



JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Fiftieth Session

DISCUSSION PAPER ON THE USE OF NITRATES (INS 251, 252) AND NITRITES (INS 249, 250)

Prepared by an Electronic Working Group (EWG) chaired by the European Union and the Netherlands

whose members included Argentina, Australia, Austria, Brazil, Chile, China, Columbia, Denmark, Ecuador, Egypt, European Union, Greece, India, Indonesia, Japan, Republic of Korea, Malaysia, the Netherlands, New Zealand, Nigeria, Norway, Russian Federation, Spain, Sweden, Switzerland, United Kingdom, United States of America, FoodDrinkEurope (FDE), International Council of Grocery Manufacturers Associations (ICGMA), International Dairy Federation (IDF), Institute of Food Technologists (IFT), International Meat Secretariat (IMS), and FAO and WHO JECFA secretariat.

Background

1. The provisions for nitrates (INS 251, 252) and nitrites (INS 249, 250) were included in the paper [CX/FA 16/48/7](#) for discussion at CCFA48. During the Physical Working Group (PWG) meeting held prior to the CCFA48 concerns were raised as to the expression of the maximum use levels for nitrates and nitrites as ingoing amount and/or residual amount, the appropriate maximum use levels, and safety of their use. After consideration of this issue, the PWG agreed to the proposal that the European Union (EU) drafts terms of reference for a discussion paper on this issue. As such, with the exception of provisions for nitrites in food categories 01.6.1 (Unripened cheese) and 01.6.2 (Ripened cheese) which were recommended for discontinuation, the PWG agreed to hold all provisions for nitrates and nitrites, pending the outcome of the consideration of the draft terms of reference for this discussion paper ([CRD 2](#), CCFA48).
2. The issue was further discussed at CCFA48 where the JECFA Secretariat clarified that the basis for the ADI was on toxicological considerations of the nitrates and nitrites as such and that while nitrosamine formation was considered, it did not form the basis for the ADI. The formation of nitrosamines in the body or in foods was well known and could occur also from nitrates and nitrites occurring naturally in food and not only from their use as food additives. Therefore, nitrates and nitrites when used as food additives should be used at the minimum levels needed to achieve the functional purpose. Risk / benefit consideration were important because the use of nitrates and nitrites as a preservative was intended to improve the microbiological safety of the product ([REP16/FA](#), para. 60). Reflecting the discussion, CCFA48 agreed that the Netherlands would prepare a discussion paper with inputs from the JECFA Secretariat identifying concerns for the food additive use of nitrates (INS 251, 252) and nitrites (INS 249, 250) for consideration at CCFA49.
3. At CCFA49 the Netherlands introduced the discussion paper ([CX/FA 17/49/11](#)) and explained the three main concerns identified, i.e. expression of maximum use levels as ingoing and/or residual amounts; the technological need that reflects the benefits and risks; and appropriate use levels that take into account the ADI. The CCFA Chairperson, noted that the paper covered matters related both to risk management and risk assessment and proposed to focus the discussion on how best to refine the paper to facilitate future work of both CCFA and JECFA. CCFA49 noted the views as regards potential health concerns related to nitrates and nitrites including risks from the consumption of vegetables, the need for further scientific inputs in a number of areas, the fact that the recommendations covered roles of both JECFA and CCFA and that they should be further elaborated to clearly define the questions to be addressed by risk management and those to be considered through an appropriate risk assessment mechanisms ([REP17/FA](#), paras. 103-105).

Mandate of the EWG

4. In the light of the above discussion CCFA49 agreed to establish an EWG, chaired by the European Union and co-chaired by the Netherlands, and working in English only with the following Terms of Reference:

On the basis of concerns identified for the food additive use of nitrates and nitrites in CX/FA 17/49/11:

- (i) Analyse which issues can be addressed by the Committee and for which scientific advice is required;

- (ii) Suggest an approach for the risk management issues to be addressed by the Committee; and
- (iii) Clarify the scope of the question(s) to be addressed by JECFA or other appropriate FAO/WHO scientific advice body by taking into consideration the feasibility and data availability for such advice.

Discussion by the EWG

5. Two rounds of consultations were undertaken within the EWG. In the first round the EWG was tasked to analyse which issues outlined in CX/FA 17/49/11 could be addressed by the Committee (CA) and for which scientific advice is required (SA). In the second round the issues were classified based on the feedback received. In addition, the information received was used to address parts (ii) and (iii) of the EWG mandate on which the EWG was consulted.

6. The following parts of the discussion paper summarise the content of the two circulars and the comments submitted by the EWG members.

First round of the consultation

Analyses which issues can be addressed by the Committee and for which scientific advice is required

7. An analysis of the three main concerns identified in CX/FA 17/49/11 paras 39-50 (i.e. the expression of use levels, the technological need and the establishment of appropriate levels) was needed to decide which issues could be addressed by the Committee and for which a scientific advice is required.

8. Based on CX/FA 17/49/11 the issues related to the three main concerns were formulated in the first circular as follows¹:

The expression of Maximum Use levels as ingoing amount and/or residual amount (i)

What is the most appropriate way of expressing the MLs in relation to:

*QI Protection of human health, i.e. inhibitory effect on bacteria (especially *Cl. botulinum*), nitrosamines formation in all routes, ADI?*

Q1 Control purposes, international trade, different production processes?

The technological need seeking a balance between the benefits and risks taking into account existence of alternatives (ii)

Q2 For which types of products or production processes is the use of nitrates and nitrites indispensable, for what purpose and at what levels? What MLs expressed as ingoing and residual amounts are needed for preservation, colour and flavour effects? Are there alternatives to nitrites and nitrates available?

QII Does exposure to nitrites and nitrates pose a health risk? What are recent exposures from all sources and from food additive uses?

QIII Does exposure to nitrosamines (exogenous and endogenous) pose a health risk? What are recent exposures from all sources and from food additives to nitrosamines generated during: i) the production process in foods; ii) heat-treatment in the domestic setting; and iii) gastrointestinal transit?

*QIV What are the appropriate levels (ingoing and residual) necessary to inhibit *Cl. botulinum* in view of risk (nitrosamines, ADI being exceeded) and benefit (microbiological safety) considerations?*

Appropriate levels taking into account the ADI's for nitrites and nitrates (iii)

Q3 Are the proposed uses and proposed levels in the step process adequate in view of the GSFA Preamble and conclusions on points (i) and (ii)?

9. The questions as outlined above were included in a table and the EWG members were requested to classify whether they related to concerns which could be addressed by the Committee itself (CA) or which should be firstly considered by a scientific advice body (SA). In addition, the EWG members were requested to indicate whether the questions were relevant to establish safe uses and use levels for nitrates and nitrites and to identify any relevant sources of data available to address the questions raised.

Outcomes of the first EWG consultation

Comments on the classification of concerns identified

¹ QI-QIV refers to SA and Q1-Q3 to CA based on the outcome of the first round of consultation; see paras 10-11

10. The main outcome of the first round consultation was the classification of Q1-3 as CA concerns, QI-IV as SA concerns, confirmation of the relevancy of the questions asked and identification of the relevant sources of information. A good level of consensus was achieved for the classification of the concerns. The table summarising the comments made by the EWG members on the first circular is in Annex 1.

Second round of the consultation

11. Based on the feedback received the second circular paper split the questions classified as CA (Q1-Q3) and SA (QI-QIV), suggested a way forward and an approach for CA concerns and asked for comments on the scope of the questions to be addressed by JECFA or other appropriate FAO/WHO scientific advice body. Furthermore, a specific feedback from the FAO/WHO JECFA secretariat on SA concerns was required.

Consideration of an approach(es) for CA concerns

12. It was pointed out that the usual approach of the Committee is to address the issues via an EWG. The provisions for nitrates and nitrites included in the step process are currently on hold due to the concerns raised. The concerns were not addressed during the previous discussions. It is observed that the provisions on hold are associated with the notes 30 and 32 which refer to residual NO₃ or NO₂ ion respectively.

13. The second circular offered the following approach for further consideration:

- To establish an EWG(s) in order to collect the relevant information and to discuss the CA concerns.
- Q1 is more general so more general information / comments could be collected from the Codex Members and Observers on the mentioned aspects. Some Codex Members have already provided some pertinent comments in the replies to the first circular or referred to the available information.
- Q2 relates to specific uses for the specific types of products or production processes. To address this question more specific information is needed. The discussion could be based on the food (sub)-categories for which there are adopted provisions in the GSFA (there are two adopted provisions for nitrites due to the alignment with the meat standards) and on the sub-categories of the provisions currently in the step process (i.e. the provisions captured in CX/FA 16/48/7). The second circular provided an example in form of a template / table on how the relevant information to address the concerns in Q2 could be collected.

Way forward to address CA concerns

14. When considering the risk management measures the Committee should take into account all relevant concerns (CA and SA). However, it is understood that the second part of the mandate, i.e. “*suggest an approach for the risk management issues to be addressed by the Committee*”, refers only to those concerns which can be addressed by the Committee without an advice from JECFA or other appropriate FAO/WHO scientific advice body. This does not apply to Q3 for which the outcomes for other CA and SA concerns would be needed. Therefore, Q3 was not considered in the way forward proposed.

15. The second circular offered 3 options as a way forward to address the questions Q1 and Q2 as follows:

- Option A: Waiting for the scientific advice as regards the concerns categorised as SA and addressing the CA concerns afterwards, i.e. when the scientific advice for SA concerns is available
- Option B: Working independently from the timeline for SA concerns and addressing the CA concerns
- Option C: Addressing the CA concerns prior to the scientific assessment (provided such assessment will be performed) and using the information obtained in the scientific assessment

Clarification of the scope of the question(s) to be addressed by JECFA or other appropriate FAO/WHO scientific advice body and feedback from the FAO/WHO JECFA secretariat

16. In the second circular the EWG members were further requested to comment on the scope of the SA questions.

17. A feedback from FAO/WHO JECFA secretariat was required on the relevancy of SA concerns for the safe use of nitrates and nitrites, availability of the relevant information in the current international scientific assessments and a feasibility to carry out assessments of SA concerns based on the information indicated in the replies to the first circular.

Outcomes of the second EWG consultation

Comments on the approach suggested for CA concerns (i.e. Q1 and Q2)

18. All respondents were generally supportive of addressing the CA concerns via the EWG(s).

19. Whilst generally agreeing with the approach to collect information on Q2 by using a template (on both the adopted provisions and the provisions in the step process), several comments on the template outlined in the second circular were made (see below).

20. Some EWG members suggested removing the word '*indispensable*' used in the context of collecting data on types of products and production processes for which nitrates / nitrites are needed since in their view such term is not appropriate, may result in failure to capture a true picture of nitrates / nitrites use and contradicts the last column requesting information on alternatives. Those EWG members proposed to replace the word '*indispensable*' by '*used*'.

21. Some EWG members were of the view that the template should not refer to '*cured taste*' as it is not a recognised functional class by Codex and CXG 36-1989 lists only '*colour retention agent*' and '*preservative*' as functional classes for nitrates and nitrites.

22. One EWG member suggested utilising only one column for each ingoing and residual amounts and to request the technological function in the column '*Types of products...*'. He pointed out that members should be encouraged to indicate both ingoing and residual levels when they know how those values correspond to each other.

23. Adding a new column requesting information on the use of other food additives intended to reduce nitrosamine formation was suggested by some EWG members.

24. One EWG member suggested including request for '*normal use levels*', another member was of the view that data on '*minimum ingoing and residual amounts to achieve the desired effect*' shall be requested instead and those data should be scrutinised by the Committee if they were higher than the levels determined by SA QIV.

25. One EWG member suggested a format to collect specific information on food additive uses, natural occurrence and dietary exposure (see Annex 2). He stressed the need to collect the necessary information before asking for the scientific advice and to refer to the Codex Committee on Contaminants in Foods as regards natural occurrence data. Another EWG indicated availability of extensive data on additive uses of nitrates and nitrites collected from business operators.

Comments on the way forward (Options A, B and C)

26. The majority of the EWG members were in favour of Option A (waiting for the scientific advice) for addressing Q1. They indicated that Q1 should be discussed and the final decision on the expression of MLs should only be taken once the scientific advice is available to take an informed decision and to avoid unnecessary discussion. One member commented that it may be necessary to establish MLs for both ingoing and residual amounts of nitrate and nitrite giving the complexity of the products available on the global market, the different curing regimes that are currently being used and international trade.

27. Only one EWG member was in favour of Option B in order to address CA and SA concerns in parallel and save time.

28. Nearly an equal number of responses in favour of Option A and C (addressing the CA concerns prior to the scientific assessment) was received for Q2. One EWG was of the view that the scientific advice would influence the discussion on both Q1 and Q2 and therefore Option A should be followed. The members preferring Option C for Q2 indicated that information obtained by the Committee in response to Q2 would provide the necessary input to JECFA on the exposure to nitrates and nitrites from their current use.

29. The FAO/WHO JECFA secretariat supported Option C for both Q1 and Q2 indicating that the benefits and drawbacks of issues related to Q1 are well understood and warrant a discussion that goes beyond a risk assessment and that a lack of information on Q2 from national competent authorities would lead to incomplete risk assessment. JECFA suggested collecting as much information on Q2 as possible and considering this information in the follow-up discussion on Q1. JECFA further noted that any lack of consensus on Q1 might impact the outcome of any risk assessment that may prevent to come to conclusions, may constitute a serious resource impact as two mutually exclusive alternatives would need to be evaluated.

Comments on the scope of the SA questions

30. The EWG members generally agreed with the scope of the SA questions outlined in the second circular. However, some suggestions were made. One EWG member was of the view that any questions posed should provide sufficient flexibility for the scientific advice body to make the determinations on relevance to the risk assessment.

31. Some EWG members noted that the major contribution to dietary exposure to nitrates / nitrites is from consumption of fruits and vegetables and they suggested amending QII that the relative contribution from food additives to the exposure from fruits and vegetables is captured. As regards exposure to nitrosamines one member referred to both food and non-food sources.

32. Two EWG members recommended adding an additional question to seek an advice to what extent does the use of additives such as ascorbic acid mitigate the potential health risk related to the formation of nitrosamines and whether such use would allow the safe use of nitrates and nitrites at higher levels. One of those members also suggested a revision of Q1 to request guidance from JECFA on what expression of MLs is 'supported by the available data'.

33. One EWG member made several suggestions related to Q1, QIII and QIV as regards clarification of the relationship between ingoing and residual amounts, nitrosamines formation during metabolism of nitrates and nitrites, approach to collect the data on nitrosamines (by summarising and analysing the information provided in the comments to the first circular), feasibility of using alternatives to nitrates and nitrites taking into account manufacturing and climatic conditions in different countries.

34. The FAO/WHO JECFA Secretariat clarified that there seemed to be limited knowledge about the correlation between ingoing vs residual amounts of nitrites and nitrates and that their consumption in food is a multi-parametric function of time and other physico-chemical attributes. The JECFA Secretariat noted that ingoing amounts are easier to control and that it is arguable that only residual amounts are relevant for human health, however, the decision which of the two is more suitable is a dilemma for the risk managers. In the view of the JECFA Secretariat re-evaluating the hazardous properties of nitrites and nitrates is not needed but there could be a need to re-evaluate the exposure from all sources in a global perspective pending the availability of relevant new occurrence data. The JECFA Secretariat acknowledged that more research may be warranted to clarify the uncertainties concerning the endogenous formation of nitrosamines from nitrites. However, it considered a request for a re-evaluation for these compounds as premature as it is very unlikely that sufficient new data are available.

Concluding remarks

35. There was a consensus on the classification of concerns as CA or SA and that the CA concerns should be address in an EWG(s).

36. The EWG members supported using a template to collect information on Q2. The template was updated by taking into account the comments of EWG and is presented for a further consideration in Recommendation 4. Some further discussion on the template might be needed. It should be noted that the updated template does not exactly correspond to the wording of Q2 which asked for '*an indispensable use and use levels for nitrates and nitrites*' in line with the comments provided by the JECFA Secretariat that '*nitrates and nitrites when used as food additives should be used at the minimum levels needed to achieve the functional purpose*' (see para 2). Instead the updated template would rather capture the current practices as regards the use and use levels. However, such information would be useful and relevant for estimating the current exposure as outlined in QII.

37. There were diverging views as regards the preferred way forward. Nearly an equal support received Option A and C for Q2. Except for one EWG member Option B was not supported. Whilst the majority of the EWG members preferred Option A for Q1 this view was not shared by the JECFA Secretariat which referred, inter alia, to a serious resource implications if there was no consensus whether the MLs should be expressed as ingoing or residual and both alternatives would need to be assessed. This issue warrants further reflection taking into account that the Committee could also consider establishing both ingoing and residual MLs.

38. The need to take into account the natural occurrence data (i.e. the exposure from fruits, vegetables, drinking water) was stressed. Whilst it is clear that the Committee shall take into account the intake from all food sources in accordance with the GSFA Preamble Section 3.1(b) a clarification is needed as regards what should be the role of the Committee in collecting the relevant natural occurrence data and whether it is not appropriate to refer this issue to the CCCF. An advice from the Codex Secretariat as regards the correct procedure to be followed might be needed.

39. The EWG members did not question the scope of the SA concerns formulated in QI-IV but some amendments and a request for adding one question (QV) were suggested. The EWG members would apparently welcome obtaining the scientific advice for the SA concerns. However, there seems to be a discrepancy between the wishes of the EWG members and the feedback provided by the JECFA secretariat. To the understanding of the chairs the JECFA Secretariat was supportive, pending the availability of data, only for the new re-evaluation of the exposure to nitrates and nitrites, i.e. addressing QII. This discrepancy would need to be further considered and addressed by the Committee.

Recommendations

Recommendation 1

40. In light of (i) the comments of the EWG members, (ii) feasibility and data availability indicated and (iii) the feedback as provided by the JECFA FAO/WHO Secretariat, the Committee is invited to discuss for each of the questions below whether a new scientific advice shall be required or whether the Committee shall take the decision without requesting new scientific advice.

QI What expression of the MLs (i.e. as ingoing or residual or both) is supported by the available data, taking into account the relationship between ingoing and residual amounts, in relation to the protection of human health, i.e. inhibitory effect on bacteria (especially Cl. botulinum), nitrosamines formation in all routes and ADI?

QII Does exposure to nitrites and nitrates pose a health risk? What are recent exposures from all sources and from food additive uses? What is the relative contribution of dietary exposure from food additive uses relative to exposure from other sources (fruits, vegetables and drinking water)?

QIII Does exposure to nitrosamines (exogenous and endogenous) pose a health risk? What are recent exposures from all sources and from food additives to nitrosamines generated during: i) the production process in foods; ii) heat-treatment in the domestic setting; and iii) gastrointestinal transit?

QIV What are appropriate levels (ingoing and residual) necessary to inhibit Cl. botulinum in view of risk (nitrosamines, ADI being exceeded) and benefit (microbiological safety) considerations taking into account other factors affecting microbial growth?

QV To what extent does the use of additives such as ascorbic acid in conjunction with nitrates and nitrites reduce nitrosamine formation and mitigate the potential health risk from the use of nitrates and nitrites? Is available information sufficient to allow the safe use of nitrates and nitrates at higher levels when used in conjunction with these additional additives?

Note: The questions above represent the issues on which the EWG members would like to obtain the answer. It is based on the questions outlined in the first circular. However, the questions were revised based on the comments received from the EWG members and QV was added.

Recommendation 2

41. Based on the outcomes for Recommendation 1 the Committee is invited to consider addressing the SA concerns (QI-V) for which no new scientific advice will be required together with the CA concerns.

Recommendation 3

42. It is recommended to address the CA concerns Q1 and Q2 (and if relevant the SA concerns for which no new scientific advice will be required) in an EWG(s).

43. In light of the outcomes for Recommendation 1 and 2 the Committee is invited to consider Option A and/or Option C as a way forward.

Note:

Q1 What is the most appropriate way of expressing the MLs in relation to control purposes, international trade, different production processes?

Q2 For which types of products or production processes are nitrates and nitrites used, for what purpose and at what levels? What MLs expressed as ingoing and residual amounts are needed for preservation and colour retention? Are there alternatives to nitrites and nitrates available?

Option A and C:

Option A: *Waiting for the new scientific advice and addressing the CA concerns (and if relevant the SA concerns for which no new scientific advice will be required) only afterwards, i.e. when the new scientific advice is available*

Option C: *Addressing the CA concerns (and if relevant the SA concerns for which no new scientific advice will be required) prior to the new scientific assessment and using the information obtained in the new scientific assessment*

Recommendation 4

44. For Q2 the Committee is invited to consider the use of the following table to collect the necessary information for each of the GSFA subcategories for which there are provisions for nitrates and nitrites (both adopted and in the step process).

Example on how the relevant information for Q2 could be collected for the use of nitrites in the category 08.2.1.1

08.2.1.1 Cured (including salted) non-heat treated processed meat, poultry, and game products in whole pieces or cuts				
Types of products or production processes	Use Level (ingoing or residual dependant on available data)		Are there alternatives to the proposed use of nitrites available?	Are other food additives available which are being used in conjunction with nitrites with the intention to inhibit the formation of nitrosamines?
	Ingoing amount on the total net content of the final product expressed as NO₂ ion	Residual amount on the total net content of the final product expressed as NO₂ ion		
<i>Indicate the types of products or production processes in which nitrites are used and why. Indicate the appropriate functional class (i.e. colour retention agent or preservative)</i>	<i>Indicate and justify the appropriate level. If available, indicate minimum, typical and maximum use level necessary to accomplish the desired effect</i>	<i>Indicate and justify the appropriate level. If available, indicate minimum, typical and maximum use level necessary to accomplish the desired effect</i>	<i>Consider alternatives available or indicate why the objective cannot be achieved by other means that are economically and technologically practical</i>	<i>Consider food additives available and indicate how they can be used to inhibit nitrosamine formation and whether they are technologically practicable</i>

Recommendation 5

45. The Committee is invited to further consider the appropriate approach for collection of the natural occurrence data on nitrates and nitrites.

Annex 1

Table summarising the replies of the EWG members to the first circular

Concerns identified	CA or SA? Please fill in below	Is this aspect relevant for the establishment of safe and technologically justified uses and use levels of nitrates & nitrites?	Are data available to address this aspect? Please specify	Remarks
<i>The expression of Maximum Use levels as ingoing amount and/or residual amount (i)</i>				
What is the most appropriate way of expressing the MLs in relation to:	-	-	-	-
- Protection of human health, i.e. inhibitory effect on bacteria (especially <i>C. botulinum</i>), nitrosamines formation in all routes, ADI	SA 10x CA 1x CA in the context of SA 1x	Relevance recognised by all EWG Members.	Availability of the data indicated.	<p>The vast majority of EWG Members categorised the aspects as applicable to the risk assessment (SA).</p> <p>One EWG Member considered that more reliable data on the conversion of nitrate to nitrite in the human saliva are needed to enable addressing the aspects listed. Another EWG was of the view that nitrosamines formation is more important aspect than inhibitory effect on <i>C. Botulinum</i>. One EWG Member considered that the aspects should be addressed by the Committee and that different approaches might be needed for different foodstuffs. Another EWG Member was of the view that these aspects are SA concerns and their relevancy should be determined by the scientific body. Then a risk management decision on the expression of the ML should be taken by the Committee.</p> <p>The view that the Committee should established the ML on the basis on the scientific advice was shared by other EWG Members.</p> <p>Conclusion: there seems to be a common understanding that the aspects listed should be considered by a scientific advice body (SA). Indeed, the decision on the expression of the ML should be taken by the Committee (i.e. risk management) taking into account the scientific advice provided.</p>

Concerns identified	CA or SA? Please fill in below	Is this aspect relevant for the establishment of safe and technologically justified uses and use levels of nitrates & nitrites?	Are data available to address this aspect? Please specify	Remarks
<p>- Control purposes, international trade, different production processes</p>	<p>SA 0x CA 12x</p>	<p>Generally, the relevance was recognised by all EWG Members.</p> <p>One EWG Member questioned the relevance of expressing MLs to enable controls as not being efficient to ensure public health and considered that availability of efficient analytical techniques should also be taken into account for this aspect. On the other hand some other EWG Members considered the aspect of “control” as being the most important from the 3 aspects listed.</p>	<p>One EWG indicated availability of some data. The vast majority of the EWG indicated that the data can be collected from the industry, governmental authorities, academy etc.</p> <p>One EWG was of the view that the data availability does not play a role and that expressing the ML as regards the mentioned aspects is a question of an approach taken.</p>	<p>Conclusion: there was an unanimous view that the aspects listed could be addressed by the Committee (i.e. a scientific advice (SA) is not required)</p>
<p><i>The technological need seeking a balance between the benefits and risks taking into account existence of alternatives (ii)</i></p>				
<p>For which types of products or production processes is the use of nitrates and nitrites indispensable, for what purpose and at what levels?</p> <p>What MLs expressed as ingoing and residual amounts are needed for preservation, colour and flavour effects?</p> <p>Are there alternatives to nitrites and nitrates available?</p>	<p>SA 3x CA 7x CA+SA 1x</p>	<p>Vast majority of the EWG Members considered the aspects listed as relevant.</p> <p>One EWG was of the view that they are relevant only if it is concluded that there is an unacceptable risk to human health from the current uses.</p> <p>Several EWG Members stressed that the relevant MLs are those related to the use of nitrates and nitrites as preservatives (i.e. providing clear benefits) and the need to consider the alternatives. One EWG considered that the aspects are relevant for the risk management but that they</p>	<p>The info / studies available were indicated.</p> <p>The EWG stressed the need to collect the data from the industry, governmental institutions, academia etc.</p>	<p>Conclusion: the majority of EWG Members considered that the aspects listed could be addressed by the Committee (i.e. a scientific advice (SA) is not required)</p>

Concerns identified	CA or SA? Please fill in below	Is this aspect relevant for the establishment of safe and technologically justified uses and use levels of nitrates & nitrites?	Are data available to address this aspect? Please specify	Remarks
		can be used as an input in the risk assessment as well.		
Does exposure to nitrites and nitrates pose a health risk? What are recent exposures from all sources and from food additive uses?	SA 12x CA 0x	Relevance recognised by all EWG Members.	References were made to the available dietary assessments and the possibility to extract this information from food consumption data and actual use levels provided.	Conclusion: there was an unanimous view that the aspects listed should be considered by a scientific advice body (SA).
Does exposure to nitrosamines (exogenous and endogenous) pose a health risk? What are recent exposures from all sources and from food additives to nitrosamines generated during: i) the production process in foods; ii) heat-treatment in the domestic setting; and iii) gastrointestinal transit?	SA 12x CA 0x	Relevance recognised by all EWG Members. Some EWG Members referred to (the existing or to be established) MLs for nitrosamines. One EWG referred to a positive correlation between nitrites added and nitrosamines formed. Another EWG Member stressed the need to take into account the growing evidence from the epidemiological studies (and not only toxicological information) as regards possible link between the intake of nitrites (nitrosamines respectively) and certain types of cancer	References were made to some scientific articles, an IARC monograph and the scientific assessment which has been recently published for one world region. Some EWG Members were uncertain as regards the data availability for their regions.	Conclusion: there was an unanimous view that the aspects listed should be considered by a scientific advice body (SA).
What are the appropriate levels (ingoing and residual) necessary to inhibit <i>Cl. botulinum</i> in view of risk (nitrosamines, ADI being exceeded) and benefit (microbiological safety) considerations?	SA 10x CA 1x CA+SA 1x	Relevance recognised by all EWG Members. Some EWG Members indicated that the risk / benefit considerations might differ in different world regions.	Based on the feedback provided some pertinent data are available.	Conclusion: the vast majority of EWG Members were of the view that the aspects listed should be considered by a scientific advice body (SA). Indeed, the decision on the appropriate levels should finally be taken by the Committee (i.e. risk management) taking into account the scientific advice provided.

Concerns identified	CA or SA? Please fill in below	Is this aspect relevant for the establishment of safe and technologically justified uses and use levels of nitrates & nitrites?	Are data available to address this aspect? Please specify	Remarks
<i>Appropriate levels taking into account the ADI's for nitrites and nitrates (iii)</i>				
Are the proposed uses and proposed levels in the step process adequate in view of the GSFA Preamble and conclusions on points (i) and (ii)?	SA 1x CA 8x CA+SA 1x	Relevance recognised by most of the EWG Members.	Two EWG Members considered that the adequacy of the proposed uses and use levels could be judged only when the previous aspects have been clarified. One EWG member considered that the Committee should first determine which provision and use levels are technically relevant and JECFA could then do an exposure assessment in the context of its safety assessment.	Conclusion: the vast majority of the EWG Members were of the view that the aspects listed could be addressed by the Committee. One EWG Member pointed out that whilst the most of the criteria in Section 3.2 of the Preamble to the GSFA can be categorised as CA, the issue whether the use of food additives does not present an appreciable health risk to consumers is clearly a SA issue. Indeed, the adequacy of any uses should be addressed by the Committee taking into account considerations on the CA and SA concerns identified.

Annex 2

Suggestion of Japan to collect information on food additive uses, occurrence of nitrates / nitrites as contaminants and dietary exposure

Information on food additive use

Are maximum use levels for nitrates and nitrites set in your country? If so, please describe them.	e.g.) Yes. 5 mg/kg for nitrates in meat products.
Are the MLs expressed as 1) ingoing amount, 2) residual or 3) other way?	e.g.) Residual amount
Reasons for the ML and its expression	

Information on contaminants

Are maximum levels for nitrates and nitrites set in your country? If so, please describe them.	
Do you have occurrence data of nitrates and nitrites in foods? If so, please provide summary by GEMS/Food format.	

Information on dietary exposure

Do you have available data on dietary exposure to nitrates and nitrites? If so, please describe the summary and sources.	
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