COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

First draft statement on potential risks from acrylamide in the diet of infants and young children

Introduction

1. The Committee on Toxicity (COT) has been asked to consider the toxicity of chemicals in the diet of infants and young children aged 1-5 years, in support of a review by the Scientific Advisory Committee on Nutrition (SACN) of Government recommendations on complementary and young child feeding. A scoping paper (TOX/2015/32), highlighting some of the chemicals for possible consideration for the diet of young children aged 1-5 years was discussed by the COT in October 2015. Members concluded that an evaluation of acrylamide should be performed.

2. A discussion paper on acrylamide (TOX/2016/12) was presented to Members in April 2016. This discussion paper provided provisional exposure estimates to acrylamide in infants and young children using the interim concentrations identified in the 27 food groups of the 2014 Total Diet Study (TDS), and provisional estimates of margins of exposure (MOEs) to the benchmark dose lower confidence limit for a 10% extra incidence of tumours ($BMDL_{10}$) estimated by the European Food Safety Authority (EFSA). The TDS indicated that potatoes, snacks and miscellaneous cereal groups were the main contributors to total dietary exposure to acrylamide. It was agreed that future exposure estimates conducted using the 2014 TDS should be refined further and expressed in terms of the main contributing subgroups forming each food group. The COT requested further explanations for the types of foods considered by EFSA in their exposure assessment, and whether the submitted data to EFSA was for food as purchased, or as eaten.

3. Members requested that a draft statement include some brief discussion of other sources of exposure. Exposure to acrylamide could also occur from tobacco smoke, including environmental tobacco smoke, but since acrylamide was unstable in soil and water exposure from these sources was unlikely.

4. Members agreed that advice from the COC should be sought about the interpretation of the MOEs in infants and young children. These MOEs were derived from relatively short periods of increased exposure to a genotoxic carcinogen, rather than reflecting average life-time exposure. However, it was also possible that these life stages were of increased susceptibility to acrylamide.

New information

5. Exposures have been recalculated after confirmation of the analytical results. Further consideration of the occurrence data from the TDS indicated that the low levels of acrylamide measured in green vegetables, fresh fruits, milk and dairy products groups were unreliable. Acrylamide is a process contaminant and is not present in raw foods such as raw fruit and boiled green vegetables and is unlikely to occur in significant quantities in milk and dairy products. Thus, the original measured values of acrylamide in green vegetables, fresh fruits, milk and dairy products groups (ranging from 6 to 9 µg/kg) were replaced with a concentration value of 1 µg/kg (the limit of detection) in the exposure assessments. This change had a minimal impact on the exposure assessments that were presented originally in TOX/2016/12.

6. Potatoes and miscellaneous cereal groups were generally the main contributors to total dietary exposure to acrylamide, accounting for up to 40% and 20% respectively in 4 to 12 months olds; 40% and 26% respectively in 12 to 18 month olds and 36% and 26% respectively in 18 to 60 month olds. The exposure to the next contributing food group in infants (other vegetables group) and young children (non-alcoholic beverages and snacks groups) were not refined further as their contribution to total dietary exposure was less than 10%. Thus, only the exposure estimates from the potatoes and miscellaneous cereal groups were refined further and expressed in terms of their contributing subgroups (see Table A below). The main contributing subgroup to exposure from the potatoes food group was 'fresh potatoes' which includes deep fried and roasted potatoes. For the miscellaneous cereal food group, the main contributing subgroup was breakfast cereals followed by sweet biscuits. .

Table A. Estimated **acrylamide** exposures (**µg/kg bw/day)** from the 2014 TDS in infants and young children aged 4 to 60 months

Food groups/ sub groups (concentration, µg/kg)	**4 to <12 month-olds (n=1408)**		**12 to <18 month-olds (n=1275)**		**18 to <60 month-olds (n=499)**	
	Mean	**97.5 percentile**	**Mean**	**97.5 percentile**	**Mean**	**97.5 percentile**
Potatoes group (181)	0.41	1.8	0.61	2.1	0.55	1.6
Sub group: Fresh potatoes including, deep-fried & roasted (183)	0.37	1.7	0.47	1.8	0.31	1.3
Sub group: Potato products: including, takeaway chips & instant potato (126)	0.029	0.33	0.10	0.57	0.16	0.58
Misc cereals group (65)	0.20	0.80	0.40	1.2	0.40	0.98

Sub group: Buns cakes and pastries (22)	0.0027	0.031	0.0087	0.059	0.013	0.071
Sub group: Savoury biscuits (203)	0.0051	0.071	0.017	0.16	0.019	0.15
Sub group: Sweet biscuits (289)	0.031	0.27	0.10	0.52	0.12	0.51
Sub group: Chocolate biscuits (246)	0.0026	0.0019	0.012	0.16	0.032	0.21
Sub group: Breakfast cereals (60)	0.068	0.35	0.11	0.43	0.090	0.32
Sub group: Other cereal products (5)	0.0083	0.50	0.016	0.067	0.014	0.050
Sub group: Pizza (15)	0.00051	0.0065	0.0031	0.036	0.0058	0.037

Rounded to 2 significant figures

7. Members are asked to comment on the draft statement, attached as Annex A.

Secretariat
August 2016

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

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Introduction

1. The Scientific Advisory Committee on Nutrition (SACN) is undertaking a review of scientific evidence that will inform the Government's dietary recommendations for infants and young children. The SACN is examining the nutritional basis of the advice. The Committee on Toxicity in Food, Consumer Products and the Environment (COT) was asked to review the risks of toxicity from chemicals in the diet of infants, most of which has been completed, and young children. The reviews will identify new evidence that has emerged since the Government's recommendations were formulated, and will appraise that evidence to determine whether the advice should be revised. The recommendations cover diet from birth to age five years.

2. This statement gives an overview of the potential risks from acrylamide in the diets of infants (0 to 12 months) and young children (1 to 5 years).

3. There are currently no Government dietary recommendations for infants and young children relating to acrylamide. However, Commission Recommendation 2013/647/EU on investigations into levels of acrylamide in food, specifies Indicative Values and groups of foodstuff to which they apply. Indicative values are not statutory maximum limits and are intended only as a guide to prompt investigation of higher levels to understand how to reduce levels of acrylamide in food. The Indicative Values are to be kept under regular review.

Background

4. Acrylamide forms in starchy food products during high-temperature cooking, including frying, baking, roasting and also industrial processing, at ≥120°C and low moisture. It was first detected in foods in April 2002 although it is likely that it has been present in food since cooking began. Acrylamide also has non-food industrial uses, particularly as polyacrylamide, and is present in tobacco smoke.

5. The key toxicological effects of acrylamide are genotoxicity, carcinogenicity, neurotoxicity and reproductive toxicity. EFSA (2015) concluded that the human data were not sufficient to be used in dose

response assessment. Therefore benchmark dose lower confidence limits (BMDLs) were calculated from the results of studies in rodents, and used in assessing margins of exposure (MOEs).

6. For the carcinogenicity of acrylamide, the European Food Safety Authority (EFSA) calculated a $BMDL_{10}$ (for a 10% increase in incidence of tumours) of 0.17 mg/kg body weight (bw)/day. For effects on the nervous system, EFSA calculated a $BMDL_{10}$ of 0.43 mg/kg bw/day, and concluded that other effects, such as on the reproductive system would only occur at higher doses. Therefore the $BMDL_{10}$ of 0.43 mg/kg body weight/day was used as a reference point for the non-cancer effects of acrylamide. The reproductive toxicity of acrylamide is unlikely to be relevant for the age groups considered in this statement.

7. The COT concluded that possible health risks arising from dietary exposure to acrylamide should be assessed by comparison with the $BMDL_{10}$ of 0.17 mg/kg bw/day for neoplastic effects and 0.43 mg/kg bw/day for non-neoplastic effects such as neurotoxicity. The Committee on Carcinogenicity (COC) advises that an MOE of less than 10,000, based on a $BMDL_{10}$ from an animal study may be a concern (COC, 2012). Interpretation of MOEs for non-neoplastic effects based on a $BMDL_{10}$ from an animal study takes into account the default uncertainty factor of 100 for inter- and intra-species differences and possible additional factors for important gaps in the toxicological database (WHO, 2009). For acrylamide the database is extensive and important gaps have not been identified. Therefore an MOE greater than 100 indicates a lack of concern for neurotoxicity or other non-neoplastic effects.

8. The interpretation of MOEs for children has not been explicitly discussed by COC or EFSA. Publications in the literature generally refer to the MOEs of greater than 10,000 as being a low concern for all age groups. However, it might be argued either that a higher MOE value should be used to allow for potential greater vulnerability of young children, or that a smaller MOE could be a low concern in young children provided that the MOE is greater than 10,000 over a longer period.

Acrylamide exposures in infants aged 0 to 12 months and young children aged 1 to 5 years

Sources of acrylamide exposure

Breast milk

9. A literature search has not identified any data on acrylamide concentrations in breast milk in the UK. Of the available data on European women, those with the most relevant maternal exposure levels (equivalent to about 0.5 µg/kg bw/day), were from a study of 14 individuals and 4 pooled breastmilk samples from non-smoking Swedish mothers. The concentration of acrylamide was below the limit of quantitation (LOQ) of 0.5 µg/kg, except in

one individual sample (0.51 µg/kg) (Fohgelberg *et al*., 2005). Therefore the COT concluded that the LOQ of 0.5 could be used in an upper bound (UB) approach[1] to the exposure assessment.

Food

10. The concentration of acrylamide was measured in the UK 2014 Total Diet Study (TDS) (FSA, 2016). The TDS consisted of selecting foods from 24 UK towns based on food consumption data, preparation of the food as consumed and subsequent pooling of related foods into 27 food groups before analysing the composite samples. The food groups investigated in the TDS were alcoholic drinks, bottled water, bread, canned vegetables, carcase meat, condiments, dairy products, desserts, eggs, fish, fresh fruit, fruit products, green vegetables, meat products, meat substitutes, milk, miscellaneous cereal (e.g. breakfast cereals, biscuits and rice), non-alcoholic drinks, nuts, offal, oils and fat, other vegetables, potatoes, poultry, snacks, sugars and preserves, and tap water. The TDS did not include samples of infant formula or commercially available infant foods.

11. The concentrations of acrylamide in the samples of the 2014 TDS ranged from below the limit of detection (1.0 µg/kg) to 360µg/kg. The highest concentrations of acrylamide were found in the snacks (360 µg/kg), potatoes (180 µg/kg) and miscellaneous cereals (65 µg/kg) food groups. Low levels of acrylamide (between 3 to 9 µg/kg) were initially found in green vegetable, fresh fruits, milk and dairy products groups. Acrylamide is a process contaminant and is not present in raw foods such as raw fruit and boiled green vegetables and is unlikely to occur in significant quantities in milk and dairy products. Therefore this finding was considered to be unreliable, for example as a consequence of possible low level contamination. Thus, acrylamide was assumed to be present at the limit of detection (LOD) (1 µg/kg) in these food groups in the reported exposure assessments.

12. EFSA (2015) evaluated a total of 43 419 analytical results from food commodities collected and analysed since 2010 and reported by 24 European countries including the UK. The food items considered by EFSA in their exposure assessment included occurrence data on a range of foods as purchased, and as consumed such as, potato fried products, potato crisps and snacks, coffee, bread and baby foods. Of the data on infant formula submitted to EFSA by Member States, 97% were affected by left censoring, i.e. the values were below the LOQ or LOD.

Non-food sources

13. Drinking water treated with polyacrylamides as flocculants can contain residual acrylamide. There is a regulatory limit for acrylamide of 0.1 µg/L for drinking water in the UK.

[1] The upper bound (UB) approach uses the value of the LOQ or LOD concentration for data that were < LOQ/LOD. The lower bound (LB) approach uses the value zero for data that were < LOQ/LOD

14. The use of acrylamide as a grouting agent can cause the contamination of ground water and soil. However, acrylamide is not considered to be highly persistent in the environment. Available data indicate that concentrations of acrylamide in the atmosphere are very low, and when present, its low vapour pressure makes it unlikely that acrylamide will be transported in the atmosphere.

15. Acrylamide is also present in tobacco smoke. EFSA (2015) concluded that tobacco smoking represents a more prominent source of acrylamide exposure than the diet in smokers. However, there is a lack of information on possible exposure of infants and young children from environmental tobacco smoke.

Exposure assessment

16. Consumption data from the Diet and Nutrition Survey of Infants and Young Children (DNSIYC) (DH, 2013), and from years 1-4 of the National Diet and Nutrition Survey Rolling Programme (NDNS) (Bates *et al*., 2014) have been used for the estimation of dietary exposures. Bodyweight data used in the estimation of exposures are shown in Table 1 below. Exposures of UK infants and young children from soil, water and air as additional potential sources of acrylamide exposure have not been estimated as they are likely to be low in comparison to dietary exposure.

Table 1. Average bodyweights used in the exposure estimations

Age group (months)	Bodyweight (kg)
0 to <4	5.9[a]
4 to <6	7.8[b]
6 to <9	8.7[b]
9 to <12	9.6[b]
12 to <15	10.6[b]
15 to <18	11.2[b]
18 to <24	12.0[c]
24 to <60	16.1[c]

[a] *DH, 1994.*
[b] *DH, 2013.*
[c] *Bates et al., 2014*

Exposure from breast milk

17. The LOQ (0.5 µg/kg) from the study of Fohgelberg *et al*. (2005) has been used in an UB approach to estimate possible exposure from breast milk, based on the assumption of exclusive breastfeeding for 6 months and using data on breast milk consumption for infants aged 6 to 18 months. There were too few records of breast milk consumption for children older than 18 months

in the NDNS to allow a reliable exposure assessment, and breast milk is expected to contribute minimally in this age group. This approach indicates that exposure is likely to be less than 0.10 µg/kg bw/day (Table 2).

Table 2. Estimated UB acrylamide exposure from breastmilk based on LOQ of 0.5 µg/kg.

Consumers	Exposure (µg/kg bw/day) by age group (months)					
	0 to <4[a]	4 to <6[a]	6 to <9[b]	9 to <12[b]	12 to <15[b]	15 to <18[b]
Mean	0.068	0.051	0.033	0.019	0.015	0.013
High level	0.10	0.077	0.080	0.058	0.038	0.026

[a] *Mean and high level exposures were based on exclusive breastfeeding and consumption of 800 and 1200mL of milk for mean and high level, respectively.*
[b] *Consumption data from DNSYIC: high level is 97.5th percentile.*

Exposure from infant formula

18. Exposure estimates for infant formula were derived using occurrence data reported in EFSA (2015). Mean LB and UB concentrations of 3 µg/kg and 26 µg/kg, respectively, reported by other European countries for dry formula are used for estimation of exposure for 0 to 6 month old infants exclusively fed infant formula. These concentrations reported for dry formula are equivalent to 0.45 µg/L and 3.9 µg/L respectively in reconstituted formula, based on the assumption that ready-to-drink infant formula contains 15% dry formula. An additional contribution from the water used in reconstitution was not included because acrylamide was not detected in drinking water in the TDS, and should not exceed the regulatory limit of 0.1 µg/L. Estimated exposure to acrylamide ranged from 0.046 to 0.79 µg/kg bw/day (Table 3).

Table 3. Estimated exposures to acrylamide from exclusive feeding on infant formula

Consumers	LB-UB[a] exposure (µg/kg bw/day) by age group (months)	
	0 to <4	4 to <6
Mean[b]	0.061 - 0.53	0.046 - 0.40
High level[b]	0.092 - 0.79	0.069 - 0.60

[a] *Exposure based on LB and UB concentrations of* 0.45 and 3.9 µg/L*, respectively, in dry infant formula.*
[b] *Mean and high level exposures were based on exclusive feeding on infant formula and consumption of 800 and 1,200mL, respectively*.

Food

19. Exposure estimates based on data from the 2014 TDS are presented only as UB, because the few food groups with concentrations below the LOQ or the LOD (bottled water, tap water, oils and fats, carcase meat, dairy products, milk, green vegetables and fresh fruits) had a minimal impact on the total dietary exposure. Table 4 summarises the total dietary exposure to acrylamide estimated for infants and young children. The total mean and 97.5th percentile exposures to acrylamide from a combination of all food groups in the 2014 TDS ranged from 0.30-0.95 µg/kg bw/day and 1.4-2.7µg/kg bw/day, respectively in infants, and from 1.2 -1.3 µg/kg bw/day and 2.3-3.2 µg/kg bw/day, respectively in children aged 1 to 5 years.

Table 4. Estimated dietary acrylamide exposures from food

	UB dietary exposure (µg/kg bw/day) from food by age group (months)						
Consumers	**4-<6 (n=116)**	**6-<9 (n=606)**	**9-<12 (n=686)**	**12-<15 (n=670)**	**15-<18 (n=605)**	**18-<24 (n=70)**	**24-<60 (n=429)**
Mean	0.30	0.64	0.95	1.2	1.3	1.3	1.3
97.5th percentile	1.4	2.2	2.7	3.2	2.9	2.3	2.6

20. The groups that made the highest contribution to total mean exposure were in the order potatoes > other vegetables > miscellaneous cereals for 4 to 6 month old infants and potato > miscellaneous cereals > other vegetables in 6 to 12 month old infants. The exposure to the next contributing food group (other vegetables group) was less than 10% of total. The contribution of potatoes and miscellaneous cereals groups to total dietary exposure in infants amounted to 40 and 20% respectively. The main contributing subgroup to mean exposure from the potatoes food group for infants was 'fresh potatoes' which includes deep fried potatoes. For the miscellaneous cereal food group, the main contributing subgroup was breakfast cereals followed by sweet biscuits.

21. The groups that made the highest contribution to total mean exposure for young children were in the order potatoes > miscellaneous cereals > non-alcoholic beverages> snacks. Mean exposure from the potato and miscellaneous cereals groups were up to 40 and 26% of total exposure in this age group. The exposure to each of the next contributing food groups (non-alcoholic beverages and snacks groups) was less than 10% of total. As noted for infants, the potato subgroup containing fried potatoes and the miscellaneous cereals sub groups containing breakfast cereals and sweet biscuits made the highest contribution to mean exposure from the potato and miscellaneous cereal food groups in 12 to 60 month old children.

Previous estimates of dietary acrylamide exposure

22. Exposures estimated from the 2014 TDS were also calculated in the age range 1.5 to <4 year old young children (toddlers) for comparison with the exposure assessments that were reported previously based on the 2005 TDS data (FSA, 2005) for children in a similar age range (1.5 to 4.5 year old). The mean and 97.5th percentile exposure estimated for toddlers using the 2014 TDS were 1.3 and 2.6 µg/kg bw/day), respectively, compared to 1.0 and 1.8 µg/kg bw/day, respectively derived from 2005 TDS. The 2005 TDS data indicated that potatoes and cereal-based products were the main contributors to total dietary exposure in the UK, which is in line with the 2014 TDS assessments.

23. The 2005 TDS comprised 20 groups compared with the 27 investigated in the 2014 TDS. For the 2014 TDS alcoholic and non-alcoholic beverages were in separate groups and there were the following additional groups: meat substitutes, snacks, desserts, condiments, tap water and bottled water. A like for like comparison of food groups between survey years should be treated with caution. The food categories comprising the food groups in 2014 TDS are not identical to the 2005 TDS in some cases and there were some differences in cooking and preparation methods. For example the 2014 Potato group included fried products whilst the 2005 Potato group did not. Thus, although this comparison does not provide evidence of a major change in exposure, it is not possible to draw firm conclusions on any temporal trends in the level of exposure to acrylamide. EFSA (2015) noted that data submitted by the food industry showed a substantial decrease in the acrylamide levels in fresh sliced potato crisp for the years 2002 to 2011, but that a downward trend was not observed for other food categories. A reliable Europe-wide temporal trend analysis was not feasible due to gaps in the databases and because the results for different years were not always comparable.

24. Dietary exposure to acrylamide was reported by EFSA (2015), based on occurrence data collected throughout Europe and consumption data for a large number of European countries. Baseline exposure to acrylamide reported by EFSA for the UK infants, toddlers (≥ 1 year to < 3 years old), older children and adults was within the range of values reported for other countries. The mean and 97.5th percentile baseline exposure estimated for infants in all countries ranged from 0.5 -1.6 and 1.4 - 2.5 µg/kg bw/day, respectively. Baseline mean and 97.5th percentile exposure reported by EFSA for the UK infants, ranged from 0.8 -1.1 and 1.8 - 2.1 µg/kg bw/day, respectively. For toddlers, the mean and 97.5th percentile baseline exposure for all countries ranged from 0.9 -1.9 and 1.4 - 3.4 µg/kg bw/day, respectively; mean and 97.5th percentile exposures reported by EFSA for UK toddlers' ranged from 1.4 -1.5 and 2.6 - 2.8 µg/kg bw/day, respectively.

Risk characterisation

25. The possible health risks arising from dietary exposure to acrylamide are assessed by comparison with the $BMDL_{10}$ of 0.17 mg/kg bw/day for

neoplastic effects and 0.43 mg/kg bw/day for non-neoplastic effects such as neurotoxicity.

26. Dividing the $BMDL_{10}$ for neoplastic effects by the highest UB exposure estimate from exclusive breastfeeding (0.10 µg/kg bw/day) indicates an MOE of greater than 1700. However the actual MOE might be very much larger since this is based on the UB estimate, and this comparison is not informative. For non-neoplastic effects the MOE is greater than 4000 which does not indicate a concern.

27. For exclusive feeding on infant formula, the highest estimated LB-UB exposure was 0.092-0.79 µg/kg bw/day. The MOE for neoplastic effects is 2000 or less, indicating a concern. For non-neoplastic effects the MOE is greater than 500 which does not indicate a concern.

28. For mean and high level exposure from food of infants and young children in all age groups the MOEs for neoplastic effects based on a UB approach range from 50 to 600 which is low for a chemical that is genotoxic and carcinogenic. Use of a LB approach has a minimal impact on the estimated exposure due to the small number of food groups with levels below the LOD, demonstrating low uncertainty in the exposure estimations compared to many other food contaminants. For non-neoplastic effects the MOEs are all greater than 100 and do not indicate a concern.

29. Dietary acrylamide exposure of infants and young children in the UK is similar to that in other European countries, and therefore not dependent on particular aspects of UK dietary habits. There have been efforts to reduce concentrations of acrylamide in food over recent years, but the evidence so far is not sufficient to demonstrate whether there has been a decrease in dietary exposure.

30. Exposure to acrylamide from soil, water and air are likely to be low in comparison to dietary exposure. Exposure of smokers to acrylamide from tobacco smoke can exceed dietary exposure, however there is a lack of information on potential exposure of infants and young children from passive smoking.

Conclusions

31. Acrylamide forms in starchy food products during high-temperature cooking. It also has non-food industrial uses, particularly as polyacrylamide, and is present in tobacco smoke.

32. The key toxicological effects of acrylamide are genotoxicity, carcinogenicity, neurotoxicity and reproductive toxicity, although the latter is unlikely to be relevant for infants and young children. The COT concluded that possible health risks arising from dietary exposure to acrylamide should be assessed by comparison with reference points of 0.17 mg/kg bw/day for

neoplastic effects and 0.43 mg/kg bw/day for non-neoplastic effects such as neurotoxicity, using a margin of exposure (MOE) approach.

33. The MOEs calculated for exposure of infants and young children to acrylamide from infant formula and food compared to the reference point for carcinogenicity are low, indicating a concern. The MOEs do not suggest a concern for other health effects such as neurotoxicity.

34. The major sources of dietary exposure include potatoes (particularly fried potatoes), other vegetables and cereals (such as breakfast cereals and sweet biscuits). Dietary acrylamide exposure of infants and young children in the UK is similar to that in other European countries, and therefore not dependent on particular aspects of UK dietary habits. There have been efforts to reduce concentrations of acrylamide in food over recent years, but the evidence so far is not sufficient to demonstrate whether there has been a decrease in dietary exposure.

35. Exposure of infants and young children to acrylamide from soil, water and air are likely to be low in comparison to dietary exposure. Exposure of smokers to acrylamide from tobacco smoke can exceed dietary exposure, however there is a lack of information on potential exposure of infants and young children from passive smoking.

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