



FRONT OFFICE FOOD AND PRODUCT SAFETY

Assessment mineral oils in cheese biscuits

Risk assessment requested by:	NVWA-BuRO
Risk assessment drawn up by:	RIVM
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Subject

Mineral oils in cheese biscuits

Research question

On 16 December 2016 a company reported high concentrations of mineral oils ('mineral oil saturated hydrocarbons' (MOSH) and 'mineral oil aromatic hydrocarbons' (MOAH)) in cheese biscuits to the Netherlands Food and Consumer Product Safety Authority [Nederlandse Voedsel- en Warenautoriteit] (NVWA). Three days later, on 19 December 2016, the Office for Risk Assessment and Research [Bureau Risicobeoordeling en Onderzoeksprogrammering] of the NVWA (NVWA-BuRO) asked the Front Office to answer the following questions:

1. Do the (increased) values of mineral oils in the cheese biscuits examined create a health risk when these products are eaten? (children/adults).
2. Can an indication be given regarding how many of these cheese biscuits, or how many grams of these cheese biscuits, provide a basis for expecting a health risk?

Because the analytical results were not clear, the NVWA asked the company about the analytical results and the recipe of the cheese biscuits. These additional details were supplied to the Front Office in March.

Conclusions

Answer to question 1:

Consumption of cheese biscuits with a MOSH content > 1,000 mg/kg in combination with MOAH contents varying from 14 to 26 mg/kg can contribute significantly to the total exposure of MOSH and, to a lesser extent, MOAH. It should be noted here that the most sensitive toxicological endpoints of both mineral oils occur after long-term exposure. For that reason, an incidental high exposure to MOSH and MOAH by consuming a large quantity of cheese biscuits will not directly constitute a health risk. However, health risks cannot be ruled out after long-term consumption of these cheese biscuits.

Answer to question 2:

No. For MOSH, the upper bound of the total background exposure via food of 0.03-0.3 mg/kg body weight (bw) estimated by the European Food Safety Authority (EFSA) already exceeds the estimated (by RIVM) acceptable daily intake of 0.19 mg/kg bw. The total exposure to MOSH via food is therefore considered to be of potential concern.

No reference value is available for MOAH, which could be used as a point of departure for the risk assessment. However, MOAH may be mutagenic and carcinogenic and therefore exposure to MOAH via food is also considered to be of potential concern. Based on these two reasons, it is not possible to indicate the quantity of cheese biscuits for which a health risk can be expected.

Introduction

Mineral oils

Mineral oil hydrocarbons (MOHs) come from crude oil, coal, etc. A distinction is made between 'mineral oil saturated hydrocarbons' (MOSH), consisting of paraffin (linear and branched alkanes) and naphthenes (alkyl-substituted cyclo-alkanes) and 'mineral oil aromatic hydrocarbons' (MOAH), consisting of primarily alkyl-substituted polyaromatic hydrocarbons. Large quantities of isomers are possible, the chemical composition is often unknown, they are often complex mixtures and the composition varies from batch to batch.

Mineral oils in cheese biscuits and cheese powder

In December 2016, a company submitted analytical data to the NVWA on, among other things, MOSH and MOAH contents in two types of cheese biscuits. The data concerned two types of cheese biscuits of a brand intended for sale in a supermarket. However, the reporting of the analytical data submitted in December 2016 with regard to the MOSH and MOAH contents in the cheese biscuits was unclear and raised questions about the actual contents in these products. After some correspondence between the NVWA and the producer it became clear that the MOSH concentration in cheese biscuits was >1,000 mg/kg: the upper limit of what could be analysed. The producer did not submit any exact MOSH contents to the NVWA. MOAH concentrations with 10-35 and 10-62 carbon atoms (C10-35 and C10-62) in cheese biscuits were also reported, as well as concentrations of MOSH and MOAH (only C10-35) in the cheese powder that is used as raw material in the production of cheese biscuits. Table 1 shows the reported concentrations of MOSH and MOAH in the cheese biscuits and cheese powder.

Table 1 Concentrations of MOSH and MOAH in cheese biscuits and cheese powder.

Product	Batch	Concentration (mg/kg)			Remark
		MOSH	MOAH (C10-35)	MOAH (C10-62)	
Cheese biscuits type 1	1	>1,000	17	26	
	2	>1,000	9.4	19	
Cheese biscuits type 2	1	>1,000	12	21	
	2	>1,000	6.8	14	
Cheese powder	1	>1,000	190	-	Concentration in cheese biscuits 9-11%
	2	>1,000	44	-	

Given that cheese biscuits contain 9-11% cheese powder it is likely that the MOSH concentration in cheese powder (reported as > 1,000 mg/kg in connection with upper limit of analysis) will have been >10,000 mg/kg.

Toxicity

The Scientific Opinion of EFSA (EFSA, 2012) indicates that MOSH can accumulate and can lead to the formation of microgranulomas (inflammation reactions) in various tissues, including lymph glands, spleen and liver. EFSA concluded that the existing acceptable daily intakes (ADIs) for MOSH needed to be revised based on new toxicological information. Given that the current ADIs are no longer considered adequate, a margin of exposure (MOE) approach was used in relation to a 'no-observed adverse effect level' (NOAEL) of 19 mg/kg body weight (bw) per day for induction of microgranulomas in the liver of rats by the most potent MOSH. The MOE is the ratio between the dose level at which no effect is observed and the level at which humans are exposed. The larger the MOE, the smaller the risk of adverse health effects. Exposure to MOSH in Europe via food is considered to be of potential concern (calculated MOEs varied from 100-680 for the mean exposure and from 59-330 for a high (P95) exposure. EFSA does not indicate what an acceptable MOE is). For the risk assessment, RIVM assumes, as is generally normal for non-genotoxic substances, that the risk is acceptable in the case of an MOE of 100 in relation to the NOAEL of the critical endpoint. On this basis it is assumed that no detrimental health effects are expected if daily intake does not exceed 0.19 mg/kg bw.

MOAH may be mutagenic and carcinogenic and therefore exposure via food is considered of potential concern (EFSA, 2012). EFSA was not able to identify a reference point for MOAH. According to the EFSA opinion the exposure to MOAH is approximately 20% of the exposure to MOSH (EFSA, 2012). The use of 'white mineral oils' is a major source of exposure to MOSH. These oils contain almost no MOAH.

Exposure and risk assessment for intake of MOSH and MOAH from cheese biscuits

Consumption of cheese biscuits

An exposure and risk assessment was carried out for the intake of MOSH and MOAH from the consumption of cheese biscuits for three age groups: 2-6, 7-18 and 19-69 years old. The consumption data of cheese biscuits were derived from the data of the food consumption surveys VCP-kids 2005/2006 (Ocké et al., 2008) and VCP 2007/2010 (van Rossum et al., 2011). The first survey contains individual food consumption data from

children aged 2-6 and the second of people aged 7-69. The consumption of cheese biscuits is based on the 'biscuits & snacks cheesy average' food group (nevo 1699). The consumption data for VCP 2007/2010 were obtained online¹, where they are reported separately for people aged 7-18 and 19-69. For VCP-kids 2005/2006 the consumptions were calculated using data from the underlying database.

The mean consumption of cheese biscuits varies from 0.22 grams per day in 2-6 year-olds to 0.4 grams per day in people aged 7-18 and 19-69 (Table 2). If only the consumption days are taken (days on which the consumption of cheese biscuits is actually reported) as input for an acute exposure estimate, the mean consumption is 34 and 42 grams per day, respectively. A high (P95) consumption varies in that case from 80 grams per day in 2-6 year-olds to 112 grams per day in people aged 7-18. The percentage of consumption days on which the consumption of cheese biscuits is reported in the food consumption surveys is very low ($\leq 1\%$). Therefore, for all days, the intake of MOSH and MOAH is only calculated based on the mean consumption of cheese biscuits.

Table 2 Consumption of cheese biscuits^a

Age (year)	Body weight (kg)	Consumption of cheese biscuits (g/day)		
		All days (g/day) ^{b,c}	Consumption days (g/day) ^d	
			Mean	Mean
2-6	18.3	0.22	34	80
7-18	49.1	0.4	42	112
19-69	79.7	0.4	42	100

^a Concerns the consumption of the 'biscuits & snacks cheesy average' food group (nevo 1699).

^b Concerns all days in the food consumption surveys, irrespective of whether the consumption of cheese biscuits is reported on a particular day.

^c If all days in the food consumption surveys are included, the P95 consumption of cheese biscuits is 0 g/day, because consumption of cheese biscuits is reported in both food consumption surveys on fewer than 1% of the consumption days. Therefore, for all days, only the mean consumption of cheese biscuits is used in the calculation (Table 3, 4, 5).

^d Concerns only the days in the food consumption surveys on which the consumption of cheese biscuits is reported.

Exposure and risk assessment for intake of MOSH from consumption of cheese biscuits

The concentrations of MOSH in cheese biscuits were higher than 1,000 mg/kg (Table 1). Based on a content of 1,000 mg/kg and the consumed quantities of cheese biscuits (Table 2), the mean and high intake (P95) of MOSH in mg/kg bw per day were calculated for the three age categories (Table 3).

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http://www.rivm.nl/Onderwerpen/V/Voedselconsumptiepeiling/Aanvullende_tabellen_en_memo_s/Tabellen_VCP_Basis

Table 3. Exposure assessment for MOSH via consumption of cheese biscuits

Age (year)	Exposure to MOSH (mg/kg bw per day)		
	All days ^{a, b}		Consumption days ^a
	Mean	Mean	P95
2-6	0.012	1.858	4.372
7-18	0.008	0.855	2.281
19-69	0.005	0.527	1.255

^a For a clarification of 'all days' and 'consumption days', see footnotes b and d of Table 2.

^b If all days in the food consumption surveys are included, the P95 intake of MOSH is 0 g/day because consumption of cheese biscuits is reported in both food consumption surveys on fewer than 1% of the consumption days. Therefore, for all days, the intake of MOSH is only calculated based on the mean consumption of cheese biscuits.

For MOSH, EFSA estimated a background exposure via food of 0.03-0.3 mg/kg bw per day. This is the range of the lowest mean exposure up to the highest P95 exposure. Children aged 3-10 are exposed most (EFSA, 2012).

If all days are included for the calculation of the intake of MOSH, the mean intake is 1.6-4% in relation to the highest background exposure of 0.3 mg/kg bw per day. In view of the minor consumption of cheese biscuits (0.22 – 0.4 g/day), this is a relatively high contribution to the total background exposure to MOSH. The mean exposure to MOSH via the consumption of contaminated cheese biscuits is lower than the estimated acceptable daily intake of 0.19 mg/kg bw.

If, as input for the acute exposure, only the consumption days on which consumption of cheese biscuits is reported are taken for the calculation of the intake of MOSH, the intake of MOSH will be substantially higher than the background estimated by EFSA in all age categories. The mean acute exposure corresponds to 176-619% in relation to the highest background exposure 0.3 mg/kg bw per day. For the high (P95) acute intake, the respective percentages are 418-1457%. The percentages in relation to the lowest background exposure of 0.03 mg/kg bw per day are a factor of 10 higher. The acute exposure to MOSH via the consumption of contaminated cheese biscuits is also substantially higher than the estimated acceptable daily intake of 0.19 mg/kg bw.

It should be noted here that the actual concentration of MOSH in the cheese biscuits was higher than 1,000 mg/kg (Table 1): consequently the exposure is probably underestimated in the above calculations.

For MOSH, the upper bound of the estimated total background exposure of 0.03-0.3 mg/kg bw already exceeds the estimated acceptable daily intake of 0.19 mg/kg bw. The exposure through eating contaminated cheese biscuits comes on top of this. Health risks through the intake of MOSH, including via consumption of these cheese biscuits, cannot, therefore, be ruled out. It should be noted here that the most sensitive toxicological endpoint of MOSH occurs after long-term exposure. For that reason, an incidental high exposure to MOSH by consuming a large quantity of contaminated cheese biscuits will not directly constitute a health risk.

Exposure and risk assessment for intake of MOAH from consumption of cheese biscuits

Based on aforementioned consumption quantities and the measured MOAH contents in cheese biscuits (Table 1), the mean and high intake (P95) of MOAH in µg/kg bw per day

were calculated for the three age categories. The reported MOAH C10-62 levels were used, given that these levels also include MOAH C10-35. A summary of the results is shown in Table 4. All calculated intakes are presented in Annex 1.

Table 4 Exposure assessment for MOAH (C10-62) from cheese biscuits

Age	Exposure to MOAH ($\mu\text{g}/\text{kg}$ bw per day)		
	All days ^{a, b}	Consumption days	
	Mean	Mean	P95
2-6	0.17-0.31	26-48	61-114
7-18	0.11-0.21	12-22	32-59
19-69	0.07-0.13	7-14	18-33

^a For a clarification of 'all days' and 'consumption days', see footnotes b and d of Table 2.

^b If all days in the food consumption surveys are included, the P95 intake of cheese biscuits is 0 g/day because consumption of cheese biscuits is reported in both food consumption surveys on fewer than 1% of the consumption days. Therefore, for all days, the intake of MOAH is only calculated based on the mean consumption of cheese biscuits.

The exposure to MOAH is highest in 2-6 year-olds, followed by children aged 7-18. Given that no health-based guidance value has been determined for MOAH, it is not possible to carry out a quantitative risk assessment. However, it is possible to assess the intake through consumption of cheese biscuits in relation to the background exposure.

Not much data is available on MOAH in food products. EFSA (2012) estimates that the exposure to MOAH is around 20% of the exposure to MOSH. On the basis of the estimated exposure to MOSH of 0.03-0.3 mg/kg bw per day it can be estimated that the exposure to MOAH is approximately 0.006-0.06 mg/kg bw per day, or 6-60 $\mu\text{g}/\text{kg}$ bw per day.

Table 5 shows the mean and high intake (P95) of MOAH from cheese biscuits as a percentage of the background exposure to MOAH, for all days, for the consumption days on which cheese biscuits were consumed and for all age categories.

Table 5 Percentage exposure to MOAH (C10-62) via the consumption of cheese biscuits in relation to background exposure^a.

Age (year)	Range background exposure ($\mu\text{g}/\text{kg}$ bw per day)	Percentage exposure to MOAH (%) in relation to background exposure		
		All days	Consumption days	
		Mean	Mean	P95
2-6	6	2.8-5.2	433-800	1017-1900
	60	0.28-0.52	43-80	102-190
7-18	6	1.8-3.5	200-367	533-983
	60	0.18-0.35	20-37	53-98
19-69	6	1.2-2.1	116-233	300-550
	60	0.12-0.21	12-23	30-55

^a On the basis of estimated exposure to MOSH via food by EFSA (2012) and the assumption that the exposure to MOAH is around 20% of the exposure to MOSH.

^b If all days in the food consumption surveys are included, the P95 intake of cheese biscuits is 0 g/day because consumption of cheese biscuits is reported in both food consumption surveys on fewer than 1% of the consumption days. Therefore, for all days, the intake of MOAH is only calculated based on the mean consumption of cheese biscuits.

It can be concluded from the table above that the exposure to MOAH via the consumption of contaminated cheese biscuits over a longer period only makes a minor contribution to the highest total MOAH background exposure of 60 µg/kg bw per day: no more than 0.52%. The percentages in relation to the lowest background exposure of 6 µg/kg bw per day are a factor of 10 higher. If only the consumption days on which consumption of cheese biscuits is reported are included, the MOAH intake is high compared to the highest background exposure, in all age categories for both the mean consumer and for the consumer with a high intake (P95) of MOAH: 12-190%. The percentages in relation to the lowest background exposure of 6 µg/kg bw per day are again a factor of 10 higher.

The risk of exposure to MOAH is that there are MOAH that can be mutagenic and carcinogenic in the longer term. This is primarily caused by MOAH with 3 to 7 rings. However, these constitute only a small fraction of the total MOAH which ends up in foodstuffs. The EFSA assessment indicates that no method is available to separate and quantify the individual MOAH. This is still the case.

In view of the possible toxic effect of MOAH, exposure to MOAH via food is considered to be of potential concern (EFSA, 2012). The exposure through eating contaminated cheese biscuits comes on top of the background exposure to MOAH from other sources. For that reason, a health risk cannot be ruled out.

Conclusions

1. For MOSH the upper bound of the estimated total background exposure via food of 0.03-0.3 mg/kg bw as estimated by EFSA (2012) already exceeds the estimated (by RIVM) acceptable daily intake of 0.19 mg/kg bw. The exposure to MOSH via food is therefore regarded to be of potential concern.
2. MOAH may be mutagenic and carcinogenic and therefore exposure to MOAH via food is also regarded to be of potential concern.
3. Consumption of cheese biscuits with a MOSH content > 1,000 mg/kg in combination with contents of MOAH (C10-62) varying from 14 to 26 mg/kg can contribute significantly to the total acute exposure of MOSH and, to a lesser extent, MOAH. In view of the minor consumption of cheese biscuits (0.22-0.4 g/day), they have a relatively high contribution to the total background exposure to MOSH and MOAH.
4. The most sensitive toxicological endpoints of MOSH and MOAH occur after long-term exposure. For that reason an incidental high exposure to MOSH and MOAH by consuming a large quantity of cheese biscuits will not directly constitute a health risk. However, health risks cannot be ruled out after long-term consumption of these cheese biscuits.
5. Based on conclusions 1 and 2, it is not possible to indicate the quantity of cheese biscuits for which a health risk can be expected.

Additional comments

- Given that cheese biscuits contain 9-11% cheese powder, the concentration of MOSH in cheese powder will have been >10,000 mg/kg.
- In two cheese powder samples, MOAH was found at levels of 44 and 190 mg/kg respectively. This means that the concentration of MOAH in these samples is no more than 0.5-2% of the total MOH concentration.

- In view of the high contents of MOSH in the cheese biscuits/cheese powder and given that the proportion of concentrations of MOAH and MOSH is much lower than 20%, it is unlikely that the MOH in cheese biscuits/cheese powder are a consequence of contamination from packaging material, processing aids, or lubricants. The MOH may have come from the coating of the cheese or from another source of contamination (e.g. white mineral oil).

References

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Appendix 1 Intake of MOAH through consumption of cheese biscuits.

Biscuits & snacks cheesy averaged (nevo = 1699)

C10-C62

	MOAH = 26 mg/kg				19 mg/kg				21 mg/kg				14 mg/kg			
	Intake (mg/kg bw per day)				Intake (mg/kg bw per day)				Intake (mg/kg bw per day)				Intake (mg/kg bw per day)			
	All days		Consumption days		All days		Consumption days		All days		Consumption days		All days		Consumption days	
	Mean	P95	Mean	P95	Mean	P95	Mean	P95	Mean	P95	Mean	P95	Mean	P95	Mean	P95
2-6	0.00031	0.00000	0.04831	0.11366	0.00023	0.00000	0.03530	0.08306	0.00025	0.00000	0.03902	0.09180	0.00017	0.00000	0.02601	0.06120
7-18	0.00021	0.00000	0.02224	0.05931	0.00015	0.00000	0.01625	0.04334	0.00017	0.00000	0.01796	0.04790	0.00011	0.00000	0.01198	0.03193
19-69	0.00013	0.00000	0.01370	0.03262	0.00010	0.00000	0.01001	0.02384	0.00011	0.00000	0.01107	0.02635	0.00007	0.00000	0.00738	0.01757