Guidance

S9.74 - Transfer of polycyclic Aromatic Hydrocarbons in oil for feed to edible food commodities

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Welcome

GMP+ International provides the GMP+ Community with support, guidance and (background) information on the GMP+ FC scheme 2020 by means of our so-called "Support documents". These documents contain explanations and give examples of how the requirements can be implemented.

Different kind of supporting materials have been developed and include various tools, ranging from Frequently Asked Questions (FAQ) lists to webinars and events.

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TNO report

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Transfer of Polycyclic Aromatic Hydrocarbons in oil for feed to edible food commodities

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1 Introduction

In pursuance of a request by GMP+ International (further referred to as GMP+), the Netherlands, TNO has derived transfer factors for Polycyclic Aromatic Hydrocarbons (PAH) present in oil for feed to edible animal commodities (food) using the TNO Transfer Database (TdB). These transfer factors were used to estimate the worst case transmission to food products when considering the use of vegetable oil, coconut oil and/or palm oil in feed when considering the presence of PAHs in these products at their respective limit values.

In report number TNO2012 R10605, TNO has elaborated limit values for PAHs in oil for feed based on the PAH4 methodology. For coconut and palm oil, a rejection limit of 400 µg/kg is proposed for the sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene (PAH4). For other vegetable oils a rejection limit of 200 µg/kg is proposed for PAH4.

Based on information provided by GMP+, oils and fats intended for use in feed for animals (excluding feed for fish), are added to feed at a final concentration of ca. 6%, up to a possible maximum amount of 10%. Based on the proposed limit values for PAH4 calculated by TNO, the amounts of oil added to feed and the transfer factors derived from the TdB, maximum amounts of PAH4 levels are calculated for edible animal commodities.

The TdB is based on a meta-analysis of public literature on the transfer of chemicals from feed to edible animal commodities (Leeman, 2007[1]). Data concerning concentrations in the feed, feeding periods, residue levels in animal products, and other parameters, were gathered and recorded in a database. Transfer factors from animal feed to edible commodities are defined as the ratio of the concentration of the chemical in the edible animal commodity (mg/kg wet weight) to the concentration of the chemical in the animal feed (mg/kg dry weight).

[1] Leeman (2007) Food Additives and Contaminants, volume 24(1), page 1–13

2 Results

None of the compounds defined as PAH4 were present in the TdB. Therefore, a more generic approach for elaborating transfer factors was used based on the physical chemical properties of the substances. For the log Po/w, a very good correlation with the respective transfer factors is known (Leeman, 2007[1]). The Log Po/w values for the individual PAH4 substances found in literature are 6.13, 5.79, 6.60 and 5.73 for benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene, respectively[2]. As the respective Log Po/w values for the PAH4 substances are in the same range, transfer factors were calculated for the group of PAH4 ± LogPo/w 0.2 (LogPo/w: 5.53 – 6.8). It should be noted that the ratios between the individual substances in the PAH4 group may also range, for which the elaboration of transfer factors using the group of PAH4 is more likely to reflect the normal situation as when the individual PAHs were used. The transfer factors based on the 95th percentiles elaborated for the group of PAH4 is given in table 1.

Table 1: Transfer factors for PAH4 (95th percentile values)

Animal	TF egg (N[1])	TF milk (N[1])	TF fat (N[1])	TF meat (N[1])	TF offal (N[1])
Overall	1.8 (87)	0.53 (132)	19.0 (142)	0.33 (50)	2.57 (56)
Cattle		0.5 (114)	8.4 (44)	0.32 (15)	2.57 (13)
Poultry	1.8 (87)		30.0 (78)	0.4 (24)	9.33 (32)
Goat		17.4 (15)			
Pig			3.8 (19)	0.07 (11)	0.26 (11)
Sheep		0.53 (3)	5.7 (1)		

[1] N= amount of data present
The TdB is using the SAS Information Delivery Portal software version 4.31_M1, SAS Institute Inc., USA.

For the PAH4, accumulation is to be expected in egg, fat and offal. For goat, accumulation in milk is also indicated, opposite to milk from cattle.

The transfer factors derived from the TdB are in general based on a significant amount of more data points and are therefore considered of relevance for the elaboration of transfer factors for PAH4. From a reasonable worst case point of view, the transfer factors based on the 95th percentile of the dataset selected are considered for conversion of feed concentrations to the concentration in the edible commodities. These calculated concentrations in the edible commodities may therefore be regarded as reasonable worst case figures which can be used for consumer risk assessment.

Based on 1) the amount of vegetable-, coconut-, and/or palm-oil, intended for use at 6% and up to a maximum of 10% in feed, 2) the proposed PAH4 rejection limits of 200 µg/kg for vegetable oil and 400 µg/kg for coconut- and palm oil, and 3) the transfer factors derived using the 95th percentile based on the log Po/w of substances within the PAH4, worst case concentrations of PAH4 were calculated

[2] http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

for each of the various edible commodities. An overview of these results is presented in table 2.

Table 2: Calculated worst case amounts for PAH4 in edible commodities

Animal	PAH4 in egg (µg/kg[1])	PAH4 in milk (µg/kg[1])	PAH4 in fat (µg/kg[1])	PAH4 in meat (µg/kg[1])	PAH4 in offal (µg/kg[1])
Overall	72	21.2	760	13.2	102.8
Cattle		20	336	12.8	102.8
Poultry	72		1200	16	373.2
Goat		696			
Pig			152	2.8	10.4
Sheep		21.2	228		

[1] calculated considering 10% oil in feed, a rejection limit of 400 µg PAH4/kg and the concerned transfer factor (=400x0.1xTF)

3 Discussion and conclusion

Maximum levels for polycyclic aromatic hydrocarbons in foodstuffs are set in Commission Regulation (EU) No 835/2011, amending Regulation (EC) No 181/2006. This regulation concerns specific foodstuffs for which maximum levels are set, related to foodstuffs of vegetable origin, fish and seafood, smoked meat and meat products, infant formulae and follow-on formulae (including infant milk and follow-on milk) and dietary foods for special medical purposes intended specifically for infants. From these products, only smoked meat and smoked meat products are considered of relevance taken into account the addition of oils to feedstuffs. Infant formulae and follow-on formulae are not taken into account as these products are highly processed and contain mainly the protein fraction of the milk, for which the possible presence of PAHs is likely to be removed from the protein fraction with the milk fat fraction.

For smoked meat and meat products, maximum levels are set of 30.0 µg PAH4/kg (as from September 1, 2012 to August 31, 2014) and 12.0 µg PAH4/kg (as from September 1, 2014). The calculated worst case amounts of PAH4 in meat, calculated as a result of a long term exposure of livestock to feed containing a 10% addition of coconut oil or palm oil containing PAH4 levels at the rejection limit of 400 µg/kg in the oil, are 2.8 to 16 µg/kg. These calculated levels are below the 30 µg/kg limit set until August 31, 2014 and up to slightly above the 12.0 µg/kg limit as set from September 1, 2014. However, it should be noted that the worst case calculation assume:

- Exposure at a 10% inclusion in the feed where 6% is a normal inclusion rate;
- Exposure at 400 µg/kg, whereas for vegetable oils a 200 µg/kg rejection limit is proposed;
- Live long exposure at the highest rejection limit where normally significant lower PAH4 levels in the oil for feed may be expected.

Considering these worst case assumptions it is unlikely that the inclusion of oil in feed at or below the proposed rejection limits for PAH4 of 200 µg/kg for vegetable oil and 400 µg/kg for coconut oil and palm oil, will lead to levels at or above the authorized levels of PAH4 in smoked meat or smoked meat products, the addition of PAH4 as a result of smoking is not taken into account.

4 Signature

Zeist, September 2012

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At GMP+ International, we believe everybody, no matter who they are or where they live, should have access to safe food.

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