

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5e

CRD21

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-Ninth Session

Macao SAR, China, 20-24 March 2017

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

Comments of Cameroon, El Salvador, Ghana, Indonesia, Nigeria, Paraguay, Russian Federation, Thailand, African Union and ICGMA

Cameroon

Observations :

Plusieurs préoccupations ont été identifiées concernant l'emploi des nitrates et des nitrites dans les aliments:

- Expression des niveaux d'emploi maximaux en tant que quantité ajoutée et/ou résiduelle ;
- Le besoin technologique établissant l'équilibre entre les bénéfiques et les risques en tenant compte de l'existence d'autres options ;
- Les niveaux appropriés tenant compte des DJA pour les nitrites et les nitrates.

Position : Au vu des risques sanitaires associés aux nitrates et aux nitrites, nous souscrivons aux 3 recommandations formulées dans le document de travail (**CX/FA 17/49/11**) pour pouvoir apporter des solutions aux différentes préoccupations identifiées concernant l'emploi de ces additifs dans les aliments.

El Salvador

El Salvador apoya el GTe coordinado por los Países Bajos relacionado con los nitratos y nitritos en los diferentes aspectos que los presenta el GTe:

(i) La expresión de las dosis máximas de uso como cantidad añadida y/o cantidad residual, teniendo en cuenta la viabilidad de los controles, el efecto de conservación (en particular la actividad inhibitoria contra *C. botulinum*) y la posible formación de nitrosaminas

(ii) La necesidad tecnológica buscando un equilibrio entre los beneficios (inocuidad microbiológica, el efecto deseado sobre el color y el aroma) y los riesgos (formación de nitrosaminas), teniendo en cuenta la existencia de alternativas eficaces.

(iii) Dosis apropiadas teniendo en cuenta las IDA de los nitritos y nitratos, y el debate sobre los puntos (i) e (ii)

Para el tema (iii), Problemas planteados y las recomendaciones, El Salvador apoya las recomendaciones

Especialmente en la:

- La necesidad tecnológica buscando un equilibrio entre los beneficios y los riesgos teniendo en cuenta la existencia de alternativas,
- Dosis apropiadas teniendo en cuenta las IDA de nitritos y nitratos

Cuadro 1 Disposiciones adoptadas sobre nitritos (SIN 249 y SIN 250) en la NGAA

Categoría de alimentos	Dosis máxima (mg/kg)	Notas ¹
08.2.2 Productos cárnicos, de aves de corral y caza elaborados, tratados térmicamente, en piezas enteras o en cortes.	80	32 288
08.3 Productos cárnicos, de aves de corral y caza picados, elaborados y congelados	80	32 286 287

¹Notas

- 32: como ion residual de NO₂
- 286: para uso en productos que corresponden a la Norma para la “carne luncheon” (CODEX STAN 89-1981) y la Norma para la carne picada curada cocida (CODEX STAN 98-1981).
- 287: excepto para uso en productos que corresponden a la Norma para la carne tipo “comed beef” (CODEX STAN 88-1981) a 30 mg/kg como ion NO₂ residuo.
- 288: para uso en productos que corresponde a la Norma para el jamón curado cocido (CODEX STAN 96-1981) y la Norma para la espaldilla de cerdo curada cocida (CODEX STAN 97-1981).

El Salvador reconoce la importancia en evaluar la cantidad añadida así como la residual ya que la residual se usa para el control de nitrosaminas en el consumidor.

(iii) Dosis apropiadas teniendo en cuenta las IDA de los nitritos y nitratos, y el debate sobre los puntos (i) e (ii)

29. La FAO, en su documento de Directrices para el sacrificio y despiece de los animales y el procesado de la carne, indicó que para el nitrito el efecto conservante podría obtenerse mediante 80-150 mg/kg, la protección del color mediante 3-50 mg/kg y la formación de sabor mediante 20-40 mg/kg (FAO, 1991). No está claro si estas cantidades son cantidades añadidas o cantidades residuales. La expresión (como ion o sal de sodio) tampoco está clara. Por lo tanto, es difícil comparar los usos propuestos con las dosis del documento de la FAO. Además, como la higiene puede haber mejorado con el tiempo, las dosis de uso indicadas para la conservación publicadas en 1991 pueden no ser ya pertinentes.

El Salvador considera que no está claro si los límites son residuales o son añadidos por tal razón se recomienda definir a qué cantidad se refiere y también si se refiere como *sal de nitrito de sodio* o como *ion nitrito*.

Es necesario determinar las dosis apropiadas de nitrito de sodio que ocupa en la fabricación de los productos cárnicos debido a que las que actualmente existen sobrepasan los valores de IDA.

Es necesario hacer estudios de la relación que existe entre la cantidad añadida de nitrito y la formación de nitrosamina.

Tomar en cuenta el CFR Capítulo 21 Volumen 3 donde se habla de sanciones para los productores que usen nitratos.

Ghana

Specific Comments

Ghana supports the three recommendations of the discussion paper.

Rationale: In its reports of 1995 and 2002, JECFA did not consider the ingoing or residual amounts nitrates and nitrites and N-nitrosamine formation during the production process. A scientific basis for setting limits on ingoing or residual amounts in relation to N-nitrosamine formation is not available from the JECFA reports.

Indonesia

Indonesia would like to propose that the use of nitrates and nitrites should be limited only in food category 08.0 to prevent the excessive quantities exposure of nitrates and nitrites. Related to the possible formation of nitrosamines, it is more appropriate to consider the use of other food additives as preservative.

Nigeria

Nigeria will like to appreciate the work done in drafting the discussion paper by the Netherlands. Nigeria supports the recommendations of the discussion paper

Paraguay

English

Paraguay supports to consider the three recommendations on the use of nitrates and nitrites, bearing in mind that the most recent JECFA assessments are from 2002 and there was no mention back then on formation of N-nitrosamines during the production process. In this sense, an updated assessment might contribute greatly in improving the technological use of these additives, and especially taking into account that nitrates and nitrites are extensively used across Paraguay.

Spanish

Paraguay agradece a los Países Bajos por la preparación del documento.

Observaciones generales

Paraguay apoya considerar las tres recomendaciones sobre el uso de nitratos y nitritos, teniendo en cuenta que las evaluaciones del JECFA más recientes datan de 2002 y no se hizo mención a la formación de N-nitrosaminas durante el proceso de producción, por lo que una evaluación más actual podría aportar en gran manera a mejorar el uso tecnológico que se le da a estos aditivos, y sobre todo teniendo en cuenta que a nivel país el uso de nitratos y nitritos está muy extendido.

Russian Federation

According to the risk assessment performed in the Russian Federation, the following MLs represent safe levels for human health (ingoining amounts and/or residual amounts, and/or limits on nitrosamines in products) in terms of chemical and microbiological food safety:

Nitrates (INS 251, 252)*	ML (mg/kg)
01.6.1 Unripened cheese	50
01.6.2 Ripened cheese	50
01.6.4 Processed cheese	50
01.6.5 Cheese analogues	50
08.2 Processed meat, poultry, and game products in whole pieces or cuts	250
08.3 Processed comminuted meat, poultry, and game products	250
Nitrites (INS 249, 250)*	ML (mg/kg)
08.2 Processed meat, poultry, and game products in whole pieces or cuts	50
08.3 Processed comminuted meat, poultry, and game products	50
*As residual NO ₂ ion.	

These levels ensure that the additives when used in foods provide sufficient protection for human health during the shelf life, including bacteriostatic effect on *Clostridium botulinum*, *Listeria monocytogenes*, *Salmonella* spp. These MLs were established in Russia more than 20 years ago.

In our opinion, in the raw meat and raw meat semi-finished products the use of nitrates and nitrites is not technologically justified and increases the risk of their negative impact on the human health.

Thailand

Thailand would like to thank the Netherlands for preparing the discussion paper on the use of nitrates (INS 251, 252) and nitrites (INS 249, 250). We would like to provide the following comments for consideration at the forthcoming 49th session of CCFA.

Comments:

In general, Thailand is of the view that the used of nitrates and nitrites in food should be limited because they would cause adverse health effects. However, the benefits of the use of nitrites and nitrates should be weighed against their risk.

We are pleased to provide our specific comments on each recommendation as follows:

Recommendation 1

We support requesting advices from JECFA as regards the appropriateness of expression of MLs as ingoining amount or residual amount, taking into account the control purposes, preserving effect and nitrosamine formation. This would be useful for codex member countries as guidance in establishing of ML for nitrates and nitrites.

Recommendation 2

We agree with requesting JECFA for an advice as regards a risk-benefit analysis, weighing the benefits of use of nitrites and nitrates against negative impact and formation of N-nitrosocompounds.

Recommendation 3

The appropriate MLs of nitrites and nitrates should be considered based on the outcome from Recommendations 1 and 2. However, we would like to note that there is no technological need for the use of nitrites and nitrates in fresh meat.

African Union

Issue: At 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. JECFA Secretariat clarified that the basis for the ADI was on toxicological considerations of the nitrates and nitrites. Although 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. 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.

As agreed by the PWG of the CCFA48, The Netherlands prepared a discussion paper and recommends:

- (i) To request JECFA for an advice as regards the aspects of the ingoing and residual amounts in relation to the appropriateness for control purposes, preserving effect and nitrosamine formation in all possible routes.
- (ii) To request JECFA for an advice as regards a risk-benefit analysis, weighing the benefits of use of nitrites and nitrates against their risks.
- (iii) For the Committee to consider the appropriate use and use levels taking into account the outcomes of points (i) and (ii) and the ADI's for nitrites and nitrates

Position: AU supports the three recommendations of the discussion paper.

Rationale: In its reports of 1995 and 2002, JECFA did not consider the ingoing or residual amounts of nitrates, nitrites, and N-nitrosamine formation during the production process. A scientific basis for setting limits on ingoing or residual amounts in relation to N-nitrosamine formation is not available from the JECFA reports and is needed.

International Council of Grocery Manufacturers Associations (ICGMA)

ICGMA recommends that:

- Nitrate/nitrite should be added to the JECFA priority list for re-assessment, in support of continued discussion at CCFA.
- CCFA delay any decisions on nitrate/nitrate policy until the conclusions of the JECFA re-assessment are complete.

Background

ICGMA welcomes and appreciates the work of the Netherlands to create the Discussion Paper on the Use of Nitrates (INS 251, 252) and Nitrites (INS 249, 250). Based on the availability of new information ICGMA encourages CCFA to add nitrates and nitrites to the Joint Expert Committee on Food Additives (JECFA) priority list so that this new information can be used to update the assessment, including the Acceptable Daily Intake (ADI). The toxicological basis for the current ADI for nitrates and nitrites is decades old (1). JECFA in its latest review did not include critical studies done in animals (2, 3) which found no evidence of cancer even when active nitrosating agent was added to drinking water. These studies should be included for deriving an ADI.

Response to the discussion paper

ICGMA supports the conclusion of the discussion paper (CX/FA 17/49/11), particularly para 39. ICGMA believes that a re-evaluation of the safety of nitrites and nitrates is necessary before CCFA reconsiders the maximum levels of these additives. Upon re-evaluation of the Acceptable Daily Intake (ADI), through the JECFA re-evaluation, an exposure assessment can then be conducted to determine whether current maximum levels exceed the ADI (addressing paragraph 36).

Toxicological summary

In contrast to the toxicological basis for the current ADI for nitrates and nitrites being decades old our knowledge on the toxicity of these compounds has advanced in many areas, such as a lack of direct chronic effects (2, 3), a lack of methemoglobinemia except under the most extreme exposure situations (4, 5), lack of the formation of N-nitrosamines *in vivo* (6). Additionally, recent studies on the biochemistry of nitrate and nitrite have demonstrated that the similarity in response between humans and animals support an uncertainty factor of less than 100 from the relevant point of departure (7).

In addition to advances in the understanding of the hazard of these compounds, the availability of new information could be used to improve the exposure assessment for nitrate and nitrite. These compounds are ubiquitous, including being found in drinking water as well as being consumed as part of a healthy diet (such as fresh vegetables). Additionally, nitrate and nitrite are formed internally in the course of normal human metabolism and in response to stress. All of these routes of exposure need to be considered as part of the exposure assessment. Recommendations about nitrate and nitrite consumption should also be balanced with the benefits of consuming foods high in these compounds. For example, people eat healthy diets with vegetables naturally high in nitrate may be at higher risk for exceeding the ADI (8). However, people who consume a healthy diet are known to have lower risks of cancer, cardiovascular disease, and other life-threatening diseases.

References

1. Lehman, A.J. (1958). Quarterly reports to the editor on topics of current interest. Nitrates and nitrites in meat products. *Quart Bull Assoc Food Drug Officials*. **22**,136–138.
2. Maekawa, A., et al. (1982). Carcinogenicity studies of sodium nitrite and sodium nitrate in F-344 rats. *Food Chem Toxicol*. **20**, 25-33.
3. National Toxicology Program. (2001). Technical Report on the Toxicology And Carcinogenesis Studies of Sodium Nitrite (CAS No. 7632-00-0) in F344/N Rats And B6C3F₁ Mice (Drinking Water Studies). NTP TR 495 NIH Publication No. 01-3954.
4. Subcommittee on Nitrate and Nitrite in Drinking Water (1995). Nitrate and Nitrite in Drinking Water. National Academy Press. Washington, DC.
5. Fewtrell, L. (2004). Drinking-water nitrate, methemoglobinemia, and global burden of disease: A discussion. *Environ Health Perspect*. **112**, 1371–1374.
6. Bryan, N.S., et al. (2012). Ingested nitrate and nitrite and stomach cancer: An updated review. *Food Chem. Toxicol*. **50**, 3646-3665.
7. Bryan, N.S. and Ivy, J.L. (2015). Inorganic nitrite and nitrate: evidence to support consideration as dietary nutrients. *Nutr. Res*. **35**, 643-654.
8. Hord, N.G., Tang, Y., and Bryan, N.S. (2009). Food sources of nitrates and nitrites: the physiologic context for potential health benefits. *Am J Clin Nutr*. **90**, 1–10.