

Bisphenol A in Thermal Paper

Experiences from a REACH restriction case

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Backdrop on BPA in thermal paper

- BPA is used as a dye developer in thermal paper
- Thermal paper is mostly applied for point-of-sale receipts and self-adhesive labels
- People get exposed to BPA through the handling of point-of-sale receipts
- France found a risk, from BPA in thermal paper, to the unborn child of cashiers and consumers in the EU
 - Proposed an EU wide restriction

Regretful substitution

Will industry substitute to a safer alternative?

- Three alternatives were evaluated by France (BPS, D8 and Pergafast)
- The cheapest alternative (BPS) was suspected to have similar hazardous properties as BPA
- If all industry actors switched to BPS, no **certain** risk reduction would be achieved
- No indication of how large part of industry would actually choose a safer alternative, and thus ensure a risk reduction from the restriction

Will industry substitute to a safer alternative?

- In the worst case, all industry actors would choose BPS
- Under this worst case scenario, it would be unlikely that a EU-wide restriction is a proportionate measure
- In the best case, all actors would switch to less hazardous alternatives.
- Best case scenario taken forward for the proportionality assessment

Analysis under information constraints

RAC's method and result

- Data for the relevant endpoints did not allow establishing dose-response relationships
- Alternative approach using a composite DNEL to account for the possible risk to multiple endpoints
- **RAC concluded there was no risk to consumers, but that there was a risks for cashiers (RCR>1).**
- The resulting risks did not relate to one specific endpoint, and the likelihood of observing effects could not be established

SEAC's choice

- The dose-response relationships could not be used for impact assessment
- SEAC had no information regarding the expected impacts, and thus no benefits to be compared with the costs of the restriction.

Two possible ways forward:

- A. Conclude that France had not shown that the cost were proportionate to the risk?
- B. Try to use the information at hand to arrive at a more informed conclusion

Available information

- Cost estimated to be between €43 - €151 million per year, with a central estimate of €86 million per year.
- The population at risk: ~ 80 000 fetuses per year
- Five endpoints representing possible adverse effects
 - Mammary gland
 - Immunotoxicity
 - Female reproductive system
 - Brain and behaviour
 - Metabolism and obesity

Break-even analysis

1. Proposed representative adverse effects for each endpoint and unit costs (WTP) for avoiding said effects
2. Allocated a share of the costs to each endpoint
3. Calculated the necessary number of cases of each adverse effect
4. Used the population at risk to derive corresponding occurrence rates
5. Evaluated the probability of BPA in thermal paper being able to caused the calculated occurrence rates

Results from the break-even analysis

Central estimates for the necessary occurrence rates from BPA in thermal paper, for the costs to be off-set

- Mammary gland: $\sim 10^{-2}$
- Immunotoxicity: $\sim 10^{-2}$
- Female reproductive system: $\sim 10^{-2}$
- Brain and behaviour: $\sim 10^{-1}$
- Metabolism and obesity: $\sim 10^{-1}$

➔ With advise from RAC, SEAC concluded that it was unlikely that such high occurrence rates would be caused by BPA in thermal paper

SEAC's final conclusions

- Still remaining large remaining uncertainties
- Additional considerations
 - The safer alternatives was considered affordable
 - The group at risk was a particular vulnerable one
- ➔ The proposed restriction was considered unlikely to be proportionate. However, there may be favorable distributional and affordability considerations.

Lessons learned

- A realistic analysis of alternatives is important to avoid regretful substitution
- Substances for which (some of the) health effects are not well understood are difficult to regulate under the standard benefit-cost paradigm
- Break-even analysis, though the last resort, can be a helpful tool for providing a new perspective on a case
- **Collaboration between risk assessor and economists is necessary to maximize the information utilisation**

Thank you

Backup

Overview of the process



Restriction dossier received

- Risk reduction analysis
- Socio economic analysis



RAC & SEAC scrutiny

- Public consultation
- Discussions and opinion development
- Joint opinion sent to the Commission



Commission decision

- xxx
- xxx

Will industry substitute to safer alternatives?

Proportionality

- **Two extreme cases constructed for illustrative purposes**
 - 1) Worst case scenario: 100% transfer from BPA to BPS
 - Close to zero benefits
 - Expected costs: €1.4 million per year
 - 2) Best case scenario: 0% transfer from BPA to BPS
 - RCR for workers between 1 and 2
 - Expected costs: € 43 million - €151 million

Results from the break-even analysis

Absolute risk reduction necessary to offset the cost				
Endpoint	Cost division	low cost - high WTP	medium cost - medium WTP	high cost - low WTP
Mammary gland*	20 %	2 %	7 %	162 %
Immunotox	20 %	0.6 %	2 %	5 %
Neurobehavior	20 %	0.4 %	3 %	16 %
Reprotox*	20 %	7 %	20 %	70 %
Metabolic	20 %	4 %	12 %	41 %

→ With advise from RAC, SEAC concluded that it was unlikely that such high occurrence rates would be caused by BPA in thermal paper

Will industry substitute to a safer alternative?

- Evidence from consultation with industry suggested that even though BPS is the cheapest alternative, many actors would nevertheless switch to a more expensive alternative with less hazardous properties.
- No indication of how large part of industry would actually choose a safer alternative, and thus ensure a risk reduction from the restriction