SNE POSITION ON TROPANE ALKALOIDS

IN CEREAL-BASED FOODS FOR INFANTS & YOUNG CHILDREN

In light of the discussions at EU level on the presence of Tropane alkaloids in foods for infants and young children, SNE is in favor of the setting an Indicative Value of 250 ppb for tropane alkaloids (sum of hyoscyamine and scopolamine) in the sorghum, millet and buckwheat used to manufacture cereal-based foods for infants and young children.

This guidance level would then be reviewed with the progress in preventive measures and in sorting performance, and also with the availability of fully validated analytical methods.

1. Key messages

Specialised Nutrition Europe (SNE) represents manufacturers of formulae and foods for infants and young children in Europe, who are dedicated and committed to delivering the highest quality nutrition for this very specific population. To that aim, SNE is willing to work with the European Commission on tropane alkaloids (hyoscyamine and scopolamine).

Due to the potential cross-contamination of some cereal-growing areas by plants of the Solanaceae family, like Datura species, tropane alkaloids may be found in cereal flours. It is not possible to completely prevent cross contamination (and therefore residual presence of tropane alkaloids in some specific flours) through the use of pesticides, as there are specific limits on the level of pesticide residues in cereal-based foods for infants and young children. There are also difficulties of sorting seeds of the same weight and color.

The survey initiated by SNE in 2014 confirms data from the Dutch authorities, which indicates the most significant cross-contamination risks concern the cereals sorghum and millet. Other industry data indicates that buckwheat flours may also be contaminated, as reported in scientific literature.

Only a few SNE members are using sorghum, millet or buckwheat in the composition of their cereal-based foods for infants and young children sold in Europe. In addition, 3 members indicated the sum of sorghum, buckwheat or millet content of the products never exceeds 2.5% of their composition.

SNE is therefore in favour of setting up an Indicative Value of 250 ppb for tropane alkaloids (sum of hyoscyamine and scopolamine) in the sorghum, millet and buckwheat used to manufacture cereal-based foods for infants and young children. This indicative value could then be reviewed with the progress in preventive measures and in sorting performance, and also in line with the availability of fully validated analytical methods.

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1 Indicative Value as defined per Commission Recommendation of 8 November 2013 on investigations into the levels of acrylamide in food (2013/647/EU): “Indicative values set by this Recommendation are only intended to indicate the need for an investigation. They are not safety thresholds. Therefore, enforcement action and/or the issuing of a Rapid Alert should only be undertaken on the basis of a sound risk assessment carried out on a case by case basis, but not merely because an indicative value is exceeded.”
2. **Scientific background**

On request of the European Commission, EFSA published a Scientific Opinion on Tropane Alkaloids in food and feed\(^2\) in September 2013. This document highlights the potential cross-contamination of some cereal-growing areas by plants of the Solanaceae family, like Datura species. Tropane alkaloids (hyoscyamine and scopolamine) are secondary metabolites of these plants, and can therefore be found in cereal flours.

A total number of 124 food samples, mainly originating from the Netherlands, were collected by EFSA between 2010 and 2012, of which 93 samples belonged to the food group cereal-based food for infants and young children. Of this category, 80% of the samples were non-quantifiable in tropane alkaloids, however others showed positive results.

On the basis of the group Acute Reference Dose (ARfD) of 0.016 µg/kg BW/day established by EFSA (for both hyoscyamine and scopolamine), an exposure assessment has been performed by EFSA for young children (aged 12 to 36 months). It indicates that this population group could potentially exceed the ARfD.

It is considered that the ARfD also covers the effects of long-term exposure, as there is no bioaccumulation of these tropane alkaloids. No genotoxic or carcinogenic potential has been found for these tropane alkaloids.

3. **SNE position**

The presence of these compounds in foods is linked to the potential cross-contamination of some cereal-growing areas by plants of the Solanaceae family, like Datura species, leading to presence of tropane alkaloids (secondary plant metabolites) into some of the cereal flours.

As the use of herbicides to prevent this cross-contamination is limited by strict pesticide residue limits in foods for infants and young children, and because the mechanical separation of Datura seeds is difficult because they are the same weight and color as those of sorghum or millet, it is not possible to completely prevent the residual presence of Solanaceae seeds, and therefore tropane alkaloids, in these flours.

SNE welcomes the EFSA scientific evaluation of these substances in advance of a regulatory decision on acceptable residual levels. SNE is however concerned by the fact that, as highlighted by EFSA itself, this evaluation was influenced by the lack of occurrence data and consumption data relevant to the available occurrence data, meaning that the exposure of young children was estimated on the basis of only two national surveys. In addition, none of the methods used for analysis of tropane alkaloids have been fully validated by inter-laboratory studies, and no certified reference materials or proficiency studies are currently available.

The survey initiated by SNE in 2014 confirms the data gathered by EFSA, which indicates that amongst 323 cereal flours analysed, the most significant cross-contamination risks are with 5% of the cereal flours, i.e. sorghum and millet flours. Other industry data indicate that buckwheat flours may also be contaminated.

Sorghum, millet or buckwheat are minor ingredients in the category of cereal-based foods for infants and young children. According to data provided by one SNE member, sorghum and/or millet-containing cereal-based foods for infants and young children represent less than 7% of the total volume of infant cereals sold in Europe by this company, when several other companies do not use them at all. Three SNE members indicated the sum of sorghum, buckwheat or millet content of the products never exceeds 2.5% of their composition.

As a consequence, the exposure of infant and young child consumers is expected to be quite limited. However, as SNE takes all potential safety concerns very seriously, our members are in favour of setting an Indicative Value\(^1\) of 250 ppb for tropane alkaloids (sum of hyoscyamine and scopolamine) in the sorghum, millet and buckwheat used to manufacture cereal-based foods for infants and young children. Setting such an indicative value would discard the use of the most contaminated samples amongst those cereal flours found to be positive according to the SNE survey, leading to a significant minimisation step of the exposure.

This indicative value will drive cereal suppliers to implement better preventive measures at field level and work on improved mechanical sorting means, while further protecting the population group at most risk of exposure to tropane alkaloids. This level could then be reviewed at a later stage, with the progress in preventive measures and in sorting performance, and also the availability of fully-validated analytical methods.

**Note:**

SNE is the EU Trade association representing the specialised nutrition industry across the European Union. SNE members are the national associations of 17 EU Member States and their members are the companies producing foods for particular nutritional needs, known at EU level as 'foods for specific groups', including the foods specifically intended for infants and young children.

SNE members provide tailor made dietary solutions for populations with very specific nutritional needs including infants and young children, individuals under medical supervision, sportsmen, overweight and obese consumers, and those suffering from coeliac disease.