

**European Union Comments**  
**CODEX COMMITTEE ON FOOD ADDITIVES**  
**Forty-Eight Session**  
**Xi'an, China, 14-18 March 2016**  
**AGENDA ITEM 5(a)**  
**FOOD ADDITIVE PROVISIONS IN FOOD CATEGORIES 01.2 THROUGH 08.4**  
**(CX/FA 16/48/7)**

*European Union Competence*  
*European Union Vote*

**General comments on CX/FA 16/48/7**

The European Union (EU) comments from the electronic Working Group (eWG) are captured in the paper CX/FA 16/48/7. The EU appreciates the possibility to discuss further the draft provisions at the Working Group on the General Standard for Food Additives.

The EU recognises the amount and the complexity of the work taking into account the number of the provisions in the step process and the efforts for a consistent approach and an equal treatment of the provisions. The EU in particular appreciates that in many proposals the provisions of the corresponding commodity standards are reflected.

In the most cases the EU's specific comments relate to the justification of the technological need and the exposure from the proposed food additive uses. The EU hopes that the Working Group on the GSFA will consider those aspects and the participants in favour of the specific provisions will provide supporting information accordingly.

***Nitrites (INS 249, 250) and nitrates (INS 251, 252)***

The EU would like to draw the attention to the proposed provisions for nitrites and nitrates. The provisions for nitrites and nitrates should be carefully considered seeking an appropriate balance between the risks and benefits of their use – i.e. especially between the technological need to assure microbiological safety and a possible risk of formation of carcinogenic nitrosamines.

In the EU's view there are many pending issues which need to be addressed before agreeing on the use and use levels for nitrites and nitrates.

***Use of nitrites and nitrates in different food categories***

The EU takes note that the provisions are proposed for discussion in approx. 20 (sub)-categories. The EU is not convinced about the necessity to use nitrites and nitrates in all those categories. The technological need for the individual food categories has to be checked taking into account the current level of hygiene standards.

In addition, the proposed use levels in CX/FA 16/48/7 seem to be excessive and it is not clear on what grounds they were proposed. For example, to the EU's knowledge based on the scientific assessment<sup>1</sup> 50 – 100 mg added nitrite (expressed as sodium nitrite which would correspond to 33 – 67 mg expressed as NO<sub>2</sub> ion) per kg of meat products may suffice for many products. In other meat products, especially those with a

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<sup>1</sup> EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Statement on nitrites in meat products. EFSA Journal 2010; 8(5):1538. [12 pp.]

low salt content and having a prolonged shelf-life, addition of between 50-150 mg/kg nitrite (i.e. 33 – 100 mg/kg expressed as NO<sub>2</sub> ion) is necessary to inhibit the growth of *C. botulinum*.

#### *Use of nitrites and nitrates in meat products*

The EU takes note that the mentioned additives when used in meat products do not act only as preservatives but have an effect on colour and flavour as well. The technological need and the appropriate maximum use level might be different for all mentioned aspects (preservation, colour and flavour) and might differ among different types of products as well. Those aspects should be taken into account when considering the use and the appropriate use levels in meat products.

#### *Expression of maximum use levels*

The EU takes note that the maximum use levels are normally expressed on the same basis as the ADI. However, there are some issues related to the use levels in case of nitrites and nitrates.

From the scientific point of view the in-going amount of nitrite, rather than the residual amount, contributes to the inhibitory activity against *C. botulinum*. The formation of nitrosamines seems to depend on the nitrite amounts that are added, and not on the much lower residual amounts, which, due to the substance's transformation in the foodstuff, are typically present in the product at the time of consumption. Therefore, it might be appropriate to control the input levels rather than the residual amounts. However, it should be noted that such approach is not easy to implement for all types of products (e.g. for immersion or dry cured products) and a certain residual amount of nitrite is necessary to assure microbiological safety as well.

As for residual amounts they tend to decrease over time significantly and they might hide excessive amounts of added nitrites, therefore, if the Committee would prefer to base the maximum levels on residual amounts it might be helpful to determine a precise point in time (e.g. at the end of the production process) when residual amounts should be checked. Indeed, this might be problematic for checking the products in international trade.

#### *Possible formation of nitrosamines*

Even if JECFA concluded that the studies available at the time of evaluation did not provide evidence that nitrite was carcinogenic to humans (49<sup>th</sup> report, 2002), there are uncertainties linked with a possible formation of carcinogenic nitrosamines from nitrite and N-nitrosatable compounds present in food and the gastrointestinal tract. This should be taken into account when considering the use and use levels for nitrites and nitrates.

In conclusion, in the EU's view several issues have to be clarified before concluding on the uses and use levels in the individual food categories. The necessity of the use of nitrites (and nitrates which might act as reservoirs for nitrites) has to be considered taking into account their low ADI (0-0.07 mg/kg bw/day, expressed as nitrite ion and applicable to all sources of intake) and a possible formation of nitrosamines. If, for certain products, the use is necessary then the use level should be minimised lowering the amounts of nitrates and nitrites added to food to the minimum required to achieve the necessary technological effect and to ensure microbiology safety.

#### ***Use of food additives in the food category 06.4.2 Dried pastas and noodles and like product***

Pasta is a staple food especially in some countries. Therefore, the use of additives with numerical ADI's has to be carefully considered. In the past the EU pointed out several times that there is a difference in the technological need between pastas and noodles. Whilst such difference is reflected in the proposals for the categories 06.4.1 and 06.4.3 it is not the case for category 06.4.2 Dried pastas and noodles and like product.

To the EU's knowledge no additives are needed for dried pasta as such. There is a specific technological need for the use of additives in gluten free pasta and pasta intended for hypoproteic diets, however, to the EU's knowledge such need could be addressed by the additives with the ADIs not specified, therefore, it is not necessary to permitted additives with numerical ADIs. For those reasons the EU does not support the eWG proposal to adopt the provisions in category 06.4.2.

***Correction of the EU's comments on certain draft provisions on polyglycerol esters of fatty acids (INS 475) and polyglycerol esters of interesterified ricinoleic acid (INS 476)***

In case of certain provisions the EU in its comments stated that it could accept the adoption of the provision for INS 476 if it is used as an alternative to INS 475 since the ADI of INS 476 is three time higher than the ADI of INS 475.

However, those comments were based on an erroneous assumption that the ADI of INS 476 is 0-75 mg/kg bw/day while in reality it is only 0-7.5 mg/kg bw/day. In addition, it was clarified that both INS 475 and INS 476 represent distinct classes of products with individual chemical and physical properties which are suitable for different applications (i.e. INS 475 is an oil-in-water emulsifier, INS 476 water-in-oil emulsifier). Therefore, the mentioned EU comments on INS 475 and INS 476 in CX/FA 16/48/7 are not valid.