

# CODEX ALIMENTARIUS COMMISSION



Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

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Agenda Item 5c

CRD 13

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD ADDITIVES

### Fifty-First Session

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

Comments of Canada, European Union, Indonesia and Russian Federation

#### Canada

Canada would like to thank the Chairs of the eWG for preparing this paper which presents balanced information on the positions of Members both for and against the need to control the incoming use-levels vs the residual levels, and on the mandate to gather more information on occurrence, health risk concerns, and risk management strategies.

Canada is of the opinion that it is premature for the Committee to consider and possibly decide on the most appropriate risk management approach for nitrates/nitrites (as per Recommendation 1). Canada is also of the opinion that this recommendation may go beyond the mandate of the eWG.

The information gathered is too extensive and complex to consider by just a discussion of the plenary. Instead, Canada recommends that at a minimum, the information gathered should be put forward as a continuation of work and the terms of reference should focus on appropriate risk management approaches. Proposals for risk management strategies should be detailed and considered by the eWG. While the JECFA Secretariat may be able to comment on the need to update their previous risk assessment at the 51<sup>st</sup> session of the CCFA, the continuation of the work may allow the JECFA Secretariat an opportunity to consider the data in greater detail before they make their recommendation.

Canada would also make the specific comment that several issues were raised on risk management approaches based on maximum levels reflecting either ingoing levels of use or residual maximum levels of use. Canada would like to recommend that the eWG consider exploring hybrid approaches where there are controls on both ingoing and residual levels. This is consistent with Canadian provisions for nitrates/nitrites.

#### European Union

The European Union (EU) would like to thank Codex Members and Observers for their contribution to the work of the electronic Working Group and the JECFA FAO/WHO secretariats for publishing the call for data on natural occurrence of nitrates and nitrites and enabling data collection via the GEMS/Food database.

#### The EU has the following comments:

##### Expressing the use levels

Based on the scientific evidence available indicating that the ingoing amount of nitrite, rather than the residual amount, contributes to the inhibitory activity against *C. botulinum*<sup>1</sup> and that exposure to preformed nitrosamines should be minimized by appropriate practices such as lowering the levels of nitrate and nitrite added to foods to the levels necessary for preservative effect<sup>2</sup>, the regulatory approach based on the ingoing amount should be preferred. However, for purposes of Codex standards, which are intended for international food trade, and taking into account challenges in controlling the ingoing amount for some traditional products<sup>3</sup>, the EU is of the view that the GSFA provisions should include both ingoing and residual maximum use levels.

##### Safety considerations

The EU is well aware of the exposure of the EU population to nitrates, nitrites and nitrosamines (overall exposure and exposure due to food additive uses) based on the recent EFSA opinions<sup>4</sup>. However, no specific EFSA's opinion has been issued for the efficacy of the use of certain additives (e.g. ascorbic acid) in conjunction with nitrates and nitrites to reduce nitrosamine formation. Therefore, the EU would welcome more

<sup>1</sup> EFSA Journal (2003) 14, 1-31

<sup>2</sup> EFSA Journal 2010; 8(5):1538

<sup>3</sup> Traditional immersion and/or dry cured products or compound products where the curing solution is injected into the product prior to cooking

<sup>4</sup> EFSA Journal 2017;15(6):4786 and EFSA Journal 2017;15(6):4787

information from those countries having specific measures in place or a further scientific advice on this matter. The EU is also concerned about the lack of references to studies which would demonstrate the effectiveness of the levels reported in Table 2 and 3 of CX/FA 19/51/9.

### Recommendations

The EU takes note that the aim of the current work was to develop an inventory of data with a view to consulting with JECFA and CCFA regarding next steps how to approach this complex matter. Therefore, it might be premature that CCFA51 decides on the recommendations outlined in the paper. Nevertheless, the EU would like to offer its view on the recommendations as follows:

#### Recommendation 1

The EU considers that the GSFA provisions should include both ingoing and residual maximum use levels.

#### Recommendation 2

The EU would not object if the Committee considers that there is a need for further scientific advice.

## Indonesia

### Indonesia Comment:

Indonesia supports recommendation 2 for further scientific advice such as data for nitrosamine formation. Indonesia also considers that it is necessary to process data on natural occurrence of nitrates and nitrites as baseline in considering this agenda.

## Russian Federation

### Recommendation 1

The evidence clearly shows that there is the need to reduce the maximum permissible levels of nitrates, nitrites and N-nitroso compounds in food. This reduction is made possible by considering intake from all possible sources (vegetables, fruits, meat and fish products).

In the Russian Federation and the countries of the Eurasian Economic Union specific MLs for nitrates in all species of vegetables and fruits, taking into account the growing conditions (indoor or outdoor), MLs pfr nitrates and nitrites used as food additives, and MLs for nitrosamines in meat and fish products.

Our exposure assessment demonstrated that in the Russian Federation the dietary intake of nitrates does not exceed the established maximum levels (in all cases HQ > 1)

The calculation of the exposure to nitrates was carried out according to the formula:

$$\text{Exp} = \sum_{i=1}^N (C_i * M_i)$$

where,

Exp - exposure value of the contaminant, mg / person / day;

CI-content of the contaminant in the I-th product, mg / kg;

Mi - consumption of the i-th product, kg / day;

N is the total number of products included in the study.

The hazard coefficients were calculated by the formula: HQ = Exp : ADI

Values of the HQ coefficient were equal to or greater than one were regarded as indicating an unacceptable risk to human health.

Based on the exposure assessment, MLs were established for nitrates and nitrites used as food additives and ML nitrosamines in meat and fish products. For nitrates and nitrites, the minimal efficiency level was also determined (suppression of growth of pathogenic and opportunistic microorganisms, including germination of spores of Clostridium botulinum).

Due to the fact that nitrates and nitrites can react with the food matrix, ML for residual amounts have been established in ready-to-eat foods (see the example for cured meat in the table).

**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	Maximum Use Level					
	Maximum ingoing amount on the total net content of the final product expressed as NO <sub>2</sub> ion			Maximum residual amount on the total net content of the final product expressed as NO <sub>2</sub> ion		
	Preservation	Colour retention	Cured taste	Preservation	Colour retention	Cured taste
<i>Meat and fish products and it's production process</i>	70-80 mg/kg	70-80 mg/kg	70-80 mg/kg	30-50 mg/kg	30-50 mg/kg (3-5 mg/kg gives a rosy tint)	30-50 mg/kg

### **Recommendation 2**

Recent data on possible risks associated with the presence of nitrates, nitrites and nitrosamines in food, the development of new, more sensitive methods of analysis of these compounds, improvements in the methodological framework for risk assessment, all justify continuing work on the risk assessment of the content of these compounds in foods.