

ENDORSED FOR PUBLIC CONSULTATION

DRAFT SCIENTIFIC OPINION

DRAFT Scientific Opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs – Part: exposure assessment¹

EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)^{2,3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The EFSA asked its Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) to provide a scientific opinion on bisphenol A (BPA). As important toxicological studies on BPA are to be published shortly, and hazard identification/characterisation requires further discussions, a two-step approach for public consultation on the draft opinion on BPA has been taken. The current draft thus addresses only the assessment of exposure to BPA. Total exposure to BPA was estimated by two different procedures, one involving exposure modelling and the other urinary biomonitoring data. Exposure modelling involved the assessment of exposure to BPA through different sources (food and non-food) and routes of exposure (oral, inhalation and dermal) in the EU population. Data on BPA concentrations in food were combined with food consumption data to estimate dietary exposure and concentration data in/from non-food sources were combined with behaviour patterns to estimate non-dietary exposure. Diet was found to be the main source of exposure to BPA in all population groups, but modelled estimates were much lower than the estimates reported by EFSA in 2006. In the previous assessment, high exposure was up to 5 300 ng/kg bw/day in toddlers and up to 11 000 ng/kg bw/day in infants aged 3 months, compared with the current estimates of up to 857 ng/kg bw/day for toddlers and up to 495 ng/kg bw/day for infants of 1-5 days. Thermal paper was the second source of exposure in all population groups above 3 years of age. The uncertainty around the estimate of exposure to BPA from thermal paper was considerably higher than that around dietary exposure. Biomonitoring estimates based on urinary BPA concentrations are in good agreement with modelled BPA exposures from all sources, suggesting that no major exposure sources have been missed for the modelled exposure assessment.

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KEY WORDS

Bisphenol A, exposure assessment, food and non-food sources

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² Panel members: Ulla Beckman Sundh, Mona-Lise Binderup, Claudia Bolognesi, Leon Brimer, Laurence Castle, Alessandro Di Domenico, Karl-Heinz Engel, Roland Franz, Nathalie Gontard, Rainer Gürtler, Trine Husøy, Klaus-Dieter Jany, Martine Kolf-Clauw, Catherine Leclercq, Wim Mennes, Maria Rosaria Milana, Maria de Fátima Tavares-Poças, Iona Pratt, Kertil Svensson, Fidel Toldrá and Detlef Wölflle. Correspondence: cef@efsa.europa.eu

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31 **SUMMARY**

32 The European Food Safety Authority (EFSA) asked the Panel on Food Contact Materials, Enzymes,
33 Flavourings and Processing Aids (CEF) to provide a scientific opinion on the risks for public health
34 related to the presence of bisphenol A (BPA) in foodstuffs. In particular, the opinion should:

35 (i) evaluate the toxicity of BPA for humans, including for specific (vulnerable) groups of the
36 population (e.g. pregnant women, infants and children, etc.) and considering all relevant toxicological
37 information available;

38 (ii) carry out an exposure assessment on the basis of the occurrence data available in the public
39 domain and other occurrence data that may be available, and quantify as far as possible not only
40 dietary exposure but also exposure from non-dietary sources;

41 (iii) consider specifically the exposure situation for the supposedly most vulnerable groups of the
42 population (e.g. pregnant women, infants and children, etc.) and take into account, if available,
43 biomonitoring data when assessing the exposure and compare the results with the calculated exposure;
44 and

45 (iv) characterise the human health risks taking into account specific groups of the population.

46 Taking into account that important toxicological studies on BPA are to be published shortly, and
47 acknowledging that the hazard identification and characterisation of BPA requires further discussions
48 before endorsement, a two-step approach for public consultation on the draft opinion on BPA was
49 proposed by the CEF Panel. The current draft document thus addresses the 2nd and 3rd part of the
50 terms of reference only i.e. the assessment of exposure to BPA. The full draft opinion on BPA is
51 intended to be released for public consultation at a later stage.

52 The previous exposure assessment of BPA by EFSA from 2006 did not consider non-dietary sources
53 of exposure and was based on basic conservative assumptions in relation to BPA occurrence in food.
54 In the present opinion, a detailed analysis of data becoming available since 2006 on food consumption
55 and BPA occurrence in food was performed. Furthermore, in the present opinion non-food sources of
56 exposure to BPA have also been addressed.

57 BPA uses

58 BPA is used in the manufacture of polycarbonate (PC) plastics, epoxy resins and other polymeric
59 materials, and also for certain paper products (e.g. thermal paper). PC is used for food and liquid
60 containers such as tableware (plates and mugs), microwave ovenware, cookware, reservoirs for water
61 dispensers and non-food applications such as toys and pacifiers with PC shields. BPA-based
62 epoxyphenolic resins are used as protective linings for food and beverage cans and as a coating on
63 residential drinking water storage tanks. BPA is also used in a number of non-food-related
64 applications, e.g. epoxy resin based paints, medical devices, surface coatings, printing inks and flame
65 retardants.

66 General approach taken for the assessment

67 Average and high total chronic BPA exposure was assessed in the different age classes, considering
68 the supposedly vulnerable groups: infants, children and women of childbearing age (in order to
69 address potential exposure in the fetus and in breastfed infants). For food the average exposure was
70 assessed based on average concentration and average consumption data, while high exposure was
71 based on average concentration and high consumption. In the present opinion BPA concentrations
72 have been assigned to more detailed food categories than in the earlier EFSA opinion on BPA. For
73 non-food sources, to estimate average exposure the average values for all parameters were chosen. To
74 estimate the high exposure from non-food sources, the same average parameters were used for
75 absorption rates and occurrence data but in line with the methodology used to assess exposure from

76 food, the frequency of use parameters was modified to account approximately for the highest 95th
77 percentile among all EU countries.

78 Total exposure to BPA was estimated by two different procedures independent of each other: one was
79 based on exposure modelling calculations and the other on urinary biomonitoring data. Exposure
80 modelling involved the assessment of chronic exposure (absorbed dose) to BPA through different
81 sources (diet, thermal paper, air, dust, toys, cosmetics, dental sealants) and routes of exposure (oral,
82 inhalation and dermal) in the EU population. Analytical/experimental BPA concentrations were
83 combined with food consumption (including human milk) to estimate dietary exposure and
84 concentration data in and from non-food sources with behaviour patterns to estimate non-dietary
85 exposure. Then, total average exposure was calculated by adding up average exposure from all dietary
86 and non-dietary sources. Total high exposure was calculated by adding up high levels of exposure
87 from the two highest sources and average exposure levels from all other sources.

88 These modelled calculations aimed to assess the total daily amount of BPA absorbed by the body by
89 any route. The absorption factors considered in these calculations were 1 for oral, 1 for inhalation and
90 0.3 for dermal. The results provide an estimate comparable to that obtained by assessing total daily
91 urinary excretion of BPA. However, while urinary biomonitoring provides estimates of total exposure
92 only, modelling allows estimation of exposure from all the sources of exposure which could be
93 identified and quantified individually. In order to quantify the relative impact of each source, the
94 assumptions made in the exposure estimates were aimed at obtaining a similar degree of
95 conservativeness among the different sources.

96 The current draft opinion is thus focused on the modelled exposure (absorbed dose) of consumers to
97 BPA (through different routes), taking into account the different absorption factors for the different
98 routes of exposure, and the comparison of these exposure estimates with the total daily urinary
99 excretion of BPA, assessed by urinary biomonitoring. The uncertainty in the exposure estimates was
100 assessed systematically both for the modelling and the biomonitoring approach. The estimates do not
101 reflect the proportion of the BPA dose bioavailable (unconjugated BPA) after absorption by the body
102 and subsequent metabolism. The conversion of the exposure estimates from each source into internal
103 (bioavailable) doses of BPA has not yet been considered. This conversion into internal doses needs to
104 be considered in the subsequent step of risk characterisation of BPA. Uncertainties affecting the
105 parameters that will be used for this conversion are not considered in the present document but will be
106 taken into consideration in later steps of the risk assessment of BPA.

107 All data on BPA occurrence in food and non-food sources and all biomonitoring data have undergone
108 a thorough quality check before being considered in the assessments. Whenever available data from
109 Europe were considered for the quantitative assessment, while non-European data related to BPA have
110 been used for comparison purposes.

111 Assessments for BPA exposure in specific disease states, occupational exposure of workers handling
112 BPA containing products, or acute exposure (with the exception of dental materials) to BPA were not
113 developed in this opinion.

114 Dietary exposure

115 Dietary exposure to BPA has been estimated in different population groups by combining information
116 on the levels of BPA in food with the corresponding consumption levels.

117 Information on BPA occurrence in food has been derived from EFSA's call for data together with a
118 systematic review of scientific literature covering the period 2006 until December 2012. For
119 biomonitoring data literature published before 2006 was also included in order to increase the
120 information for certain countries or matrices, e.g. human milk.

121 A total of 2 521 samples of food and beverages were selected as the basis to assess BPA
122 concentrations in the different food categories for the scope of the present opinion. Data from the
123 literature and from the call for data did not show major differences in BPA concentrations and so have
124 been merged for each food category. These merged BPA concentrations have been used in the
125 exposure calculations.

126 Left-censored data, i.e. from samples with concentrations below the limit of detection (LOD) or
127 quantification (LOQ), were handled through the substitution method. The lower bound (LB) was
128 obtained by assigning a value of zero to all the samples reported as less than the left-censoring limit,
129 the middle bound (MB) by assigning half of the left-censoring limit, and the upper bound (UB) by
130 assigning the left-censored limit (LOD or LOQ) as the sample result.

131 Systematic differences in BPA concentration between canned and non-canned food were observed in a
132 large majority of food categories, with higher BPA concentrations in the canned food. Seven out of 17
133 canned food categories presented an average (MB) BPA concentration above 30 µg/kg (“Grain and
134 grain-based products”, “Legumes, nuts and oilseeds”, “Meat and meat products”, “Fish and other
135 seafood”, “Herbs, spices and condiments”, “Composite food”, and “Snacks, desserts, and other
136 foods”). Lower levels were found in other categories and in particular average (MB) BPA
137 concentration was lower than 3 µg/kg in canned beverages (water, alcoholic and non alcoholic
138 beverages, fruit and vegetables juices). Among the 19 non-canned food categories, the highest levels
139 of BPA were found in the categories “Meat and meat products” and “Fish and other seafood” with
140 average (MB) BPA concentrations of 9.4 and 7.4 µg/kg, respectively. When comparing European with
141 non-European concentration data for food, average BPA levels were mostly in the same range.

142 In residential buildings where water pipes had been repaired with a two-components technique the
143 average and high BPA concentrations in cold water were 0.1 and 1.1 µg/l, respectively. These values
144 have been considered when calculating exposure through drinking water in specific population groups.

145 Biomonitoring studies suggested relatively high levels of BPA in the initial human milk (colostrum),
146 which is produced during the first to approximately 5th day after delivery, compared with mature
147 human milk. The CEF Panel noted that only very few data from Europe and/or obtained by a reliable
148 analytical method were available and therefore decided to take into account data from Japan, reporting
149 an average BPA concentration of 3 µg/l and a modelled high concentration estimate of 6.6 µg/l in
150 initial human milk. However, these data from Japan were obtained using ELISA methodology and the
151 samples dated back to 2000. These limitations were addressed in the uncertainty analysis. Based on
152 different studies, the average and high concentrations of total BPA in mature human milk were found
153 to be 1.2 µg/l and 2.6 µg/l, respectively.

154 BPA migration data from food packaging materials into food simulants, retrieved from the literature
155 and EFSA’s call for data, were used to assess the exposure of specific groups of consumers. In
156 particular, average BPA migration levels were derived for the following PC articles: water coolers
157 with PC reservoirs (0.81 µg/l in water), PC water kettles (0.11 µg/l in warm water), PC filters (0.04
158 µg/l in water), PC tableware and cookware (0.09 and 0.29 µg/l, respectively, in foods that can be
159 consumed hot).

160 Data from the EFSA Comprehensive European Food Consumption Database were used to assess
161 dietary exposure to BPA in all age groups, from infants (6-12 months) to the elderly and very elderly
162 (older than 65 years), excluding infants aged 0 to 6 months. Consumption data observed in toddlers
163 were used as an estimate of consumption in infants aged 6 to 12 months since no data were available in
164 the latter age class. Consumption data from a total of 32 different dietary surveys carried out in 22
165 different Member States covering more than 67 000 individuals are included in the Comprehensive
166 Database. In order to consider separately women of childbearing age, in the present assessment the
167 adult age group has been broken down in three subgroups, comprising women from 18 to 45 years,
168 men from 18 to 45 years and other adults from 45 to 65 years. Only a limited number of dietary

169 surveys in the Comprehensive Database have information on the type of packaging (canned or non-
170 canned, in particular).

171 Two scenarios were therefore developed to consider the higher levels of BPA in canned foods. In
172 scenario 1 only foods specifically codified as canned in the dietary survey are assigned the
173 corresponding occurrence level for BPA. In scenario 2 any food category (at the lowest available level
174 of food category classification) which has been codified as canned in at least one survey is always
175 considered to be consumed as canned in all dietary surveys included in the Comprehensive Database.

176 In the case of infants a consumption of 150 g/kg bw/day was used as a standard for both human milk
177 and infant formula with the exception of breastfed infants over their first five days of life for whom the
178 consumption was assumed to be 75 g/kg bw/day.

179 Due to a very low percentage of left censored samples, in particular among canned foods, the
180 techniques used to model data below the LOD or LOQ had a very small impact on the average
181 concentration in the different food categories and, consequently, on the exposure. Therefore, middle
182 bound average BPA concentration values were used in the final exposure assessment.

183 *Dietary exposure for the population older than 6 months*

184 The modelled dietary exposure (MB) obtained by scenario 2, for infants (6 to 12 months), toddlers (12
185 to 36 months) and other children (3 to 10 years) ranged from 290 to 375 ng/kg bw/day for the average
186 exposure and from 813 to 857 ng/kg bw/day for the high exposure, respectively. Additional dietary
187 exposure from a number of food contact articles was also assessed in specific population groups. The
188 highest estimated high exposure from PC tableware and cookware was observed for infants and
189 toddlers (14 ng/kg bw/day for PC tableware and 46 ng/kg bw/day for cookware). This age class is also
190 the one in which regular use of tableware (made of PC but also other materials) is most likely to occur
191 since `unbreakable` plastic mugs and beakers are often used for toddlers. The highest estimated
192 exposures to BPA migrating from water coolers with PC reservoirs and PC filters into drinking water
193 were also observed in infants and toddlers (22 ng/kg bw/day for water coolers and 3.8 ng/kg bw/day
194 for PC filters). High estimated exposure in residents of buildings with old water pipes repaired with
195 epoxy resins was up to 29 ng/kg bw/day in infants and toddlers.

196 The modelled dietary exposure (MB) obtained by scenario 2, for teenagers, adults (including women
197 of childbearing age) and elderly/very elderly, ranged from 116 to 159 ng/kg bw/day for the average
198 exposure and from 335 to 388 ng/kg bw/day for the high exposure, respectively. Additional dietary
199 exposure from a number of food contact articles was also assessed in specific population groups
200 within this population. Estimated exposure from PC kettles ranged from 2 to 3.2 ng/kg bw/day with
201 the highest values being observed in adults and the elderly due to their higher consumption of coffee
202 and tea.

203 The ratio between the modelled exposures derived from one or other of the two scenarios related to the
204 food categories consumed as canned was lowest in countries where many food codes were available
205 for canned products and/or where canned products are largely consumed. This was the case for UK
206 men and women 18 to 45 years where the ratio was 1.9 and 2.2 at the average, respectively and 1.7
207 and 2.1 at the high exposure level, respectively. The highest difference was noted in Belgian toddlers
208 with a ratio equal to 5.0 and 6.8 for the average and the high exposure level, respectively.

209 Under scenario 1, canned foods contributed always with less than 50 % to the average exposure for all
210 age classes with the exemption of one survey related to men 18 to 45 years old where it was 50– 75 %.
211 Under scenario 2, canned products dominated in all surveys, with the percentage contribution to BPA
212 from non-canned foods mainly ranging between 10-25 %. Under scenario 1, non-canned “meat and
213 meat products” turned out to be a major contributor to BPA average exposure in the large majority of
214 countries and age classes. “Vegetables and vegetable products” was the only canned food category
215 that contributed up to 25-50 % in some of the population groups under this scenario. “Meat and meat

216 products” was the major contributor among the non-canned food categories also under scenario 2 but
217 never exceeded 10-25 % of total exposure. On the other hand, the canned versions of “vegetables and
218 vegetable products”, “meat and meat products” and “composite food” were the major sources of
219 average BPA exposure under scenario 2.

220 Overall, among the population older than 6 months, infants and toddlers presented the highest
221 estimated average (375 ng/kg bw/day) and high (857 ng/kg bw/day) dietary exposure. The CEF Panel
222 considered that this was mainly due to their higher consumption of foods and beverages per kg bw.

223 Compared with the current assessment, dietary exposure to BPA estimated by EFSA in 2006 for the
224 population older than 6 months was far higher (up to 5 300 ng/kg bw/day in toddlers), due to the lack
225 of data at that time which led to the use of very conservative assumptions in relation to both the level
226 of consumption of canned food and the estimated BPA concentration in these foods.

227 *Dietary Exposure for infants aged 0-6 months*

228 For breastfed infants, the estimated average dietary exposure was 225, 135 and 119 ng/kg bw/day for
229 infants in the first five days of life, infants from 6 days up to 3 months and infants 4-6 months,
230 respectively. The estimated high dietary exposure was 495, 390 and 343 ng/kg bw/day, respectively.
231 The CEF Panel noted that, due to the lack of recent European data related to initial human milk, the
232 estimated dietary exposure in the first five days of life was based on BPA concentration in samples
233 collected in Japan in 2000 and generated using ELISA methodology. The Panel noted these limitations
234 in the data and the consequent uncertainties in the estimates for this age group.

235 Average and high additional exposure to infants that would derive from the consumption of herbal tea
236 prepared with water heated in a PC kettle would be as low as 2 and 4 ng/kg bw/day, respectively.

237 In the case of formula-fed infants (0-6 months), the estimated average and high exposure were 30 and
238 80 ng/kg bw/day, respectively. These estimates are based on the most common situation i.e. the use of
239 non-PC baby bottles and the use of water containing low BPA levels to reconstitute the infant formula.
240 Additional dietary exposure may occur in specific population groups due to i) the use of tap water in
241 buildings where old water pipes have been relined with epoxy resins releasing BPA (estimated high
242 exposure: 165 ng/kg bw/day) and ii) the use of old PC bottles bought before the 2011 ban (estimated
243 high exposure: 684 ng/kg bw/day). The percentage of infants to which these cases would apply is
244 unknown. If this percentage was higher than 5 % in some countries, it would lead to a high dietary
245 exposure which is significantly higher than 80 ng/kg bw/day.

246 Dietary exposure from further sources in other specific population groups of infants was assessed:
247 average exposure in infants fed powdered formula reconstituted with water heated in PC kettles or
248 with water from PC filters were 16.5 ng/kg bw/day and 6 ng/kg bw/day, respectively. The assumptions
249 used to estimate these average exposure values were conservative and would also cover high exposure.

250 Compared with the current assessment dietary exposure to BPA estimated by EFSA in 2006 in the
251 population 0 to 6 months was far higher (up to 11 000 ng/kg bw/day in infants aged 3 months in one of
252 the scenarios considered), due to the lack of data at that time, which led to very conservative
253 assumptions in relation to BPA concentration in infant formula and to BPA migration from PC bottles.

254 Non-dietary exposure

255 Exposure to BPA was estimated from the non-food sources of thermal paper, indoor air (including air-
256 borne dust), dust, dental materials, toys and articles intended to be mouthed and cosmetics. The CEF
257 Panel noted that outdoor air and surface water are also sources of BPA. However, data on BPA
258 concentrations in outdoor air vary widely and depend on regional factors. Reported concentrations of
259 BPA in surface water are very low and, together with contact to surface water, e.g. swimming in lakes
260 and rivers, will constitute only negligible exposure to BPA. Therefore these sources were not included

261 in the current exposure assessment. Medical devices other than dental materials were also not
262 considered. Since the BPA levels in saliva after dental treatment are reported to be very low (the BPA
263 level before treatment is the same as about 24h after treatment), it could be argued whether this really
264 represents exposure to dental materials. Therefore, exposure to dental materials was not included in
265 the total exposure calculation.

266 Data on occurrence, migration and transfer of BPA from non-food sources are scarce. The following
267 concentration data were selected from the scientific literature and other risk assessment reports to
268 calculate exposure in the EU: for indoor air 1 ng/m³; for dust 1 460 µg/kg, and for cosmetics (such as
269 body wash, and body lotions, etc.) 31 µg/kg. A migration of 0.14 µg/toys and 0.32 µg/pacifiers with
270 PC shield into saliva over a 24 h period was assumed. The transfer of BPA from thermal paper to
271 fingers was estimated to be 1.4 µg/finger considering 10 s of contact with paper. Handling events were
272 assumed as 1 per day for teenagers and adults to assess average exposure and as 4.6 per day to assess
273 high exposure. For children the handling events were assumed as 0.5 time per day for average
274 exposure and 2 times per day for high exposure. The thermal paper was assumed to be handled mainly
275 by the finger tips of three fingers each of one (average exposure) or two hands (high exposure).

276 For the calculation of total exposure the contributions of dust, toys, indoor air, thermal paper and
277 cosmetics were summed up for the respective age groups.

278 The contribution of the different non-dietary sources to average exposure was similar in infants aged 6
279 days to 3 years. The sources of BPA were identified and distinguished between infants (6 days to 12
280 months) and toddlers. The obtained values, given in brackets for infants and toddlers, respectively,
281 show that the main non-food source is cosmetics (e.g. body lotions, etc., 2.9 and 1.7 ng/kg bw/day),
282 followed by dust (2.6 and 1.1 ng/kg bw/day), indoor air (2.4 and 1.4 ng/kg bw/day) and toys (0.3 and
283 0.02 ng/kg bw/day). When considering the high exposure, the main source was dust (31 and 12.9
284 ng/kg bw/day), followed by indoor air (5.8 and 3.4 ng/kg bw/day), cosmetics (5.6 and 3.3 ng/kg
285 bw/day), and toys (1.2 and 0.5 ng/kg bw/day). Infants and toddlers using pacifiers with PC shields
286 were considered as a specific group. The exposure estimates from this source were 7.6 and 9.8 ng/kg
287 bw/day for infants with average and high exposure. For toddlers the exposure estimate was 6.6 ng/kg
288 bw/day.

289 For the rest of the population (children above 3 years, teenagers and adults) handling of thermal paper
290 was considered as a source and changes this pattern. When considering the average exposure, thermal
291 paper became the main non-food source (21, 28 and 18 ng/kg bw/day), followed by cosmetics (1.3, 1.5
292 and 1.2 ng/kg bw/day), indoor air (0.7, 1.1 and 0.7 ng/kg bw/day) and dust (1.3, 0.2 and 0.1 ng/kg
293 bw/day). When considering the high exposure, thermal paper was still the major source of exposure
294 (165, 259 and 163 ng/kg bw/day), but then exposure to dust (4.6, 4.6 and 2.9 ng/kg bw/day) becomes
295 higher than that of cosmetics (2.5, 2.9 and 2.4 ng/kg bw/day) and was followed by indoor air (1.8, 2.1
296 and 1.3 ng/kg bw/day) as the lowest contributor. The CEF Panel noted that the average values for dust
297 and thermal paper differed by a factor 10 from the respective high values. This is due to highly
298 conservative assumption for dust ingestion and frequency of and number of fingers handling thermal
299 paper when assessing high exposure.

300 **Total exposure**

301 The modelled average total exposure for the populations older than 6 months ranged from 314 to 383
302 ng/kg bw/day in infants, toddlers and children aged 3 to 10 years of age and from 136 to 190 ng/kg
303 bw/day in teenagers, adults and elderly/very elderly.

304 The modelled high total exposure for population older than 6 months ranged from 873 to 981 ng/kg
305 bw/day in infants, toddlers and children aged 3 to 10 years and from 500 to 642 ng/kg bw/day in
306 teenagers, adults and elderly/very elderly.

307 In formula-fed infants, the modelled average and high total exposure for infants 0-6 months were 38
308 and 117 ng/kg bw/day, respectively.

309 In breastfed infants, the modelled average total exposure was 228, 143 and 127 ng/kg bw/day for
310 infants in the first five days of life, infants from day 6 to 3 months and infants 4-6 months,
311 respectively. The modelled high total exposure was 501, 427 and 380 ng/kg bw/day, respectively.

312 Biomonitoring studies have been used to assess how much total BPA is excreted in urine, allowing for
313 an estimation of exposure from all sources to total BPA. A relatively large amount of information on
314 urinary BPA concentration is available for Europe. All age classes are covered in the different studies
315 available: children (except 1-3 years old toddlers), 14-15 years old teenagers, pregnant women, and
316 20-74 year old adults.

317 The distributional characteristics of the total BPA concentrations in urine in terms of shape and spread
318 are generally quite homogeneous across the different studies. Total BPA concentrations (GM) were,
319 with some exceptions, in the range of 1.1-3.6 µg/l. Estimates for the average and high levels of daily
320 BPA exposure were calculated by using the geometric mean (GM), the median (P50) and the 95th
321 percentile (P95) of the urinary BPA. The following average exposure estimates were derived: 20 ng/kg
322 bw/day (for 7-44 days old newborns) and <10 ng/kg bw/day (for 1-2 month old infants), 107 ng/kg
323 bw/day (for the children 3-5 years old) and 58 ng/kg bw/day (for children 5-10 years old), 49 ng/kg
324 bw/day (for teenagers and adults), and 40-73 ng/kg bw/day (for the elderly). The estimates for high
325 BPA exposure were 136 ng/kg bw/day (for infants), 676 ng/kg bw/day (for 3-5 years old children),
326 311 ng/kg bw/day (for 5-10 years old children), 225 ng/kg bw/day (for the teenagers), 234 ng/kg
327 bw/day (for the adults), and 203 ng/kg bw/day (for the very elderly).

328 The estimates for the average and high total exposure to BPA in the general population, as obtained by
329 the modelling approach, were compared with the biomonitoring estimates. The modelling approach
330 gave estimates which were approximately 4-fold higher (38-383 ng/kg bw/day vs. <10-107 ng/kg
331 bw/day) than those obtained by the biomonitoring approach for average exposure, and 3-fold higher
332 for high exposure. The different statistical procedures used to derive central tendency and the
333 scenarios for modelling the dietary and non-dietary exposure are important contributions to these
334 discrepancies. These comparative results show however that the existence of unrecognised sources of
335 exposure is unlikely.

336 Diet was the main source of total exposure in all population groups (from 78-99%). Dietary exposure
337 in women of childbearing age was slightly higher (132 and 388 ng/kg bw/day for average and high
338 exposure, respectively) than that for men of the same age (126 and 355 ng/kg bw/day for average and
339 high exposure, respectively). This may be due to different food items consumed by women as reported
340 in the individual surveys. The uncertainty around the estimates of dietary exposure based on the EFSA
341 comprehensive database was judged as relatively low.

342 Thermal paper was the second source of total exposure in all population groups above 3 years of age
343 whereas exposure to BPA from thermal paper was considered to be negligible under the age of 3. The
344 contribution to the total average exposure ranged between 7 and 15 %, taking into account all
345 population groups above 3 years of age. The uncertainty around the estimate of exposure to BPA from
346 thermal paper was judged to be considerably higher than that around dietary exposure. The CEF Panel
347 is aware of an ongoing study on BPA pharmacokinetic and dermal exposure in cashiers sponsored by
348 the National Institute of Environmental Health Sciences (NIEHS) under the National Toxicology
349 Program (NTP). The results of this study will be considered by the CEF Panel as they will be an
350 additional source of information regarding the absorption of BPA from thermal paper.

351 Dust was the second source of exposure for children under the age of 3 years (except infants in the
352 first few days of life). However, dust contributed comparatively little (2.1 %) to the average total
353 exposure with the exception of formula-fed infants 0-6 months for which it was up to 6.9 %.

354 Average exposure to BPA from other sources such as toys and cosmetics was estimated to be less than
355 0.3 ng/kg bw/day and 2.9 ng/kg bw/day, respectively in all population groups.

356 Overall, the CEF Panel concluded that diet is the major source of exposure to BPA in the EU
357 population. Another important source for BPA exposure could be thermal paper in all population
358 groups above 3 years. Due to the relatively large uncertainty around the estimate of exposure for this
359 source, the CEF Panel considered that more data would be needed in relation to BPA absorption
360 through the skin and to patterns of thermal paper handling by the general population in order to
361 provide a refined estimate of exposure from this source.

362 **TABLE OF CONTENTS**

Abstract 1

ERROR: invalidfont
OFFENDING COMMAND: show

STACK: