Annex A

Committee on carcinogenicity of chemicals in food, consumer products and the environment

Exposure data related to the consumption levels of hydroxyanthracene derivatives.

This section provides a summary of the available information regarding the dietary and cosmetic exposure to hydroxyanthracene derivatives.

Secretariat

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Exposure Data

- 1. Following a request to industry, the CRN UK provided the following information regarding exposure in food, aloe drinks and cosmetics.
- 2. Dietary exposure data for HADs are presented in Table 1. The food commodity that results in the highest level of HADs is dried thyme, with a sum of HADs measured at 303.5 mg/kg.

Table 1. Reported concentration of HADs in Foodstuffs

Food Description [Latin name, if reported], plant parts (form)	Reported median (min to max) Emodin concentrations (mg/kg)	Reported median (min to max) Chrysophanol concentrations (mg/kg)	Reported median (min to max) Physcion concentrations (mg/kg)	Reported median (min to max) Summed/ Unspecified concentration s (mg/kg)	Reference	Comments
Cabbage Lettuce [Latuca sativa var. capitata cv.] (fresh)	0.025 (0.02 to 0.03)	0.02 (0.01 to 0.03)	2.92 (0.03 to 5.8)	2.98 (0.06 to 5.9)	Mueller et al (1999) ^b	All types of lettuce (non-iceberg form)
Green Beans [Phaseolus vulgaris] (fresh)	0.04 (0.02 to 0.06)	1.76 (0.02 to 3.5)	16.01 (0.01 to 32)	18.03 (0.05 to 36)	Mueller et al (1999) ^b	Beans that are green in colour (French bean, runner bean, long yard bean)
Garden Peas [Pisum sativum] (fresh)	0.025 (0.02 to 0.03)	not detected	1.81 (0.02 to 3.6)	1.82 (0.04 to 3.6)	Mueller et al (1999) ^b	
Iceberg salad [Latuca sativa var. capitata cv.] (fresh)	< 0.01*	< 0.01*	<0.02*	<0.04*	Mueller et al (1999) ^b	Iceberg lettuce only
Grape vine leaves [Vitis vinifera] (dry herb)	0.15 (0.1 to 0.2)	0.15 (0.1 to 0.2)	0.3 (0.2 to 0.4)	0.6 (0.4 to 0.8)	Mueller et al (1999) ^b	Food code available in the UK NDNS (2008- 2014) and DNFCS (2007- 2010) datasets only.
Thyme [Thymus vulgaris] (leaves)	no data	no data	no data	303.5	Oramadike and Ogunbanwo (2017) ^c	Food codes for dried forms only were identified

a Food codes for boiled, canned or frozen food types are also included in the assessment

- b Minimum of 32 samples analysed
- c The number of samples analysed was not reported
- * Limit of Quantification

Taken from a poster by Martyn et al. (2019) provided by the CRN UK.

- 3. Based upon consumption data derived from years 1 to 6 of the National Diet and Nutrition Survey (NDNS) (Bates *et al.* (2014, 2016) it was indicated that exposure to HADs from the diet could range between 142 698µg/person/day, equivalent to 1.8 to 8.9µg/kg bw/day in a 78.6kg adult (Table 2).
- 4. The FSA Exposure Assessment Team commented that the NDNS data that has been used is dated as the FSA is currently using years 1 to 11 (Bates *et al.* 2014, 2016, 2020; Roberts *et al.* (2018)) for their assessments. The exposure team further added that rhubarb should also be considered in the dietary exposure as this is mentioned in the EFSA 2018 opinion on the safety of hydroxyanthracene derivatives (EFSA 2018).

Table 2. Summary of the estimated daily intake of individual (emodin, chrysophanol and physcion) and summed/unspecified HADs

Survey	Age (years)	n	% consumers (n)	Emodin Mean Range (µg/person/day)	Emodin High Range (µg/person/day)	Chrysophanol Mean Range (µg/person/day)	Chrysophanol High Range (µg/person/day)
UK NDNS, 2008-2014	≥1.5	9374	69.8 (6007)	<1 to 1	1 to 2	2 to 12	13 to 66

Survey	Age (years)	n	% consumers (n)	Physcion Mean Range (µg/person/day)	Physcion High Range (µg/person/day)	Summed/ Unspecified HADs Mean Range (µg/person/day)	Summed/ Unspecified HADs High Range (µg/person/day)
UK NDNS, 2008-2014	≥1.5	9374	69.8 (6007)	35 to 145	128 to 626	38 to 160	142 to 698

Unreliable intake estimates from sample sizes not meeting the minimum reporting requirements were not considered when determining the range of intake.

- 5. Exposure to HADs from Aloe Vera drinks is presented in Table 3. For UK consumption it is calculated that exposure could range between 0.1 to 864 µg/person/day, equivalent to 0.001 to 11.0µg/kg bw/day.
- 6. It is worth noting that the FSA Exposure Assessment Team reviewed the data provided and commented that the information presented in Table 3 is not a worst-case scenario as the exposure calculations are based upon the daily recommended serving size and people frequently consume more than the suggested amount. However, if the product were to be consumed chronically, this may average out over time.

Table 3. Measured levels of HADs, as Aloin A and B, in selected drinks containing Aloe Vera in the UK.

Aloins		Calculated	
VIOII12	Recommended	Exposures to Aloins	
Measured	Serving *		
(mg/kg)	(mL/day)	(µg/person/day)	
1.02	15 to 45	15 to 45	
0.82	15 to 45	12 to 37	
<0.01 a	10	0.1	
4.02	25	101	
3.19	25	80	
<0.01 a	120	0.6	
<0.01 a	120	0.6	
7.2	120	864	
5.83	120	700	
	Measured (mg/kg) 1.02 0.82 <0.01 a 4.02 3.19 <0.01 a <0.01 a	Measured (mg/kg) Serving * (mL/day) 1.02 15 to 45 0.82 15 to 45 <0.01 a	

^{*} Based on product label instructions

^a Limit of Detection

- 7. CRN UK also provided an estimate of aggregate dermal exposure to HADs from cosmetic products from the Scientific Committee on Consumer Safety (SCCS) (Table 4). The conservative value was calculated based upon cosmetic products containing an average of 35% aloe. This was a conservative approach and is probably an overestimate of daily exposure. The exposure to HADs from cosmetic products was estimated as 0.47µg/kg bw/day.
- 8. It should be noted that the exact types of cosmetic products included in the assessment are not described. Additionally, there is not a break-down of the presence or contribution of individual HADs.

Table 4. Estimation of average exposure to HADs from cosmetics containing aloe vera in the UK.

Aggregate	Average content	Transdermal	Aggregate	HAD conc.	Aggregate
exposure	of Aloe Vera (%)	absorption (%)	exposure to Aloe	in Aloe	exposure to
(mg/kg bw/day)			in cosmetics	(ppm)	HAD's from
			(mg/kg bw/day)		cosmetics
					(mg/kg
					bw/day)
269	35%	50%	47.075	10	0.00047

Aggregate Assessment

9. An aggregate exposure for total HADs of 20.4µg/kg bw/day was calculated from the data provided by CRN by assuming: a high-level consumption of the foodstuffs; the recommended intake of aloe containing drinks; and average bodyweight of 78.6kg.

References

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