National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

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RIVM Letter report 2015-0195
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Colophon

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De blootstelling aan het voedseladditief titaniumdioxide (E 171). Berekeningen op basis van data van de industrie.

Titaniumdioxide (E 171) is een kleurstof die gebruikt wordt om voedingsmiddelen als snoep, sauzen en decoraties van banketwaren, toetjes of ijs (zoals glazuur, fondant of pareltjes) een witte kleur te geven. Het RIVM heeft op basis van de meest recente inzichten berekend aan hoeveel milligram per kilo lichaamsgewicht mensen gemiddeld door de jaren heen blootstaan. Er bestaat geen maximum voor de inname van deze kleurstof.

Bij verschillende leeftijdsgroepen is de inname berekend. Mensen van 70 jaar en ouder worden door de jaren heen per dag aan gemiddeld 0,5 milligram per kilo lichaamsgewicht blootgesteld (met een bovenste limiet van 1,1 mg/kg lichaamsgewicht per dag). Bij mensen tussen 7 en 69 jaar is dat ietsje hoger (0,7; bovenste limiet 1,3). Voor kinderen van 2 tot en met 6 jaar is de inname het hoogst doordat zij in verhouding meer binnenkrijgen per kilo lichaamsgewicht: 1,4 milligram per kilo lichaamsgewicht per dag voor kinderen (met als bovenste limiet 3,2 mg/kg lichaamsgewicht per dag). Afhankelijk van de leeftijdsgroep is de hoogste blootstelling een factor 3 tot 4 hoger. Mensen krijgen de kleurstof vooral binnen via (gedecoreerde) banketwaren, toetjes en sauzen.

De resultaten zijn gebaseerd op informatie die de industrie heeft aangeleverd over de voedingsmiddelen waarin zij E 171 gebruiken en de hoeveelheid kleurstof die daarin wordt verwerkt. De werkelijke inname is waarschijnlijk wat lager doordat onder meer een bredere range aan producten is meegeteld in de innameberekening (bijvoorbeeld alle cakes in plaats van alleen cake met een wit laagje) dan uitsluitend die producten waar de kleurstof daadwerkelijk aan is toegevoegd. Dit is gedaan omdat gegevens over de consumptie van wit-gekleurde producten ontbreken. De blootstellingschattingen kunnen verder worden verfijnd door de schattingen te preciseren.

De studie is uitgevoerd op initiatief van het ministerie van Volksgezondheid, VWS en de Federatie van de Nederlandse Levensmiddelenindustrie (FNLI).

Kernwoorden: Titaniumdioxide, kleurstoffen, E 171, jonge kinderen, volwassenen, ouderen, lange-termijn blootstelling, voedsel

Synopsis

Exposure assessment of the food additive titanium dioxide (E 171) with use levels provided by the industry.

Titanium dioxide (E 171) is a food colour that provides foods such as confectionary, sauces, and decorations of food (e.g. fondant or icing) a white colour. The best estimate of the median long-term exposure to titanium dioxide (E 171) in the present study ranges from 0.5 mg/kg bw/d (upper limit 1.1 mg/kg bw/d) for elderly adults to 1.4 mg/kg bw/d (upper limit 3.2 mg/kg bw/d) for children. The 95th percentiles of the exposure are about a factor of 3-4 higher. Many foods contribute to the exposure to E 171; the most important food groups are (decorated) fine bakery wares, desserts and sauces. The estimated exposure of both children and adults is comparable to other recent exposure estimates.

The estimate is based on information obtained from the industry about the application of E 171 in food products and the levels of this food additive used in these products. The exposure assessments are performed without taking into account the consumption frequency of brands and more detailed information of the foods consumed. In addition, the exposure estimate is based on the average intake of two consumption days, without taking into account the within-subject variability in consumption patterns. This implies that the estimated intake of E 171 is most likely conservative and the true exposure may be lower. By addressing these aspects, the exposure assessments could be refined further.

The study was performed on the initiative of the Dutch Ministry of Health, Welfare and Sport (VWS) and the Federation of the Dutch Food and Grocery Industry (FNLI). This work applies a system as requested in EU Regulations EU 1333/2008 (food additives) and 1334/2008 (flavourings), and is developed by VWS, FNLI and RIVM.

Keywords: Titanium dioxide, E 171, food additive, young children, adults, elderly, long-term dietary exposure

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1 Introduction

Titanium dioxide (E 171) is a common food additive used as white food colorant in various food products (EFSA 2004; Weir et al. 2012; Peters et al. 2014). Until recently, E 171 was regarded as inert and for this reason considered as safe for consumption. However, with the growing knowledge on nanoparticles, E 171, of which approximately 10-30 % of the particles (number based) is present in nano-size (<100 nm) (Peters et al., 2014; Warheit et al., 2015), is receiving increasing attention. For example, the European Food Safety Authority (EFSA) has planned to re-evaluate E 171 by the end of 2015. In addition, the National Institute for Public Health and the Environment (RIVM) is preparing a number of publications on the possible health risks of titanium dioxide nanoparticles originating from food.

To assess whether E 171 is safe for consumption, it is important to know the level of dietary intake of this additive. On request of the Dutch Ministry of Health, Welfare and Sports (VWS), the present study assessed the dietary intake of E 171. To this aim, data on use levels were collected and a subsequent exposure assessment was performed. E 171 is authorised as a food colour at quantum satis (QS) in several food categories of Annex II of EU Regulation 1333/2008. An acceptable daily intake (ADI) has not been specified for E 171. It is therefore not possible to compare the dietary exposure of E171 with the ADI.

To obtain concentration data on E 171 added to foods, use levels from the food industry were collected using a system developed in 2011 by VWS, the Federation of Dutch Food and Grocery Industry (FNLI) and RIVM. Such a system is requested in EU Regulations 1333/2008 (food additives) and 1334/2008 (flavourings). In the Dutch system, VWS requests FNLI to approach their members and other branch organisations with a call for data for a selected (number of) additive(s) or flavourings. The food industry subsequently sends their data to the RIVM, whom, after a data check, performs the exposure calculations. This system has been used earlier for the food colours E 120 (Carmine), E 133 (Brilliant Blue) and E 150 (caramel colours) and for smoke flavourings (Wapperom et al., 2011; Sprong et al., 2013; Sprong et al., 2014a). In the case of E 171, the data collection from the industry was supplemented with recent analytical data on titanium in food products where use levels were absent, but E 171 was allowed according to legislation. Subsequently, the dietary intake was assessed for the Dutch population (children, adults and elderly people) according to four different tiers. The estimated intakes are discussed with regard to uncertainty and possible refinements and are compared with results from other studies.

2 Intake calculations

2.1 Collection of E 171 concentration data

Data on use levels of E 171 were obtained from the food industry with products on the Dutch market. Food companies were explicitly asked to provide data on products containing E 171, as well as on products not containing it (‘zeroes') for food products in which the use of E 171 is authorised. For example if a producer uses E 171 in only one out of seven mayonnaises, it was the intention to obtain detailed information of all those mayonnaises. Figure 1 shows a schematic overview of the data collection process. To obtain data on E 171 use levels, a template made by RIVM (see Appendix A) was used. When uncertainties regarding the concentration of E 171 in food products occurred (e.g. appearance of E 171 in the whole product or a part of the product), food companies were contacted for a second time and asked to provide more detail on the use levels in their product. Collection of all these data was facilitated by FNLI (Figure 1).

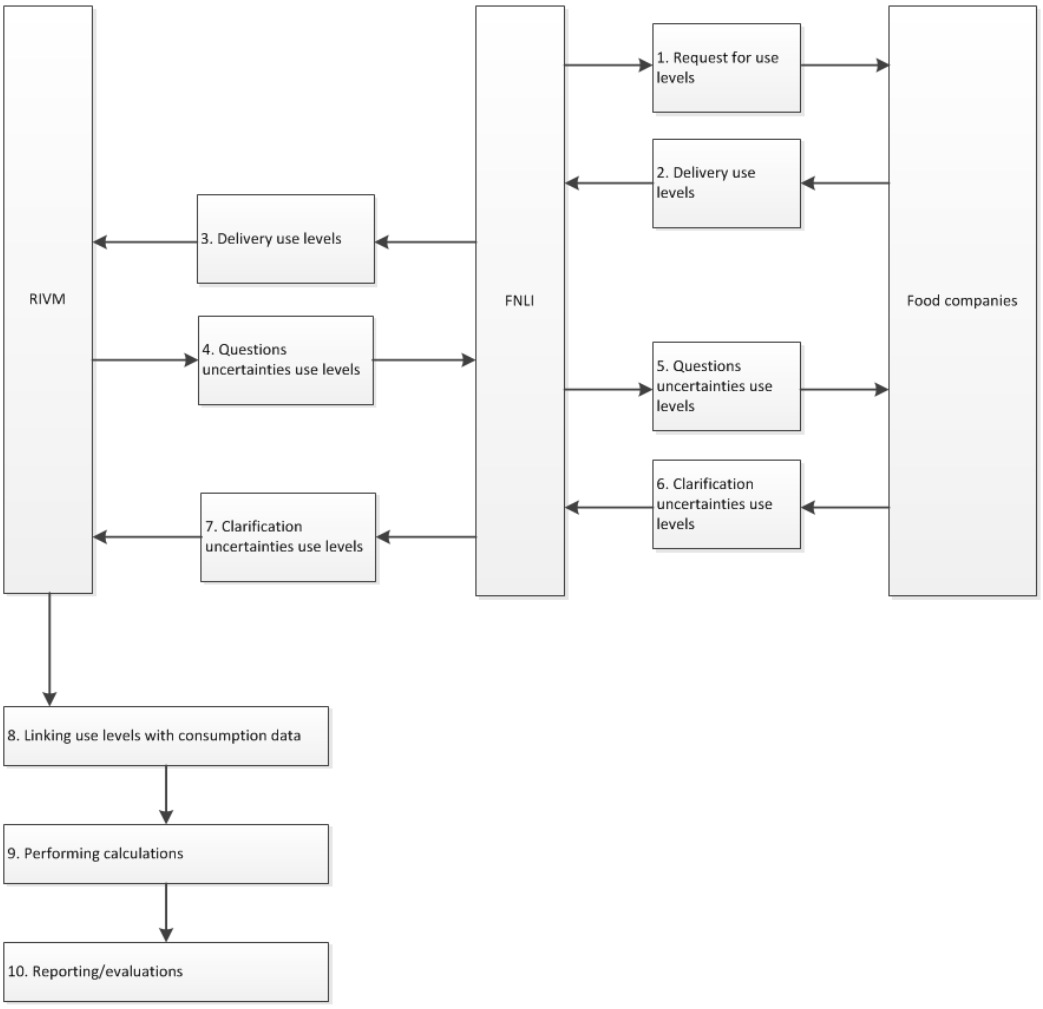

Figure 1. Process of data collection of E 171.

Use level data were supplemented with analytical data in case no use levels were provided for food categories in which E 171 is allowed. Analytical data on titanium dioxide were obtained from Rompelberg et al. (manuscript in preparation).

2.2 Food label information

Food label information was obtained by reading on-line labels of web shops or by visiting three large supermarkets. See also section 2.6 in cases label information was obtained.

2.3 Food consumption data

To estimate the exposure to E 171, Dutch food consumption data were used of 1) young children aged 2 to 6 years old, 2) the population aged 7 to 69 years old and 3) the population aged 70 years or more. For young children, the food consumption data of the Dutch National Food Consumption Survey (DNFCS)-Young children (Ocké et al., 2008) were used. This survey covers the dietary habits of young children aged 2 to 6 years and was conducted in 2005 and 2006. Regarding the population aged 7 to 69 years, food consumption data of the Dutch National Food Consumption Survey 2007-2010 (van Rossum et al., 2011) were used. This survey includes the dietary habits of people aged 7 to 69 years. The consumption data of the Dutch National Food Consumption Survey Older Adults (Ocké et al., 2013) were used for the population above 70 years. This survey includes the dietary habits of community dwelling older adults and was performed in 2010-2012. Results of the three consumption surveys were weighted for small deviances in socio-demographic characteristics in order to give results that are representative for the Dutch population.

2.4 Food coding

The above-mentioned food consumption surveys collected dietary data by the 24-hour recall method (by interview or record assisted interview), or in case of young children by dietary record method, using the dietary recall software EPIC-Soft (IARC©) (Slimani et al., 1999). With this software foods are identified using facets describing additional characteristics of a food, such as processing, colour, fat content, etc. For example, semi-skimmed milk is entered as the food 'milk' with the facet 'semi-skimmed' for its fat content. Linking of use levels of E 171 to food consumption data was however performed using the Dutch EPIC-Soft codes neglecting these facets. This means that E 171 levels in milk were linked to the EPIC-Soft food 'milk', irrespective of the fat content, and that levels in different types of fine bakery wares were linked irrespective of whether regular or decorated fine bakery wares were consumed. This coding system was used because the same system is applied in the study of Rompelberg et al. (manuscript in preparation).

Ready-to-eat composite foods like 'mashed potatoes with kale, gravy and cooked smoked sausage' are coded in the Dutch National Food Consumption Surveys according to their individual components, such as 'cooked kale', 'mashed potatoes', 'gravy' and 'cooked smoked sausage'. Therefore, ready-to-eat composite foods were included as such in the exposure assessment.

2.5 Tiered approach

According to Annex II of R 1333/2008, use of E 171 is authorised QS in 48 aggregated food categories. Appendix B lists these food categories (first column of Appendix B) along with their restrictions of use (second column of Appendix B). For the exposure assessment, this authorised use was taken into account using four tiers:

1. Aggregated food categories linked to maximum reported use levels: All food products within a certain food category of Annex II of R 1333/2008 which may contain E 171 are assumed to contain this food colour at the maximum reported level for the particular food category (worst-case scenario);
2. Aggregated food categories linked to mean reported use levels: Identical to Tier 1 except that the mean of the positive reported use levels (zeroes excluded) were used for the particular food category. This tier assumes that the Dutch population varies the brands consumed over time and is thus exposed to the average E 171 content of the available brands per food category, or do at least not consume the worst case brand of each food category;
3. Refinement within the food categories using less aggregated food categories linked to maximum reported use levels. For the foods present in a particular food category of Annex II of R 1333/2008 for which the food industry declared that no E 171 is used, and/or for which the presence of E 171 could be excluded based on food label information, a use level of zero was assumed. For all other foods within the same food category, the maximum reported use level of the particular food category was applied;
4. Refinement within the food categories using less aggregated food categories linked to the mean of positive reported use levels: Identical to Tier 3, except that the mean of positive reported use levels was applied.

The data handling for the particular tiers are described in more detail in the section below.

2.6 Data handling

Most food companies provided a single use level for a particular food product. However, in some cases a range of use levels was reported. As part of a conservative approach, the highest value of the range was used. Also, in a few cases use levels lower than a certain use level was reported. In that case, as part of a conservative approach, the use level as such was used in the assessment. For example, if the use level in a certain chewing gum was < 100 mg/kg, it was assumed that the particular chewing gum contained 100 mg/kg E 171.

Figure 2 shows the decision process of assigning use levels of E 171 to foods. As mentioned above, E 171 is authorised in 48 aggregated food categories. First, relevant foods coded according to EPIC-soft were grouped in each of the 48 food categories (step 1, Figure 2). For example, all EPIC-soft codes encoding flavoured fermented milk products (such as flavoured yoghurts) were assigned to food category 1.4 ‘flavoured fermented milk products’. The grouping of foods was based on the ‘Guidance document describing the food categories in Part

E of Annex II to Regulation (EC) No 1333/2008 on Food Additives' (EU 2015). This step of the process resulted in 48 aggregated food categories resembling all authorised uses.

Next, each of the 48 food categories was checked for the availability of use level data (step2, Figure 2). When at least one positive use level was available for a food category (Step 3, Figure 2), then use levels were used for that particular food category within the exposure assessment. For some food categories, only zero concentrations were received from the food industry for all foods aggregated in that food category. Since the market coverage of the received use levels is unknown, it is very well possible that some brands of these foods may contain E 171. For foods for which it was assumed that E 171 could be present because of their white colour, food labels were screened in (web) shops (Step 4, Figure 2). For the foods that contained E 171 according to the label, substitute values were used. For food additives having a maximum permitted level, substitution with the maximum permitted level is common practice. However, E 171 is authorised QS and therefore another substitution procedure was needed. Therefore, for those foods that contained E 171 according to the label, maximum or mean analytical values obtained from Rompelberg et al. (manuscript in preparation) (see also section 2.1) were used (Step 5, Figure 2). If E 171 was not declared on the food label for that specific food, a concentration of zero was assumed. In case use of E 171 could not be established or no analytical information was available, these foods were excluded from the exposure assessment (Step 6, Figure 2). Examples of food categories excluded according to Step 6 of Figure 2 are edible cheese rind, food supplements and alcoholic beverages. Appendix C describes the qualitative effect of excluding these foods on the exposure estimates.

Appendix B and C describe in more detail decisions made in the assignment of use levels and analytical concentrations to foods.

Subsequently, use levels were assigned to the 48 food categories according to the four tiers. In tier 1, the maximum use level reported for each of the food categories was applied to all EPIC-soft coded foods assigned to the particular food category. For example, all foods categorised for the allowed use in fine bakery wares (e.g. biscuits, cakes and pies) were assigned the maximum value of a fondant-coated pie. In tier 2, the mean of positive use levels reported for each of the 48 aggregated food categories was applied to all categorised foods within a food category. For example, for fine bakery wares, the mean value of all decorated fine bakery wares was assigned to all foods aggregated in the fine bakery ware food category. Appendix B lists in more detail the use levels or analytical values used per food category in the exposure assessments according to tiers 1 and 2.

For the more refined tiers 3 and 4, foods coded according to EPIC-Soft were divided in two groups per food category. One group represented foods in which the industry indicated that no E 171 is used or for which information on the label indicated absence of E 171. These foods were assigned a use level of zero. The other group represented foods for which use of E 171 was indicated by the industry or for which use could

not be excluded based on label information. The latter foods were assigned the maximum of reported use levels or analytical values for the particular food category (tier 3) or the mean of positive reported use levels or mean analytical values (tier 4). For example, all EPIC-soft coded foods for which no discrimination between regular and decorated fine bakery wares could be made were assigned the maximum or mean value of decorated fine bakery wares, whereas all EPIC-soft coded foods representing undecorated fine bakery wares only were assigned a use level of zero. Another example is the foods representing food category 05.2 'other confectionery including breath refreshening microsweets', where the maximum or mean of positive use levels was assigned to mints, and zero to marshmallows.

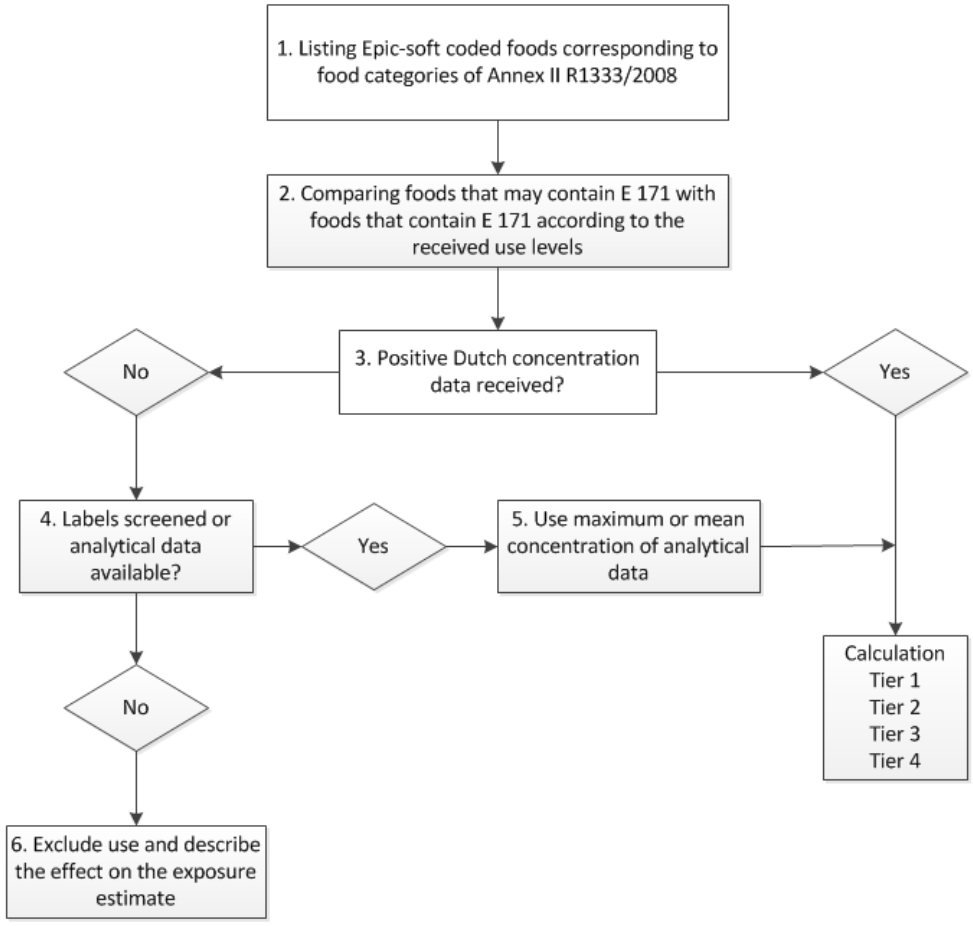

Figure 2. Decision tree on data handling for received and absent E 171 use level and concentration data.

2.7 Monte Carlo Risk Assessment

According to recent toxicological studies of E 171 nanoparticles, dietary exposure is associated with chronic effects rather than with acute effects (Iavicoli et al., 2011, 2012; Shi et al., 2013; Gerearts 2014). Therefore, long-term exposure (usual intake) to E 171 was assessed. For this, ideally statistical models should be used that correct the variation in long-term exposure between individuals for the within individual

(between days) variation (Hoffmann et al., 2002; Nusser et al., 1996; Slob, 1993). An important prerequisite to use these models is that the logarithmically transformed daily exposure distribution is normally distributed (de Boer et al., 2009). Since the exposure data were not normally distributed for E 171 (not shown), the observed individual means (OIM) method was used. The OIM method calculates the intake per day per subject and averages the intake of the 2 recall or recording days per subject. This implies that the high exposure percentiles are overestimated (Figure 3). The Monte Carlo Risk Assessment programme (MCRA), Release 8.1 (de Boer and van der Voet, 2015) was used for the exposure assessment.

By using the bootstrap approach, the uncertainty around the exposure estimate due to the limited size of the food consumption dataset was determined. Since one fixed concentration level (either use or analytical value) the uncertainty due to the limited size of the concentration data could not be quantified. The uncertainty is reported as the 95% confidence interval around the median (P50) and the 95th percentile (P95) of exposure.

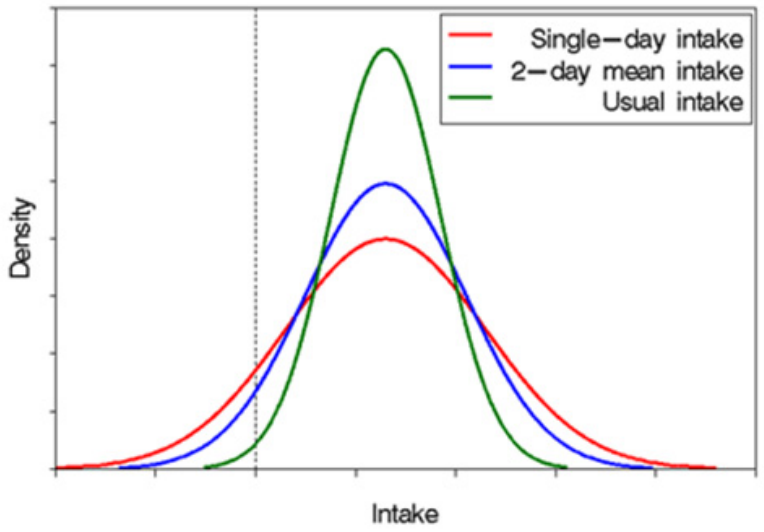

Figure 3. The Observed Individual Means (OIM) method used in this report is based on a 2-day mean intake. Therefore, this method deviates from the usual intake, since a mean intake based on two days is more sensitive to extreme consumption levels of foods than those based on a longer period. The OIM method may underestimate the mean intake and may overestimate the upper percentiles. Figure is obtained from the National Cancer Institute.

3 Results

In this chapter the results of the data collection process, received E 171 use levels and analytical values, exposure estimates of E 171 and contributors to the exposure to E 171 are presented.

3.1 Data collection process

Data collection was started at the beginning of June 2015. The food industry was asked to provide use levels of E 171 to the RIVM before the end of August 2015. In case no data was received, a gentle reminder was sent to the company by the FNLI. Data received after September 2015 were not included.

Use levels were obtained from 51 food companies (108 contacted; 47%) with food products on the Dutch market. Due to the high number of main brands in the concentration dataset, the data are expected to cover a large part of the market, but the actual coverage rate cannot be calculated due to unknown market shares.

3.2 Concentration data

Use levels of approximately 1603 foods were obtained, of which 133 had a positive value for E 171 (including those reported as < a certain value). The remaining foods were reported to contain no E 171.

Table 1 shows the number of positive use levels received per authorised food category according to Annex II of R 1333/2008, as well as the total number of use levels received. The difference between these two numbers is explained by the number of foods for which the industry declared not to use E 171, the so called zeroes. So for food category 'flavoured, fermented milk', 116 obtained values were zeroes. For the calculation of the mean concentration (Table 1), these zero values were not taken into account.

The largest number of use levels (> 100) were received for the food categories ‘flavoured, fermented milk’ and ‘sauces’. Appendix B shows more detailed data, including food categories with zero concentrations.

Due to the coverage of many different types of food products within one food category, use levels of E 171 could vary widely within one food category. For example, for the food category ‘edible ices’ the use of E 171 varied from 0 mg/kg in plain ice cream to 1902 mg/kg in special coated ice cream.

As described in section 2.5, analytical values were used in the exposure assessment in case no use levels were obtained. Table 2 shows the analytical values used.

Table 1. Number of use levels, minimal positive concentration and maximum use levels (mg/kg) per food category for foods for which at least one positive use level was obtained. Data were received from the industry.

Food (sub)category	**Overall N**	**Number positives**	**Range (mg/kg)**	**Mean of positive use level (mg/kg)**
01.4 Flavoured, fermented milk	117	1	48	48
01.8 Dairy analogues, including beverage whiteners	9	1	5000	5000
03 Edible ices	47	21	1-1902	395
05.2 Other confectionary	38	10	9-2013	830
05.3 Chewing gum	59	54	100-5480	3580
05.4 Decorations, coatings and fillings	43	14	0.08-527	201
07.2 Fine bakery wares	37	3	76-2338	1138
12.6 Sauces	762	19	500-2598	1479
12.9 Protein products, excluding products covered in 1.8	36	5	1700-5000	3040
15.2 Processed nuts	3	3	500-1250	563
16 Desserts	58	2	130-190	160

Table 2. Analytical values[1] (mg/kg) per food category used in the exposure assessment

Food category	**Mean analytical value (mg/kg)**	**Maximum analytical value (mg/kg)**
01.7.1 Flavoured unripened cheese excluding products falling in category 16	Goat cheese: 1 Sheep cheese: 3	Goat cheese: 1.5 Sheep cheese 11.5
01.7.4 Whey cheese	1	1.5
01.7.5 Processed cheese	1	1.5
01.7.6 Cheese products (excluding products falling in category 16)	1	1.5
06.3 Breakfast cereals	2.1	2.2
06.5 Noodles	3.5	3.5
06.7 Pre-cooked or processed cereals	3.5	3.5
12.5 Soups and broths	1	1.5
14.1.4 Flavoured drinks	Dairy-based drinks:5.7 Fruit-based drinks: 0.1	Dairy-based drinks 7.4 Fruit-based drinks: 0.1
15.1 Potato-, cereal-, flour- or starch-based snacks	1.9	1.9

[1] Analytical values were obtained by Rombelberg et al. (manuscript in preparation)

3.3 Exposure calculations

Table 2 shows the median (P50) and high (P95) exposure percentiles of E 171 for the different Dutch subpopulations per tier. Progressing from tier 1 to tier 4 resulted in a decrease in exposure (Table 2) with tier 3 and 4 still containing a level of conservativeness (Section 2.4). Median exposure was, depending on the age group, a factor 6 to 7 lower in tier

4 compared to tier 1. The P95 exposure was a factor 3 to 5 lower in tier 4 compared with tier 1.
The calculated intake at tier 4 is considered the best estimate within the restraints of the present assessment, while the upper limit of this value is given by the upper confidence interval of tier 3 (see Table 2) to take uncertainty around loyalty to brands and products into account (see also section 4.2).

Table 2. Median (P50) and high (P95) exposure percentiles (mg/kg bw/d) for the different Dutch subpopulations according to four different tiers. Values between brackets reflect the uncertainty around the estimated exposure percentile due to the limited size of the food consumption data.

		Children 2-6 years	**Population 7-69 years**	**Population > 70 years**
P50				
	Tier 1	10.5 (10.2-11.0)	3.2 (3.1-3.3)	2.8 (2.6-3.1)
	Tier 2	5.0 (4.8-5.3)	1.6 (1.6-1.7)	1.5 (1.3-1.6)
	Tier 3	2.9 (2.7-3.2)	1.3 (1.2-1.3)	0.9 (0.7-1.1)
	Tier 4	1.4 (1.3-1.5)	0.7 (0.6-0.7)	0.5 (0.4-0.6)
P95				
	Tier 1	25.8 (23.9-28.5)	10.9 (10.3-11.8)	6.8 (6.2-7.2)
	Tier 2	12.3 (11.4-13.4)	5.3 (5.0-5.7)	3.6 (3.3-3.9)
	Tier 3	11.4 (10.4-12.3)	6.1 (5.6-6.4)	3.6 (3.2-4.2)
	Tier 4	4.9 (4.5-5.6)	2.8 (2.6-3.0)	1.8 (1.7-2.2)

3.4 Main contributors

The contribution of foods to the exposure of E171 was very diverse: almost all single foods contributed less than 10% to the total exposure. When foods are categorized according the authorized uses as defined in Annex II of R 1333/2008, food categories contributing more than 10% to the total exposure were fine bakery wares, sauces and desserts for tier 4 (Table 3). Within the food category fine bakery wares, no major contributors to exposure could be determined within this tier because this category was highly diverse. For sauces, mayonnaise and sauce for French Fries were the major contributors to exposure of young children and the population aged 7-69 years, and mayonnaise-based garlic sauce for the elderly. Normal custard was the predominant contributor to exposure for the food category desserts contributing 12%, 5.6% and 7.6% to the total exposure of young children, the population aged 7 to 69 years and the elderly, respectively.

Table 3. Contribution (%) of the food categories to the total exposure to E 171 of the different Dutch subpopulations for tier 4: disaggregated food categories and mean of positive use levels.

Food Category	**Children 2-6 years**	**Population 7-69 years**	**Population > 70 years**
01.4 Flavoured, fermented milk	4.4	4.2	5.4
01.8 Dairy analogues, including beverage whiteners	0.0	3.9	2.8
03 Edible ices	9.9	6.8	3.8
05.2 Other confectionary	8.3	5.4	1.0
05.3 Chewing gum	1.3	1.7	0.2
05.4 Decorations, coatings and fillings	2.2	1.2	0.8
07.2 Fine bakery wares	43.0	42.5	53.4
12.6 Sauces	10.3	20.1	15.1
12.9 Protein products, excluding products covered in 1.8	6.2	5.9	6.1
15.2 Processed nuts	0.2	1.1	0.6
16 Desserts	14.1	7.2	10.6

4 Discussion

4.1 Data collection

The data collection system developed by VWS, FNLI and RIVM was successful to obtain use level of E 171 in food from the food industry (response 47 %) and resulted in a win-win-situation for all parties:

- Delivery of use levels by the industry is a cost-effective approach to monitor exposure to agents added to food, since collection of data on use levels is less costly than a monitoring system based on analysing food;
- Exposure assessors obtain a more reliable and more representative data set compared with other methods of data collection of use levels;
- A more accurate exposure estimate is important for both government and industry.

A limitation of this approach is that the collection of use levels is not likely to cover all foods that may contain the additive since it is not likely to have a 100% response from the food industry. For E 171 the response rate was 47%, which was in line with the use levels obtained for the intake calculations of caramel colours (47%; Sprong et al., 2014) and smoke flavourings (45%; Sprong et al., 2013), and was higher than that of the food colours E 120 and E 133 (40%; Wapperom et al., 2011). It is not known whether the food companies that did not respond, use E 171 in their products. Some companies do not react when they do not use a particular food additive, but this is not true for all companies. The response rate could be increased by a priori establishment of presence of the additive in certain food products by checking food labels, e.g. by using food composition or food label databases. This allows a more targeted call for data by contacting only those food companies placing these particular products on the Dutch market. This decreases the chance of non-responding in case an additive is not used in any of the products of a certain company.

For some food categories no use levels were reported by the industry. In case presence of E 171 could not be excluded, analytical data were used (when available). For food categories for which both analytical levels and reported use levels were available, the latter were used. Several analytical measurements were based on total titanium which is not necessarily added as a food additive (Rompelberg et al., manuscript in preparation), but may also be present as a 'natural' background concentration, albeit probably at low concentrations. As the present study considered the intake of the food additive titanium dioxide, the reported use levels were preferred over the analytical levels.

4.2 Exposure estimates at the different tiers

In the present studies, four tiers were calculated with tier 1 being the most conservative and the other tiers being a refinement of tier 1 by including mean positive use levels (tier 2 and 4) rather than the maximum use level (tier 1 and 3) and/or refinement of the food categories in which E 171 is used (tier 3 and 4). Comparison of the long-

term exposure estimates at the different tiers results in the following observations:

The estimated exposures at tier 2 were a factor two lower than at tier 1, due to the use of mean rather than maximum reported use levels per food category. Logically, the same applied to tier 4 (mean use levels) compared to tier 3 (maximum use levels). The tiers with the maximum use levels can be considered as worst case, whereas the mean tiers are assumed to be more realistic. This is because it is not very likely that consumers are loyal users of all foods containing E 171 at maximum levels over a longer period of time. However, loyalty to some products cannot be excluded. In the new EFSA refined brand loyalty scenario, used in the re-evaluation of food additives, maximum use levels or analytical values, whichever is highest, are assigned to the food category contributing most to the exposure at the level of the individual, while mean values are assigned to all other food categories (EFSA 2015). The EFSA scenario does not take into account consumers that are loyal to more than one food category. Within MCRA, realistic scenarios with loyalty to certain brands or products can be included as has been done in the exposure assessment to steviol glycosides (Brosens et al., 2014). Given the time restrain, calculation of scenarios with product or brand loyalty was not feasible in the present report, but it is recommended for further refinement. As a pragmatic approach, in the present study the exposure calculated at tier 3 may serve as an upper confidence limit of the estimated exposure including consumers with product or brand loyalty. The calculated intake at tier 4 is considered the best estimate within the restraints of the present assessment, while the upper limit of this value is given by the upper confidence interval of tier 3 (see Table 2) to take uncertainty around loyalty to brands and products into account. For example, for children the P50 is 1.4 mg/kg bw/d with an upper confidence limit of 3.2 mg/kg bw/d.

Tier 3 is not necessarily a refinement of tier 2 as shown in Table 2. Although the median exposure to E 171 decreased with about 30% in all three population groups when going from tier 2 to tier 3 because of assignment of zero concentrations to specific foods within the food categories in tier 3, this did not account for P95 exposure. Apparently, for these population groups the assignment of zeroes to specific foods was overcompensated by the use of maximum rather than mean reported use levels. The use of label information for assigning ‘true’ zeroes to food products, as done in the present study, is similar to the strategy as advised by the Food Chain Evaluation Consortium (2014). This Consortium emphasizes the inclusion of true zeroes as a major tool for refining exposure assessments to additives. The use of true zeroes was also recognized by the RIVM in their reports on food additives as an important tool to refine exposure assessments to these compounds (Wapperom et al., 2011, Sprong et al., 2014a). In the present study this was done by checking online label information and by visiting supermarkets, but both are time consuming. Use of specific databases may be a more cost-efficient approach. As stated before by Sprong (2014a), product databases like Mintel or Innova are less useful to this end, since these databases cover new product launches rather than food actually on the market and are not updated for foods removed from the

market or unacknowledged reformulated food. Databases such as the GS1 data source, which is the underlying database for label information of web shops, cover foods that are currently on the market and may therefore serve as a more reliable food label source.

It is likely that tier 4 is still conservative, as within a food category all products were considered to contain the same –mean- use level, although it is likely that E 171 is only used in a fraction of these products. The used EPIC-soft coding is not highly discriminative between e.g. decorated and undecorated foods and for particular flavours, which may be associated with the food colour. For example, checking food labels for 'fine bakery wares', which contributed for approximately 40 to 50% to the exposure in tier 4, using a large online supermarket showed that only a minor fraction of (decorated) 'fine bakery wares' contained E 171. To get a more precise estimate, tier 4 can be refined by linking the reported use levels to the specific products (and specific brands) as consumed, using the more detailed description of the consumed food products present in the food consumption survey. In addition, an estimation could be made of the fraction of decorated foods in the food category 'fine bakery wares', which will affect the estimation of E 171 intake via this food category. This refining can be done, but was not feasible within the time scale of the present study.

4.3 Uncertainties not quantified

In addition to the uncertainties mentioned in Section 4.1, there are a number of other, unquantified uncertainties that influence the exposure estimates presented:

Completeness and representativeness of dataset:
As the response to the request for data was 47%, it is clear that the data set obtained was not complete. Due to the high number of main brands in the concentration dataset, the data are expected to cover a large part of the market. However, the actual coverage rate is not known, since market shares are unknown. By approaching (multinational) companies with food products on the Dutch market, the data collection included also imported foods. Although the FNLI contacted other branch organisations, some food companies that are not a member of FNLI may not have been included in this study. Again, no exact figures of the completeness could be used, since market shares are not known. This may have resulted in missed high use levels for one or more food categories. However, because of the conservative nature of the exposure assessment using maximum or mean positive use levels for aggregated food categories, it is not likely that missed high use levels would have led to an underestimation of exposure.

The completeness and representativeness can be improved by more detailed information on product composition (e.g. on cake decorations), the inclusion of market shares[1] available from the food consumptions surveys (Sprong et al., 2014b) or market survey agencies, use of detailed description (facet/descriptor-codes) available within the food

[1] Data on market share are highly confidential and therefore not easily obtained from the food industry.

coding and use of databases containing label information such as the GS1 database[2].

Food categories in which E 171 is allowed and for which concentration data from the food industry or analytical data were not available were not taken into account in the intake estimation. Examples are certain alcoholic drinks that are niche products in the Netherland and food supplements which are consumed in small quantities (See Appendix B). It is expected that this has led to a small underestimation of the intake.

Exposure calculation

As pointed out in Section 2.6, the calculated the long-term exposure distributions did not allow for a statistical correction for the variation in dietary intake of E 171. This may have led to an overestimation of the high percentiles of the calculated intakes. MCRA has an additional model available to estimate the long-term exposure called Model-Then-Add (van der Voet et al., 2014). In this approach the statistical model is applied to subsets of the diet (single foods or food groups) rather than the whole diet. The resulting usual exposure distributions are added to obtain an overall usual exposure distribution. The advantage of this approach is that separate foods or food groups may show a better fit to the normal distribution model as assumed in all common models for usual exposure (e.g. the LNN model) and therefore may result in a better estimate of the high exposure percentile as outlined in Section 2.6. An exposure study into the intake of smoke flavours using Model-Then-Add showed that this resulted in a lower exposure estimate than reported by Sprong et al. (2013; van der Voet et al., 2014). Because this method is laboriously compared with the currently OIM methods, the Model-Then-Add method is not used in the present study, but can be used to refine the exposure estimate.

MCRA has also a function for taking uncertainties around the mean concentration into account. To this end, individual data rather than mean values need to be introduced in MCRA. Due to time constrain, mean values were used in the current calculations and uncertainties due to the limited size of the concentration database could not be quantified resulting in more narrow confidence intervals around the exposure estimates.

Overall effect on the exposure

Overall, we assume that the exposure is overestimated due to ignoring foods for which only a fraction of the foods contain E 171 (such as particular flavours of desserts that only contains E 171 or only a small fraction of decorated fine bakery wares that contains E 171) and because of the exposure calculation method used. For tier 1 and tier 3, the use of maximum use levels for all food categories most likely result in an overestimation of exposure.

[2] https://www.gs1.nl/gs1-data-source.

4.4 Results of the present study compared to other exposure estimations

As mentioned in Section 4.2, the best estimate for the median of the long-term intake for children in the present study was 1.4 mg kg bw/d (upper confidence limit 3.2 mg/kg bw/d). There is one other exposure estimate for Dutch children available, namely that of the EXPOCHI study (Huybrechts 2010), reporting a median exposure of 12.0-13.0 mg/kg bw/d in a conservative scenario using maximum reported use levels and assuming 100% use in all foods in which E 171 is authorized. This scenario is comparable with tier 1 in our calculations and resulted in comparable median exposure estimates for this tier. In the EXPOCHI study, the intake of the Dutch children was on the high end of children living in other European countries: the median intake, averaged over 14 European countries included in the study, was 9.31 (range: 3.89 – 13.8) mg/kg bw/d.

Weir et al. (2012) estimated similar median exposure values for E 171 intake in children < 10 years in the UK and USA as calculated in the present study: 2-3 and 1-2 mg/kg bw/d, respectively.

The present median of the long-term exposures estimated for adults aged 7 to 69, 0.7 mg/kg bw/d (upper confidence limit 1.3 mg/kg bw /d) and elderly, 0.5 mg/kg bw/d (upper confidence limit 1.1 mg/kg bw/d), were also similar to those recently reported for Germany (0.5-2.0 mg/kg bw/d; Bachler et al. 2012), UK (1.0 mg/kg bw/d; Weir et al. 2012) and USA (0.2-0.7 mg/kg bw/d; Weir et al., 2012).

A Dutch study using analytical data of E 171 is currently under construction by RIVM. This new study will include a comparison between that study and the current one.

5 Conclusion and recommendations

- In the present study the exposure was estimated in four tiers. The best estimate for median long-term exposure to E 171, calculated with use levels obtained from food industry and with analytical values, ranged from 0.5 mg/kg bw/d (upper limit 1.1 mg/kg bw/d) for the population older than 70 years to 1.4 mg/kg bw/d (upper limit 3.2 mg/kg bw/d) for children.

- Many food groups contributed to the exposure of E 171; the predominant ones for the most refined tier 4 were fine bakery wares, desserts, and sauces.

- The best estimated exposure in the current study was comparable to other recent intake estimates for Germany, while the intake of adults was similar to those reported for Germany, UK and USA.

- The exposures estimated in tier 3 and 4 are still assumed to be conservative, as all foods within a certain subcategory are considered to contain the same (mean or maximum) reported use level or analytical value, while it is very likely that many of these do not contain E 171 (because they are not white or do not contain decorations). The exposure estimations may be further refined by linking the reported use levels to the specific brands and products as consumed, using more detailed description of the consumed food products present in the food consumption survey and/or estimation of the frequency of decoration used in foods and by using more refined statistical models.

- Since no health-based guidance level has been established for E 171, a risk evaluation of the intake of E 171 in the Netherlands was not performed. EFSA is presently re-evaluating the use of E 171 in Europe. The publication of the opinion is expected by the end of 2015. It is unknown whether the safety evaluation will result in the derivation of an ADI for E 171. Additionally, a risk evaluation regarding titanium dioxide nanoparticles will be performed by RIVM in 2015.

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Appendix A. Template and examples of actual use levels, to be completed by the food industry

Examples are fictitious.

Company	**Brand**	**Product**	**Product description**	**Food category in Annex II (drill down)**	**Use of any E 171 color in product (yes/no)**	**If yes: E 171 (mg/kg product)**	**Concentration in whole food (yes/no)**	**If no: in which part of the food and % of total food**
Yoghurt company	Yoghiyog	Yoghurt drink	All flavours	01.4 Flavoured fermented milk products including heat treated products	No			
Yoghurt company	Yoghiyog	Yoghurt mousse	Coconut	16. Desserts excluding products covered in category 1, 3 and 4	Yes	100	Yes	
Yoghurt company	Yoghiyog	Yoghurt mousse	3 other flavours	16. Desserts excluding products covered in category 1, 3 and 4	No			
Cookie company	Cookcook	Snow cake	Cake with white icing	07.2 Fine bakery wares	Yes	368	No	Only in the icing, 10% of snow cake

Appendix B. Number of use levels, minimal positive and maximum use levels (mg/kg) per food category in which E 171 is allowed at quantum satis. If use levels were missing, values were obtained from an analytical study[1] or zero values were used based on food labels

Food category Annex II R 1333/2008	**Restrictions**	**Number of use levels received**	**Number of positive use levels**	**Range of positive use levels**	**Mean value of positive values**	**Maximum value obtained from analytical data[1]**	**Mean value obtained from analytical data[1]**	**Value zero from labels or assumed E 171 is not used in the product**
01.4 Flavoured fermented milk products including heat-treated products		117	1	48	48			
01.5 Dehydrated milk as defined by Directive 2001/114/EC	Except unflavoured products	7	0					Labels: no E 171
01.6.3 Other creams	Only flavoured creams	4	0					No consumption data available

Food category Annex II R 1333/2008	**Restrictions**	**Number of use levels received**	**Number of positive use levels**	**Range of positive use levels**	**Mean value of positive values**	**Maximum value obtained from analytical data[1]**	**Mean value obtained from analytical data[1]**	**Value zero from labels or assumed E 171 is not used in the product**
01.7.1 Unripened cheese excluding products falling in category 16	only flavoured unripened cheese	0				Goat cheese: 1.54, sheep cheese 11.5 Other cheese: 1.54	Goat cheese: 1, sheep cheese 3 Other cheese: 1	
01.7.3 Edible cheese rind		1	0					No consumption data available
01.7.4 Whey cheese		1	0			1.54	1	
01.7.5 Processed cheese	only flavoured processed cheese	7	0			1.54	1	
01.7.6 Cheese products (excluding products falling in category 16)	only flavoured unripened products	5	0			1.54	1	

Food category Annex II R 1333/2008	**Restrictions**	**Number of use levels received**	**Number of positive use levels**	**Range of positive use levels**	**Mean value of positive values**	**Maximum value obtained from analytical data[1]**	**Mean value obtained from analytical data[1]**	**Value zero from labels or assumed E 171 is not used in the product**
01.8 Dairy analogues, including beverage whiteners		9	1	5000	5000			
03. Edible ices		47	21	1-1902	395			
04.2.4.1 Fruit and vegetable preparations excluding compote	*only mostarda di frutta and fish roe analogues*	0						No consumption data available
04.2.5.3 Other similar fruit or vegetable spreads	except *crème de pruneaux*	0						Labels fruit syrup and chutney: no E 171.
05.2 Other confectionery including breath refreshening microsweets		38	10	9.45-2013	830			
05.3 Chewing gum		59	54	100-5480	3580			

Food category Annex II R 1333/2008	Restrictions	Number of use levels received	Number of positive use levels	Range of positive use levels	Mean value of positive values	Maximum value obtained from analytical data[1]	Mean value obtained from analytical data[1]	Value zero from labels or assumed E 171 is not used in the product
05.4 Decorations, coatings and fillings, except fruit based fillings covered by category 4.2.4		43	14	0.08-527	201			Limited consumption data available
06.3 Breakfast cereals	only breakfast cereals other than extruded, puffed and/or fruit flavoured breakfast cereals	10	0			2.2	2.1	
06.5 Noodles		o				3.47	3.47	Labels: no E 171.
06.6 Batters		1	0					No consumption data available
06.7 Pre-cooked or processed cereals		0				3.47	3.47	
07.2 Fine bakery wares		37	3	76-2338	1138			

Food category Annex II R 1333/2008	Restrictions	Number of use levels received	Number of positive use levels	Range of positive use levels	Mean value of positive values	Maximum value obtained from analytical data[1]	Mean value obtained from analytical data[1]	Value zero from labels or assumed E 171 is not used in the product
08.3.3 Casings and coatings and decorations for meat	except edible external coating of pasturmas	17	0					Part with E 171 is not consumed
09.2 Processed fish and fishery products including molluscs and crustaceans	only surimi and similar products and salmon substitutes.	0						Missing, surimi consumed little (labels checked: no E 171), salmon substitutes not in consumption data.
09.3 Fish roe	except Sturgeons' eggs (Caviar)	0						Labels: no E 171 in fish roe
12.2.2 Seasonings and condiments	only seasonings, for example curry powder, tandoori	97	0					Assumption: E 171 not used

Food category Annex II R 1333/2008	**Restrictions**	**Number of use levels received**	**Number of positive use levels**	**Range of positive use levels**	**Mean value of positive values**	**Maximum value obtained from analytical data[1]**	**Mean value obtained from analytical data[1]**	**Value zero from labels or assumed E 171 is not used in the product**
12.4 Mustard		3	0					Assumption: E 171 not used, consumed little
12.5 Soups and broths		75	0			1.54	1	
12.6 Sauces	excluding tomato-based sauces	762	19	500-2598	1479			
12.7 Salads and savoury based sandwich spreads		14	0		No data, value from category 12.6 applied because mayonnaise based products			
12.9 Protein products, excluding products covered in category 1.8		36	5	1700-5000	3040			

Food category Annex II R 1333/2008	**Restrictions**	**Number of use levels received**	**Number of positive use levels**	**Range of positive use levels**	**Mean value of positive values**	**Maximum value obtained from analytical data[1]**	**Mean value obtained from analytical data[1]**	**Value zero from labels or assumed E 171 is not used in the product**
13.2 Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5)		101	0					Consumed by very small part of population
13.3 Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet)		0			For pudding value from category 16	For soup value from category 12.5	For soup value from category 12.5	Labels (white/vanilla products) no E 171

Food category Annex II R 1333/2008	**Restrictions**	**Number of use levels received**	**Number of positive use levels**	**Range of positive use levels**	**Mean value of positive values**	**Maximum value obtained from analytical data[1]**	**Mean value obtained from analytical data[1]**	**Value zero from labels or assumed E 171 is not used in the product**
13.4 Foods suitable for people intolerant to gluten as defined by Regulation (EC) No 41/2009		0			For cake, biscuits and crackers value from category 7.2			Labels (white bread, cookies) no E 171
14.1.4 Flavoured drinks	excluding chocolate milk and malt products	48	0			Dairy drinks 7.41; fruit based drinks: 0.11	Dairy drinks 5.72 Fruit based drink 0.11	

Food category Annex II R 1333/2008	**Restrictions**	**Number of use levels received**	**Number of positive use levels**	**Range of positive use levels**	**Mean value of positive values**	**Maximum value obtained from analytical data[1]**	**Mean value obtained from analytical data[1]**	**Value zero from labels or assumed E 171 is not used in the product**
14.1.5 Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products	Only in flavoured instant cofee	0				156	28.3	Missing, little consumed and not expected.
14.2.3 Cider and perry	excluding cidre bouché	0						Labels no E171
14.2.4 Fruit wine and made wine	excluding wino owocowe markowe	0						Missing, but assumed no E 171
14.2.5 Mead		0						Missing, but assumed no E 171

Food category Annex II R 1333/2008	Restrictions	Number of use levels received	Number of positive use levels	Range of positive use levels	Mean value of positive values	Maximum value obtained from analytical data[1]	Mean value obtained from analytical data[1]	Value zero from labels or assumed E 171 is not used in the product
14.2.6 Spirit drinks as defined in Regulation (EC) No 110/2008	except: spirit drinks as defined in Article 5(1) and sales denominations listed in Annex II, paragraphs 1-14 of Regulation 110/2008 and spirits (preceded by the name of the fruit) obtained by maceration and distillation, Geist (with the name of the fruit or the raw material used), *London Gin*, *Sambuca, Maraschino, Marrasquino* or *Maraskino* and *Mistrà*	0						Missing, but assumed no E 171

Food category Annex II R 1333/2008	**Restrictions**	**Number of use levels received**	**Number of positive use levels**	**Range of positive use levels**	**Mean value of positive values**	**Maximum value obtained from analytical data[1]**	**Mean value obtained from analytical data[1]**	**Value zero from labels or assumed E 171 is not used in the product**
14.2.7.1 Aromatised wines	except americano, bitter vino	0						Missing, but assumed no E 171
14.2.7.2 Aromatised wine-based drinks	except bitter soda, sangria, claria, zurra	0						Missing, but assumed no E 171
14.2.7.3 Aromatised wine-product cocktails		0						Missing, but assumed no E 171
14.2.8 Other alcoholic drinks including mixtures of alcoholic drinks with non-alcoholic drinks and spirits with less than 15 % of alcohol		0						Missing, but assumed no E 171
15.1 Potato-, cereal-, flour- or starch-based snacks		3	0			1.97	1.97	
15.2 Processed nuts		3	3	500-1250	563			

Food category Annex II R 1333/2008	Restrictions	Number of use levels received	Number of positive use levels	Range of positive use levels	Mean value of positive values	Maximum value obtained from analytical data[1]	Mean value obtained from analytical data[1]	Value zero from labels or assumed E 171 is not used in the product
16. Desserts excluding products covered in category 1, 3 and 4		58	2	130-190	160			
17.1 Food supplements supplied in a solid form including capsules and tablets and similar forms, excluding chewable forms		0						Missing
17.2 Food supplements supplied in a liquid form		0						Missing
17.3 Food supplements supplied in a syrup-type or chewable form		0						Missing

[1] Data to be published by Rompelberg.

Appendix C. Food categories not taken into account in the intake assessment

1.6.3 Other creams. Not consumed in the three Dutch National Food Consumption Surveys.

1.7.3 Edible cheese rind. No positive use levels were obtained for edible cheese rind. Gouda-like cheeses and other (semi-)hard cheeses are the most frequent consumed cheeses in the Netherlands. These cheeses contain non-edible cheese rinds. Brie, Camembert and blue cheeses, are the most frequent consumed cheeses with an edible cheese rind in the Netherlands. Other cheeses with an edible cheese rind are niche products. Neglecting this food category may result in a small underestimation of exposure.

4.2.4.1. Fruit and vegetable preparations excluding compote, only mostarda di frutta and seaweed based fish roe analogues: These items are niche products and not recorded in the Dutch National Food Consumption Surveys. Therefore, these foods were not taken into account in the exposure calculations. This may result in a minor underestimation of exposure.

4.2.5.3 Other similar fruit or vegetable spreads: These items are spreads often used in the Netherlands as a topping on bread: apple syrup, apple-pear-syrup and other concentrated fruit syrups. Labels of these dark coloured spreads were checked and no E 171 was mentioned on the labels. Also chutneys are in this category, but they are seldom consumed. Labels were checked and did not contain E 171.

5.4 Decorations, coatings and fillings, except fruit based fillings covered by the category 4.2.4: Use level data were received for decorations and coatings. However, several foods of this food category are not eaten as such, but can be part of a compound food classified by the industry as fine bakery ware (e.g. iced cakes or decorated pies), edible ices or confectionary. Since concentration data were obtained for the particular compound foods, these use levels were used rather than those obtained for decorations, coatings and fillings. Chocolate sprinkles and flakes, which are consumed as sandwich fillings in the Netherlands, were classified to this category according to the industry. Also coated chocolates were classified to this category according to the industry. These items are calculated in the tiers to this category.

6.6 Batters: Similar to decorations and coatings, batters are part of composite foods and are present in the Dutch National Food Consumption Surveys as composite foods such as meat covered in breadcrumbs. We received one zero value for batters, and assumed all meat products are zero.

8.3.3 Casings and coatings and decorations for meat, except edible external coating of pasturmas: Use levels were obtained for non-edible sausage casings. However, because these casings are not consumed,

these use levels are not taken into account in the exposure calculation. No positive use levels were obtained for edible casings, coatings and meat decorations. White-coloured edible casings, coatings and meat decorations are not common in the Netherlands. Therefore, the lack of these use levels will result in only a minor underestimation of the exposure.

9.2 Processed fish and fishery products including molluscs and crustaceans, only surimi and similar products and salmon substitutes: No use levels obtained for surimi and salmon substitutes. A few labels of surimi were checked and no E 171 was present. Surimi is little consumed and salmon substitutes are not present in the consumption data. This may result in a minor underestimation of exposure.

9.3 Fish roe, except sturgeon's eggs (caviar): No use levels were obtained. We checked labels in shops and no E 171 was declared for salmon eggs. Fish roe is a niche product, only consumed rarely and in small quantities. Neglecting this food category may result in a minor underestimation of exposure.

12.2.2 Seasonings and condiments: All use levels obtained were zeroes. This category contains many foods and it was not possible to check all labels. Because of use levels obtained were from two large companies we assumed E 171 is not used often in this category.

12.4 Mustard: Use levels obtained were zeroes. Because of the colour of mustard it was assumed that no E 171 is to be expected in mustard. Consumption is in small quantities.

13.2 Dietary foods for special medical purposes defined in Directive 1999/21/EC (excluding products from food category 13.1.5): Use levels obtained were zeroes from one large company. These products are consumed only by a very small part of the population.

13.3 Dietary foods for weight control diets intended to replace total daily food intake or an individual meal (the whole or part of the total daily diet): No use levels were obtained. For puddings we calculated maximum or positive mean values of category 16, for soup we used values of category 12.5. We checked labels in shops for white coloured or vanilla flavoured shakes and bars, which had no use of E 171.

13.4 Foods suitable for people intolerant for gluten: No data were received for these food types. Levels of similar products with gluten were used as proxy levels for these foods, e.g. for gluten free cookies, cakes and crackers, the value of 7.2 fine bakery wares was used. Labels were checked for white bread and some cookies and no E 171 was used.

14.1.5 Coffee, tea, herbal and fruit infusions, chicory; tea, herbal and fruit infusions and chicory extracts; tea, plant, fruit and cereal preparations for infusions, as well as mixes and instant mixes of these products, only in flavoured instant coffee: This type of coffee is not often consumed and E 171 use is not expected because it is not added to unflavoured instant coffees. Neglecting this food category may result in a minor underestimation of exposure

14.2 Alcoholic beverages, including alcohol-free and low-alcohol counterparts: We expect no use of E 171 in this category. Labels of cider were checked and no E 171 was found.

17 Food supplements: No use levels were obtained for this food category. Due to the limited time available for the intake calculations and the expected small contribution (supplements consumed in the Dutch National Food Consumption Surveys are mostly consumed as pills, capsules, sachets, spoons or powdered or liquid formula's, indicating consumption of only a few grams), this category was not taken into account. This very likely will result in a minor underestimation of the exposure assessment.

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