Food and Agriculture Organization of the United Nations

World Health Organization

JOINT FAO/WHO EXPERT COMMITTEE ON FOOD ADDITIVES

Ninetieth meeting

Virtual meeting, 26 October – 6 November 2020

SUMMARY AND CONCLUSIONS

Issued on 10 December 2020

A meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was held on a virtual online platform from 26 October – 6 November 2020, with an additional day for approval of the report on 24 November 2020. The purpose of the meeting was to evaluate the acceptability of certain substances as previous cargoes and the safety of certain food contaminants. The present meeting was the 90th in a series of similar meetings.

The 90th meeting of JECFA was originally scheduled for 27 October – 5 November 2020 at WHO headquarters in Geneva, Switzerland. Because of the travel restrictions and lock-downs due to the COVID-19 pandemic in many countries, it was not possible for the joint FAO/WHO JECFA secretariat to convene the meeting as scheduled. Therefore, the meeting was held as a video-conference.

In view of the time differences in the countries of origin of the invited experts, the only possible time for a video-conference was restricted to a 4-hour time slot (12:00–16:00 CEST) a day. This allowed only 40% of the usual daily length (8–10 hours) of a JECFA meeting, precluding complete evaluation of all the 23 scheduled compounds. In an effort to regain some additional meeting time, the ninetieth JECFA meeting was extended by 3 days, adding Monday 26 October, Friday 6 November and Tuesday 24 November 2020.

As these circumstances meant that less meeting time had been available, compared to a normal JECFA meeting, some of the previous cargoes and contaminants that were originally scheduled for discussion could not be considered, namely: previous cargoes (solvents and reactants) and the ergot alkaloids. All items that were deleted from the agenda of the 90th JECFA meeting will be re-scheduled for evaluation at future JECFA meetings.

Dr D. Benford served as Chairperson and Dr R. Cantrill as Vice-Chairperson.

Dr M. Feeley, Ottawa, Canada and Ms K.B. Laurvick, FAO, served as joint rapporteurs.

The Committee evaluated 18 substances that may occur as previous cargoes and the trichothecenes T-2 and HT-2. The tasks before the Committee were a) to elaborate principles governing the evaluation of the acceptability of previous cargoes; (b) to undertake toxicological evaluations and dietary exposure assessments, and (c) to undertake toxicological evaluations and dietary exposure assessments in relation to contaminants in food. It became apparent during the meeting that the time limitations precluded the toxicological evaluation of the trichothecenes T-2 and HT-2. The toxicological evaluation and overall risk assessment will therefore follow at a future meeting.

The report of the meeting will be published in the WHO Technical Report Series. The report will summarize the main conclusions of the Committee in terms of acceptability of substances proposed as previous cargoes. Its presentation will be similar to that of previous reports – namely, general consideration, comments on specific previous cargoes or groups of previous cargoes, and on trichothecene contaminants in food, followed by recommendations. An annex will include a summary (similar to the summary in this report) of the main conclusions of the Committee in terms of acceptability of previous cargoes and other toxicological and safety recommendations.

The participants are listed in Annex 1 to this summary document. Information of a general nature that

the Committee wishes to disseminate quickly is provided in Annex 2. Future work and recommendations arising from the meeting are summarized in Annex 3. Annex 4 summarizes observations by experts with regard to the practicability of holding these expert meetings online rather than in-person.

Toxicological and dietary exposure monographs on the previous cargoes or groups of previous cargoes considered will be published in WHO Food Additives Series No. 81.

More information on the work of JECFA is available at:

http://www.fao.org/food-safety/resources/publications/en/

and

https://www.who.int/foodsafety/en/

Toxicological and dietary exposure information and conclusions

Previous cargoes evaluated

Previous cargo	Evaluations
Alcohols (Group 2)	
Tridecyl alcohol, myristyl alcohol and unfractionated fatty alcohols	The Committee noted the limitations of the current dataset of toxicological evaluations, and the need to use a read-across approach where appropriate. Based on the weight of evidence across long-chain fatty alcohols, tridecyl and myristyl alcohol and unfractionated fatty alcohols can be considered not to raise concerns for genotoxicity. For **tridecyl alcohol**, the Committee used the dose level of 184 mg/kg bw per day, at which mild histopathological changes were reported in the liver following a 14-day study of oral gavage exposure in rats, as a reference point. This was supported by the data on other long chain alcohols, for which the NOAELs recorded in the rat upon subchronic administration via the diet range from approximately 200 to 1000 mg/kg per day. The Committee noted limitations in the study design, but concluded that it could be used to establish a margin of exposure in the absence of longer-term studies. Considering the estimated human dietary exposure of 0.3 mg/kg bw per day, the margin of exposure is 610, which is adequate to address the uncertainties in the database. For **myristyl alcohol,** the Committee identified a NOEL of 167 mg/kg bw per day as the reference point from a 90-day dietary study with a C14-16 branched and linear alcohol in rats, based on decreased body weight gain at 702 mg/kg bw per day, possibly attributable to reduced palatability of the diet. Considering the estimated human dietary exposure of 0.3 mg/kg bw per day, the margin of exposure is 560, which is adequate to address the uncertainties in the database. For **unfractionated fatty alcohols**, the Committee adopted a read-across approach, using data on two representative fatty alcohols, tridecyl alcohol and myristyl alcohol, and long chain alcohols. NOAEL values of between 200 mg/kg bw per day and 1000 mg/kg bw per day have been reported for fatty alcohols with chain lengths in the C6-C22 range, based upon subchronic dietary studies in the rat. Based upon read-across, plus the fact that unfractionated fatty alcohols are present in natural food sources, the Committee concluded that the unfractionated fatty alcohols with components in the C6-C22 range are not of toxicological concern at the estimated dietary exposure level of 0.3 mg/kg bw per day. There are no reports of allergenicity following oral exposure to tridecyl and myristyl alcohols and to unfractionated fatty alcohols that would indicate that they are or contain a known food allergen. Tridecyl alcohol, myristyl alcohol and unfractionated fatty alcohols may react with a previous cargo in transesterification reactions with glycerides or esterification reactions with free fatty acids present, but the rates of reaction are likely to be slow at ambient temperature and any products would be naturally occurring waxes. Therefore, **the Committee concluded that tridecyl alcohol, myristyl alcohol and unfractionated fatty alcohols meet the criteria for acceptability as previous cargoes.**

Isodecyl alcohol, isononyl alcohol and isooctyl alcohol

The Committee noted the limitations of the current dataset of toxicological evaluations, and the need to use a read-across approach where appropriate.

The Committee noted the negative data for mutagenic activity for isooctyl alcohol and isononyl alcohol, lack of clastogenic activity of isodecyl alcohol, and the weight of evidence across long-chain fatty alcohols for a lack of mutagenic potential. The Committee considered that isodecyl alcohol, isononyl alcohol and isooctyl alcohol can be considered non-genotoxic. The Committee noted that no carcinogenicity studies have been identified for isodecyl alcohol, isononyl alcohol and isooctyl alcohol. Based upon the weight of evidence across several aliphatic alcohols, including the linear alcohol 1-dodecanol, the Committee concluded that isodecyl alcohol, isononyl alcohol and isooctyl alcohol are unlikely to possess carcinogenic potential.

For **isodecyl alcohol**, the Committee concluded that a NOAEL of 158 mg/kg bw per day for maternal toxicity from a comparative developmental toxicity study on rats was a suitable reference point. Considering the estimated dietary exposure of 0.3 mg/kg bw per day, the margin of exposure is approximately 520, which the Committee concluded is sufficient to address the uncertainties in the database.

For **isononyl alcohol**, the Committee considered that a NOAEL of 158 mg/kg bw per day for maternal toxicity from a comparative developmental toxicity study on rats was a suitable reference point. Considering the estimated dietary exposure of 0.3 mg/kg bw per day, the margin of exposure is approximately 520, which the Committee concluded is sufficient to address the uncertainties in the database.

For **isooctyl alcohol**, no reproductive or developmental toxicity studies were identified. Using read-across from isodecyl alcohol and isononyl alcohol, the Committee concluded that it is highly unlikely that isooctyl alcohol possesses significant reproductive or developmental toxicity. The Committee considered that the dose of 130 mg/kg bw per day, which resulted in mild histopathological changes in the liver following a 14-day oral gavage exposure in rats, was a suitable reference point. The Committee noted limitations in the study design but concluded that it could be used to establish a margin of exposure in the absence of longer-term studies. Considering the estimated dietary exposure of 0.3 mg/kg bw per day, the margin of exposure is approximately 430, which the Committee concluded is sufficient to address the uncertainties in the database.

There are no reports of allergenicity upon oral exposure to isodecyl alcohol, isononyl alcohol and isooctyl alcohol that would indicate that they are or contain a known food allergen.

Isodecyl alcohol, isononyl alcohol and isooctanol may react with a previous cargo in transesterification reactions with glycerides or esterification reactions with free fatty acids present, but the rates of reaction are likely to be slow at ambient temperature and any products would be naturally occurring waxes.

Therefore, **the Committee concluded that isodecyl alcohol, isononyl alcohol and isodecyl alcohol meet the criteria for acceptability as previous cargoes.**

1,3-Propanediol (1,3-PD)

1,3-PD is not genotoxic.

The Committee considered that the LOEL of 250 mg/kg bw per day, based on marginal fetal effects in rats should be used as the reference point. Considering the estimated dietary exposure of 0.3 mg/kg bw per day, the margin of exposure is 830, which is adequate to address the uncertainties in the database.

There are no reports of allergenicity upon oral exposure to 1,3-PD that would indicate that it is or contains a known food allergen.

1,3-PD is a very stable liquid at room temperature and it is unlikely to polymerize or participate in hydrogenation or dehydrogenation reactions without the presence of a catalyst or microorganism.

Therefore, **the Committee concluded that 1,3-propanediol meets the criteria for acceptability as a previous cargo.**

1,4-Butanediol (1,4-BD)

The Committee noted that both 1,4-BD and γ-butyrolactone are rapidly metabolized to γ-hydroxybutyric acid, whereupon they share metabolic fates. The Committee concluded that data on γ-butyrolactone could be used for read-across to fill data gaps with 1,4-BD.

The Committee concluded that 1,4-BD is not genotoxic, and that the data for γ-butyrolactone are consistent with 1,4-BD being unlikely to possess carcinogenic potential.

The Committee noted that a range of toxic end-points have been reported for 1,4-BD and γ-butyrolactone from various studies. The Committee concluded that acute and transient central nervous system effects, most notably hyperactivity, provided the most relevant end-point. A NOAEL of 100 mg/kg bw was identified by the NTP, and the Committee considered that this was appropriate as a reference point in the current evaluation. Considering the estimated dietary exposure of 0.3 mg/kg bw per day, the margin of exposure is approximately 330, which the Committee concluded is sufficient to address the uncertainties in the data.

There are no reports of allergenicity upon oral exposure to 1,4-BD that would indicate that it is or contains a known food allergen.

1,4-BD is unlikely to polymerize or participate in hydrogenation or dehydrogenation reactions without the presence of a catalyst or microorganism. There is a low possibility of ester formation with free fatty acids.

Therefore, **the Committee concluded that 1,4-butanediol meets the criteria for acceptability as a previous cargo.**

Butyl ethers (Group 5)

Methyl tertiary butyl ether (MTBE)

Upon evaluating the available toxicity studies and examining the toxicological relevance of effects reported therein, the Committee considered that the NOAEL of 300 mg/kg bw per day identified from the 90-day oral subchronic study of MTBE in rats was the most appropriate RP. The Committee concluded that the estimated exposure to MTBE from drinking-water is a minor contributor (0.008 mg/kg bw per day) as compared with the estimated exposure to MTBE in food oil commodities from previous cargoes (0.3 mg/kg bw per day), and that there are no other known potential sources of dietary exposure to MTBE. A comparison of the RP of 300 mg/kg bw per day with the estimated exposure of 0.3 mg/kg bw per day for MTBE as a previous cargo yields a margin of exposure of 1000, which is sufficient to address the uncertainties in the databases.

There are no data on allergenicity upon oral exposure to MTBE that indicate that it is or it contains a known food allergen.

MTBE as a previous cargo is not expected to react with edible fats and oils to form any reaction products.

Therefore, **the Committee concluded that MTBE meets the criteria for acceptability as a previous cargo for edible fats and oils.**

Ethyl tertiary butyl ether (ETBE)

Upon evaluating the available toxicity studies and examining the toxicological relevance of effects reported therein, the Committee concluded that the NOAEL of 100 mg/kg bw per day identified from the 180-day oral subchronic study of ETBE in rats was the most appropriate RP. The Committee concluded that the estimated exposure to ETBE from drinking-water is a minor contributor (0.01 mg/kg bw per day) compared with the estimated exposure to ETBE in food oil commodities from previous cargoes (0.3 mg/kg bw per day), and that there are no other known potential sources of dietary exposure to ETBE. A comparison of the RP of 100 mg/kg bw per day with the estimated exposure of 0.3 mg/kg bw per day for ETBE as a previous cargo yields a margin of exposure of 330, which is sufficient to address the uncertainties in the databases.

There are no data on allergenicity upon oral exposure to ETBE that indicate that it is or it contains a known food allergen.

ETBE as a previous cargo is not expected to react with edible fats and oils to form any reaction products.

Therefore, **the Committee concluded that ETBE meets the criteria for acceptability as a previous cargo for edible fats and oils.**

Oils and waxes (Group 3)

Mineral oil, medium and low viscosity, class II and class III	The critical toxicological end-point for evaluation of mineral oil saturated hydrocarbons (MOSH) is liver granuloma formation and increase in liver weight in F344 rats. The Committee acknowledged that F344 rats represent the only strain and species that have shown liver granulomas accompanied by an inflammatory response due to MOSH exposure. In humans, lipogranulomas in the liver associated with exposure to MOSH have been observed, but these have not been associated with inflammatory reactions or other adverse consequences with clinical relevance. Given the lack of sufficient information on the mechanism of liver granuloma formation in F344 rats, the Committee concluded that it could not dismiss the human relevance of these liver granulomas and used them and the increase in liver weight in its assessment of mineral oil hydrocarbons (MOH) as previous cargoes. The Committee decided to use the NOAEL of 22 mg/kg bw per day of a MOSH mixture (C14-C50, including class II and class III mineral oil, medium and low viscosity) as a RP. The Committee applied an MOE approach to assess the acceptability of MOSH as a previous cargo. Considering the estimated dietary exposure of 0.4 mg/kg bw per day (0.3 mg/kg bw per day from previous cargoes, plus 0.1 mg/kg per day from other sources), the MOE is 55. In its judgement of this MOE, the Committee took into account that the end-point of granuloma formation is determined in the most sensitive species, sex and strain, that the RP used is one tenth of the dose showing the effect and the uncertainty of the human health significance of the end-point. Furthermore, the exposure estimate is conservative. Based on these considerations the Committee concluded that the MOE of 55 was sufficient to address the uncertainties in the databases. There are no data on allergenicity upon oral exposure to the mineral oil, medium and low viscosity, class II and class III, or MOSH that would indicate that they are or contain a known food allergen. No potential information has been identified with respect to the reaction of mineral oil with edible fats and oils, although migration studies have confirmed that mineral oil migrates into fats and oils. **The Committee concluded that mineral oil, medium and low viscosity, class II and class III meet the criteria for acceptability as previous cargoes provided the MOH is food grade**. Commercial MOH products range from being free of mineral oil aromatic hydrocarbons (MOAH) (food grade mineral oil) to containing 30% MOAH (crude mineral oil). **The Committee noted that crude mineral oil is banned as a previous cargo and MOAH, which contain mutagenic and carcinogenic substances, would be unacceptable as previous cargoes.** The current evaluation is based on the assumption that MOH products shipped as previous cargoes are highly refined food-grade products free of MOAH.
Montan wax	While oral bioavailability of montan wax is expected to be limited and the material appears to be of low acute toxicity, in the only repeat dose study available montan wax produced toxicity at all doses tested. The Committee noted that montan wax is a highly variable and poorly defined material. Given the high degree of variability in composition, the extent to which the particular test article in the subchronic study is representative of the diversity of the various forms of crude, deresinated or refined montan wax currently in commerce is unknown. Therefore, the Committee could not characterize the hazard of montan wax shipped as a previous cargo. No specific information was found on the reactions of montan wax with edible fats and oils. **The Committee determined that the available evidence was not sufficient to characterize the risk of montan wax; as a result, it was concluded that montan wax does not meet the criteria for acceptability as a previous cargo for edible fats and oils.**
Propylene tetramer	Although no chronic or carcinogenic studies were identified, the Committee concluded that propylene tetramer does not have genotoxic potential in vitro nor any structural alerts for carcinogenicity. These findings are consistent with other individual olefins

	present in propylene tetramer or mixtures thereof. The Committee noted the availability of a recent guideline-compliant subchronic study in rats and decided to use the NOAEL from this study of 40 mg/kg bw per day based on increased liver weights as an RP in a margin of exposure approach to evaluate the acceptability of propylene tetramer as a previous cargo for edible fats and oils. Comparison of the generic maximum anticipated oral exposure to propylene tetramer from previous cargoes of 0.3 mg/kg bw per day with the RP of 40 mg/kg bw per day yields a margin of exposure of approximately 130. This margin is considered adequate to address uncertainties in the health effects database. Therefore, and in consideration of the fact that this substance is not known or anticipated to be a food allergen, **the Committee concluded that propylene tetramer meets the criteria for acceptability as a previous cargo for edible fats and oils.**
Soybean oil epoxidized (ESBO)	The overall toxicity database for ESBO is relatively complete, including acute, subchronic and chronic toxicity studies. ESBO is not genotoxic or carcinogenic and is not a reproductive or developmental toxicant. The overall systemic toxicity of ESBO is considered to be low and no toxicologically relevant impurities or reaction products with edible fats or oils are anticipated. The Committee decided to use the NOAEL of 125 mg/kg bw per day based on organ weight changes at the next highest dose in a 2-year rat oral bioassay as a reference point (RP) to evaluate the acceptability of ESBO as a previous cargo for edible fats and oils. It should be noted that ESBO is also used in a variety of food packaging applications, which may contribute significantly to exposure. A recent study estimated the cumulative daily intake of ESBO from its use in PVC-based food-contact articles to be 0.13 mg/kg bw per day for the general US population. A worst-case exposure estimate of 0.43 mg/kg bw per day can therefore be derived by combining the maximum estimated exposure from ESBO as a previous cargo (0.3 mg/kg bw per day) with other sources associated with food packaging. Comparison of the RP with this estimate yields a margin of exposure of approximately 290. The Committee considered this margin adequate to account for uncertainties in the health effects and exposure databases. ESBO is not known or anticipated to be a food allergen. No specific information has been identified on the reaction of ESBO with edible fats and oils, although migration studies have confirmed that ESBO migrates into oily foods and oil-based food simulants (e.g. olive oil). Therefore, **the Committee concluded that ESBO meets the criteria for acceptability as a previous cargo for edible fats and oils.**
Solutions (Group 4)	
Calcium nitrate and calcium ammonium nitrate	Considering that toxicological datasets on calcium nitrate and calcium ammonium nitrate are sparse, the Committee evaluated available toxicological data on calcium, ammonium and nitrate to conduct their toxicological evaluation. The Committee also reviewed available toxicological data on magnesium and phosphates, as dolomite and phosphate rock could be used in the manufacture of calcium ammonium nitrate and calcium nitrate, respectively. The Committee estimated exposure to calcium nitrate and calcium ammonium nitrate from previous cargoes for edible fats and oil as 0.3 mg/kg bw per day each, which is much less than the exposures to calcium, nitrate, ammonium, magnesium and phosphates expected from dietary sources. The Committee considered health-based guidance values for calcium, nitrate, ammonium, magnesium and phosphates, established under previous evaluations, to conduct the toxicological evaluation of calcium nitrate and calcium ammonium nitrate at the anticipated exposure level from previous cargoes for edible oils and fats. The estimated exposure value for calcium nitrate and calcium ammonium nitrate as previous cargoes for edible fats and oils is 0.3 mg/kg bw each, which does not exceed the ADI for nitrate of 0–3.7 mg/kg bw, expressed as nitrate ion, and the MTDI of 70 mg/kg bw for phosphates, diphosphates and polyphosphates. The previous Committees did not assign a numerical ADI and allocated an ADI “not specified” for most calcium, ammonium and magnesium salts based on their low oral toxicity profiles. Furthermore, the Committee considered that human exposure to these substances resulting from their use as previous cargoes would be a minor contributor to the total dietary exposure. There are no data on allergenicity upon oral exposure to calcium nitrate and calcium

	ammonium nitrate that would indicate that these substances are, or contain, known food allergens. The Committee concluded that the formation of calcium, ammonium or magnesium salts of free fatty acids is possible. However, due to the anticipated absence of alkaline conditions and an insufficient concentration of counter ions and free fatty acids (necessary for the reactions to occur), these reaction products are not expected to be formed in detectable amounts in a cargo of edible fats and oils. Therefore, **the Committee concluded that calcium nitrate and calcium ammonium nitrate meet the criteria for acceptability as previous cargoes for edible fats and oils.**
Calcium ligno-sulfonate	The Committee previously established an ADI of 0–20 mg/kg bw for the food-grade calcium lignosulfonate (40-65), the upper bound of which is above the estimated exposure for calcium lignosulfonate as a previous cargo for edible fats and oils of 0.3 mg/kg bw per day. There are no data on allergenicity of oral exposure to calcium lignosulfonate (40-65) that would indicate that it is or it contains a known food allergen. Therefore, food-grade calcium lignosulfonate (40-65) meets the criteria for acceptability as a previous cargo for edible fats and oils. Lignosulfonates are unlikely to react with free fatty acids and triglycerides present in cargoes of fats and oils under the conditions of transport. The Committee could not determine the specific chemical composition or molecular weight distribution of the non-food grade calcium lignosulfonate that is shipped as a previous cargo but recognized that it has a wide molecular weight distribution. The Committee acknowledges that no toxicokinetic data to determine oral bioavailability of or systemic exposure to the non-food grade calcium lignosulfonate shipped as a previous cargo are available. Therefore, the ADI for calcium lignosulfonate (40-65) does not apply to the material that is shipped as a previous cargo unless it is food-grade calcium lignosulfonate. In the absence of adequate data on chemical specifications and toxicokinetics, the Committee concluded that the systemic effects of oral exposure to the non-food grade calcium lignosulfonate cannot be evaluated as no oral toxicity, genotoxicity or allergenicity data are available on this substance. **In the absence of relevant toxicological data on test substances that are sufficiently representative of different molecular weight fractions constituting the non-food grade calcium lignosulfonate that is shipped as a previous cargo, the Committee concluded that the non-food-grade calcium lignosulfonate does not meet the criteria for acceptability as a previous cargo for edible fats and oils.**

Food contaminants

Trichothecenes, T-2 and HT-2	**Conclusions on the chemical characterization and dietary exposure assessment**
	The Committee reviewed the information regarding analytical methods, sampling, effect of processing, prevention and control, occurrence in food commodities and dietary exposure since the last evaluation of T-2 and HT-2 at the fifty-sixth meeting in 2001. Analytical methods have been improved in the last two decades with multi-mycotoxin HPLC-MS methods allowing the quantification of T-2 and HT-2 below or close to 1 µg/kg. There were a large number of occurrence data for T-2 and HT-2 submitted to the GEMS/Food contaminants database in the last two decades, but these were largely from Europe with a paucity of data from other regions. This may be due to the generally low incidence and low concentrations of T-2 and HT-2 found outside Europe. In Europe T-2 and HT-2 occur frequently in cereal crops, particularly in oats. There is also evidence of co-occurrence of several other type A trichothecenes and their metabolites in cereals. It was concluded that dietary exposure to T-2 and HT-2 covering the known geographical distribution of T-2 and HT-2 was suitably covered by existing European estimates of chronic and acute dietary exposure. No additional international or national estimates of chronic or acute dietary exposure were derived by the Committee. **The Committee derived chronic dietary exposure estimates of 6.0 to 18 ng/kg**

bw per day for T-2, HT-2 and diacetoxyscirpenol (DAS) combined. The toxicological evaluation and overall risk assessment will follow at a future meeting.

Annex 1

Ninetieth meeting of the Joint FAO/WHO Expert Committee on Food Additives
Virtual meeting, 26 October – 6 November 2020

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Annex 2

General consideration

An edited version of this section will appear in the report of the ninetieth meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). It is reproduced here so that the information can be disseminated quickly. This draft will be subject to editing.

A2.1 Dietary exposure assessment for previous cargo chemical substances

As a consequence of considering a range of previous cargo chemical substances at its ninetieth meeting, the Committee concluded that it was appropriate to review the approach to estimating dietary exposure set out in the 2006 document *Development of criteria for acceptable previous cargoes for fats and oils* (criteria document).

The Committee noted that since the 2006 criteria document was drafted, newer and better-quality data on the consumption of fats and oils by adults, infants and young children have become available.

The Committee also noted that some of the previous cargo chemical substances assessed have additional sources of dietary exposure and expressed the view that it may be necessary to consider this in the exposure assessment.

A2.2 Exposure estimates in the 2006 criteria document

Based on the best available data at that time, the 2006 criteria document set out the following approach to dietary exposure assessment of previous cargo chemical substances present in fats and oils:

- Estimated mean per capita consumption of 0.025 kg/day of a single type of fat or oil. The value was rounded up from the maximum per capita consumption of refined soybean oil of 22 g/person per day from the GEMS/Food cluster diets.
- A factor of 2.5 to cover children and high consumers was derived from a rounded ratio between the mean and 97.5th percentile consumption of total vegetable oil from a food consumption survey in the United Kingdom (20 and 52 g/person per day for the population aged > 18 years). The criteria document also noted that dietary exposure of children to contaminants is frequently 2.5 times that of adults.
- A worst-case concentration of 100 mg/kg for a previous cargo contaminant in fats or oils.
- A body weight of 60 kg.

These data were used to define a worst-case dietary exposure estimate:

$$\frac{\text{Consumption of oil (0.025 kg/day)} \times 2.5 \times \text{concentration (100 mg/kg fat or oil)}}{\text{60 kg body weight}}$$

= 0.1 mg/kg bw per day

Based on the **mean per capita consumption of fats and oils, and a factor of 2.5**, there would be no health concern to the general population from exposure to previous cargoes if the acceptable daily intake (ADI) or tolerable daily intake (TDI) is sufficiently protective, for

example, the ADI or TDI is greater than, or equal to **0.1 mg/kg bw per day**.

A2.3 Exposure estimates based on up-to-date consumption data for adults

Since 2006, the GEMS/Food cluster diets have been revised, and the FAO/WHO Chronic Individual Food Consumption – summary statistics database (CIFOCOss) has become available. The 2006 criteria document noted that food consumption information from dedicated surveys would be more appropriate than the food consumption estimates from the GEMS/Food cluster diets. However, it used the cluster diets, as food consumption survey data were only available from a very limited number of countries at that time. CIFOCOss currently contains food consumption data from 37 countries.

From the current version of CIFOCOss, the maximum mean consumption for a single fat or oil type is 35 g/person per day for consumption of virgin or extra-virgin olive oil by elderly Italians. The maximum 95th percentile (p95) consumption of a single fat or oil is 138 g/person per day for edible cottonseed oil by women (age 15–49 years) from Burkina Faso. This group also has the highest 97.5th percentile consumption of 189 g/person per day.

Based on the protocols currently used by JECFA for veterinary drugs, the number of consumers of cottonseed oil in the Burkina Faso survey (n = 116) would suggest that the 95th percentile is the highest reliable percentile.

These data suggest that for adults, a mean fat or oil consumption of 35 g/person per day and a high consumption of fat or oil of 140 g/person per day would be a conservative estimate consistent with available data.

The use of updated food consumption data will result in a revised estimated worst-case dietary exposure for adults:

$$\frac{\text{p95 consumption of oil (0.140 kg/day)} \times \text{concentration (100 mg/kg fat or oil)}}{\text{60 kg body weight}}$$

$$= \mathbf{0.2\ mg/kg\ bw\ per\ day}$$

A2.4 Exposure estimates for infants and young children

Potentially vulnerable population groups, like infants and young children, were not specifically considered in the 2006 criteria document. Since then, individual consumption data for several population groups, including infants and young children, have become available through CIFOCOss and other sources. Infants and young children should be considered in the risk assessment because they could potentially experience high exposure to previous cargo chemical substances per kg body weight while they are undergoing growth and development.

Information on consumption of food oils by infants and young children was also available from the US Environmental Protection Agency's Food Commodity Intake Database (FCID), which in turn is based on data from the US National Health and Nutrition Survey/What We Eat In America, 2005–2010 cycles. The highest oil consumption for infants and young children based on FCID is comparable to those in the CIFOCOss database; however, oil consumption information based on FCID is available based on individual body weights.

The highest reported consumption of a specific fat or oil type was for palm oil. Estimated mean and p95 consumption by infants and young children were 7.6 and 19 g/day, respectively. Estimated mean and p95 consumption on a body weight basis were 1 g/kg bw per day and 3 g/kg bw per day, respectively.

These data were used to define a worst-case dietary exposure estimate for infants and young children:

$$\text{p95 consumption of oil } (0.003 \text{ kg/kg bw/day}) \times \text{conc. } (100 \text{ mg/kg fat or oil})$$

= 0.3 mg/kg bw per day

A2.5 Exposure from other dietary sources

For some previous cargo chemical substances potentially present in food oils, there are additional sources of dietary exposure, such as contamination (e.g. contaminated drinking-water) or food additive uses (Table A2.1). Dietary exposures from these different sources should be considered in exposure assessment.

Table A2.1.

List of substances for evaluation by JECFA arising from the development of a list of acceptable previous cargoes by the Codex Committee on Fats and Oils: Other sources of exposure

Substance (synonyms)	Other sources of exposure
1,4-Butanediol (1,4-butylene glycol)	Used in food contact material
Calcium ammonium nitrate solution	Calcium, nitrate and ammonium are ubiquitous in the human diet
Calcium lignosulfonate liquid (lignin liquor; sulfite lye), molecular weight not specified	Calcium lignosulfonate (40-65) is used as a food additive, an additive in animal feed and as an ingredient in pesticides
Calcium nitrate (CN-9) solution	Calcium and nitrate are ubiquitous in the human diet
iso Decyl alcohol (isodecanol)	None
Myristyl alcohol (1-tetradecanol; tetradecanol)	Flavouring agent, formulation agent, lubricant, release agent
iso Nonyl alcohol (isononanol)	None
iso Octyl alcohol (isooctanol)	Used in food contact material
Tridecyl alcohol (1-tridecanol)	Used in food contact material
Unfractionated fatty alcohol mixture or mixtures of fatty alcohols from natural oils and fats[a]	Occurs naturally in foods
Methyl tertiary butyl ether (MTBE)	Drinking-water
Mineral oil, medium and low viscosity, class II and III	Used in food contact material; direct food additive
Montan wax	Food additive
1,3-Propylene glycol	Used in place of 1,2-propanediol as a food additive
Propylene tetramer (tetrapropylene, dodecene)	none

Soybean oil epoxidized	Used in food contact material
Ethyl tertiary butyl ether (ETBE)	Drinking-water

[a] Discussed with Group 2 – Alcohols.

A2.6 Conclusion

The Committee concluded that, based on up-to-date data on consumption of single fats and oils in the general population, which have become available since 2006, the generic human exposure value of 0.1 mg/kg bw per day used in the 2006 Criterion no. 2 to determine the acceptability of a previous cargo should be revised. Consequently, the updated, more conservative generic human exposure value of 0.3 mg/kg bw per day should be used in the evaluation of these substances.

The Committee noted that these estimates of dietary exposure were derived from a more conservative approach to using data on consumption of single fats and oils and a worst-case concentration of previous cargo chemicals in a single fat or oil of 100 mg/kg.

The Committee also concluded that additional sources of dietary exposure need to be considered in exposure assessment of previous cargo chemical substances.

A2.7 Recommendations

The Committee recommended that the Codex Committee on Fats and Oils (CCFO) consider revising Criterion no. 2 in RCP-36-1987 as adopted by CAC 34 (2011).

1. Based on the consumption of fats and oils by infants and young children, there is no health concern for the general population from dietary exposure to previous cargo chemical substances if the ADI or TDI is sufficiently protective, for example, the ADI or TDI is greater than, or equal to 0.3 mg/kg bw per day. Substances for which there is no numerical ADI or TDI should be evaluated on a case by case basis (e.g. margin of exposure (MOE) approach).
2. Where there are additional sources of dietary exposure to the previous cargo chemical substances, they should be considered in the exposure assessment.

Annex 3

Future work and recommendations

1. The Committee recommended that the Codex Committee on Fats and Oils (CCFO) consider revising Criterion no. 2 in RCP-36-1987 as adopted by CAC 34 (2011).

    - Based on the consumption of fats and oils by infants and young children, there is no health concern for the general population from dietary exposure to previous cargo chemical substances if the ADI or TDI is sufficiently protective, for example, the ADI or TDI is greater than, or equal to 0.3 mg/kg bw per day. Substances for which there is no numerical ADI or TDI should be evaluated on a case by case basis (e.g. margin of exposure (MOE) approach).
    - Where there are additional sources of dietary exposure to the previous cargo chemical substances, they should be considered in the exposure assessment.

2. The Committee recommended that sufficient chemical and toxicological information that allows the evaluation of montan wax as shipped should be made available prior to the next evaluation. At a minimum this information should address the following:

    - degree of refinement and chemical constituents;
    - repeat dose toxicological data on representative products in a relevant animal model.

3. The Committee recommended that sufficient chemical and toxicological information that allows the evaluation of non-food-grade calcium lignosulfonate liquid as shipped should be made available prior to the next evaluation. At a minimum this information should address the following:

    - molecular weight range(s), chemical component identification and relative composition;
    - toxicological data on representative products.

4. The Committee recommended the following:

    - development of multi-mycotoxin methods and standards for the quantification of type A trichothecenes and their various metabolites that occur in planta;
    - research to investigate the spatial distribution of T-2 and HT-2 in agricultural commodities to ensure standard sampling methods for mycotoxins are appropriate;
    - that occurrence data from a wider range of countries be generated using analytical methods with suitably low LODs, to decrease the uncertainty in dietary exposure estimates and confirm the geographical distribution of these toxins.

Annex 4

Procedural matters

The ninetieth meeting of JECFA was originally scheduled to be held from 27 October – 5 November 2020 at WHO headquarters in Geneva, Switzerland. Owing to the travel restrictions and lockdowns due to the COVID-19 pandemic in many countries, it was not possible to convene the meeting as scheduled and it was decided to hold the meeting online by video-conferencing. In view of the time differences in the countries of origin of the invited experts, the only possible time for a video-conference was restricted to a 4-hour time slot (12:00–16:00 CET) each day. This allowed only 40% of the usual daily length (8–10 hours) of a JECFA meeting, precluding complete evaluation of all the scheduled compounds. In an effort to regain some additional meeting time, the ninetieth JECFA meeting was extended by 3 days, adding Monday 26 October, Friday 6 November and Tuesday 24 November 2020.

Although the experts participated fully, they noted that an online meeting does not permit the necessary in-depth, robust scientific discussions and that online meetings are therefore not a suitable substitute for face-to-face meetings for JECFA. In particular, the experts felt that the online format did not foster the atmosphere of trust, inclusiveness and openness that has marked all JECFA meetings. The experts considered that the success of the ninetieth meeting was due to a large extent to the cohesion between them, which resulted from the trust generated during previous face-to-face meetings.

The experts decried the significant difficulty of meeting informally outside the scheduled meeting times because of the widely differing time zones. They noted that such informal interactions during physical meetings are instrumental to solving problems and to discussing issues in depth, bilaterally or in small groups, and added that such informal meetings often gave rise to solutions to stubborn problems. The inability to hold such meetings was considered to have impeded progress at the current meeting, as lack of sufficient time for discussion had slowed progress in developing safety evaluations.

The experts emphasized further that an invitation to a physical JECFA meeting at FAO or WHO headquarters gives rise to significantly more recognition by the expert's employer of the weight, reach, responsibility and workload required for full participation in a JECFA meeting. The same degree of recognition was not granted by employers for this online meeting, as the experts remained available locally. This lack of recognition of the workload and significance of participation in a JECFA meeting led to an increase in other demands on experts, resulting in distraction and more frequent scheduling conflicts. The experts concluded that, cumulatively, such factors would be counterproductive for participation in future JECFA meetings if FAO and WHO maintained the online-only format.

In recognition of the difficulties and the tremendous effort made, the joint FAO/WHO secretariat expresses its deep gratitude to all the experts for their commitment and flexibility, not least as the scheduled meeting times were exceedingly inconvenient for many.

The meeting report was adopted on 24 November 2020.