(5-Isopropyl-2-methyl-tetrahydrothiophen-2-yl)-ethyl acetate	III
CCFA51	4843	1838169-65-5	3-(Allyldithio) butan-2-one	III
CCFA51	4822	61407-00-9	2,6-Dipropyl-5,6-dihydro-2H-thiopyran-3-carboxaldehyde	II
CCFA51	4823	33368-82-0	1-Propenyl 2-propenyl disulfide	II
CCFA51	4782	1679-06-7; 1633-90-5	2(3)-Hexanethiol	I
CCFA51	4779	1416051-88-1	(±)-2-Mercapto-5-methylheptan-4-one	I
CCFA51	4792	548740-99-4	(±)-3-Mercapto-1-pentanol	I
CCFA51	4791	22236-44-8	3-(Acetylthio)hexanal	III
CCFA51	4769	851768-51-9	5-Mercapto-5-methyl-3-hexanone	I
CCFA51	4730	1241905-19-0	O-Ethyl S-1-methoxyhexan-3-yl carbonothioate	III
CCFA51	4734	1256932-15-6	3-(Methylthio)-decanal	I

CCFA History (submitted at)	FEMA	CAS	PRINCIPAL NAME	Structural class
CCFA51	4733	1006684-20-3	(±)-2-Mercaptoheptan-4-ol	III
CCFA51	4761	75631-91-3	Prenyl thioisovalerate	I
CCFA51	4760	53626-94-1	Prenyl thioisobutyrate	I
CCFA45	4700	614-60-8	<i>o</i> -trans-Coumaric acid	III
CCFA43	4622	61683-99-6	Piperonal propyleneglycol acetal	III
CCFA43	4627	6414-32-0	Anisaldehyde propyleneglycol acetal	III
CCFA43	4618	23495-12-7	2-Phenoxyethyl propinate	III
CCFA43	4625	6314-97-2	Phenylacetaldehyde diethyl acetal	I
CCFA43	4629	5468-05-3	Phenylacetaldehyde propyleneglycol acetal	III
CCFA43	4620	122-99-6	2-Phenoxyethanol	III
CCFA43	4619	92729-55-0	Propyl 4-tert-butylphenylacetate	I
CCFA43	4314	61810-55-7	Phenethyl decanoate	I
CCFA43	2860	94-47-3	Phenethyl benzoate	I
CCFA43	4438	591-11-7	<i>beta</i> -Angelicalactone	I
CCFA43	4195	87-41-2	Phthalide	III
CCFA45	4768	67936-13-4	2,6,10-Trimethyl-9-undecenal	I
CCFA45	4612	645-62-5	2-Ethyl-2-hexenal	II
CCFA45	4616	13019-16-4	2-Hexylidenehexanal	II
CCFA45	4486	5694-82-6	Citral glyceryl acetal	I
CCFA52	4902	22122-36-7	3-Methyl-2(5 <i>H</i>)-furanone	III
CCFA52	4915	2142634-65-7	(5 <i>Z</i>)-3,4-Dimethyl-5-propylidene-2(5 <i>H</i>)-furanone	III
CCFA52	4784	57548-36-4	(±)-4-Hydroxy-6-methyl-2-heptanone	I
CCFA52	4939	2180135-09-3	<i>S</i> -Methyl 5-(1-ethoxyethoxy)decanethioate	I
CCFA52	4894	116229-37-9	2-Mercapto-3-methyl-1-butanol	I
CCFA52	4883	556-27-4	<i>S</i> -Allyl- <i>L</i> -cysteine sulfoxide	II
CCFA52	4935	98139-71-0	3-Methylbutane-1,3-dithiol	III
CCFA52	4916	124831-34-1	2-Methyl-3-butene-2-thiol	I
CCFA52	4938	2180135-08-2	<i>S</i> -Methyl 5-(1-ethoxyethoxy)tetradecanethioate	I
CCFA52	4901	2097608-89-2	<i>O</i> -Ethyl <i>S</i> -(3-methylbut-2-en-1-yl)thiocarbonate	I
CCFA52	4900	64580-54-7	Hexyl propyl disulfide	I
CCFA52	4914	24963-39-1	bis-(3-Methyl-2-butenyl)disulfide	III
CCFA52	4889	3877-15-4	Methyl propyl sulfide	I
CCFA52	4930	159017-89-7	4-Isopropoxycinnamaldehyde	I
CCFA52	4888	1945993-01-0; 828265-08-3	Mixture of 5-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-7-methylchroman-2-one and 7-hydroxy-4-(4'-hydroxy-3'-methoxyphenyl)-5-methylchroman-2-one	III
CCFA52	4879	21145-77-7	1-(3,5,5,6,8,8-Hexamethyl-5,6,7,8-tetrahydronaphthalen-2-yl)ethanone	II
CCFA52	4892	4707-61-3	<i>cis</i> -2-Hexylcyclopropaneacetic acid	II
CCFA52	4890	27841-22-1	3- <i>p</i> -Menthen-7-al	I
CCFA52	4928	554-14-3	2-Methylthiophene	II
CCFA52	4839	163460-99-9 163461-01-6	Mixture of 3- and 4-butyl-2-thiophenecarboxyaldehyde	II

CCFA History (submitted at)	FEMA	CAS	PRINCIPAL NAME	Structural class
CCFA52	4813	1612888-42-2	2-(5-Isopropyl-2-methyltetrahydrothiophen-2-yl)ethanol	II
CCFA52	4884	1569-60-4	6-Methyl-5-hepten-2-ol	I
CCFA52	4827	6090-09-1	1-(4-Methyl-3-cyclohexen-1-yl)-ethanone	I
CCFA52	4869	886449-15-6	4-(<i>l</i> -Menthoxyl)-2-butanone	II
CCFA52	4844	118026-67-8	(2 <i>E</i> ,4 <i>E</i>)-2,4-Decadien-1-ol acetate	I
CCFA52	4747	91212-78-1	(±)-2,5-Undecadien-1-ol	II
CCFA52	4913	18478-46-1	3,7-Dimethyl-2-methyleneoct-6-en-1-ol	II
CCFA52	4785	25234-33-7	2-Octyl-2-dodecenal	II
CCFA52	4786	13893-39-5	2-Hexyl-2-decenal	II
CCFA52	4929	60857-05-8	4-Methylidene-2-(2-methylprop-1-enyl)oxane	III
CCFA52	4920	220462-51-9	1-Ethyl-2-(1-pyrrolylmethyl)pyrrole	III
CCFA52	4832	108715-62-4	2-(3-Benzoyloxypropyl)pyridine	III
CCFA52	4829	616-45-5	2-Pyrrolidone	I
CCFA52	4818	1370711-06-0	<i>trans</i> -1-ethyl-2-methylpropyl 2-2-butenolate	I
CCFA52	4867	18374-76-0	(3 <i>S</i> ,5 <i>R</i> ,8 <i>S</i>)-3,8-Dimethyl-5-prop-1-en-2-yl-3,4,5,6,7,8-hexahydro-2 <i>H</i> -azulen-1-one	II
CCFA52	4840	38427-80-4	Tetrahydronootkatone	II
CCFA52	4807	1078-95-1	Pinocarvyl acetate	II
CCFA52	4906	36687-82-8	<i>L</i> -Carnitine tartrate	III
CCFA52	4868	61315-75-1	4-(4-Methyl-3-penten-1-yl)-2(5 <i>H</i>)-furanone	III
CCFA52	4896	2186611-08-3	<i>N</i> -(2-Hydroxy-2-phenylethyl)-2-isopropyl-5,5-dimethylcyclohexane-1-carboxamide	III
CCFA52	4882	1857330-83-9	<i>N</i> -(4-(Cyanomethyl)phenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
CCFA52	4899	1622458-34-7; 2079034-28-7	<i>N</i> -(1-((4-amino-2,2-dioxido-1 <i>H</i> -benzo[<i>c</i>][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)-2,6-dimethylisonicotinamide	III
CCFA52	4880	2015168-50-8	2-(4-Ethylphenoxy)- <i>N</i> -(1 <i>H</i> -pyrazol-3-yl)- <i>N</i> -(thiophen-2-ylmethyl)acetamide	III
CCFA52	4881	1857331-84-0	<i>N</i> -(3-Hydroxy-4-methoxyphenyl)-2-isopropyl-5,5-dimethylcyclohexanecarboxamide	III
CCFA52	4877	76733-95-4	(<i>E</i>)-3-(3,4-Dimethoxyphenyl)- <i>N</i> -[2-(3-methoxyphenyl)-ethyl]-acrylamide	III
CCFA52	4835	877207-36-8	2,4-Dihydroxy- <i>N</i> -[(4-hydroxy-3-methoxyphenyl)methyl]benzamide	III
CCFA53	4948	1129-69-7	2-Hexylpyridine	II
CCFA53	4958	2308574-23-2	4-Formyl-2-methoxyphenyl <i>l</i> -menthyl glutarate	I
CCFA53	4959	301310-73-6; 79894-05-6	9-Dodecen-12-olide	III
CCFA53	4960	13474-59-4	<i>trans</i> - α -Bergamotene	I
CCFA53	4961	2369713-22-2	4-Methyltrideca-2 <i>E</i> ,4-dienal	I
CCFA53	4965	1622458-32-5	<i>N</i> -(1-((4-Amino-2,2-dioxido-1 <i>H</i> -benzo[<i>c</i>][1,2,6]thiadiazin-5-yl)oxy)-2-methylpropan-2-yl)isonicotinamide	III
CCFA53	4966	6137-11-7	4-Methylheptan-3-one	II
CCFA53	4967	483-76-1	δ -Cadinene	I
CCFA53	4970	2413115-68-9	2-Methyl-1-(2-(5-(<i>p</i> -tolyl)-1 <i>H</i> -imidazol-2-yl)piperidin-1-yl)butan-1-one	III
CCFA53	4971	18794-84-8	β -Farnesene	I

CCFA History (submitted at)	FEMA	CAS	PRINCIPAL NAME	Structural class
CCFA53	4972	23060-14-2	Diethyl mercaptosuccinate	I
CCFA53	4973	2411762-60-0	3-Mercapto-3-methyl-1-pentyl acetate	I
CCFA53	4974	23986-74-5	Germacrene D >85%	I
CCFA53	4977	65210-18-6	10-Hydroxy-4,8-dimethyldec-4-enal	I
CCFA53	4979	142062-38-2	2-(Furan-2-yl)-4,6-dimethyl-1,3,5-dithiazinane	III
CCFA53	4980	2415657-73-5	Mixture of (8Z,11Z)-heptadeca-8,11-dienal and (Z)-heptadec-8-enal	
CCFA54	4943	111-20-6	Decanedioic acid	I
CCFA54	4944	6402-36-4	<i>trans</i> -2-Dodecenedioic acid	I
CCFA54	4945	174155-46-5	<i>cis</i> -8-Decenal	I
CCFA54	4825	2277-20-5	(<i>E</i>)-6-Nonenal	I
CCFA54	3811	20702-77-6	Neohesperidin dihydrochalcone	III
CCFA54	3038	126-14-7	Sucrose octaacetate	III
CCFA55	4981	6820-02-6	8-Methyl-4-methylenenon-7-en-2-one	II
CCFA55	4982	2492342-84-2	4-(4-Methylpent-3-en-1-yl)-5,6-dihydro-2H-pyran-2-one	III
CCFA55	4983	2491702-14-6	4-Mercapto-1-octanol	I
CCFA55	4984	2099712-94-2	2,11-Tetradecadienal	III
CCFA55	4985	1801275-27-3	4,9-Dodecadienal	I
CCFA55	4993	34776-60-8	Methyl 3-methyl-2-buten-1-yl disulfide	III
CCFA55	5003	149231-57-2	2,6-Octadienal	III
CCFA55	5004	40556-69-2	2-Methyloctan-4-olide	II
CCFA55	5005	10191-24-9	3-Hydroxyhexanoic acid	I
CCFA55	5006	58156-49-3	3-Methyl-3-butene-1-thiol	I
CCFA55	5012	2762033-61-2	Ethyl 5-acetoxyoctadecanoate	I
CCFA55	5021	2775350-66-6	S-(3-Methylbut-3-en-1-yl) 4-(formyloxy)butanethioate	III
CCFA55	5022	2775350-67-7	S-Butan-2-yl 4-(formyloxy)butanethioate	III

Appendix IId – Twenty-one (21) compounds previously submitted to the Codex Committee on Food Additives for specification modifications.

History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation	Status	Update
Old	3488	214	39255-32-8	Ethyl 2-methyl pentanoate	2000 (Session 55)	Full	The Refractive Index does not reflect the material currently in commerce.
Old	2563	315	928-96-1	cis-3-Hexen-1-ol	1998 (Session 51)	Full	The Refractive Index does not reflect the material currently in commerce.
Old	2665	427	89-78-1	Menthol	2018 (Session 86)	Full	The Specific Gravity and Refractive Index could be removed, as they are not meaningful parameters for this substance. The Solidification Point/Melting Point could be added to reflect the material currently in commerce.
Old	3748	433	61597-98-6	I-Menthyl I-lactate	2018 (Session 86)	Full	The Melting Point does not reflect the material currently

History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation	Status	Update
							in commerce
Old	2656	1480	118-71-8	Maltol	2018 (Session 86)	Full	The Melting Point does not reflect the material currently in commerce
Old	3163	1503	1192-62-7	2-Furyl methyl ketone	2018 (Session 86)	Full	The Specific Gravity, Refractive Index and Acid Value could be removed, as they are not meaningful parameters for this substance. The Melting Point could be added to reflect the material currently in commerce.
Old		1506	10599-70-9	3-Acetyl-2,5-dimethylfuran	2020 (Session 89)	Full	IOFI proposes to remove the specification for this material
Old	3159	1520	13679-46-4	Furfuryl methyl ether	2018 (Session 86)	Full	The Minimum Assay Value, Refractive Index, and Specific Gravity do not reflect the material currently in commerce. The Acid Value could be removed as it is not a meaningful parameter for this material.
Old	3539	1338	13877-91-3	3,7-Dimethyl-1,3,6-octatriene	2004 (Session 63)	Full	The Minimum Assay Value does not reflect the material currently in commerce.
Old	2160	1388	125-12-2	Isobornyl acetate	2004 (Session 63)	Full	The Minimum Assay Value does not reflect the material currently in commerce.
Old	3513	499	13679-85-1	2-Methyltetrahydrothiophen-3-one	2000 (Session 55)	Full	The Minimum Assay Value does not reflect the material currently in commerce.
Old	3415	461	505-10-2	(3-Methylthio) propanol	2001 (Session 57)	Full	The Specific Gravity, Solubility Description and possibly Purity does not reflect the material currently in commerce.
Old	3376	500	23550-40-5	4-(Methylthio)-4-methyl-2-pentanol	2000 (Session 55)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3897	510	75-33-2	2-Propanethiol	2001 (Session 57)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	3475	543	828-26-2	Trithioacetone	2001 (Session 57)	Full	The Specific Gravity and Refractive Index do not reflect the material currently in commerce.
Old	2911	896	120-57-0	Piperonal	2001 (Session 57)	Full	The Melting Point does not reflect the material currently in commerce.
Old	3557	973	2111-75-3	p-Mentha-1,8-dien-7-al	2018 (Session 86)	Full	The Purity Specification, Acid Value and Specific Gravity do not reflect the material currently in commerce.
Old	2349	1093	622-45-7	Cyclohexyl acetate	2002 (Session 59)	Full	The Specific Gravity does not reflect the material currently

History	FEMA No	JECFA No	CAS	Principle Name	Most Recent Specification Evaluation	Status	Update
							in commerce.
Old	2467	1529	97-53-0	Eugenol	2005 (Session 65)	Full	The Density Range does not reflect the material currently in commerce.
Old	4321	1763	116505-60-3	Pyrrolidino-[1,2e]-4H-2,4-dimethyl1,3,5-dithiazine	2007 (Session 68)	Full	The melting point does not reflect the material in commerce.
Old	3507	49	2050-01-3	Isoamyl isobutyrate	1997 (Session 49)	Full	The specific gravity and refractive index does not reflect the material in commerce.

International Sweeteners Association (ISA)

The International Sweeteners Association (ISA), following the inclusion of Neohesperidin Dihydrochalcone (NHDC) in the priority list of substances proposed for evaluation by JECFA (Report of the Fifty-Fifth Session of the Codex Committee on Food Additives, 24–28 March 2025), and in response to Circular Letter CL 2025/32 from the JECFA Secretariat, confirms its previous request and the availability of data for the evaluation of NHDC as a sweetener for inclusion in the Codex General Standard for Food Additives.

As requested in Circular Letter CL 2025/32, the ISA has completed Annex 4 (confirmation of previous requests and data availability) as provided below. The corresponding data package was submitted to WHO/FAO, with receipt confirmed by the WHO JECFA Secretariat on 10 December 2025.

Annex 4 - Confirmation of previous request and data availability	
Name of Substance (as it appears in Annex 3):	Neohesperidin Dihydrochalcone
Is the request still in effect? (yes/no)	Yes
Are the data available? (yes/no)	Yes
Change to data provider? (yes/no)	No