National Institute for Public Health
and the Environment
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# Colophon



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# Publiekssamenvatting

## Indicatieve inname van 3-MCPD via het voedsel in Nederland

Tijdens de productie van plantaardige oliën en vetten, en dan vooral van palmolie, wordt een stof (3-MCPD) gevormd die schadelijk kan zijn voor de nieren. Voedingsmiddelen die hoge gehalten van deze stof kunnen bevatten zijn margarine, sauzen, koffiecreamers en bakkerswaren. Het RIVM heeft berekend hoeveel 3-MCPD mensen via voedsel kunnen binnenkrijgen om te bepalen of de inname boven de gestelde gezondheidslimiet voor deze stof uitkomt. Om hier een conclusie over te kunnen trekken, zijn echter gegevens nodig die momenteel zeer beperkt beschikbaar zijn. Dit betreft gegevens over de concentratie van 3-MCPD in relevante voedingsmiddelen.

Op basis van de beschikbare concentratiegegevens blijkt dat gemiddeld 18 procent van de jonge kinderen van 2 tot en met 6 jaar een inname heeft die boven de gezondheidslimiet voor 3-MCPD ligt. Bij 7-jarigen is de inname het hoogst per kilogram lichaamsgewicht, en heeft 35 procent van hen een inname boven de gezondheidslimiet. Daarna daalt de inname: vanaf 17 jaar wordt bij minder dan 5 procent van de bevolking de gezondheidslimiet overschreden. Vanwege de beperkt beschikbare concentratiegegevens kan geen uitspraak worden gedaan over de mogelijk schadelijke effecten voor de gezondheid.

Voor dit onderzoek zijn de beschikbare concentratiegegevens van 3-MCPD in voedingsmiddelen gecombineerd met voedselconsumptiegegevens van de Voedselconsumptiepeiling (VCP). Daarna is de berekende inname vergeleken met de gezondheidslimiet die voor deze stof geldt. Deze limiet is gebaseerd op de gemiddelde hoeveelheid van een stof waar mensen langdurig dagelijks aan mogen worden blootgesteld, zonder dat dit nadelige gevolgen heeft voor de gezondheid.

Kernwoorden: 3-monochloorpropaan-1,2-diol en zijn esters, 3-MCPD, voedsel, kinderen, volwassenen, langetermijninname, statistisch modelleren

# Synopsis

**Preliminary assessment of dietary exposure to 3-MCPD in the Netherlands**

During the production of refined vegetable oils and fats, and especially palm oil, a process contaminant called 3-MCPD is formed that may be harmful to the kidney. Foods that may contain high levels of this compound are margarines, sauces, coffee creamers and bakery products. The Dutch National Institute for Public Health and the Environment (RIVM) has calculated how much people may ingest via food to assess if the intake exceeds the health-based guidance value for 3-MCPD. Data on the concentration of 3-MCDP in foods are required in order to draw properly substantiated conclusions. However, only very limited data are available at present.

Based on the available concentration data, on average 18 percent of young children aged 2 to 6 have an intake exceeding the health-based guidance value for 3-MCPD. Seven-year-olds have the highest intake per kilogramme of body weight, and 35 percent of this age group has an intake above the health-based guidance value. Thereafter, the intake decreases: from the age of 17 less than 5 percent of the population has an intake above the guidance value. Due to the limited concentration data available, it is not possible to indicate whether possible detrimental effects to health occur.

In this study, the available data on the concentration of 3-MCPD in foods have been combined with food consumption data derived from the Dutch National Food Consumption Survey (VCP). The indicative intake was subsequently compared to the health-based guidance value for 3-MCPD. This value is based on the daily quantity of 3-MCPD that people may ingest on average over a long period without detrimental consequences to health.

Keywords: 3-monochloropropane-1,2-diol and its esters, 3-MCPD, food, children, adults, long-term exposure, statistical modelling

# Contents

# 1 Introduction

During the refinement procedure of vegetable oils and fats, 3-monochloropropane-1,2-diol (3-MCPD) esters are produced, in which the deodorization step (the last step of refining in which unwanted aromas and off-flavourings are removed) is the most critical (ILSI, 2009; Craft et al., 2013). Because of this, 3-MCPD esters are present in edible refined vegetable oils and fats and composite foods containing these oils and fats (ILSI, 2009; Li et al., 2015; MacMahon et al., 2013). Especially high levels have been reported in palm oil (ILSI, 2009, Craft et al., 2013, MacMahon et al., 2013). The main factors of 3-MCPD ester formation are the presence of chloride ions and triacylglycerols, and temperature (Craft et al., 2013). Palm fruits, the precursor of palm oil, are known to contain organochlorines, which can act as a 'chlorine' source for the formation of 3-MCPD (Nagy et al., 2011, Zulkurnain et al., 2013). Apart from the ester-form, 3-MCPD can also be present in the free form in food, such as soy sauce, which is regulated at a maximum level of 2 mg/kg (EC, 2001).

The free form of 3-MCPD is classified as a possible human carcinogen (IARC, 2012) for which the Scientific Committee on Food (SCF) established a tolerable daily intake (TDI) of 2 µg/kg bw, based on the lowest-observed-adverse-effect-level (LOAEL) for renal tubular hyperplasia from a 2-year bioassay in rats (SCF, 2001). This TDI was confirmed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2006 and was based on the same study (JECFA, 2007). Esters of 3-MCPD are of toxicological concern due to the release of free 3-MCPD through the action of lipases in the gut, resulting very likely in an equivalent oral bioavailability of 3-MCPD in its free form as in its ester form (EFSA, 2013; Peters, 2015).

In 2013, the European Food Safety Authority (EFSA) performed a preliminary dietary exposure assessment of 3-MCPD esters in Europe (EFSA, 2013). This assessment was preliminary because the analytical method to analyse 3-MCPD esters was still under development at the time of the EFSA publication. The EFSA assessment showed that Dutch children aged 1-9 have a dietary exposure to these contaminants exceeding the TDI of 3-MCPD. The exposure in adults living in the Netherlands remained below this health-based guidance value. The high exposure to 3-MCPD esters in young children was to a large extent due to the consumption of margarines (EFSA, 2013).

Based on these findings and the fact that the analytical method to analyse 3-MCPD esters was still under development at the time of the EFSA publication, RIKILT Wageningen UR (hereafter referred to as RIKILT), commissioned by the Office for Risk Assessment and Research of the Netherlands Food and Consumer Product Safety Authority (BuRO-NVWA), analysed several food products available on the Dutch market for the presence of 3-MCPD esters, using a validated analytical method. The analytical results became available in the second half of 2015. These results, together with some preliminary results of 2013 also generated by RIKILT using the same validated method, were used in the

present study to perform a refined exposure assessment to 3-MCPD esters in the Dutch population. Since also the exposure to free 3-MCPD present in soy sauce was included in the present assessment, to avoid possible underestimation of the exposure, and the very likely equivalent oral bioavailability of both 3-MCPD forms, the term 3-MCPD used in this report refers both to free 3-MCPD and 3-MCPD esters.

# 2 Intake calculations

## 2.1 Food consumption data

Exposure calculations were performed for young children aged 2 to 6, and for the population aged 7 to 69. These two populations were addressed because two separate food consumption databases were available for these population groups: DNFCS-Young children (Ocké et al., 2008) and DNFCS 2007-2010 (van Rossum et al., 2011), respectively. For a detailed description of both surveys, see Appendix A.

## 2.2 Concentration data

Concentration data of 3-MCPD in food were obtained from RIKILT. In total 50 foods (30 in 2014 and 20 in 2013) were purchased in regular shops and analysed for 3-MCPD. A description of the analytical method can be found in Peters (2015). The concentrations per food are listed in Appendix B. The data on infant formula were not used in the exposure assessment, because this source of exposure was not relevant for the ages 2 to 69. Information on the foods analysed was available at brand level.

Only one analysed sample contained 3-MCPD at a level below the limit of detection / quantification: extra virgin olive oil. Given the nature of the production of this olive oil (no heat treatment), no 3-MCPD are to be expected in (extra virgin) olive oil[1]. This sample was therefore considered to contain no 3-MCPD in the exposure assessment.

No recent analytical results of 3-MCPD in soy sauce were available for the exposure assessment. It was therefore assumed that soy sauce contained 3-MCPD at the maximum level to avoid underestimation of the exposure.

## 2.3 Food mapping

Mapping is the process of matching the foods analysed to those recorded in food consumption surveys. For the exposure assessment to 3-MCPD, the 50 foods analysed for this process contaminant were first categorised in 15 food groups (Appendix B). These food groups were subsequently mapped to more than 5,000 foods recorded in both food consumption databases, excluding the food group ‘infant formula’ (see section 2.2). These 5,000 foods were coded according to the food codes of the Dutch Food Composition Database NEVO[2]. Direct mapping was used: the analysed foods were mapped as much as possible to the same foods or to appropriately similar foods recorded in both food consumption databases. Since 3-MCPD is present in the fat fraction of foods, the concentrations analysed in the relevant food groups were assigned to the foods consumed based on the fat content of the consumed food as recorded on NEVO online, the online version of the Dutch Food Composition Database[2]. NEVO-online provides nutritional

[1] http://www.eufic.org/page/de/page/FAQ/faqid/3MCPD-3MCPD-esters/
[2] http://nevo-online.rivm.nl/

information, including fat content (g), of the majority of foods recorded in both food consumption databases. If a relevant consumed food was not present in NEVO-online, information on the fat content was obtained from the more extended version of the food composition database present at the National Institute for Public Health and the Environment (RIVM).

Given the discrepancy between food groups analysed and the foods consumed, assumptions were needed to map the foods. The aim was to include all foods that may contain 3-MCPD, based on the possible presence of refined vegetable oil or fat, in the exposure assessment. The following assumptions were applied:

1. Fats present in the analysed food groups were assumed to be representative of the fat present in the mapped foods. For example, three types of sauces were analysed: mayonnaise, garlic sauce and meat gravy. It was assumed that the fat present in the foods mayonnaise and garlic sauce was the same, but differed from that in meat gravy, resulting in two food groups: 'mayonnaise-garlic sauce' and 'gravy'. The food group 'mayonnaise-garlic sauce' was subsequently mapped to 363 sauces recorded in the food consumption databases, and the food group 'gravy' to 93 different meat gravies.
2. The analysed food group 'chocolate' was mapped to foods in which the fat was assumed to be cocoa butter. For foods containing also other sources of fat in addition to cocoa butter, the total amount of fat was assumed to be vegetable oil, or in the case of chocolate bakery products, to be similar to the fat present in the analysed food group 'cake and cookies'. Since the 3-MCPD concentration in vegetable oil and the food group 'cake and cookies' was higher than in the food group 'chocolate', this may have resulted in an overestimation of the exposure. Examples of these foods were chocolate biscuits and some candy bars, such as Kitkat and Twix.
3. Consumed foods that contain refined vegetable oils or fats, and which could not be mapped to any of the analysed composite food groups, were mapped to the food group 'vegetable oil'. Examples of these foods were bread, mini cracker with olive oil and oregano, pancake, pasta with cheese filling, and vegetarian meat.
4. Foods for which the fat source was derived from other sources than refined vegetable oil or fat, such as milk fat (milk, cream, butter, etc.) or animal fat, were assumed to contain no 3-MCPD. Examples of these foods were custard, yoghurt and cheese.
5. Consumption of olive oil as such was assumed to be extra virgin olive oil. Since the 3-MCPD levels in refined olive oil are expected to be higher than in extra virgin olive oil (ILSI, 2009; MacMahon et al., 2013), this may have resulted in an underestimation of the exposure.
6. Edible ice cream based on milk and cream ('creamy ice cream') was assumed to contain no 3-MCPD.

In total, 3,087 foods were not mapped to any analysed food group. These foods included those that were not expected to contain refined vegetable oils or fats, such as vegetables, legumes, fruit, nuts and

olives, meat and meat products, fish and fish products, and (non)alcoholic beverages. For foods fried or baked in oil or fat (such as meat and fish), the oil or fat was recorded separately in the food consumption databases and as such linked to the appropriate food group (either ‘margarines, including cooking fat’ or ‘vegetable oil’).

## 2.4 Long-term dietary exposure assessment

The long-term (or usual) dietary exposure to 3-MCPD was assessed, because repeated exposure to this process contaminant may result in adverse effects (JECFA, 2007; SCF, 2001). To assess the long-term exposure, the LogNormal-Normal (LNN) model was applied as implemented in the Monte Carlo Risk Assessment (MCRA) software, release 8.1 (de Boer et al., 2015).

For this model, first daily consumption patterns of individuals were multiplied with the mean 3-MCPD concentration per consumed food and summed over foods per day per individual. Subsequently, these daily exposures were corrected for the day-to-day variation in exposure using LNN to estimate the long-term exposure. See Appendix C for a description of LNN.

All daily estimated exposures were divided by individual body weight and expressed as “ng/kg bw per day”. All results were weighted for small deviances in socio-demographic factors and season, and additionally for day of the week for persons aged 7 to 69, to make the results representative for the relevant Dutch population and for all days of the week and all seasons (Ocké et al., 2008; van Rossum et al., 2011). The reported percentiles of the usual exposure distributions are P50 and P95. The exposure was estimated with age as covariate.

The sample sizes per analysed food groups were very small (1 to 7) and were therefore not expected to represent the whole range of possible concentrations to which a population may be exposed when consuming foods belonging to these food groups. Because of this, it was assumed in the exposure assessments that the concentration data follow a lognormal distribution. In this way, concentrations above, between and below the observed values per food group were modelled (van der Voet et al., 2015). To use this approach, at least two quantifiable concentrations per analysed food group are needed. This approach could therefore not be used for coconut milk and soy sauce.

By using the bootstrap approach, the uncertainty in the dietary exposure assessment due to the sampling size of concentration and food consumption database was quantified. The uncertainty is reported as the 95% confidence interval around the percentiles of exposure. See Appendix D for a description of the bootstrap.

## 2.5 Exposure versus health based guidance value

To assess if there is a possible health risk related to the exposure to 3-MCPD, the exposure was compared to the TDI of 2 µg/kg bw (JECFA, 2007; SCF, 2001) by calculating the percentage of individuals per age with an estimated long-term dietary exposure to 3-MCPD exceeding this health-based guidance value.

# 3 Results

## 3.1 Long term dietary exposure to 3-MCPD

Figure 3-1 shows the best estimates of the median (P50) and P95 of long-term exposure to 3-MCPD via food for the ages 2 to 69, including the corresponding lower and upper limits of the 95% confidence interval. In the 2- to 6-year olds, the exposure seemed to increase slightly from 2 up to 3-4 years, and decreased at ages 5 and 6, to an

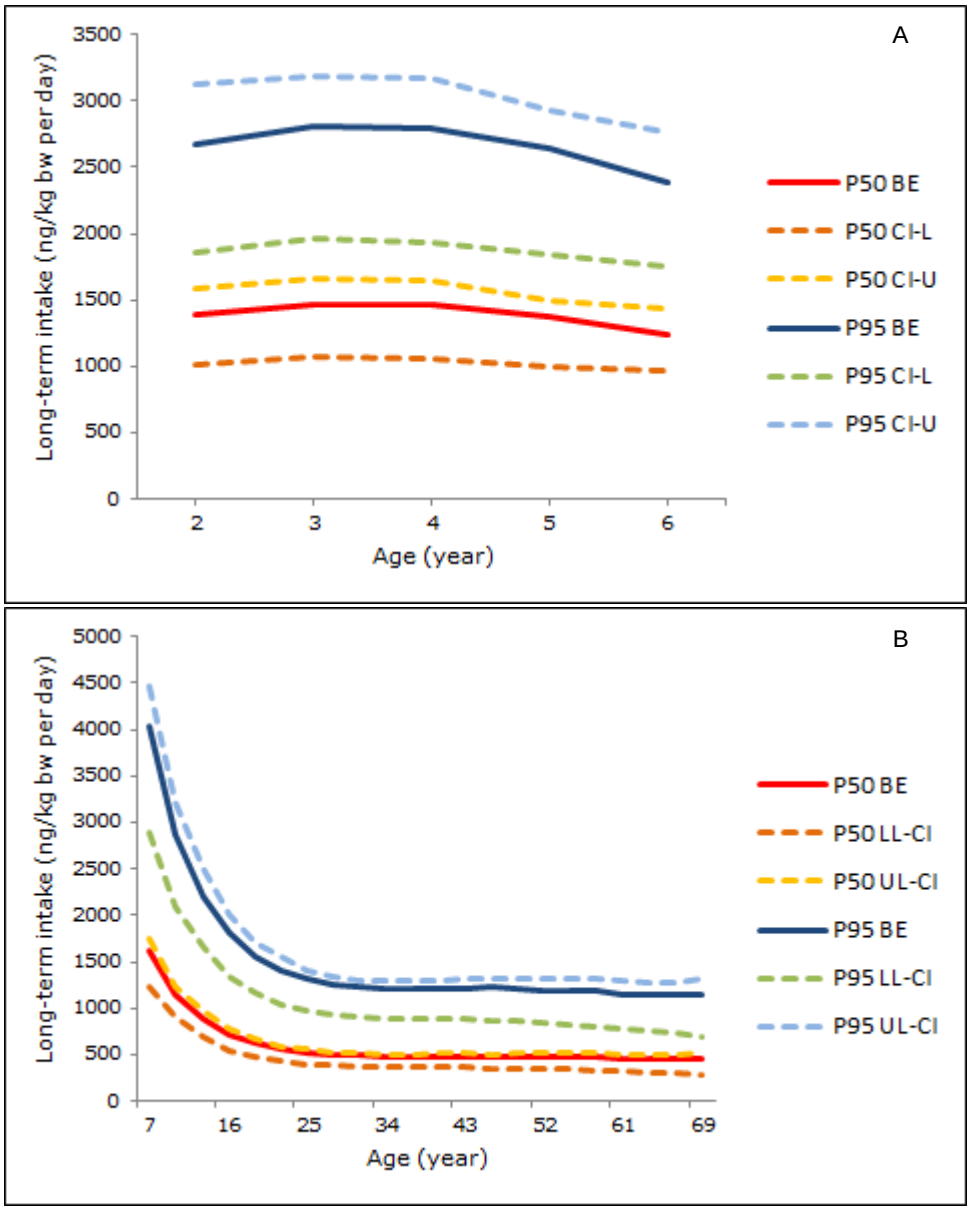


*Figure 3-1. Best estimates (BE) of the median (P50) and high (P95) long-term dietary exposure to 3-MCPD per age in young children aged 2 to 6 (A) and in persons aged 7 to 69 (B) in the Netherlands, including their 2.5% lower (LL-CI) and 97.5% upper confidence limits (UL-CI).*

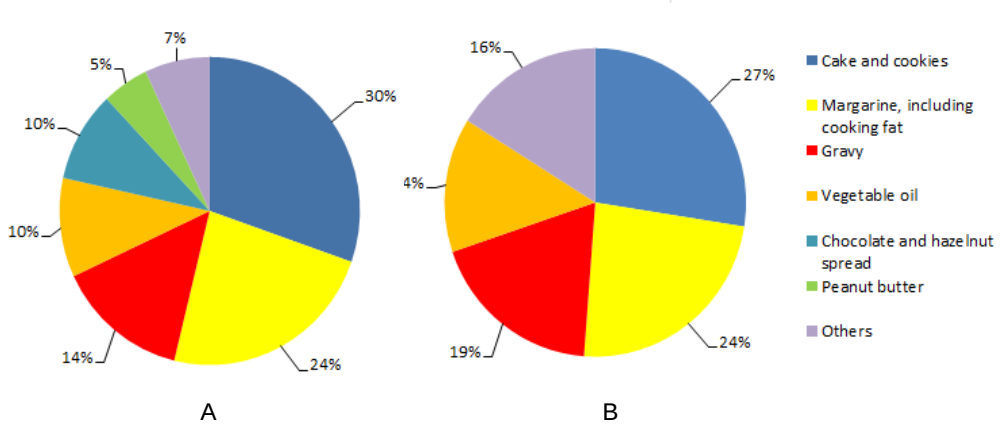


*Figure 3-2. Contribution (%) per analysed food group to the long-term total dietary exposure to 3-MCPD in young children aged 2 to 6 (A) and in persons aged 7 to 69 (B) in the Netherlands.*

exposure level lower than at age 2[3]. Overall, the best estimates of the P50 and high (P95) exposure in this age group equalled 1383 and 2679 ng/kg bw per day, respectively. Given the uncertainty around the best estimates of the exposure due to sampling size of the concentration and consumption database (section 2.4), the high (P95) exposure to 3-MCPD could be as high as 3193 ng/kg bw per day in 3-year olds.

In persons aged 7 to 69, exposure decreased with age (Figure 3-1). The best estimate of the median exposure ranged from 454 ng/kg bw per day in 67-year olds up to 1611 ng/kg bw per day in 7-year olds. Corresponding numbers for the best estimates of the high (P95) exposure were 1144 and 4041 ng/kg bw per day. Given the sampling size uncertainty around these exposure estimates, the high (P95) exposure to 3-MCPD could be as high as 4473 ng/kg bw per day in 7-year olds.

Appendix E lists the exposure estimates per age, including the 95% confidence intervals.

## 3.2 Contribution of food groups

The food groups that contributed at least 5% to the total long-term exposure to 3-MCPD in 2- to 6-year olds and in persons aged 7 to 69 are presented in Figure 3-2. In both age groups, the food groups ‘cake and cookies’, ‘margarine, including cooking fat’, ‘gravy’ and ‘vegetable oil’ contributed most to the overall exposure to 3-MCPD. These food groups contributed together more than 75% to the exposure. In 2- to 6-year olds, also the food groups ‘chocolate and hazelnut spread’ and ‘peanut butter’ contributed for at least 5% to the exposure.

Examining the contribution of the food groups to the upper 5% of the exposure distribution in 2- to 6-year olds showed that in this upper tail of the exposure distribution food group ‘gravy’, with a contribution of 46%, became the highest contributor, followed by the food groups ‘cake and cookies’ (21%) and ‘margarine, including cooking fat’ (13%). This

[3] The exposure data could be described by a quadratic polynoom (P=0.01).

was also true for persons aged 7 to 69. Corresponding percentages were 36%, 27% and 16%, respectively.

## 3.3 Exposure versus health based guidance value

For an indication of a possible health risk related to the estimated exposure to 3-MCPD via food, the percentage of persons aged 2 to 69 with an exposure exceeding the TDI of 2 ug/kg bw per day was estimated. On average, 18% of the 2- to 6-year olds exceeded the TDI. Given the uncertainty in the dietary exposure assessment due to the sampling size of the food consumption and concentration database, this percentage could be as high as 32% in 4-year olds.

The percentage of persons aged 7 to 69 with an intake exceeding the TDI ranged from 0.4% for those aged 61-69 and 35% in 7-year olds, with a 97.5% upper confidence limit of 40% (Figure 3-3). This percentage dropped below 5% (including the 97.5% upper confidence limit) around the age of 16.

Appendix G lists the numerical values of the percentage of individuals with an intake of 3-MCPD exceeding the TDI per age.

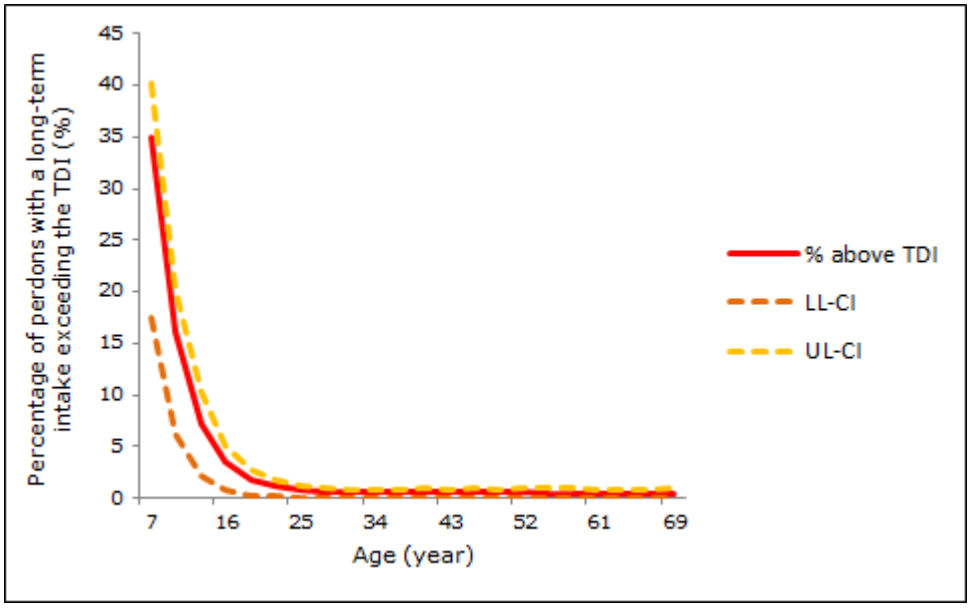


*Figure 3-3. Percentage of persons aged 7 to 69 living in the Netherlands with a long-term dietary exposure to 3-MCPD exceeding the tolerable daily intake (TDI) of 2 µg/kg bw per day. LL-CI and UL-CI = 2.5% lower and 97.5% upper confidence limit of the percentage persons with an intake exceeding the TDI, respectively.*

# 4 Discussion

The present study describes the dietary exposure to 3-MCPD in the population aged 2 to 69 in the Netherlands. Below, the results are discussed in relation to a study into the dietary exposure in the Netherlands performed by EFSA in 2012 and some other studies reporting on the exposure to 3-MCPD, and to the methodology and input data used. The exposure estimates are also discussed in relation to the tolerable daily intake (TDI) of 3-MCPD to evaluate if there is a possible health risk related to the reported exposure estimates.

## 4.1 Exposure results of 3-MCPD

In general, exposure to compounds decreases with age, due to higher food consumption levels per kg bw in young children. In the present study, the exposure to 3-MCPD was however lower in 2- to 6-year olds compared to those aged 7 to 10 (Figure 3-1 and Appendix E). A comparison of the consumption levels of the food groups contributing to the exposure to 3-MCPD of these two age groups did however not show a clear difference in consumption amounts that could explain this surprising result. Very likely differences in study design between the food consumption surveys of the 2- to 6-year olds and persons age 7 to 69 have resulted in this difference in exposure rather than real differences in exposure. In a recent dietary exposure assessment of cadmium, it was also observed that the exposure to cadmium in 5- and 6-year olds was lower than in 7-year olds (Sprong & Boon, 2015). The new DNFCS 2012-2017 that is presently being conducted will cover ages of 1 up to 79[4], foreclosing possible differences in intake between age groups due to differences in study design.

The high exposure to 3-MCPD in 7- to 10-year olds compared to a lower exposure in children aged 11 to 17 (Figure 3-1 and Appendix E) was due to differences in consumption amounts, combined with high levels of 3-MCPD, of three food groups, namely ‘cake and cookies’, ‘gravy’, and ‘margarine, including cooking fat’.

## 4.2 Comparison with other studies into the dietary exposure to 3-MCPD

### *4.2.1 EFSA study*

In 2013, EFSA published a scientific report regarding the occurrence of 3-MCPD in food in Europe (EFSA, 2013). Based on these data, EFSA performed a preliminary exposure assessment by combining country-specific consumption data present in the EFSA Comprehensive food consumption database to all occurrence data on 3-MCPD submitted to EFSA by several member states. No concentration data from the Netherlands were included in this database. For the Netherlands, EFSA calculated the exposure for three age classes: toddlers (1-2 years),

[4] http://www.rivm.nl/Onderwerpen/V/Voedselconsumptiepeiling/Overzicht_voedselconsumptiepeilingen/VCP_Basis_1_79_jaar_2012_2017

*Table 4-1. Dietary exposure to 3-MCPD in the Netherlands for different age classes as reported by EFSA (2013) and in the present study*

| Age class (years) | Exposure to 3-MCPD (ng/kg bw per day) | |
|---|---|---|
| | Mean | P95 |
| EFSA (2013) | | |
| 1-2[1] | 1400 | 2830 |
| 3-9[2] | 1210 | 2510 |
| 18-64[3] | 540 | 1270 |
| This study | | |
| 2-6 | 1490 (1151-1642) | 2660 (1981-2914) |
| 7-69 | 674 (498-748) | 1605 (1167-1801) |

[1] Actual age included in this age group was 2 years (underlying food consumption data were derived from DNFCS-Young children 2005/2006 (Ocké et al., 2008))

[2] Actual ages included in this age group were 3-6 years (underlying food consumption data were derived from DNFCS-Young children 2005/2006 (Ocké et al., 2008))

[3] Actual ages included in this age group were 19-30 years (underlying food consumption data were derived from DNFCS-Young adults (Ocké et al., 2005)

other children (3-9 years) and adults (18-64 years). For these classes, Dutch food consumption data were available in the EFSA Comprehensive database. The exposure estimates reported by EFSA per age class, together with those calculated in the present study, are listed in Table 4-1.

The exposure results are more or less similar. The exposure in the age group 7 to 69 as estimated in the present study tended to be higher compared to the exposure in adults reported by EFSA. The reason for this is the inclusion of children (7 to 17 years) in this age group with a higher exposure to 3-MCPD compared to adults (Figure 3-1).

The food groups that contributed most to the exposure to 3-MCPD according to the EFSA study were ‘margarine and similar products’, ‘bread and rolls’ and ‘fine bakery wares’. Contribution ranged from 66-72%, 9-10%, and 5-9%, respectively, depending on the age group. In the present study, the food group ‘margarines, including cooking fat’ (similar to the EFSA food group ‘margarine and similar products’) was less important for the exposure to 3-MCPD (23-24%), whereas the food group ‘cake and cookies’ (comparable to the EFSA food group ‘fine bakery ware’) was more important (27-30%) (Figure 3-2).

For the mapping of the foods consumed to those analysed, EFSA used broad food categories and did not adjust the mapping based on fat content. For example, if mainly high fat margarines were analysed, the contribution of margarines to the total exposure to 3-MCPD may have been overestimated, since more low fat spreads are consumed than margarines[5]. The high contribution of the food group ‘cake and cookies’ in the present study compared to its counterpart within the EFSA study

[5] The consumption of low fat spreads among children aged 2 to 6 was 6.5 g per day opposed to 3.2 g per day for margarines.

was due to a difference in 3-MCPD concentrations: the concentration assigned to the food group 'cake and cookies' was substantially higher than the concentrations used for its EFSA counterpart: 289 (216-580) vs 41 (30-51) µg/kg product[6]. For bread and rolls no comparison can be made, since no 3-MCPD concentrations were available for this food group in the present study (Appendix B). Bread and rolls were included in the present study via mapping to the food group 'vegetable oil' (section 2.3).

The methodology to analyse levels of 3-MCPD in food was still under development at the time of the EFSA 2013 publication. Because of this, formation of artefact 3-MCPD during the analytical process could not be ruled out with some analytical methods. Due to this, the reported 3-MCPD level would have been higher than the actual levels (EFSA, 2013). It is therefore uncertain if the concentrations used by EFSA were correct. In the present report, 3-MCPD levels were obtained with a validated analytical method (Peters, 2015).

In conclusion, we expect that the contributions reported in this study are likely to represent better the 'real' contributions to 3-MCPD in the Netherlands compared to the EFSA study. Furthermore, EFSA did not correct the exposure for day-to-day variation (section 2.4), which may also have resulted in other results.

#### *4.2.2 Other exposure studies*

A short (not exhaustive) search in the literature showed that since 2013, several studies have been published reporting the intake of 3-MCPD via food. These studies cover the intake of 3-MCPD in China (Li et al., 2015), Hong Kong (Chung et al., 2013), Poland (Starski et al., 2013) and Brazil (Arisseto et al., 2013). An overview of the results is listed in Table 4-2.

In these studies, the estimated intakes were all lower than those calculated for the Netherlands. Reasons for this could be 1) foods included in the assessment, 2) type of fat or oil present in the food, 3) methodology used to assess the exposure and 4) differences in food consumption patterns between countries. For example, the Polish study only addressed the intake of 3-MCPD via bakery products and the one from China via the consumption of refined oils. From the description of this last study, it is not clear whether this also included the consumption of refined oils as an ingredient in foods. All four studies used deterministic approaches to assess the exposure. The mean exposure was estimated by combining the average consumption of a food (group)

*Table 4-2. Dietary exposure to 3-MCPD in four different countries*

| Study[1] | Population | Exposure to 3-MCPD (ng/kg bw per day) | |
|---|---|---|---|
| | | Mean | High |
| Brazil | Whole population | 60 | 510 |
| China | From age 7 onwards | 670-1310 | 900-1910 |
| Hong Kong | Adult population | 200 | 530 |
| Poland | Children (4 and 16-18 years) | 15-128 | - |

[1] For the references per study, see section 4.1.2.

with an average 3-MCPD concentration of that food (group), and subsequently adding the exposure over foods or food groups to obtain an overall exposure. The high exposure was calculated by combining either the average consumption with a high (e.g. P95) concentration per food (group), or a high consumption with an average concentration per food. Corrections for body weight were either based on individual or average body weights. Due to these differences in approaches, as well as very likely differences in dietary habits, these exposure results are different from those reported here and cannot be compared directly.

## 4.3 Methodological issues

The exposure estimates of 3-MCPD presented in this report are influenced by different sources of uncertainty. The most important sources are summarized in Table 4-3, including the direction and magnitude of the uncertainty relative to the exposure estimate, using the format as proposed by EFSA (2006).

*Concentration data*
The main limitation of the present study was the concentration data. Only for a limited number of foods analytical data of 3-MCPD were

*Table 4-3. Sources, direction and magnitude of uncertainty in dietary exposure assessment to 3-MCPD.*

| Source of uncertainty | Direction & magnitude[a] |
|---|---|
| **Food consumption data** | |
| Sampling uncertainty (bootstrap)[b] | -/+ |
| **Concentrations** | |
| Sampling uncertainty (bootstrap)[b] | -/+ |
| Representativeness samples for consumed foods | --/++ |
| **Food mapping** | |
| Calculation via 15 food groups | --/++ |
| Foods containing cocoa butter and other sources of fat were assumed to contain 3-MCPD at the level analysed in food groups 'vegetable oil' or 'cake and cookies' | + |
| Consumption of olive oil as such was assumed to be extra virgin olive oil | - |
| Fat type of the analysed food groups was similar to that of the mapped foods | --/++ |
| **Model uncertainty** | |
| LNN[c] | • |
| **Overall assessment:** Based on this qualitative evaluation of different uncertainty sources it was concluded that the exposure to 3-MCPD might either be under- or overestimated due to the limited number of foods analysed per food group and the wide range in 3-MCPD levels between brands of some food groups. | --/++ |

[a] Key to direction and magnitude
+, ++, +++ = uncertainty likely to cause small, medium or large overestimation of exposure
-, --, --- = uncertainty likely to cause small, medium or large underestimation of exposure
• = uncertainty likely to cause a negligible effect on exposure
[b] In the analyses, sampling uncertainty of food consumption and concentration data was quantified simultaneously via a bootstrap analysis. For more details, see section 2.4.
[c] LNN = LogNormal-Normal (Appendix D)

available. To map these data to the large number of foods recorded in the food consumption database, the analysed foods were grouped in 15 food groups. This grouping resulted in very divergent concentration data within several food groups. For example, the 3-MCPD concentrations in two meat gravy samples were either 89 or 624 µg/kg fat, and for example in margarines the concentrations in four samples ranged from 580 up to 1800 µg/kg fat. Because of this, the concentration data were incorporated in the assessment using a parametric approach. With this approach, the concentration data are assumed to follow a lognormal distribution. Parametric modelling may be useful when the observed concentrations per food (group) are not expected to represent the whole range of possible concentrations to which a population may be exposed.

The large difference in 3-MCPD levels within a food group could have been due to different brands analysed of the same product. For some food groups, including ‘crisps’ and ‘ice’ only one brand was analysed, resulting in 3-MCPD concentration that were almost, if not completely, identical (Appendix B). This was very likely due to the use of fat as an ingredient obtained from one source by the producer. This may indicate that 3-MCPD concentration are brand dependent, and that people who are over a longer period faithful to one brand may be either exposed for a longer period to a high or lower concentration of 3-MCPD via the consumption of this food. This needs however further investigation: the dataset available was too limited to arrive at a conclusion about brand dependent 3-MCPD concentrations.

For the food group ‘coconut milk’, the actual analysed level was used in the assessment, since there was only one 3-MCPD concentration available for this food group. It is however not expected that this influenced the exposure assessment significantly, because of a low consumption of coconut milk in the Netherlands. This was also true for soy sauce.

In 2015, the Joint Research Centre (JRC) developed and validated analytical methods for the analysis of 3-MCPD in various food matrices (Wenzl et al., 2015). This method was applied to more than 600 different food samples. The analytical results were reported to EFSA and have not been published so far. Examining the foods analysed by the JRC, smoked fish and smoked meat products were not included in the present assessment. Since 3-MCPD is predominantly present in refined vegetable oils and fats (EFSA, 2013), we estimate that ignoring the exposure to 3-MCPD via the consumption of smoked fish and smoked meat products, combined with the relatively low fish consumption in the Netherlands, will not have resulted in an underestimation of the exposure to 3-MCPD.

As stated earlier, the concentration data were very limited and could be quite diverse within a food group (Appendix B). Furthermore, given the origin of 3-MCPD, the presence of this process contaminant in chocolate and coconut milk was unexpected. A larger concentration database covering more foods could shed a light on these discrepancies between measured and expected values, and may give the possibility to refine the mapping of foods analysed to those consumed. Due to the possible

differences in 3-MCPD concentrations between brands, these analyses should preferably be performed in individual foods.
Overall, we estimate that due to the limited number of 3-MCPD concentration data available and the large variation in concentrations within food groups, the actual exposure estimate could have been higher or lower than the exposure reported here.

*Food mapping*
Since the number of foods recorded in the two food consumption surveys exceeded by far the number of foods analysed, assumptions were needed to map analysed food groups to the foods consumed (section 2.3). An important assumption was that the fat type used in the analysed food groups was similar to that of the mapped foods. This assumption may not always have been applicable, due to the limited number of foods analysed per food group and the wide range of 3-MCPD concentrations observed in some of them. This assumption may therefore have resulted in either an over- or underestimation of the exposure.

In cases where a food could contain fat from different sources (e.g. chocolate biscuits), a conservative approach was taken to avoid possible underestimation of the exposure (section 2.3). This uncertainty can be reduced by mapping the consumed fat fractions of a food to their respective 3-MCPD concentrations. This information is however not readily available.

*Modelling of exposure*
To model the exposure to 3-MCPD, LNN was used (Appendix C). With this statistical model, long-term exposure to food chemicals can be estimated based on only a limited number of consumption days per individual present in the food consumption database (in our case two; Appendix A). Like other long-term exposure models, LNN is based on the assumption that daily positive exposures are normally distributed after transformation. A normal distribution is a prerequisite for removal of the within-person's variation from the daily positive exposure distribution (Appendix C). If this condition is not met, the use of LNN might be debatable or not fit for purpose. Normality can be checked by using the normal quantile–quantile (q–q) plot, a graphical display of observed vs. theoretical residuals (de Boer et al., 2009). Examination of the q-q plots showed that the daily positive exposure distributions to 3-MCPD in both age groups could be considered close to normal (Appendix G), justifying the use of LNN to model the long-term exposure to 3-MCPD. The positive exposure distribution can be considered close to normal when the observed (in red) vs. theoretical residuals (in black) follow approximately a straight line (Appendix G).

*Summary*
The different issues contributing to the uncertainty of the exposure estimates are summarized in Table 4-3. Overall, the estimated exposure to 3-MCPD may be either under – of overestimated due to the limited number of foods analysed per food group and the wide range of 3-MCPD levels within some of the food groups.

## 4.4 Comparison with health based guidance value

The TDI of 2 µg/kg bw per day was used to assess whether there is a possible health risk related to the exposure to 3-MCPD (section 1), as used by EFSA (2013).

Up to the age of 17, the percentage of individuals with an estimated 3-MCPD intake above the TDI was more than 5% (including the upper level of the 95% confidence interval) with a maximum best estimate of 35% at the age of 7 (Figure 3-2; Appendix F). The corresponding best estimate of the P95 exposure in 7-year olds was 4041 ng/kg bw per day. During adulthood, the percentage of persons with an intake exceeding the TDI dropped to approximately 1%.

The question whether an exceedance of the TDI only in childhood may be acceptable was discussed in a scientific NVWA panel of experts in 2007 (VWA, 2008). This panel proposed a decision tree to assess possible health risks in young children when health-based guidance values are exceeded (VWA, 2008). This decision tree is applicable to evaluate long-term effects for which such guidance values (such as the TDI) are established (VWA, 2008). The panel stated that there is a very limited health risk if the TDI is derived from a life-time study in which young animals received a higher exposure than the full-grown animals due to their lower body weight and relative high food consumption. An exposure level that exceeds the TDI value with a factor two or less for a limited period of time in children would in that case not give reason for concern.

For 3-MCPD, the underlying study for the derivation of the TDI was a 2-year study in which 3-MCPD was added to food. The concentration of 3-MCPD was kept constant during the study, and therefore, because of higher feed intake relative to body weights in the young animals as compared to the adult animals, juvenile exposure was 2-3 times higher than exposure in adult life. Since the LOAEL from this study (critical endpoint: renal tubular hyperplasia), which provided the basis for setting the TDI, is predominantly based on exposure in adults, the higher exposure of the young animals is implicitly taken into account in the LOAEL and thus in the TDI.

Based on the criteria as formulated by the NVWA expert panel combined with negligible exceedance of the TDI in adult life, the exposure results reported in this study, may show that there is a negligible health risk related to the estimated exceedance of the TDI in children aged 2 up to and including 17 living in the Netherlands. However, given

- the uncertainty in the exposure data (section 4.2),
- a percentage of at least 5% of the children with an exposure exceeding the TDI over a long, rather than limited, period during childhood (2-16 years; Appendix F)
- an upper limit of the confidence interval of the P95 exposure level in 7-year olds that exceeded the TDI with a factor larger than 2 (4473 ng/kg bw per day; Appendix E),

it is not possible to conclude conclusively that the health risk related to the intake of 3-MCPD in the Dutch population is negligible.

## 4.5 Conclusion

The aim of the present study was to estimate the exposure to 3-MCPD based on the analytical data generated by RIKILT in 2013 and 2015. On average 18% of young children aged 2 to 6 had an intake exceeding the TDI for 3-MCPD. Seven-year-olds had the highest intake per kg bw, and 35% of this age group had an intake above the TDI. Thereafter, the intake decreased: from the age of 17 less than 5 % of the population had an intake above the guidance value.

The dietary exposure assessment was based on very limited concentration data. Due to this, the mapping of analysed foods to those consumed was subject to assumptions that may have resulted in an over- or underestimation of the exposure. As far as possible, conservative choices were made to avoid underestimation of the exposure, but given the few foods analysed per relevant food group and the large variation in concentrations observed in some of the food groups, it cannot be concluded conclusively that the exposure estimates were conservative. Due to this, and exposure estimations that were close or exceeding the TDI during childhood, no properly substantiated conclusions regarding health risk could be drawn. More analyses of 3-MCPD in foods are needed to determine the exposure to 3-MCPD. For this, the sampling strategy as defined by the JRC could be used as a guideline (Wenzl et al., 2015), in combination with information on actual foods consumed as recorded in the Dutch food consumption database.

Based on the concentration data produced by the JRC (Wenzl et al., 2015), EFSA is currently performing a risk assessment to 3-MCPD which is expected to be published in 2016. Since most palm oil is imported in Rotterdam, refined in the Netherlands and, subsequently, distributed all over Europe[6], we expect that the concentrations of 3-MCPD that will be used in the exposure assessment by EFSA may not be very different from comparable foods available on the Dutch market. As soon as these data become available, it may be worthwhile to compare the concentrations used by EFSA with those used in the present study and to determine whether an exposure assessment using the concentration data of EFSA will result in improved exposure estimates compared to the present study.

[6] http://www.mvo.nl/factsheet-palmolie-verschenen

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# Appendix A Description of consumption data used in the exposure assessment to 3-MCPD

**DNFCS-Young Children 2005/2006** (Ocké et al., 2008)
The target population of the DNFCS-Young Children 2005/2006 consisted of boys and girls aged 2 to 6 living in the Netherlands. Respondents were selected from representative consumer panels of Market Research Agency GfK. Panel characteristics, such as socio-demographic characteristics, are known to GfK. Persons in these panels participate in all types of surveys and were not specially selected on nutritional characteristics. Institutionalised persons were excluded, as well as children whose parents/carers did not have sufficient knowledge of the Dutch language. Per family, only one child was included to avoid correlations in dietary consumption patterns between children of the same family. In total, 1,634 children were invited to participate in the study, of which 1,279 consented (net response of 78%). During recruitment, the representativeness of the study population was monitored and, if necessary, the recruitment was adjusted for age and sex, education of the head of the household, level of urbanisation, place of residence and region. The study population was representative regarding socio-demographic characteristics (including region and education of the head of the household), but densely populated areas were slightly underrepresented.

The food consumption data were collected in the period October 2005 to November 2006 via a food diary on two non-consecutive days (separated by about 8 to 13 days). Parents/carers were visited at home by a trained employee of GfK. During the home visit survey materials were presented and overall instructions were given.

Portion size of the foods and meals were estimated by using photographs, domestic measures (a small and a large spoon were supplied to standardise estimates), standard units, weight and/or volume. The usual volume of cups and glasses used was measured by the carer. All days of the week were equally represented, but the winter and autumn period were slightly overrepresented compared to the spring and summer period. National and/or religious holidays or holidays of the participants were not included in the survey.

**DNFCS 2007-2010** (van Rossum et al., 2011)
The target population of the DNFCS 2007-2010 consisted of people aged 7 to 69 living in the Netherlands. Pregnant and breast-feeding women, as well as institutionalised people were not included. Respondents were selected from representative consumer panels of GfK. A maximum of one person per household was included in the survey to avoid correlations in dietary consumption patterns between members of the same family. In addition, the panels only included people with sufficient knowledge of the Dutch language. In total, 5,502 individuals were invited to participate in the study, of which 3,819 consented (net response of 69%). Children were overrepresented in the study population and adults underrepresented.

The food consumption data were collected over a 3-year period from March 2007 to April 2010 via two non-consecutive 24-hour dietary recalls (separated by 2 to 6 weeks). Children aged 7 to 15 were interviewed face to face during home visits in the presence of at least one of the child's parents or carers. Participants aged 16 and over were interviewed by telephone, at dates and times unannounced to the participants.

Portion sizes of the foods consumed were quantified in several ways: by means of quantities as shown on photos in a provided picture booklet, or in household measures, standard units, by weight and/or volume. The survey covered all days of the weeks and all four seasons. National and/or religious holidays or holidays of the participants were not included in the survey.

# Appendix B Foods analysed and their individual 3-MCPD concentration (µg/kg fat)

| Food group | Food | Brand[1] | 3-MCPD (µg/kg fat) |
|---|---|---|---|
| **Infant formula**[2] | | | |
| Infant formula | Infant formula | A | 116 |
| Infant formula | Infant formula | A | 100 |
| Infant formula | Infant formula | A | 97 |
| Infant formula | Infant formula | A | 66 |
| Infant formula | Infant formula | A | 52 |
| Infant formula | Infant formula | B | 162 |
| Infant formula | Infant formula | B | 52 |
| Infant formula | Infant formula | B | 91 |
| Infant formula | Infant formula | C | 596 |
| Infant formula | Infant formula | D | 582 |
| Infant formula | Infant formula | E | 337 |
| Infant formula | Infant formula | A | 410 |
| Infant formula | Infant formula | F | 1400 |
| **Coffee creamer and coconut milk** | | | |
| Coffee Creamer | Coffee Creamer | A | 1177 |
| Coffee Creamer | Coffee Creamer | B | 1186 |
| Coffee Creamer | Coffee Creamer | B | 1100 |
| Coconut milk | Creamy coconut milk | - | 86 |
| **Fat** | | | |
| Margarine, including cooking fat | Baking fat | A | 620 |
| Margarine, including cooking fat | Baking fat | B | 1500 |
| Margarine, including cooking fat | Baking fat | C | 160 |
| Margarine, including cooking fat | Margarine | D | 680 |
| Margarine, including cooking fat | Margarine | E | 580 |
| Margarine, including cooking fat | Margarine | F | 1800 |
| Margarine, including cooking fat | Margarine | G | 990 |
| Olive oil | Extra virgin olive oil | E | <10 |
| Vegetable oil | Sunflower oil | F | 630 |
| Vegetable oil | Olive oil | E | 420 |
| **Potato products** | | | |
| French fries | French fries | A | 1100 |
| French fries | French fries | B | 870 |
| **Sauces** | | | |
| Mayonnaise-garlic sauce | Garlic sauce | A | 177 |
| Mayonnaise-garlic sauce | Mayonnaise | A | 385 |

| Food group | Food | Brand[1] | 3-MCPD (µg/kg fat) |
|---|---|---|---|
| Gravy | Meat gravy | B | 889 |
| Gravy | Meat gravy | C | 6235 |
| **Spreads** | | | |
| Chocolate and hazelnut spread | Chocolate spread | A | 545 |
| Chocolate and hazelnut spread | Hazelnut paste | B | 860 |
| Chocolate and hazelnut spread | Hazelnut paste | C | 1300 |
| Peanut butter | Peanut butter | D | 288 |
| Peanut butter | Peanut butter | E | 270 |
| Peanut butter | Peanut butter | C | 870 |
| **Cakes and confectionary** | | | |
| Cake and cookies | Cake | A | 2000 |
| Cake and cookies | Cake | A | 1800 |
| Cake and cookies | Cookies | B | 2900 |
| Cake and cookies | Cookies | A | 2100 |
| Cake and cookies | Cookies | C | 1079 |
| Crisps | Crisps | D | 410 |
| Crisps | Crisps | D | 410 |
| Chocolate | Chocolate | E | 180 |
| Chocolate | Chocolate | F | 230 |
| Ice cream | Ice cream | G | 260 |
| Ice cream | Ice cream | G | 240 |

[1] Brand: same letter within a food group indicates that the foods had the same brand. For example, within the food group 'spreads' foods of 5 different brands were sampled.
[2] Analytical results in infant formula were not included in the assessment, because no consumption of this food was recorded in the food consumption surveys considered in this study

# Appendix C Modelling of long-term exposure using LNN

LNN models exposure frequencies and exposure amounts separately, followed by an integration step (Goedhart et al., 2012). For the consumption frequencies, LNN fits a logistic regression model to the number of days with consumption per individual, providing both an estimate of the mean consumption frequency and of the variation between individuals in this frequency (dispersion factor). For the modelling of the positive amounts, LNN first transforms the positive daily exposure distribution into a more normal distribution using a logarithmic or power function. Then, a normal-distribution based variance components model is fitted to remove the within-person's variation. The resulting between-person normal distribution is then back-transformed and combined with the exposure frequency distribution to estimate the long-term dietary exposure distribution. This is achieved by sampling a large number of times from both the exposure frequency distribution and the back-transformed positive exposure distribution (Monte Carlo integration). In this report, we used a logarithmic transformation for the positive daily exposure distribution. The correlation between intake frequency and amount was assumed zero.

# Appendix D Description of the bootstrap

There are different sources of uncertainty in dietary exposure assessments. One of these sources is the uncertainty due to the limited size of the dataset. The smaller the dataset, the more uncertain the data are. This uncertainty can be quantified by using the bootstrap method (Efron, 1979; Efron and Tibshirani, 1993).

With this method a bootstrap database is generated of the same size as the original database for both the food consumption and concentration database by sampling with replacement from the original datasets. These bootstrap databases are considered as databases that could have been obtained from the original population if another sample was randomly drawn. These two bootstrap databases are then used for the exposure calculations and derivation of the relevant percentiles. Repeating this process many times results in a bootstrap distribution for each percentile that allows for the derivation of confidence intervals around it. The bootstrap approach was used in this report by generating 100 food consumption and 100 concentration bootstrap databases and calculating the chronic or acute (with at least 10,000 iterations each) dietary exposure. Of the resulting bootstrap distributions per percentile a 95% uncertainty interval was calculated by computing the 2.5% and 97.5% points of the empirical distribution.

Note that by bootstrapping both the consumption and concentration database in one analysis it is not possible to quantify which part of the uncertainty was due to a limited number of consumption or concentration data.

# Appendix E Median (P50) and high (P95) exposure estimates (µg/kg bw per day) to 3-MCPD per age in young children aged 2 to 6 and persons aged 7 to 69 in the Netherlands

*Young-children 2-6 years*

| Age (years) | Percentiles of exposure per scenario (ng/kg bw per day) | |
|---|---|---|
| | P50 | P95 |
| 2 | 1389 [1017-1582] | 2674 [1856-3123] |
| 3 | 1460 [1073-1660] | 2808 [1959-3193] |
| 4 | 1460 [1063-1653] | 2800 [1935-3178] |
| 5 | 1379 [995-1501] | 2642 [1849-2929] |
| 6 | 1235 [970-1438] | 2386 [1756-2765] |
| 2-6 | 1383 [1044-1562] | 2679 [1863-3079] |

Note: 2.5% lower – 97.5% upper confidence limits of the percentiles of exposure are reported between brackets.

*Population 7 to 69 years*

| Age (years) | Percentiles of exposure per scenario (ng/kg bw per day) | |
|---|---|---|
| | P50 | P95 |
| 7 | 1611 [1232-1741] | 4041 [2895-4473] |
| 10 | 1149 [900-1233] | 2880 [2102-3224] |
| 13 | 883 [685-969] | 2209 [1659-2496] |
| 16 | 726 [554-789] | 1820 [1345-2015] |
| 19 | 624 [476-676] | 1563 [1159-1706] |
| 22 | 561 [431-597] | 1407 [1029-1549] |
| 25 | 523 [398-556] | 1312 [973-1414] |
| 28 | 503 [385-529] | 1260 [926-1350] |
| 31 | 491 [372-517] | 1231 [900-1302] |
| 34 | 484 | 1221 |

| Age (years) | Percentiles of exposure per scenario (ng/kg bw per day) | |
|---|---|---|
| | P50 | P95 |
| | [367-510] | [889-1289] |
| 37 | 484 [367-509] | 1210 [885-1293] |
| 40 | 485 [366-514] | 1214 [885-1291] |
| 43 | 488 [365-513] | 1220 [885-1313] |
| 46 | 487 [361-511] | 1230 [869-1312] |
| 49 | 484 [360-515] | 1217 [872-1313] |
| 52 | 478 [353-519] | 1199 [856-1328] |
| 55 | 475 [343-523] | 1192 [832-1309] |
| 58 | 469 [333-517] | 1180 [795-1311] |
| 61 | 460 [320-504] | 1156 [779-1294] |
| 64 | 456 [308-497] | 1146 [749-1280] |
| 67 | 454 [301-499] | 1144 [728-1270] |
| 69 | 456 [293-515] | 1146 [705-1314] |
| 7-69 | 537 [403-568] | 1613 [1189-1767] |

Note: 2.5% lower – 97.5% upper confidence limits of the percentiles of exposure are reported between brackets.

# Appendix F Percentage of individuals with an exposure to 3-MCPD exceeding the tolerable daily intake (TDI) of 2 µg/kg bw per day per age in young children aged 2 to 6 and persons aged 7 to 69 in the Netherlands

*Young-children 2-6 years*

| Age (years) | Percentage of individuals with an exposure to 3-MCPD exceeding the TDI (%) |
|---|---|
| 2 | 18<br>[5-28] |
| 3 | 22<br>[4-32] |
| 4 | 21<br>[4-31] |
| 5 | 18<br>[3-24] |
| 6 | 11<br>[2-20] |
| 2-6 | 18<br>[3-27] |

Note: 2.5% lower – 97.5% upper confidence limits of the percentages are reported between brackets.

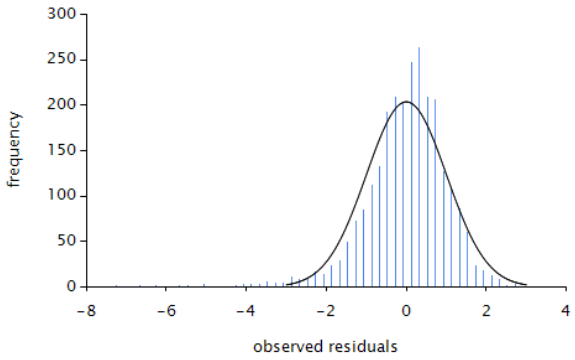
*Population 7 to 69 years*

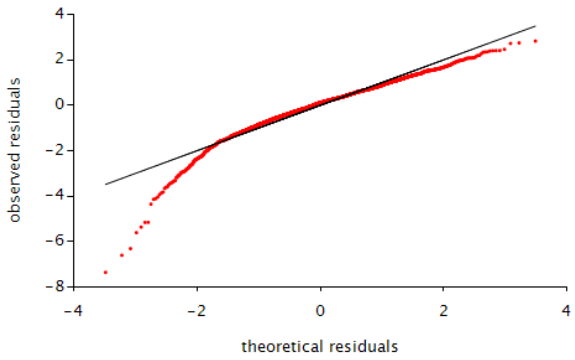
| Age (years) | Percentage of individuals with an exposure to 3-MCPD exceeding the TDI (%) |
|---|---|
| 7 | 35<br>[18-40] |
| 10 | 16<br>[6-20] |
| 13 | 7<br>[2-10] |
| 16 | 4<br>[1-5] |
| 19 | 2<br>[0.3-3] |
| 22 | 1<br>[0.2-2] |
| 25 | 0.8<br>[0.1-1] |
| 28 | 0.7<br>[0.1-1] |
| 31 | 0.6<br>[0.1-0.8] |

| Age (years) | Percentage of individuals with an exposure to 3-MCPD exceeding the TDI (%) |
|---|---|
| 34 | 0.6 [0.1-0.8] |
| 37 | 0.6 [0.1-0.8] |
| 40 | 0.6 [0.04-0.9] |
| 43 | 0.5 [0.1-0.9] |
| 46 | 0.6 [0.04-0.9] |
| 49 | 0.6 [0.04-0.9] |
| 52 | 0.5 [0.05-0.9] |
| 55 | 0.5 [0.04-0.9] |
| 58 | 0.5 [0-0.9] |
| 61 | 0.4 [0-0.9] |
| 64 | 0.4 [0-0.9] |
| 67 | 0.4 [0-0.7] |
| 69 | 0.4 [0-0.9] |
| 7-69 | 3 [1-4] |

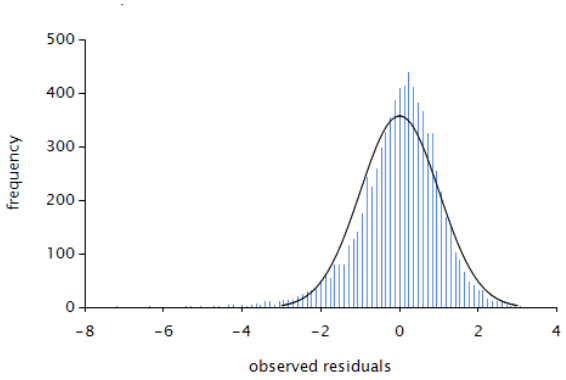
Note: 2.5% lower – 97.5% upper confidence limits of the percentages are reported between brackets.

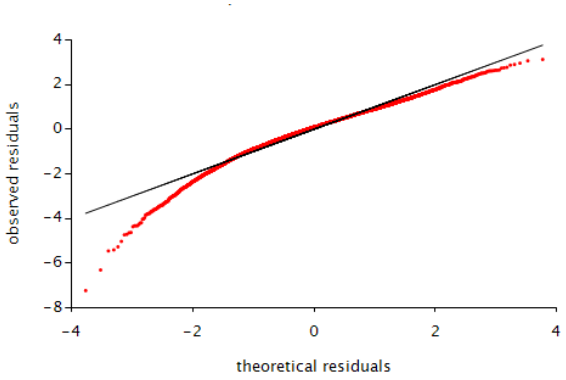
# Appendix G Normality of the lognormal transformed long-term dietary exposure distributions to 3-MCPD for young children aged 2 to 6 and persons aged 7 to 69 in the Netherlands




Young children aged 2 to 6




Persons aged 7 to 69

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