

Potential Consumer Exposures to Certain Low Calorie Sweeteners

Project Update 14-10-18

Sweetener Usage Survey

FoodDrinkEurope has completed a round of data collection and the data have been analysed to identify a typical and maximum use level for each approved food category. Reported typical values were averaged for each category and the highest reported use level was adopted as the maximum. Values for the category 14.1.4.2 Flavoured drinks (only energy reduced or with no added sugar) were merged with data for the same category provided by UNESDA. Data for category 11.4.2 Table top sweeteners in powder form were provided by ISA and used to represent all tabletop use levels in accordance with ISA proposals for exposure assessment. Since nectars are known to contain non-nutritive sweeteners and the Mintel GNPD shows over 5% of product contain them, it has been assumed that use levels are identical to flavoured drinks with sweeteners. All values were tabulated with MPL values and data on percentage occurrence taken from the Mintel GNPD database (see Usage Master 11-10-18.xls attached).

Although data were provided for most important categories, there were several categories where the Mintel GNPD indicated limited but where FDE members were unable to provide use levels. Previous examples of EFSA ANS Panel Opinions have shown that in this situation the Panel has assumed either the MPL or analytical values if available. This can result in potential consumer exposures exceeding ADIs because there is relatively high consumption relating to some of these categories. The Mintel GNPD has been studied to identify food and drink products where frequencies of occurrence are very low. These generally correspond to niche usages where foods are likely to be consumed by particular population groups who are not representative of the general population. As a consequence it is proposed that food categories where the GNPD indicates usage of 1% or less should be regarded as niche applications and excluded from exposure estimates for the general population. It must be stressed that this is not the EFSA ANS Panel's current approach and so may under-estimate exposure estimates produced by the Panel.

The data provided in Usage Master 11-10-18.xls have been run through the EFSA FAIM 2 maximum model under three scenarios:

1. Worst case scenario: Assumes that all categories where no data are provided (except beers) contain MPL. All other use levels are the maximum reported.
2. Niche/max scenario: Assumes that all categories where GNPD occurrence is less than 1% are niche products and for general population use level in these categories is zero. All other use levels are the maximum reported.
3. Niche/brand-loyal scenario: Assumes that all categories where GNPD occurrence is less than 1% are niche products and for general population use level in these

categories is zero. The category contributing most to average intakes is set at the maximum reported use level, whilst all other use levels are the typical reported. This represents a simulation of the method used internally by EFSA to estimate intakes of brand-loyal consumers.

The population groups with the highest consumption can be identified from the niche/max scenario using the FAIM 2.0 model. The foods contributing most to average intakes for these groups can also be identified. These factors can then be used to define the parameters for the niche/brand-loyal scenario. It is considered unlikely that the ASN Panel would consider the non-brand-loyal scenario in this situation.

Acesulfame K: ADI=9

Scenario 1: Worst case scenario

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	1.850	8.196	16.274	21.574
Toddlers	8.318	18.489	14.134	28.714
Other children	5.654	15.539	11.820	27.554
Adolescents	3.116	9.168	6.270	16.876
Adults	1.518	5.267	3.968	10.960
Elderly and very elderly	1.555	6.371	4.175	12.888

Main sources of exposure: Processed fruit and vegetables, fine bakery wares, breakfast cereals,

Scenario 2: Niche/max scenario

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.008	0.820	0.000	4.560
Toddlers	0.809	4.313	3.061	12.027
Other children	0.191	3.683	1.215	10.162
Adolescents	0.056	2.241	0.473	6.160
Adults	0.015	1.147	0.102	3.875
Elderly and very elderly	0.006	0.639	0.000	1.826

Groups with highest total exposure: Toddlers/Netherlands and Other children/Netherlands

Main source of exposure: Flavoured fermented milk products.

Scenario 3: Niche/brand-loyal scenario

Assuming Flavoured fermented milk products are the main source of exposure:

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.008	0.740	0.000	4.117
Toddlers	0.565	3.194	2.336	11.210
Other children	0.114	2.834	0.847	9.077
Adolescents	0.029	1.263	0.230	3.766
Adults	0.011	0.635	0.071	2.115
Elderly and very elderly	0.003	0.381	0.000	1.271

Groups with highest total exposure: Toddlers/Netherlands and Other children/Netherlands. All other population groups were less than 9 mg/kg bw/day.

Cyclamates: ADI = 7

Scenario 1: Worst case scenario

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	1.164	5.959	6.327	16.466
Toddlers	2.989	10.178	6.965	17.345
Other children	1.467	7.644	4.093	15.089
Adolescents	0.749	4.275	2.201	8.915
Adults	0.698	2.699	1.719	6.280
Elderly and very elderly	0.914	3.151	2.696	7.417

Main source of high exposures: Processed fruit and vegetables

Scenario 2: Niche/max scenario

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.000	0.256	0.000	1.838
Toddlers	0.004	1.552	0.000	3.497
Other children	0.040	1.788	0.160	5.413
Adolescents	0.013	1.265	0.037	3.886
Adults	0.016	0.730	0.000	3.103
Elderly and very elderly	0.003	0.601	0.000	3.955

Groups with highest total exposure: Other children/Netherlands

Main sources of exposure: Flavoured drinks with sweetener (69.2%); Desserts (56.1%)

Scenario 3: Niche/brand-loyal scenario

Assuming Flavoured drinks with sweetener are main source of exposure:

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.000	0.211	0.000	1.515
Toddlers	0.004	1.552	0.000	3.224
Other children	0.036	1.757	0.160	5.129
Adolescents	0.012	1.240	0.037	3.858
Adults	0.015	0.716	0.000	3.103
Elderly and very elderly	0.003	0.601	0.000	3.955

Group with highest total exposure: Other children/Netherlands.

Assuming Desserts are main source of exposure:

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.000	0.211	0.000	1.515
Toddlers	0.004	1.379	0.000	3.224
Other children	0.035	1.539	0.160	4.604
Adolescents	0.012	1.079	0.037	3.285
Adults	0.015	0.635	0.000	2.900
Elderly and very elderly	0.003	0.594	0.000	3.867

Group with highest total exposure: Other children/Netherlands.

Saccharin: ADI=5

Scenario 1: Worst case scenario

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.368	1.264	0.874	4.974
Toddlers	1.040	4.495	2.419	8.301
Other children	0.484	3.854	1.245	8.395
Adolescents	0.356	2.260	0.888	4.889
Adults	0.226	1.361	0.669	3.705
Elderly and very elderly	0.249	1.274	0.695	3.047

Main sources of high exposures: Processed fruit and vegetables, Fine bakery wares

Scenario 2: Niche/max scenario

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.000	0.082	0.000	0.588
Toddlers	0.002	0.552	0.000	1.265
Other children	0.014	0.601	0.064	1.777
Adolescents	0.005	0.420	0.020	1.277
Adults	0.005	0.243	0.000	0.993
Elderly and very elderly	0.001	0.201	0.000	1.273

Groups with highest total exposure: Toddlers/Netherlands and Other children/Netherlands

Main source of exposure: Toddlers: Desserts (77.7%), Other children: Flavoured drinks with sweetener (65.9%), Desserts (61.4%).

Scenario 3: Niche/Brand-loyal scenario

Assuming Flavoured drinks with sweetener are main source of exposure:

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.000	0.064	0.000	0.463
Toddlers	0.000	0.321	0.000	0.881
Other children	0.002	0.449	0.000	1.531
Adolescents	0.000	0.337	0.000	1.173
Adults	0.003	0.188	0.000	0.874
Elderly and very elderly	0.001	0.124	0.000	0.897

Group with highest total exposure: Other children/Netherlands.

Assuming Desserts are main source of exposure:

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.000	0.064	0.000	0.463
Toddlers	0.002	0.483	0.000	1.220
Other children	0.012	0.501	0.064	1.411
Adolescents	0.004	0.344	0.020	1.015
Adults	0.004	0.197	0.000	0.760
Elderly and very elderly	0.001	0.145	0.000	0.864

Group with highest total exposure: Other children/Netherlands.

Sucralose: ADI = 15

Scenario 1: Worst case scenario

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.868	3.657	6.477	9.643
Toddlers	4.155	10.195	8.363	19.209
Other children	2.618	8.359	5.858	16.483
Adolescents	1.455	4.712	3.215	9.894
Adults	0.661	2.611	1.705	5.770
Elderly and very elderly	0.641	2.674	1.733	5.155

Main sources of high exposures: Processed fruit and vegetables, Fine bakery wares

Scenario 2: Niche/max scenario

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.009	0.937	0.000	5.212
Toddlers	0.913	4.652	3.279	13.584
Other children	0.298	3.937	1.409	11.536
Adolescents	0.060	2.234	0.521	6.301
Adults	0.014	1.137	0.117	3.735
Elderly and very elderly	0.005	0.646	0.000	1.872

Groups with highest total exposure: Toddlers/Netherlands and Other children/Netherlands

Main source of exposure: 01.4 Flavoured fermented milk products (67.9%)

Scenario 3: Niche/brand-loyal scenario

Assuming Flavoured fermented milk products are main source of exposure:

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.009	0.843	0.000	4.680
Toddlers	0.617	3.610	2.599	12.811
Other children	0.125	3.194	0.968	10.374
Adolescents	0.032	1.353	0.239	4.062
Adults	0.011	0.677	0.079	2.280
Elderly and very elderly	0.003	0.408	0.000	1.313

Group with highest total exposure: Toddlers/Netherlands.

Thaumatococcus: ADI = N.S.

Scenario 1: Worst case scenario

the worst case scenario for thaumatococcus is based on MPL values because no usage data, apart from TTS, were supplied.

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.002	0.019	0.006	0.089
Toddlers	0.018	0.099	0.100	0.277
Other children	0.020	0.098	0.057	0.277
Adolescents	0.012	0.040	0.040	0.119
Adults	0.005	0.024	0.024	0.075
Elderly and very elderly	0.002	0.026	0.010	0.058

Main sources of exposure: edible ices, cocoa and chocolate products and fermented flavoured milk products.

Scenarios 2 & 3: Niche/max/brand-loyal scenario

The Mintel GNPD indicated use of thaumatin only in 'artificial sweeteners' (3.7%), 'carbonated beverages' (0.2%), 'energy drinks' (0.1%), 'gum' (0.9%), 'meal replacements and other drinks' (0.4%), 'other natural sweeteners' (1.2%), 'pastilles, gums, jellies & chews' (0.1%), 'snack/cereal/energy bars (<0.1%) and sucrose (0.1%). Uses are thus effectively niche in all categories except tabletop sweeteners. This means that scenarios 2 and 3 will yield the same results.

No concentration data were available for Thaumatin in powder TTS and so the value for tablet form products (100 mg/kg) was applied in the model:

Population Group	Min Average	Max Average	Min 95th	Max 95th
Infants	0.0000	0.0000	0.0000	0.0000
Toddlers	0.0000	0.0000	0.0000	0.0000
Other children	0.0000	0.0003	0.0000	0.0000
Adolescents	0.0000	0.0001	0.0000	0.0001
Adults	0.0000	0.0004	0.0000	0.0025
Elderly and very elderly	0.0000	0.0006	0.0000	0.0043

Group with highest total exposure: Elderly & very elderly/Belgium.

Source of exposure: 11.4 Table top sweeteners (100%)

Conclusion

Sweetener use levels data provided by FDE do not cover all categories where sweeteners are approved and in particular specific categories where the Mintel GNPD has identified uses from labels. If these data gaps are allowed to remain, EFSA is likely to insert MPL values resulting in exposures under Scenario 1. This would lead to apparent exceedances of ADIs.

If it can be assumed that for food categories where there are data gaps and where frequencies of occurrence in GNPD are very low (<1%) use levels are effectively zero (Scenario 2), then maximum intakes are significantly reduced. Further small reductions are seen of the typical use levels data are incorporated into a simulated brand-loyal exposure scenario (Scenario 3). It seems unlikely that the ANS Panel would contemplate using the non-brand-loyal scenario in this case.

The consumer groups that consistently lie at the highest levels in every exposure scenario are Toddlers and Other children in the Netherlands. These groups appear to have significantly higher high level consumption of non-alcoholic beverages (with sugar or with sweeteners), desserts and Flavoured fermented milk products than any other European population. These data are drawn from the Dutch DNFCs-Young-Children 2005/2006 survey and are summarised in the EFSA Comprehensive European Food Consumption Database. A new Dutch food consumption survey has been recently published¹, although these data do not they appear in the FAIM 2.0 or Comprehensive Food Consumption Database. Further investigations into the 2005/2006 Dutch data and comparisons with 2012-2016 data are recommended.

David Tennant

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ⁱ National Institute for Public Health and the Environment, C. van Rossum, K. Nelis, C. Wilson, M. Ocké, 2018. National dietary survey in 2012-2016 on the general population aged 1-79 years in the Netherlands. EFSA supporting publication 2018:EN-1488. 25 pp. 10.2903/sp.efsa.2018.EN-1488