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European Food Safety Authority (EFSA) Safety Assessment of Food Additives: Data and Methodology Used for the Assessment of Dietary Exposure for Different European Countries and Population Groups

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Abstract : Objectives: To assess chronic dietary exposure to food additives in different European countries and population groups. Method and Design: The European Food Safety Authority's (EFSA) Panel on Food Additives and Nutrient Sources added to Food (ANS) estimates chronic dietary exposure to food additives with the purpose of re-evaluating food additives that were previously authorized in Europe. For this, EFSA uses concentration values (usage and/or analytical occurrence data) reported through regular public calls for data by food industry and European countries. These are combined, at individual level, with national food consumption data from the EFSA Comprehensive European Food Consumption Database including data from 33 dietary surveys from 19 European countries and considering six different population groups (infants, toddlers, children, adolescents, adults and the elderly). EFSA ANS Panel estimates dietary exposure for each individual in the EFSA Comprehensive Database by combining the occurrence levels per food group with their corresponding consumption amount per kg body weight. An individual average exposure per day is calculated, resulting in distributions of individual exposures per survey and population group. Based on these distributions, the average and 95th percentile of exposure is calculated per survey and per population group. Dietary exposure is assessed based on two different sets of data: (a) Maximum permitted levels (MPLs) of use set down in the EU legislation (defined as regulatory maximum level exposure assessment scenario) and (b) usage levels and/or analytical occurrence data (defined as refined exposure assessment scenario). The refined exposure assessment scenario is sub-divided into the brand-loyal consumer scenario and the non-brand-loyal consumer scenario. For the brand-loyal consumer scenario, the consumer is considered to be exposed on long-term basis to the highest reported usage/analytical level for one food group, and at the mean level for the remaining food groups. For the non-brand-loyal consumer scenario, the consumer is considered to be exposed on long-term basis to the mean reported usage/analytical level for all food groups. An additional exposure from sources other than direct addition of food additives (i.e. natural presence, contaminants, and carriers of food additives) is also estimated, as appropriate. Results: Since 2014, this methodology has been applied in about 30 food additive exposure assessments conducted as part of scientific opinions of the EFSA ANS Panel. For example, under the non-brand-loyal scenario, the highest 95th percentile of exposure to α-tocopherol (E 307) and ammonium phosphatides (E 442) was estimated in toddlers up to 5.9 and 8.7 mg/kg body weight/day, respectively. The same estimates under the brand-loyal scenario in toddlers resulted in exposures of 8.1 and 20.7 mg/kg body weight/day, respectively. For the regulatory maximum level exposure assessment scenario, the highest 95th percentile of exposure to α-tocopherol (E 307) and ammonium phosphatides (E 442) was estimated in toddlers up to 11.9 and 30.3 mg/kg body weight/day, respectively. Conclusions: Detailed and up-to-date information on food additive concentration values (usage and/or analytical occurrence data) and food consumption data enable the assessment of chronic dietary exposure to food additives to more realistic levels.

Keywords : α-tocopherol, ammonium phosphatides, dietary exposure assessment, European Food Safety Authority, food additives, food consumption data
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