Committee for Socio-economic Analysis (SEAC)

Opinion

On an Annex XV dossier proposing restrictions on

Bisphenol A

Draft

11 September 2015

(Draft)

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Opinion of the Committee for Socio-economic Analysis

on an Annex XV dossier proposing restrictions of the manufacture, placing on the market or use of a substance within the EU

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation), and in particular the definition of a restriction in Article 3(31) and Title VIII thereof, the Committee for Risk Assessment (RAC) has adopted an opinion in accordance with Article 70 of the REACH Regulation and the Committee for Socio-economic Analysis (SEAC) has adopted an opinion in accordance with Article 71 of the REACH Regulation on the proposal for restriction of

Chemical names:	**Bisphenol A (4,4'-isopropylidenediphenol; BPA)**
EC No.:	201-245-8
CAS No.:	80-05-7

This document presents the opinion adopted by SEAC. The Background Document (BD) provides support to both RAC and SEAC opinions, giving the detailed ground for the opinions.

PROCESS FOR ADOPTION OF THE OPINIONS

France has submitted a proposal for a restriction together with the justification and background information documented in an Annex XV dossier. The Annex XV report conforming to the requirements of Annex XV of the REACH Regulation was made publicly available at: http://echa.europa.eu/web/guest/restrictions-under-consideration
on **18 June 2014.** Interested parties were invited to submit comments and contributions by **18 December 2014.**

ADOPTION OF THE OPINION OF SEAC

The draft opinion of SEAC

The draft opinion of SEAC on the suggested restriction has been agreed in accordance with Article 71(1) of the REACH Regulation on ***11 September 2015.***

The draft opinion takes into account the comments of and contributions from the interested parties provided in accordance with Article 69(6) of the REACH Regulation.

The draft opinion was published at http://echa.europa.eu/web/guest/restrictions-under-consideration on ***16 September 2015.*** Interested parties were invited to submit comments on the draft opinion by ***16 November 2015.***

THE OPINION OF SEAC

The restriction proposed by the Dossier Submitter is as follows:

Entry [#]. 4,4'-isopropylidenediphenol (Bisphenol-A) CAS No 80-05-7 EC No 201-245-8	"Shall not be placed on the market in thermal paper in concentration equal to or greater than 0.02% by weight, after [entry into force + 36 months]"

THE OPINION OF SEAC

SEAC has formulated its opinion on the proposed restriction based on information related to socio-economic benefits and costs documented in the Annex XV report and submitted by interested parties as well as other available information as recorded in the Background Document.

From an economic efficiency perspective, i.e., comparing the socio-economic benefits to the socio-economic costs, the proposed restriction is considered unlikely to be proportionate. However, there may be favourable distributional and affordability considerations.

JUSTIFICATION FOR THE OPINION OF SEAC

JUSTIFICATION THAT ACTION IS REQUIRED ON AN EU WIDE BASIS

Summary of proposal:
To justify that action is required on an EU-wide basis, the dossier notes that the adverse health effects arising from exposure to BPA can occur to the descendants of exposed female cashiers and consumers in the EU, and hence the risks are extended across all the EU countries. It is also highlighted that an EU-wide restriction would remove any potential distorting effects that national restrictions might have on the free circulation of goods on the market, thereby ensuring a level playing field for all the actors in the internal market.

Key elements underpinning the SEAC's conclusion

Based on the key principles of ensuring a harmonised level of protection across the EU and of maintaining the free movement of goods within the EU, SEAC supports the view that any necessary action to address risks associated with BPA in thermal paper should be implemented in all Member States.

Consumers

RAC in its opinion has concluded that the risks from BPA in thermal paper to human health are adequately controlled for consumers across the EU. Based on this SEAC concludes that action in relation to risks for human health aimed at consumers is not justified on an EU wide basis.

Workers

RAC in its opinion has concluded that the risks from BPA in thermal paper to human health are not adequately controlled for workers across the EU, and that measures to minimise exposure should be implemented on a EU-wide basis. Based on this, SEAC concludes that action to address risks to human health aimed at workers is justified on an EU wide basis.

SEAC's conclusion

SEAC agree that action is justified on an EU wide basis.

JUSTIFICATION THAT THE SUGGESTED RESTRICTION IS THE MOST APPROPRIATE EU WIDE MEASURE

Summary of proposal

Several measures are discussed in the dossier, and two restriction options have been chosen for further evaluation:

- RMO 1 (the proposed restriction): A concentration limit on BPA in thermal paper.
- RMO 2: A limit on the migration of BPA from thermal paper.

The dossier concludes that there is insufficient evidence to conclude that migration barriers, such as top coatings, would mitigate all migration and associated risks arising from thermal papers containing BPA. It is also stated that using protective barriers would probably imply a significant cost for industry. RMO 2 was thus deemed a less efficient and less

proportionate measure, compared to RMO 1.

An additional third RMO, namely a concentration limit on all bisphenols in thermal paper, was mentioned, but due to the current lack of toxicological data on some of the bisphenols, this option was not evaluated further.

The Dossier Submitter also acknowledges the possibility to use other EU wide risk management options, but they are all disregarded for different reasons:

- Authorisation
  - Does not cover risks from imported thermal paper
- Voluntary industry agreement
  - Does not give enough incentives for sufficient substitution
- Worker protection:
  - Regulatory requirement for pregnant workers to wear protective gloves
    - discriminatory measure among workers
    - would not protect workers who ignore their pregnancy
    - would not protect workers who have not declared their pregnancy yet or who wouldn't like to
    - would not protect consumers
  - Regulatory requirement for workstation re-layout, minimising cashiers contact with BPA containing receipts
    - would not be economically suitable
    - would not protect consumers

The dossier points out that the low concentration limit in the proposed restriction is equivalent to a total ban. As a result, it is expected that BPA will be fully phased out, thereby removing all human exposure from thermal paper. However, the least expensive alternative to BPA is BPS, which is suspected to have many of the same adverse health effects as BPA. A restriction on BPA in thermal paper may thus only ensure that there is a reduction in risk if alternatives other than BPS are chosen by industry as a replacement.

The proposed restriction was considered to be the most appropriate EU wide measure due to its effectiveness, proportionality and practicality, compared to the other RMOs.

Key elements underpinning the SEAC's conclusion

Consumers

Since there is no identified risk to human health for consumers identified by RAC, SEAC concludes that no action is required on an EU wide basis to protect consumers' health.

Workers

RAC found that the RCR is above 1 for workers (cashiers), thus SEAC considers that risk management might be appropriate. However, some of the risk management options evaluated by the Dossier Submitter were discarded mainly due to their inability to protect consumers. This argument is no longer valid since RAC has concluded that the risks for consumers are adequately controlled.

The Dossier Submitter did not provide any cost estimates for the worker protection risk management measures, but claimed that workstation re-layout would be economically infeasible. Without any more evidence to justify this claim, SEAC cannot exclude the possibility that rearranging the workstation might be equally or less expensive than the proposed restriction. In the same way, a regulatory requirement for pregnant (or all) workers to wear protective gloves may also be more or less expensive than the proposed

restriction.

Another restriction option that would have been worth investigating is a narrower scope, e.g., excluding non-Point of Sale (non-POS) tickets[1], top-coated paper (RMO 2) or ATM receipts. The Dossier Submitter did not provide information, or recommend that the committees evaluated a restriction option with a narrower scope, meaning that SEAC has insufficient information to evaluate such a restriction option. In case such a narrowing of scope was both technically practicable and possible without consequence for workers risks, then this option could reduce costs and make the restriction more likely to be proportionate. However, SEAC does not have any specific information on the possible risks and costs from a narrower scope. For example information related to whether workers only handle POS receipts or whether they also handle non-POS tickets, and if it is technically and/or financially viable for thermal paper producers to have separate production lines for different types of thermal paper, would be necessary to determine if a narrower scope would be a more appropriate measure than the proposed restriction. SEAC is not able to recommend any derogation from the original scope. SEAC notes that having a narrow scope could complicate enforceability of the restriction. Forum stated that from an enforcement perspective, it would be difficult to distinguish between thermal papers produced for one application or another.

The Dossier Submitter also mentions a restriction option with a larger scope (RMO 3), where BPS is also included. Based on RAC's advice of avoiding BPS as an alternative, SEAC finds that preparation of a restriction proposal on BPS should be considered if a restriction on BPA will be implemented.

SEAC's conclusion

As a result of gaps in the assessment of risk management measures, SEAC expresses reservations to the conclusion of the Dossier Submitter that the proposed restriction is the most appropriate EU wide measure. However, SEAC has concluded that the proposed restriction cannot be rejected as an appropriate EU wide measure to address human health risks to workers. SEAC cannot exclude the possibility that a narrower scope of the restriction or another risk management measure might be more cost-effective, and thus more appropriate.

Proportionality to the risks

Summary of proposal

Benefits

The benefits are based on the identified risks for the unborn child for the following human health endpoints:

- Female reproductive system
- Metabolism and obesity
- Mammary gland
- Brain and behaviour

The Dossier Submitter has performed a partial quantitative evaluation of health benefits for the progeny of cashiers and consumers who are exposed to BPA, through "eco-paper" Point

[1] Self-adhesive labels, lottery tickets, fax paper and others, see Table 3

of Sale (POS) tickets and receipts. The evaluation of benefits is based only on exposures related to "ecopaper" POS tickets and receipts, which constitute a 65% use share of all thermal paper in the EU. The Dossier Submitter suggests that 70% is a reasonable estimate for the share of all POS thermal tickets and receipts that contain BPA as a dye developer.

The estimations of disease burden are based on:

- A modelled internal exposure dose distribution for the two population groups (female cashiers and consumers)
- Modelled dose-response functions, based on linear extrapolation from animal studies, which are used to derive the excess risk of the relevant health effects
- The use of the DNEL as a toxicological benchmark to define an effect threshold

The dossier underlines that the quantified benefits of the restriction constitute only a part of the benefits, as there were identified health effects that were unquantifiable. Adverse effects from BPA that could not be quantified as monetised benefits were:

- Increase in ovarian cysts
- Disruption of ovarian cysts
- Alteration of spacial memory
- Alteration of learning functions

In the BD the Dossier Submitter also considers the kidney effects for the risk assessment. Two main conclusions were drawn:

- The kidney effects were only observed at quite high doses in animal studies, so it may be expected that no cases of kidney effects will occur in the human population.
- If any cases would occur, it would be difficult to clearly identify the disease (i.e. the actual impact on the individual and furthermore society) attributable to an increase in kidney weight.

The excess risk estimates from Table 1 were used to calculate the benefits.

Table 1 Excess Risk estimates from Table 108 in the BD

	Excess Risk estimates from the BD	
	Consumers	**Workers**
*Terminal end buds (TEB)**	*0.06%*	*0.61%*
*Terminal ducts (TD)**	*0.05%*	*0.55%*
*Hyperplastic duct (HD)**	*0.01%*	*0.055%*
Mammary gland* - worst case	0.12%	1.22%
Neurobehavior	N/A	N/A
Reprotox*	0.006%	0.07%
Metabolic – cholesterol	0.07%	0.73%
Metabolic – obesity	0.032%	0.33%

* only female offspring are at risk for these endpoints.

The resulting quantified part of the benefits was estimated to be

Consumers: €1 677 218 - €2 552 485
Workers: €1 863 178 - €2 654 870

The total quantified benefits were than estimated to be in the range > [€3 540 395; €5 207 355] per year. The absolute worst case scenario was excluded, since this scenario involved adding up the different excess risk estimates for the mammary gland (TEB, TD and HD), which was not considered to be realistic.

These numbers were supposed to constitute the lower bound for the benefits, since part of the identified health effects were not quantified.

It is also made clear in the dossier that the benefits are highly contingent on the alternative chosen by industry to replace BPA. A transition from BPA to BPS is expected to yield very small or even zero benefits, while the Dossier Submitter expects a significant risk reduction if other alternatives are chosen.

The Dossier Submitter underlines that information provided by large retailers indicate that although BPS is technically and economically feasible and is already used as an alternative, it still may be expected that industry would not necessarily switch to BPS if it is expected that BPS will be regulated in the near future (INERIS 2013).

Costs

The Dossier Submitter's approach to cost estimation is based on estimating the substitution costs and compliance control[2] costs for the thermal paper producers. This includes thermal paper production both for EU use (58%) and for export (42%). The size of the import market of BPA containing thermal paper is unknown, and the costs to importers are thus not included[3].

To calculate the substitution costs, the Dossier Submitter has considered the expected price increase for thermal paper, when switching from BPA to other dye developers. The alternatives included in the analysis are: BPS, D8, and Pergafast 201. Three scenarios were constructed (low, medium and high) varying all the input prices as well as the concentration of the dye developers (loading) used in the thermal paper.

The main assumptions used in the substitution cost calculations included:

- Only costs for "ecopaper" POS tickets and receipts are calculated
- Period of analysis 2019-2030
- Growth in thermal paper market 5-7%
- Price decrease in alternatives of 8% between 2013 and 2023, and then 5% decrease from 2023-2030.
- All alternatives are treated as "drop-in" used in the same concentration as BPA

Based on these assumptions, as well as additional industry consultations performed by the ECHA secretariat and the Dossier Submitter (see Annex 9 to the BD), the medium scenario substitution costs are estimated to be in the range €1 million to €22 million per year. Excluding BPS the range is €19 million to €22 million per year.

In addition to the substitution costs compliance control costs in the range €150k – €250k

[2] The Dossier Submitter is here referring to testing costs.

[3] The need to include costs for export in the cost estimate depends on whether industry will produce BPA free thermal paper for export as a consequence of the restriction or whether a separate production line for BPA containing thermal paper remains in place for export after the restriction. In the latter case, no costs for export would occur, and the costs would be overestimated. On the other hand, the costs borne by importers are not included, which will underestimate the costs. As long it is unknown whether the EU is a net exporter or a net importer of BPA containing thermal paper, it is not possible to determine whether the costs are under- or overestimated in this respect.

per year are expected.

Proportionality

In the BD, proportionality is evaluated under two extreme scenarios:

1) All companies will move from Bisphenol A to Bisphenol S

2) No company will move to BPS and instead will move to non-bisphenol alternatives, including D8 (4-hydroxyphenyl 4-isoprooxyphenylsulfone) and Pergafast 201.

A summary of the Dossier Submitters' assessment is presented for the two scenarios in Table 2.

Table 2 Costs and benefits ratio in two scenarios (taken from section E.2.1.1.2.1 in the BD)

	Human health benefits (B)	Costs (substitution+control) (C)
Scenario 1 (BPS)	(likely) ≈ 0	medium cost = €1.4 million
Scenario 2 (non-bisphenol alternatives – D8 and Pergafast)	> €3.5 million and €5.2 million (not all benefits quantified and valued)	medium cost = [€19.3 million; €25.3 million] (upper bound likely to be overestimated)

The Dossier Submitter concludes that scenario 1 is not considered proportionate, but that the benefits may outweigh the costs for scenario 2 (if unquantified benefits would be large enough) and the restriction may thus be deemed proportionate.

Key elements underpinning SEAC's conclusion

Benefits

Consumers

The Dossier Submitter's assessment of benefits was premised on a risk being identified. However, given RAC's conclusion that the risks from BPA exposures for consumers are adequately controlled, there are consequently no expected impacts, and thus no benefits to society from implementing risk management measures directed towards consumer protection.

Workers

The quantitative analysis of the benefits of the restriction is based on a health impact assessment that estimates the change in the burden of disease as a result of the restriction. The disease burden is estimated by linking the number of progeny of females exposed to BPA at levels above the DNEL to the excess risk for the effects of concern.

According to RAC, the available data for effects on the mammary gland, the immune system, the reproductive system, metabolism and neurobehaviour was not robust enough to be used as a point of departure for DNEL derivation. Instead however, RAC has chosen to follow EFSA's approach by using the kidney weight changes as a starting point for DNEL derivation and to account for the uncertainty regarding the other potential effects by using

an additional assessment factor of 6 (six). Based on a DNEL for the dermally absorbed total BPA dose and a reasonable worst case exposure estimate, RAC concluded that risk from dermal contact with thermal paper is not adequately controlled for workers (RCR=2).

According to RAC, the various endpoints considered in the risk assessment have a number of effect types that are of relevance for human health impact assessment. The identified endpoints of relevance to SEAC for undertaking its proportionality assessments are[4]:

- Mammary gland
- Immunotoxicity
- Female reproductive system
- Brain and behaviour
- Metabolism and obesity

All of these categories might lead to several possible health effects. RAC has considered studies related to the various endpoints used in the risk assessment, and evaluated the evidence on the associated health effects. In each case the target population is children of pregnant cashiers.

Since RAC concluded that the available data on these effects do not allow a quantification of the dose-response relationship, SEAC cannot use the benefit estimates described in the BD for its proportionality assessment.

It should be noted that the population at risk which is used in the break even analysis is based on the worker population considered by the Dossier Submitter in their restriction proposal analysis, namely cashiers handling POS tickets and receipts only. This was also the population considered by the Dossier Submitter to be consistent with the risk assessment and for whom a risk was demonstrated and EU wide action found to be appropriate by RAC[5]. In assessing the exact number of such workers to be included in the break-even analysis, SEAC were mindful of a number of issues and uncertainties regarding the relevant population:

- As previously noted, the extent to which the risks to workers relate to exposures from POS applications as distinct from non-POS applications has not been assessed by the Dossier Submitter and hence it has not been possible to consider the risks and costs of a narrower scope. As such, and given that the risk assessment was focussed on cashiers handling till receipts (i.e., POS applications), it is also unclear whether the risks also apply to other workers besides cashiers, and hence to what extent such other workers e.g., in distribution industries, who are only exposed to non-POS applications should also be included within the relevant population at risk.

- The population of cashiers estimated by the Dossier Submitter potentially includes other workers employed in retail sales than just cashiers and hence may include workers who might never be exposed since they are not strictly in contact with tickets and receipts. According to estimates provided by the Dossier Submitter in the BD (section F1.1.1), it is possible that the number of cashiers actually in contact with receipts and tickets, may be 40% - 80% lower than indicated.

- The population of cashiers is not a static group of workers since there will be periodic turnover of staff. However it is unclear whether this will significantly affect the total population that should be included in the analysis since a significant part of staff

[4] Note that the exact wording used for these endpoints in opinion of RAC and in the BD is variable.
[5] The risk assessment was based on a scenario of occupational exposure focused on exposure via the cutaneous route of cashiers handling receipts with a particular focus on pregnant women. Other professions exposed to thermal papers (lottery tickets, self-adhesive labels) were not taken into account.

turnover is likely to be within the same occupation. Moreover, the pregnancy incidence rates (upon which the number of offspring is calculated) are annual rates that relate to the possibility of pregnancy during a given whole year period. Turnover of staff within any year would thus not have any impact on the number of offspring estimated on the basis of the static population of female cashiers.

The uncertainties surrounding the population at risk are pulling in different directions, so there are no indications of systematic over- or underestimation.

Costs

SEAC in principle agrees with the approach taken by the Dossier Submitter to estimate the costs of the proposed restriction. SEAC however made some modifications in order to correct for some errors identified, to include new cost information received, as well as to incorporate other changes considered necessary by SEAC. In particular, the following assumptions are different from the Dossier Submitter assumptions:

- New information was obtained from industry by the ECHA secretariat and the Dossier Submitter (Annex 9 to the BD) late in the opinion making process. This additional information from several stakeholders indicates that Pergafast-containing thermal paper is only 10-35% more expensive than BPA-containing thermal paper. SEAC has used this new information as a basis for producing new cost estimates.

- The Dossier Submitter had assumed that the thermal paper market would grow by 5-7% per year. Although SEAC found some justification for assuming a growing thermal paper market, evidence on specific growth rates was lacking. Furthermore, there are aspects like the growing paper-free alternatives market, which might lead to a decrease in market size, but, SEAC has no corroborating evidence to support this. For simplicity SEAC has assumed that the tonnages will be constant during the period of analysis, though this may mean that the resulting costs are underestimated in accordance with the evidence put forward by the Dossier Submitter.

- The Dossier Submitter assumed an 8% (followed by 5%) yearly price decline for the alternatives. SEAC could not find any justification for this assumption. Furthermore, new information obtained from industry (Annex 9 to the BD) indicated that raw material inputs were the main driver of the cost of alternatives, and that no significant economies of scale were to be expected. As such, the price difference when using an alternative dye developer in the manufacture of thermal paper is expected to persist over time. Based on this information, SEAC has assumed a constant price difference over time between the alternatives and BPA.

- The scope of the restriction includes both thermal paper used for Point-of-Sale (POS) and non-Point-of-Sale (non-POS) applications:

Table 3 Applications of thermal paper in Europe (Table 6 from the BD)

Application	Share over total thermal paper (2008-2012)
Point-of-sale receipts	50% - 65%
Self-adhesive labels	20% - 30%
Lottery tickets	≈10%
Fax	≈5% - 10%
Other	< 0.5%
TOTAL	100%

However, the costs estimates derived by the Dossier Submitter only included the

POS applications. SEAC could not find any justification for assuming that there would be no costs connected to non-POS applications, so the cost estimates produced by SEAC were extended to include the entire scope. SEAC assumed that the cost of using an alternative in non-POS thermal paper would be the same as using alternatives in POS thermal paper[6].

- The Dossier Submitter estimated that a switch to D8 or Pergafast 201 would lead to a 13.5% or 15% price increase in thermal paper respectively. SEAC has based its cost assessment on three different cost scenarios using 10%, 15% and 20% as the respective increases in the price of thermal paper, which will cover both these alternatives. This range corresponds to the mid and lower range price increases for Pergafast reported in the new information gathered by the ECHA Secretariat and the Dossier Submitter, which showed a price increase between 10-35% (Annex 9 to the BD).[7] SEAC took a conservative approach and chose 10-20% as the price increase range, which means that the upper and medium cost estimates might be underestimated (see Appendix 3).

Based on these updates, as well as the price and tonnage information from the dossier, SEAC has estimated the cost of the restriction as presented in Table 4.

Table 4 Three cost scenarios for the average yearly costs in € over the period 2019 - 2030

Alternative	Cost scenarios		
Cost scenario	low (10%)	med (15%)	high (20%)
Average yearly costs in € over the period 2019 - 2030	43 000 000	65 000 000	86 000 000

SEAC has taken into account the RAC advice: "*[BPS]… may have a toxicological profile similar to BPA and thus RAC advises against substitution with BPS. […] If substitution trend towards BPS is observed, the need to propose a restriction on BPS should be considered.*" Furthermore, evidence from consultation with industry suggests that even though BPS is the cheapest alternative, many actors would nevertheless switch to a more expensive alternative with less hazardous properties. Due to the assumed very limited risk reduction associated with BPS, as well as doubts as to whether industry would choose this option, a quantitative proportionality assessment was not undertaken for BPS. Instead, SEAC only evaluated those alternatives for which there was strong evidence of risk reduction, namely D8 and Pergafast 201. Still, it is important to keep in mind that if industry chooses BPS as an alternative, the restriction might be less costly, but achieve little reduction in risk.

Proportionality

In accordance with the proportionality considerations of the Dossier Submitter, and alongside the RAC advice noted in the previous paragraph, SEAC agrees that the restriction is unlikely to be proportionate if industry primarily uses BPS as the alternative for BPA. The largest benefits are likely to be achieved if substitution from BPA was to a non-bisphenol alternative, whereupon the corresponding costs would be €43 - €86 million per year as indicated above. In case of substitution with non-bisphenol alternatives, it is assumed that

[6] As noted above, a narrower scope would be worth investigating. However, SEAC does not have the necessary information about potential costs or risks associated with a narrower scope, and is thus only evaluating the proposed restriction. Please also see the section on benefits for a discussion of the uncertainties surrounding the population at risk.

[7] SEAC does not distinguish between D8 and Pergafast in calculating the price increase scenarios, since both are within the same thermal paper price increase interval.

any risks to workers from thermal paper would be adequately controlled.

As mentioned above, the available information does not allow the quantification of dose-response relationships necessary to perform a health impact assessment and corresponding cost-benefit assessment of the proposed restriction. One approach, used in previous restrictions where fully quantified cost-benefit comparisons have not been possible, is to instead perform a 'break-even' analysis in order to aid the proportionality assessment.

One complication in the present case is that it is not clear how the DNEL should be interpreted, since it encompasses uncertainties associated with multiple endpoints. In the case of a partial analysis involving only a single endpoint, e.g., mammary gland changes, a 'break-even' analysis could be constructed as follows:

1. According to the various cost of alternatives scenarios presented above, the medium discounted cost to industry of switching to a non-bisphenol alternative is around €65 million per year. Using a valuation factor of €6 301[8] for mammary gland changes based on 5.5%[9] breast cancer occurrence rate, the number of cases of mammary gland changes that would need to be avoided in order to offset the costs of the restriction, would be around 10 280 per year.

2. The relevant population at risk here is the unborn daughters of cashiers exposed to BPA from thermal paper. According to the information in the restriction dossier, this group consists of 79 000[10] female offspring in total per year. Furthermore, from Table 12 in the RAC opinion it is known that the 50th percentile (median) exposure is approximately at the DNEL, i.e. RCR=1. This means that out of the 79 000 unborn female offspring 50% have RCR>1 and 50% have RCR<1. Consequently, 39 500 children per year would potentially be at risk of mammary gland changes.

3. Combining the information above it can be seen that in order to reach the 'break-even' level of benefits, 10 280 of the 39 500 children at risk[11] would need to avoid developing mammary gland changes from exposure to BPA from thermal paper, i.e. the necessary absolute risk reduction from the restriction would have to be 26% in order to offset the costs of the restriction.

Whilst the above example demonstrates the case in which only a single endpoint contributes to adverse effects in the population, the actual situation is somewhat more complex, and the break-even analysis is not as straight forward as presented above. In accordance with the risk characterisation performed by RAC, there may be possible adverse health effects related to more than one endpoint. As such, the break-even approach requires that the costs of the restriction are apportioned across all potentially contributing endpoints (and their associated adverse effects) included in the risk characterisation. The extent to which each of the endpoints included in the risk characterisation will actually generate adverse effects is not known. Neither is there any indication that any one endpoint is likely to contribute more or less to the benefits than another. Based on this and in order to keep the analysis transparent, SEAC has apportioned the costs in this break even analysis equally

[8] See Table 7 in Appendix 1 for an explanation of the valuation factors used.

[9] The analysis undertaken here assumes that some individuals with mammary gland changes as a result of exposure to BPA may consequently go on to develop breast cancer. Some mammary gland changes are reversible and will not be adverse. In general, however, it is unknown whether the observed effects on the architecture of the mammary gland, including effects on Terminal End Buds and Terminal Ducts do lead to increased susceptibility to cancer when co-exposed to carcinogens. Nevertheless, for the purpose of this example, SEAC errs on the side of caution and assumes that there is a 5.5% conditional probability of getting breast cancer given any observed mammary gland change (see explanation in section F.1.1.4. of the BD).

[10] Derived from 180 000 children at risk, and 48% being female.

[11] Some effects affect both genders, but the mammary gland changes only affects female offspring. The population at risk is different for the different endpoints, which is taken into account in the analysis.

across the different endpoints included in the risk characterisation performed by RAC in this break-even analysis. Since there are 5 endpoints this means that each endpoint is allocated 20% of the cost. Based on this cost allocation, the implied minimum absolute risk reductions that would be necessary to offset the costs can be computed.

For each endpoint, the required risk reduction is calculated as shown in the 'single endpoint' example shown above, and based only on the population with RCR>1. The main difference as compared to the 'single endpoint' example is that the cost allocated to each endpoint is lower, as it is divided across the different effects. In the break-even analysis a population size of 39 500 daughters was used for the mammary gland and the reproduction toxicity endpoints. For immunotoxicity, neurobehaviour and effects on the metabolism, the relevant population at risk includes both daughters and sons of exposed cashiers, bringing the population at risk to 81 149 per year.

In computing the break-even number of cases for each effect, SEAC has taken the valuation factors provided by the Dossier Submitter as the starting point, but where necessary these have been updated to correct for missing or insufficiently justified values. The valuation factors included are used to represent the entire spectrum of illness and disease associated with exposure to BPA for each endpoint. As such they are not be considered as only representing one single disease for each endpoint. Indeed for some of the endpoints the valuation factor is constructed using the average of the valuations found in the literature for a number of different diseases that are relevant. It is not known how representative the valuation factors are for the entire spectrum of health effects associated with the exposure to BPA. However, since the factors are constructed using diseases indicative of the class of health effects associated with the endpoint, they can be used as average indicators for the likely order of magnitude of the willingness to pay to avoid diseases within that class. Furthermore, it should be noted that the valuation factors chosen to be representative could equally be over- or underestimated, thus the end results are considered to be unbiased. The complete list of valuation factors, the derivation and the corresponding sources can be found in Appendix 1.

The results of the break-even analysis can be found in the Table 5 below. Three scenarios are constructed by combining high valuation factors with low costs, medium valuation factors with medium costs and low valuation factors and high costs. As such they represent possible upper and lower bounds for a range of the necessary absolute risk reduction. Although these ranges incorporate some of the uncertainties associated with the cost and valuation factors, a number of additional uncertainties are discussed in Appendix 2. Details of the derivation of the valuation factors used across the 3 sensitivity scenarios and for each endpoint are further described in Appendix 1. In Appendix 3 an additional analysis testing the sensitivity of some of the parameters is included.

Table 5 Absolute necessary risk reductions to offset the cost of the proposed restriction. Due to the underlying uncertainties (see Appendix 2) the figures should be interpreted as indicators representing orders of sizes rather than accurate estimates

Absolute risk reduction necessary to offset the cost				
Endpoint	Cost division	low cost – high WTP	Medium cost – Med WTP	High cost – low WTP
Mammary gland*	20%	2%	5%	92%
Immunotox	20%	4%	8%	19%
Neurobehavior	20%	0.4%	2%	9%
Reprotox*	20%	3%	6%	17%
Metabolic	20%	2%	4%	11%

* only female offspring are at risk for these endpoints.

Interpretation and conclusions from the Break-Even analysis

The percentages displayed in the above table represent the absolute risk reductions necessary to offset the costs. This is equivalent to the proportion of the known population at risk (i.e. RCR>=1) who would have to experience effects within the given endpoints. It should be noted that the break-even analysis does not imply that any effects actually will occur. It only describes the incidence rates that would be necessary in order for the benefits to offset the costs of the restriction.

To be able to correctly interpret the results, one need to look at each column as a whole, i.e. all of the absolute risk reductions within a given scenario (column) would have to happen in the same year, for the cost to be offset[12]. In general, the higher the proportion of the population at risk that needs to experience effects in order for the costs to be offset, the less likely is it that the restriction is proportionate.
The above results thus suggest that in order for the health benefits of the restriction to offset the total costs of transition to a non-bisphenol alternative (D8 or Pergafast 201), the hypothetical absolute risk reduction resulting from the reduction of exposure to BPA in thermal paper for the given adverse effects would have to be (medium cost-medium valuation WTP shown with upper and lower bound in parenthesis): 5% (2-92%[13]) having mammary gland changes, 8% (4-19%) having immunotoxicity-related allergies, 2% (0.4-9%) having neurobehavioral effects, 6% (3-17%) experiencing adverse reprotoxic effects and 4% (2-11%) having hypercholesterolemia or weight gain. These risk reductions would be incremental to the baseline rates of these adverse effects in the general population. Accordingly, this means that if, for example, the general population risk level for reprotoxic effects would be 0.2%[14], one would need to observe this disease in 0.2%+6%=6.2% of the population at risk from BPA from thermal paper. Note that care needs to be taken in any interpretation of background incidence rates in the general population since the population at risk is very small compared to the general population and thus high incidences in the population at risk would not necessarily be at odds with observing low rates in the general population.

For the restriction to be proportionate, it would thus need to reduce the risks of all the different health effects (across the population at risk from BPA exposure from thermal paper) by at least the order of magnitudes ('break-even' risk change levels) indicated above. As such, in order for SEAC to conclude on the proportionality of benefits and costs it is necessary to assess the plausibility of these hypothetical break-even risk change estimates for each effect individually, as well as concurrently. In the absence of any directly applicable information or data, SEAC consulted RAC on the plausibility of observing such risk estimates in reality. Specifically, SEAC asked RAC for their expert judgement on the likelihood of observing the hypothesised 'break-even' risk change levels (incidence percentage point change) in the population at risk. In response RAC concluded (by simple majority) that *"concurrent incidences of such high magnitude for these types of effect* [are] *exceptionally unlikely for any substance"*. Moreover RAC emphasised that *"it is exceptionally unlikely that all of the incidence rates* [shown in the table] *would occur concurrently in the population at risk due to exposure of workers to BPA from thermal paper"*.

[12]Note that if a risk reduction on one endpoint is larger than required for break-even, this can in principle compensate for a smaller than required risk reduction on one of the other endpoints. This is equivalent to using a different cost division among the endpoints.
[13] The reason for the large difference in the min and max absolute risk increases for the mammary gland changes is due the assumption of a clear link between BPA and cancer in the medium and maximum, whilst no such link is assumed in the low valuation scenario.
[14] For the purposes of this example the general population risk level for reprotoxic effects is based on the rates for endometrial hyperplasia as an exemplar of disease/illness in humans associated with reprotoxic effects. The risk level is from Lancey et al. (2012).

It should be noted that the risk estimates presented to RAC were different from those given here, since those estimates were based on a preliminary analysis undertaken by SEAC. The incidence rates presented to RAC were central estimates. RAC was informed that the presented estimates were uncertain and could change, but that they would remain within the three orders of magnitude (10^3). As such, SEAC considers that the estimates are sufficiently similar so that the reply of RAC can still inform SEAC's opinion[15]. Even by comparing the low cost – high WTP (see third column Table 5) estimates from the main break-even analysis with the estimates shown to RAC, the same order of magnitude is observed. The full question posed to RAC and the response of RAC to SEAC can be found in Annex 10 to the BD. Table 6 below shows the estimates from the preliminary analysis that was shown to RAC, alongside the final and sensitivity check estimates.

Table 6 Comparison of the different necessary risk reduction estimates used in the opinion

Absolute risk reduction necessary to offset the cost			
Endpoint	Estimates from the preliminary analysis (shown to RAC)	Estimates used in the main break-even analysis (Table 5)	Estimates from the sensitivity analysis (Appendix 3)
Mammary gland*	17%	5%	7%
Immunotox	13%	8%	5%
Neurobehavior	N/A	2%	3%
Reprotox*	7%	6%	20%
Metabolic	4%	4%	12%

* only female offspring are at risk for these endpoints.

SEAC's break-even analysis discussed above has assumed, despite the uncertainties and lack of conclusive evidence, that there would indeed be observed impacts in terms of the above disease and illness effects in human populations, and that these are causally linked to exposure of BPA in thermal paper. Moreover, SEAC notes that although there are other uncertainties with the break-even analysis[16], there is no indication that these will change the conclusion regarding proportionality.

Hence, SEAC concludes that the proposed restriction is unlikely to be a proportionate measure in terms of standard benefit cost considerations. It is also worth noting that the same conclusion would have been reached using the dossier submitter's cost and benefit estimates (see Table 2), since these suggest that costs outweigh benefits by around an order of magnitude[17].

Distributional equity and 'affordability' considerations

In order to gain additional insights regarding the consequences of the restriction and thereby aid the policy-making process further, SEAC considered additional impact assessment criteria beyond those considered in the Dossier Submitter's analysis. In particular, SEAC considered that distributional equity and affordability aspects of the restriction could be relevant elements to consider.

[15] 'Similar' here means within the same order of magnitude (<10), and bearing in mind the context of disease incidence rates directly attributable to individual chemicals.
[16] See Appendix 2 for an overview of the identified uncertainties.
[17] Although it is acknowledged that not all benefits were quantified and valued in the Dossier Submitter's assessment, SEAC has not been provided with any indication that these non-monetised benefits would eclipse the order of magnitude difference in monetised costs and benefits.

SEAC considered the impacts of the restriction in terms of 'affordability' for the cost bearing actors. Affordability in this case can be defined[18] as the actor's ability to pay, e.g., in terms of income or profits, relative to the size of the enforced costs. As long as the actor is able to pay, that is, the enforced cost is not larger than the income or profit, the measure can be seen as 'affordable'. However, it should be underlined that an affordable measure is not necessarily economically feasible, and affordability does not imply a measure is (net) beneficial for society. Still, SEAC considered this to be an additionally relevant and potentially helpful factor to be included in the opinion.

Accordingly, SEAC notes that the cost of the restriction in terms of the price increase per roll of thermal paper amounts to around 5 to10 cents (10-20%), whilst the additional cost expressed in terms of the increase per cashier in the affected business sectors is around €4.3 – €8.6 per year per cashier. This amounts to a very small proportion of total personnel costs (<0.05%) or gross operating surplus (≈0.05%) in the affected sectors in the EU[19]. Furthermore, no comments were received in the public consultation on possible affordability issues for industry. If the costs are transferred into increased prices of consumer goods, the amount per EU-citizen will amount to ca. €0.1 – €0.2 per person per year. As such, SEAC considers that the restriction is unlikely to have serious affordability concerns at the micro level.

With regards to distributional equity, the BD contained no specific information on the likely impacts of the restriction on affected subpopulations. Nevertheless, SEAC was able to surmise that exposure to BPA in thermal paper may have disparate and unequal impacts in terms of adverse health consequences befalling a relatively small and vulnerable sub-population, namely, the progeny of cashiers/workers, as compared to the general EU population. To the extent that the restriction might reduce the degree that this sub-population are 'disproportionately' affected by these health impacts, whilst at the same time sharing the economic impact in terms of small (on a per household basis) cost increases (in the form of higher prices that are passed on) evenly across the wider EU population, it can be said to have favourable distributional equity effects. In this respect one can say that the restriction might lead to a more 'equitable' distribution[20].

Given that it has not been possible to assess the extent that there are actual health impacts in the relevant population, the risk assessment undertaken by RAC can be used as a proxy of the health impacts, with which to assess the distributional change. As indicated elsewhere in the opinion, the results of the risk assessment indicate that risks are distributed specifically amongst workers rather than the general population (consumers), and that as a result of the restriction the risks to workers would be controlled. However, it should be noted that (as a general rule) the outputs from risk assessment are an imperfect proxy of health impacts, since such outputs (e.g., risk characterisation ratio) do not easily translate into measures of actual human health impacts that are the ultimate objective of the distributional analysis. Even though the restriction will reduce the risk to workers there still exists the possibility that health impacts might not actually occur in reality in the first place. In this case the restriction will not have positive distributional effect, and could result in distorting risk management priorities away from actual health impacts[21].

SEAC's conclusion

Based on the results from the break-even analysis, the proposed restriction is unlikely to be

[18] There is no general definition of affordability, as it is not an analytically defined concept.
[19] Based on total personnel costs and gross operating surplus (2009 – latest year available) in the retail sector in the EU of around €300 Billion and €160 Billion respectively (Eurostat: sbs_na_dt_r2).
[20] 'Equitable' distribution as seen from an environmental justice perspective – see for example, USEPA (2014).
[21] To the extent that exposures would not in reality result in actual health impacts, then the restriction would indeed have unfavourable distributional effects.

proportionate from an efficiency perspective (i.e., benefit-cost comparison). Moreover, due to the lack of dose-response relationships, it is uncertain whether illness or disease will actually occur in the population at risk and at which severity and incidence rates. On the other hand, assuming adverse human health impacts are occurring as a result of BPA exposure in the worker population, some support for the restriction may be derived from considerations of distributional equity (i.e., who gains and who loses) and affordability, which can also be considered alongside economic efficiency arguments. Whether the proposed restriction is socially acceptable will then depend on the extent to which any distributional equity and affordability considerations override economic efficiency arguments and concerns. SEAC does not have any information on societal preferences for different distributional compositions.

In conclusion, from an economic efficiency perspective, comparing the socio-economic benefits to the socio-economic costs, the proposed restriction is considered unlikely to be proportionate. However, there may be favourable distributional and affordability considerations.

Practicality, incl. enforceability

Summary of proposal

The Dossier Submitter considers the restriction implementable, since the industry actors affected by the proposed restriction should be capable of complying with the requirements in practice, since concentration tests and alternatives are available and are technically and economically feasible.

There is no standard analytical method to measure the content of BPA in thermal paper today in the EU, but several methods exist to measure BPA in other materials and could be used for that purpose. Therefore, given that test methods exist, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.

The means of implementation of the proposed restriction (concentration tests, substitution of BPA, etc.) are clear and understandable to the actors involved, in particular because substitution of BPA in thermal paper is already underway. Some market actors might have to get some information and make additional training efforts in order to be able to carry out the compliance tests needed, but overall, the restriction is considered manageable.

The transitional period of 3 years (36 months) is deemed reasonable in terms of timing and manageability in order to give enough time for the supply chain to comply and for the control authorities to organise and anticipate the controls.

Key elements underpinning the SEAC's conclusion

For ecopaper, some of the alternatives seem to be widely available and already in use. This means that at least to some extent there exist technically and economically feasible alternatives. For the remaining 35% of the thermal paper market, which is not categorized as ecopaper, there is little information in the dossier. It is thus uncertain whether the conclusion that technically and economically feasible alternatives exist and are available applies to the entire thermal paper market.

However, based on the draft Forum's Advice, which states that the proposed restriction is practicable and enforceable, SEAC concludes that the proposed restriction can be considered implementable, enforceable and manageable.

The dossier does not present any information on the time it will take to sell out of existing stock nor did the public consultation reveal any new information about the transition period. According to the information gathered by the ECHA Secretariat and the Dossier Submitter (see Annex 9 to the BD) some industry actors indicated that 3 years would be sufficient time to adjust the production of phenol free thermal paper to an increase in demand. Albeit based on limited evidence, SEAC thus considers it likely that 3 years would be sufficient time for industry to complete the substitution process.

SEAC's conclusion

SEAC agrees that the proposal is implementable, enforceable and manageable.

Monitorability

Summary of proposal

Given that several existing analytical methods could be used to measure BPA content in thermal paper (although no standard exists), the restriction proposed is considered to be monitorable by control authorities and customs services. However, as regards monitorability there might be some concern about the exact product to be monitored since no specific existing TARIC (or Prodcom) code is attributed to 'thermal paper'.

Key elements underpinning the SEAC's conclusion

SEAC agrees with both the Dossier Submitter and Forum in that the restriction is monitorable. Forum also mentions the possibility to use biomonitoring in addition to the methods described in the dossier. A concern could be the control of imported thermal paper into the EU, since no specific existing TARIC code is attributed to thermal paper.

SEAC's conclusion

SEAC agrees that the restriction is monitorable.

BASIS FOR THE OPINION

The Background Document, provided as a supportive document, gives the detailed grounds for the opinions.

Basis for the opinion of SEAC

The basis for SEAC's conclusion on the restriction as proposed in the Annex XV restriction Dossier Submitted by France, is related to the information presented in the Background Document, the justification to the opinion and information submitted by interested parties.

ADDITIONAL REFERENCES

AAAAI (2015). Webpage "Allergy Statistics" on the website of American Academy of Allergy, Asthma & Immunology (AAAAI), accessed on 10 August 2015. Available at: http://www.aaaai.org/about-the-aaaai/newsroom/allergy-statistics.aspx

AIHW (2015). Webpage "Determinants key indicators" on the website of Australian Institute of Health and Welfare (AIHW), accessed on 10 August 2015. Available at: http://www.aihw.gov.au/chronic-diseases/key-indicators/determinants/

ABIM Foundation (2015). Webpage "Breast Biopsy" on the website of Choosing Wisely, an initiative of the ABIM Foundation, accessed on 10 August 2015. Available at http://www.choosingwisely.org/patient-resources/breast-biopsy/

ACS (2015). Webpage "Ductal or lobular hyperplasia" on the website of the American Cancer Society (ACS), accessed on 10 August 2015. Available at http://www.cancer.org/healthy/findcancerearly/womenshealth/non-cancerousbreastconditions/non-cancerous-breast-conditions-hyperplasia

Alberini A and Ščasný M (2014). *Stated-preference study to examine the economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union.* Service contract for the European Chemicals Agency No. ECHA/2011/123, FD7. Final Report, Part III: Carcinogens. Charles University in Prague (Environment Center), September 2014. Available at http://www.echa.europa.eu/documents/10162/13630/study_economic_benefits_avoiding_adverse_health_outcomes_3_en.pdf

CDC (2015). Webpage "Obesity and Overweight" on the website of the Centers for Disease Control and Prevention (CDC), US Department of Health and Human Services, accessed on 10 August 2015. Available at: http://www.cdc.gov/nchs/fastats/obesity-overweight.htm

ECHA (2011). *Opinion on an Annex XV dossier proposing restrictions on lead and lead compounds in jewellery*. European Chemicals Agency (ECHA), Helsinki 2011. Available at: http://echa.europa.eu/documents/10162/aae1d985-ae57-44f9-8556-c952a6e6d09b

ECHA (2014). *Opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use.* European Chemicals Agency (ECHA), Helsinki 2011. Available at: http://echa.europa.eu/documents/10162/f5a59251-8ef0-4f44-bfd4-95bffca7f807

FARE (2015). *Food Allergy Facts and Statistics for the U.S.* Food Allergy Research & Education (FARE). Available at: http://www.foodallergy.org/document.doc?id=194

Gupta R, Holdford D, Bilaver L, Dyer A, Holl JL and Meltzer D (2013). The economic impact of childhood food allergy in the United States. *JAMA Pediatr.* **167(11)**:1026-1031. doi: 10.1001/jamapediatrics.2013.2376.

Lacey JV Jr, Chia VM, Rush BB, Carreon DJ, Richesson DA, Ioffe OB, Ronnett BM, Chatterjee N, Langholz B, Sherman ME and Glass AG (2012). Incidence rates of endometrial hyperplasia, endometrial cancer and hysterectomy from 1980 to 2003 within a large prepaid health plan. *Int J Cancer.* **131(8)**: 1921-1929.

MNT (2015). Webpage "Ovarian Cysts: Causes, Symptoms and Treatments" on the website of Medical News Today (MNT), accessed on 10 August 2015. Available at:

http://www.medicalnewstoday.com/articles/179031.php

Reed SD, Newton KM, Clinton WL, Epplein M, Garcia R, Allison K, Voigt LF and Weiss NS (2009). Incidence of endometrial hyperplasia. *Am J Obstet Gynecol.* **200(6)**: 678.e1-6. doi: 10.1016/j.ajog.2009.02.032.

Simoens S (2012). The cost-effectiveness of immunotherapy for respiratory allergy: a review. *Allergy* **67(9)**: 1087-1105. doi: 10.1111/j.1398-9995.2012.02861.x.

Suijkerbuijk AW, de Wit GA, Wijga AH, Heijmans M, Hoogendoorn M, Rutten-van Mölken M, Maurits EE, Hoogenveen RT and Feenstra TL (2013). Maatschappelijke kosten van astma, COPD en respiratoire allergie [Societal costs of asthma, COPD and respiratory allergy]. *Ned Tijdschr Geneeskd.* **157(46)**: A6562.

USEPA (2014). *Guidelines for Preparing Economic Analysis.* National Center for Environmental Economics, Office of Policy, U.S. Environmental Protection Agency, May 2014.

Wikipedia (2015). Webpage "Endometriosis" on the website of Wikipedia, accessed on 10 August 2015. Available at: https://en.wikipedia.org/wiki/Endometriosis

APPENDIX 1 Valuation factors

All of the valuation factors must be seen as proxy representatives for the group of human health effects within each endpoint. There might be considerable variation in outcomes and their severity, so there will be uncertainty connected to the representativeness of the different factors. However, SEAC considers the derived valuation factors to be based on sufficiently robust evidence and hence appropriate to be used in the analysis. For the valuation factor for which no low and high estimates exist, a default ±50% is used for the lower and upper bound estimates.

Mammary gland effects

In accordance with the opinion of RAC, some mammary gland changes are reversible and will not be adverse, while some mammary gland changes may develop into breast cancer if the individual is also co-exposed to carcinogenic agents. In general, however, it is unknown whether the observed effects on the architecture of the mammary gland, including effects on terminal end buds and terminal ducts do lead to increased susceptibility to cancer when co-exposed to carcinogens. SEAC errs on the side of caution and assumes in the analysis that there is a clear link between BPA and breast cancer when constructing the medium and high valuation factor. SEAC uses a 5.5% conditional probability of getting breast cancer if an individual has mammary gland changes. As explained in section F.1.1.4 of the BD, this is based on information from American Cancer Society (ACS 2015) about the increased risk of breast cancer from different types of mammary gland changes. It is furthermore assumed that all of the mammary gland changes are of such severity that a biopsy is necessary. Costs of a needle biopsy (from ABIM Foundation 2015) is thus added to all the mammary gland change valuation factors.

For the medium valuation factor, the willingness to pay to avoid a statistical cancer case (which incorporates the survival rate of cancer) is used from Alberini and Ščasný (2014), while the high valuation factor assumes a 50% higher WTP to avoid a statistical cancer case.

Since there are significant uncertainties about the nature of any actual relationship between BPA and cancer, the low valuation factor is based on the assumption that no breast cancer cases actually arise. However, cost of the biopsy procedure is still included, implying correspondingly severe and noticeable mammary gland changes.

Immunotoxic effects

The valuation factor for immunotox was constructed as a simple average of a valuation factor for food allergies (Gupta et al. 2013) and a derived valuation factor for respiratory allergy. The latter was derived from a metastudy on medical costs (Simoens 2012) and a single study on societal costs of respiratory allergy (Suijkerbuijk et al 2013). An average of the low, medium and high valuation factor estimates from the respiratory allergy studies were respectively used (together with the food allergy estimates where the default ±50% were used for sensitivity) for the low, medium and high valuation factors for immunotox.

Neurobehavioral effects

Neurobehavioral effects may be diverse, but for the purpose of this analysis SEAC has chosen to use the value of an IQ point as a proxy valuation factor for neurobehavioral changes. IQ loss is a commonly used health valuation endpoint used to assess neurobehavioral deficits associated with exposure to hazardous substances. The low, medium and high estimates were based on values found in previous REACH restriction dossiers and corresponding SEAC opinions on lead in jewellery (ECHA 2011) and lead in consumer products (ECHA 2014). Although SEAC is aware of potential deficiencies in the

existing measures of IQ point value, a discussion of this issue is beyond the scope of the present assessment since it relates to the problem of IQ valuation more generally and not specifically in the context of the present case.

Reprotoxic effects

As a valuation factor for the potential reprotoxic effects, SEAC has used the valuation factor for endometrial hyperplasia derived by the Dossier Submitter. See section F.1.1.2.2 of the BD for more information.

Metabolic effects

For the metabolic effects SEAC has combined the two valuation factors for cholesterol and obesity derived by the Dossier Submitter by a simple average. See sections F.1.1.3.2 and F.1.1.3.1 of the BD for more information on the valuation factor for cholesterol and obesity respectively.

Table 7 Valuation factor estimates used in the break-even analysis, and the corresponding sources

Endpoint	Valuation factors EUR/incidence			Sources
	Low	Medium	High	
Mammary gland*	473	6 301	9 228	ABIM Foundation (2015); Alberini and Ščasný (2014)
Immunotox	1 124	1 987	2 850	Simoens (2012); Suijkerbuijk et al 2013; Gupta et al (2013)
Neurobehavior	2 140	7 134	22 292	ECHA (2011,2014)
Reprotox*	2 540	5 079	7 619	BD
Metabolic	1 853	3 725	5 646	BD

* only female offspring are at risk for these endpoints.

APPENDIX 2 Assumptions and Potential Bias

Table 8 presents the assumptions and potential biases in the break-even analysis.

Legend to the table:

↑ (↓) means that the uncertainty evaluation indicates that the "benefits" tend to be overestimated (underestimated) as compared to the cost, i.e. it pulls in the direction of making the proposal less (more) proportional.

? means that it is unknown in which direction the uncertainty will pull, thus the uncertainty is considered 'a priori' unbiased.

Table 8 Assumptions and potential biases in the break-even analysis

Assumption	Effect on proportionality	Explanation
Percent of thermal paper containing BPA	↑	In the Background Document the Dossier Submitter states that the data from their own survey indicates that the "*estimated share of BPA-containing thermal paper compared to the total thermal paper placed on the EU market ranging from 75% (1 claim) to 100% (1 claim) with a central estimate between 90% and 99% (3 claims). ETPA indicates that around 70-80% of thermal paper produced in Europe contains BPA (ETPA 2013 consultation)*". SEAC has accepted the 70% market share proposed by the Dossier Submitter, but based on the above, this is likely to underestimate the costs of the restriction.
Constant baseline tonnages of thermal paper containing BPA	↑	SEAC has more corroborating evidence pointing towards an increase in the use of thermal paper containing BPA in the coming years, than for a constant tonnage or decrease. Keeping the tonnages constant may thus underestimate the costs, at least to some extent.
Low upper and medium estimates used for the price increase of switching to alternatives	↑	In the analysis SEAC has used 15% price increase as the medium bond and 20% as the upper bond for the cost calculations. However, the new information provided by Dossier Submitter and ECHA indicated that the price increase may be as high as 35%, and the most reported estimates were in the range 15%-25%. (see Appendix 3)
Mammary gland valuation factor	↑	It is not clear from the literature that these mammary gland changes are adverse, and will lead to cancer. This will pull in a direction of too high valuation factor for mammary gland changes. This link is not assumed in the high cost/low valuation factor scenario.
Immunotox valuation factor	↓	There is uncertainty around the representativeness of the factor for all the immunotox effects (respiratory allergies and food allergies are used). A one year valuation factor was used for respiratory allergies, which is likely to result in an underestimation of the valuation factor for immunotox effects (see Appendix

		3)
Metabolic valuation factor	?	There is uncertainty around the representativeness of the factor for all the metabolic effects (obesity is used instead of weight gain, and this is combined with a cholesterol valuation factor). As a consequence of this, it is unknown whether the factor is under- or overvalued, and thus the effect on the proportionality balance is unknown.
Neurobehavior valuation factor	?	There is uncertainty around the representativeness of the factor for all the neurobehavioral effects (reduction of 1 IQ point is used). As a consequence of this, it is unknown whether the factor is under- or overvalued, and thus the effect on the proportionality balance is unknown.
Reprotox valuation factor	?	The reprotox evaluation factor was based on the highest estimate for endometrial hyperplasia found in the dossier, but there is still uncertainty around the representativeness of the factor for all the reprotoxic effects (increase in occurrence and bursting of ovarian cysts). As a consequence of this, it is unknown whether the factor is under- or overvalued, and thus the effect on the proportionality balance is unknown.
Not accounting for export of thermal paper	↓	Including the exported part of the thermal paper market in the cost estimate may mean that the costs within the EU can be overestimated (depending on the ability to separate the production process for exported and domestic paper).
Not accounting for import of thermal paper	↑	Not taking into account the imported part of the thermal paper market may mean that the costs within the EU are likely to be underestimated.
Net export	?	The net effect from not taking into account export and import is not known, since the two effects pull in opposite directions and most likely differ in magnitude.
Population at risk	?	There are several uncertainties connected to the population at risks: - Only cashiers has been considered, while other workers may potentially also be at risk - The number of cashiers at risk may be overestimated, as many workers called "cashiers" is not actually handling receipts to a large extent. - The population at risk may change over time The effect on the proportionality balance from uncertainties around the population at risks is unknown.

Identified Hazards and risks and resulting health effects	?	The DNEL is based on assessment factors and expert judgement. Per endpoint there is uncertainty about the actual human health effects that will occur due to exposure to BPA. Some effects might not be relevant at all, in which case other effects would need to be more pronounced to break-even. It is unknown whether this causes under- or overestimation, and thus the effect on the proportionality balance is unknown.
Cost share	?	The division of the costs amongst the different endpoints is highly uncertain, in the sense that any cost division could be possible, as long as it sums up to 100% of the costs.
Onset of disease	↑	Only the mammary gland changes was assumed to occur later in life, while all of the other diseases was assumed to occur at time of exposure. This is not realistic, as most of the diseases would usually occur later in life than the infant stage. This will overestimate all of the relevant discounted valuation factors (see Appendix 3)

APPENDIX 3 Sensitivity analysis

The break-even analysis was meant to only be an indicator of order of magnitude of absolute risk reduction needed to offset the cost. To ensure that no large mistakes were made an additional analysis was preformed, trying to account for some simplifications that were made in the main break-even analysis. The following elements were changed as compared to the original analysis:

- Respiratory allergies is assumed to last 10 years, rather than 1 year.
- The valuation factor for food allergies was changed from €3 504 (WTP) to €4 505 (cost to society)
- The different expected onsets of the diseases were included, as this was previously only done for mammary gland changes. The assumed expected onset times:
    - Mammary gland effects – expected onset at age 50 (unchanged)
    - Reprotoxic effects – expected onset at age 35 (Wikipedia 2015; Reed et al. 2009; MNT 2015)
    - Immunotoxic – expected onset at age 10 (AAAAI 2015; FARE 2015)
    - Metabolic – expected onset at age 30 (CDC 2015; AIHW 2015)
    - Neurobehavior – expected onset at age <1
- The cost estimates were updated with less conservative values (10%, 20% and 35%), instead of (10%, 15%, 20%).

The result of this additional analysis is shown in the Table 9 below.

Table 9 Result of the additional break-even analysis

Absolute risk reduction necessary to offset the cost				
Endpoint	Cost division	low cost - high WTP	medium cost - Med WTP	high cost - low WTP
Mammary gland*	20 %	2 %	7 %	162 %
Immunotox	20 %	2 %	5 %	12 %
Neurobehavior	20 %	0.4 %	3 %	16 %
Reprotox*	20 %	7 %	20 %	70 %
Metabolic	20 %	4 %	12 %	41 %

* only female offspring are at risk for these endpoints.

These results show that the necessary risk reduction estimates are not radically different from those in in the main break-even analysis (Table 5). None of the conclusions would change, and thus the main break-even analysis was kept.