Risiken erkennen – Gesundheit schützen

Di-isobutylphthalate in food-contact paper and board

Minutes of the meeting of the working group “Paper and board” on 5 July 2007 at BfR

Concentrations of up to 5 milligram per kilogram of the chemical di-isobutylphthalate (DiBP) have been found in food packaged in cartons. Fat-containing, powder and fine grain foods like rice, baking mixtures or breadcrumbs were particularly affected. In animal experiments DiBP is reprotoxic and embryotoxic. It is used as a plasticiser in dispersion glues for paper and packaging and when they are recycled DiBP can be found in paper and board packaging. The Federal Institute for Risk Assessment (BfR) together with the Federal Environmental Agency (UBA) and manufacturers of paper and board discussed this problem at a special meeting of the working group “Paper and board” and proposed initial measures.

So far, there are no scientifically established limit values for the migration of DiBP from packaging to food. The data from long-term toxicity studies, which would be needed for this, are not available. However, the European Food Safety Authority (EFSA) has undertaken a health assessment of di-n-butylphthalate (DnBP) which has a similar structure and effect. On this basis BfR recommends a specific restriction on the migration of DiBP to foods, a so-called specific migration guidance value, of 1 milligram DiBP per kilogram food. For baby and infant formula this value should be 0.5 milligram. BfR proposes re-examining the effectiveness of this restriction on the DiBP level in foods after one year and, if necessary, taking further steps. In order to generally reduce the DiBP content in recycled paper, BfR and UBA advocate a voluntary undertaking by the manufacturers and processors of paper and board to no longer use DiBP-containing glues or printing inks.

The problem of the presence of di-isobutylphthalate (DiBP) in food-contact paper and carton was discussed at a special meeting of the working group “Paper and board” on 5 July 2007 at BfR.

The meeting was convened because of reports of the presence of DiBP in foods packaged in paper and board (up to 5 mg/kg food). Fat-containing foods as well as powder or fine grain foods like rice, baking mixtures or breadcrumbs are particularly at risk when it comes to the possible migration of DiBP. This substance is deemed to be reprotoxic on the basis of studies from 2006. This means that in animal experiments it causes damage to offspring and impairs fertility. Dispersion glues used for instance in folding cartons and corrugated paper production in particular are deemed to be an input pathway into foods. When recycled DiBP is released from them into the paper cycle.

The purpose of the meeting was to discuss with the manufacturers of paper and board and packaging made from these materials the current situation and possible measures to reduce the levels of DiBP in paper and carton packaging. In this area BfR co-operates with the Federal Environmental Agency (UBA).

At the present time, no scientifically established limit values are available for assessing the migration of DiBP from packaging to food. The European Food Safety Authority (EFSA) undertook a health assessment of the isomer compound di-n-butylphthalate (DnBP) in 2005 and set a tolerable daily intake (TDI) of 0.01 mg/kg bodyweight. Based on the available toxicological studies a TDI value can still not be established for DiBP as the necessary data from long-term toxicity studies with various DiBP doses are not available. Developmental studies in rats exposed to high doses of DiBP and DnBP do, however, show that both substances have comparable effects on offspring. It is, therefore, proposed that DiBP is classified as a

reprotoxic substance with the European Chemicals Agency (planned inclusion in Annex I of the Dangerous Substances Directive 67/548/EEC).

Given the similarities in chemical structure and toxic effects on male pups BfR considers a specific restriction on migration (specific migration guidance value) of DiBP to food to be appropriate. At the meeting of the working group “Paper and board” BfR proposed a provisional guidance value of 1 mg DiBP/kg food and this was supported by UBA. This value was derived from the TDI for DnBP assuming that as a rule no more than 300 g/day of the foods contaminated with DiBP are consumed. This restriction also takes into account the fact that consumers may ingest phthalates from various exposure sources and that consequently exposure via food packaging should only account for part (in this case 50%) of the tolerable daily intake (TDI). The established guidance value for DiBP should apply initially for one year and then the impact of the measures to reduce DiBP levels in food and food packaging should be examined. For baby and infant formula there should be a guidance value of only 0.5 mg/kg food as a higher consumption of foods in relationship to body weight is assumed for this age group. Further efforts to reduce DiBP migration to foods are deemed to be urgently necessary.

It was suggested that the associations of all companies involved in the production and processing of paper and board into printing products, packaging or other products should enter into a voluntary undertaking to permanently phase out the use of glues, printing inks and other products containing DiBP in order to reduce DiBP levels in recycled paper. The effectiveness of a voluntary undertaking of this kind should be reviewed every six months.