Risiken erkennen – Gesundheit schützen

Constituents of printing inks in beverages from cartons

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Cartons for beverages like milk, cocoa or juice are often printed in different colours. The printing inks may contain the photo initiator isopropyl thioxanthone (ITX). Public agencies in Italy and Germany have detected residues of ITX in foods from cartons.

The Federal Institute for Risk Assessment (BfR) has assessed the risk associated with ITX in foods on the basis of the data available up to now. At present, these data only refer to the genotoxicity of the substance, i.e. its mutagenic properties.

The chemical ITX can reach foods via various paths. During unrolling of the printed carton, it can migrate by means of spread (set-off) from the outside to the non-printed inside of the package that comes into contact with the food. Furthermore, it can pass through packaging if no barrier layer, for instance aluminium, has been applied.

BfR is of the opinion that ITX residues in foods are not mutagenic based on the scientific knowledge currently available. At present, there are no signs that the observed levels of ITX constitute a risk to health. However, the Institute does not have sufficient data at its disposal to undertake a full health assessment. BfR recommends to lay down on the European level requirements to be met by printing inks with regard to their use in packaging for foods.

1 Subject-matter of the assessment

In studies into the levels of isopropyl thioxanthone (ITX), the official food control authorities observed levels of 165 µg ITX/kg in children's cocoa and 108 µg ITX/kg in olive oil.
It can be assumed that the observed ITX levels are due to the use of UV-hardening printing inks. ITX is used as a photo initiator in this type of printing ink. The cardboard used to make the packaging may be transported on rollers to the food filling plant and then moulded on site into the corresponding packaging.

Constituents of the printing inks applied to the outer packaging material can, by means of spread (set-off), reach the inside that comes into contact with food. Furthermore, there may be migration through the packaging material in the case of pre-moulded packaging unless effective barrier layers, e.g. aluminium foils, have been applied. BfR has examined the available toxicological data for the chemical isopropyl thioxanthone (ITX).

2 Results

For the toxicological assessment of ITX BfR only has data on the genotoxicity of the substance. These data encompass three *in vitro* studies (only the abridged versions) and two *in vivo* studies: a DNA repair test in rat hepatocytes and a micronucleus test in bone marrow cells from mice. The following can be derived from this limited data situation:

- The available data on the gene mutation test in bacteria and mice lymphoma cells indicate a positive result.
- The result of another *in vitro* study on chromosomal changes can be deemed to be negative.
- A DNA repair test in rat hepatic cells permits the conclusion that ITX does not have any *in vivo* mutagenic potential.

- A micronucleus test with bone marrow cells from male mice *in vivo* did not reveal any chromosome-changing potential.

Overall, the data on ITX permit the interim conclusion that the mutagenic *in vitro* effects in animal experiments could not be confirmed. Therefore, it can be assumed that ITX has no genotoxic potential. However, it is pointed out that no evidence was supplied for bioavailability in the target organs of the animals.

Furthermore, BfR has in its possession the report of an independent expert commissioned by industry that comes to the conclusion, on the basis of structure-effect comparisons, that ITX does not lead to any relevant health effects. As BfR does not, however, have access to the data on which the expert opinion is founded, it cannot comment on this.

In line with the assessment scheme of the European Food Safety Authority and customary assessment practice at BfR and regarding substances used in the production of food commodities, the available data on the exclusion of genotoxicity are only sufficient to evaluate substances with a maximum migration level of 50 µg/kg food. As, however, the ITX measurements in Germany revealed far higher levels, additional data would be needed for toxicological assessment. BfR does not have the necessary data on toxic effects, bioavailability or toxicokinetics of the substance. Hence, at the present time, the Institute is not in a position to undertake a full health assessment.

3 Action / Recommendations

A larger manufacturer of beverage cartons has informed BfR that it switched to a new printing method for infant and baby food on 30 September 2005. It no longer uses any UV-hardening printing inks in order to prevent migration of ITX from the package to the food. All packaging materials for milk and fat-containing products are to follow suit by 31 December 2005 and juice products by 31 January 2006.

The phenomenon of the migration of constituents from printing inks used on the outer packaging to foods as a consequence of both penetration of the packaging material and set-off to the inner packaging is a fundamental issue. Set-off cannot, in principle, be ruled out for any packaging material processed on rollers or in stacks. Besides the data on ITX, BfR is also aware of migration findings from packaging to food for other photo initiators used in printing inks like 2-ethylhexyl-4-dimethyl aminobenzoate and 4,4'-bis(diethylamino)-benzophenone and 4,4'-bis(dimethylamino)-benzophenone. BfR is, therefore, of the opinion that there is an urgent need to lay down requirements for the use of printing inks for food commodities on the European level.