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**Opinion of the
Scientific Committee on Food
on
Potential risks from organotin compounds used as
catalysts in silicone-coated baking papers**

(expressed on 5 March 2003)

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Terms of Reference

Taking into account the conclusion of RPA Final Report of 19 July 2002 [1] where a potential risk was identified for the consumer using silicone-coated baking paper containing organotin compounds as catalyst residues, the Committee is requested to comment on these results and assess the risk (if any) to consumers from this application.

Information provided by industry

In response to the RPA report, the CES (European Centre for Silicones, with seven company members representing 100% of the integrated producers of silicones in Europe) stated that no CES members supply the butyltin catalysed silicones for baking paper applications that were highlighted in the RPA report [2]. CES further stated that 98.5% of the silicone baking paper (market) uses catalytic systems based on platinum. Just 1.5% of the market, supplied by two paper companies, using not dibutyl- but dioctyltin catalysed formulations. CES undertook to obtain data on actual migration levels from silicone-coated baking paper within 2-3 months.

Assessment of the information provided by industry

Considering the composition and migration data for butyltins from reference [3] it can be seen that the propensity of the tin compounds to migrate is about equal. This can be expected given the harsh contact conditions during baking cookies - intimate contact between a hot fatty food and the baking paper.

Migration of butyl tin compounds from a baking paper to cookies, adapted from reference [3]

Substance	composition, mg/kg paper	mg/kg paper as tin (Sn)	Migration, mg/kg cookie	mg/kg cookie as tin (Sn)	Ratio comp./migrat.
Monobutyl tin	35	23	0.26	0.18	0.8%
Dibutyl tin	69	35	0.72	0.37	1.0%
Tributyl tin	0.66	0.27	0.015	0.006	2.2%

In a similar study [4], also conducted in Japan, investigators sponsored by the Mainichi Daily News, analysed 22 household items for butyltins, including such items as kitchen gloves, sponges, film wrap, baking paper and toothbrushes. Baking paper had the only prominent concentrations of butyltins at ca. 60 to 90 mg/kg total butyltin (as Sn) consisting of primarily di-

and monobutyltin. The migration of butyltins (sum of TBT, DBT and MBT) from baking paper to pancakes baked in an oven at 170°C for 14 minutes, was up 0.9 mg/kg (as Sn).

Consequently, it can be expected that, a) if dioctyl tin compounds are used instead of dibutyl tin compounds as catalysts to make silicones for baking papers, b) assuming that the residual catalyst content (as Sn) in the paper is about the same, and c) assuming that the propensity of dioctyltin to migrate is about the same as for dibutyl tin, then

- the migration level of monoctyltin (as Sn) would be about 0.2-0.3 mg/kg food.
- the migration level of dioctyltin (as Sn) would be about 0.4-0.6 mg/kg food.

In the consolidated Plastics Directive 72/2002/EC, group limits are placed on the specific migration of monoctyl tin compounds (SML(T) = 1.2 mg/kg food/simulant) and dioctyl tin compounds (SML(T) = 0.04 mg/kg food/simulant). These migration restrictions are based on a Group-TDI of 0.02 mg/kg bw (as Sn) for monoctyltin stabilisers, and a Group-TDI of 0.0006 mg/kg bw (as Sn) for dioctyltin stabilisers, adopted at the 118th SCF meeting, 23 September 1999 [5]. The latter group-TDI was derived from a NOAEL for dioctyltindichloride of 0.234 mg/kg bw (equivalent to 0.06 mg Sn/kg bw) from a 2-year study in rats and the application of a 100-fold safety factor.

It can be concluded that, if dioctyl tin catalysts were used to make silicones used in turn to make baking papers, then migration of dioctyltin could be excessive.

Further information provided by industry

European production of baking papers

In further information provided by the silicones industry [5] CES stated that its members would cease the supply of tin-catalysed silicone coating formulations for baking papers in Europe, effective at the end of 2002. CES estimated [6] that the European production of baking papers using tin-catalysed silicone coatings, would cease at the end of the first quarter of 2003, once the existing stocks of silicones had been used-up by the manufacturers of these papers. As a result of this decision to cease using tin-catalysts for silicones used on baking papers, CES stated that the aforementioned program of work to measure migration would not be conducted.

Production of baking papers outside of Europe

Non-EU baking paper manufacturers would need more time to implement changes in their manufacturing equipment and processes. CES confirmed [7] that its members, foreign affiliates and headquarters had agreed to cease the supply of tin-catalysed silicone coatings for baking paper globally by the end of 2005 at the latest.

As CES members and their foreign affiliates or headquarters altogether represent about 99% of the global silicones market, this change would equally affect the proportion of baking papers imported from outside the EU. Consequently, in their opinion, the likelihood of tin-catalysed silicone coated baking papers being imported into the EU after 2005 is negligible.

Conclusion of the SCF

The Committee concludes on the basis of a comparative analysis that the use of silicone-coated baking paper containing organotin compounds as catalyst residues, may lead to a migration level of monoethyl and dioctyl tin compounds into fatty food such as cookies of 0.2-0.3 mg/kg and 0.4-0.6 mg/kg, respectively. The Committee notes that the estimated migration level exceeds the specific migration limit of dioctyl tin compounds (SML(T)=0.04 mg/kg food) by a factor of 10 and is therefore not in compliance with the consolidated Plastics Directive 2002/72/EC.

The Committee was informed by industry that the European production of such baking paper, with a present market share of 1.5%, would cease at the end of the first quarter of 2003. Consequently it is very unlikely that these baking papers will be used on a regular basis in the future.

If such a tin-containing paper is used for baking cookies, the consumption of 60 g of these cookies by an adult would exhaust the respective Group-TDI of 0.0006 mg/kg bw for dibutyltins. However, taking into account the ongoing phasing out of the particular baking paper in European production, and given that the group TDI incorporates a safety factor of 100 on the NOAEL, the occasional consumption of foods baked on such paper is unlikely to pose a risk.

The Committee notes that an integral assessment of the health risk to consumers associated with exposure to organotins from all food sources is ongoing in a task force on organotin compounds.

References

- [1] Floyd, P., Corden, C., Howe, P., Dobson, S. (2002) Assessment of the risks to health and the environment posed by the use of organostannic compounds (excluding use as a biocide in antifouling paints) and a description of the economic profile of the industry. *Final Report for the European Commission (DG Enterprise). Contract no. ETD/FIF.20010617.* 19th July 2002. Risk & Policy Analysts (RPA) and European Centre for Silicones (CEH),
- [2] Letter from M.DePoortere, Secretary General of CES (a CEFIC sector group) to Mr. Corden of RPA, dated 9th July 2002. Copied by CES to Dr Rossi of DG SANCO on 5th September 2002.
- [3] Takahashi, S., Mukai, H., Tanabe, S., Sakayama, K., Miyazaki, T., Masuno, H. (1999) Butyltin residues in livers of humans and wild terrestrial mammals and in plastic products. *Environmental Pollution*, 106, 213-218.
- [4] Mainichi Daily News (Japan), 24th August 1998, Headline. Hormone-disrupting chemicals found in baking paper.

- [5] Opinion on an additional list of monomers and additives for food contact materials (expressed on 23 september 1999).
http://www.europa.eu.int/comm/food/fs/sc/scf/out41_en.pdf
- [6] Letter from M. DePoortere, Secretary General of CES (a CEFIC sector group) to Mr. Rossi of DG SANCO, dated 12th September 2002.
- [7] Letter from M. DePoortere, Secretary General of CES (a CEFIC sector group) to Mr. Rossi of DG SANCO, dated 10th December 2002.
- [8] Letter from M. DePoortere, Secretary General of CES (a CEFIC sector group) to Mr. Rossi of DG SANCO, dated 30th January 2003.