

Frequently Asked Questions about Printing Inks and Primary Aromatic Amines in Food Contact Materials

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Unless countermeasures have been taken, printing inks contain substances which can transfer to food and be ingested by consumers. For this reason, the Federal Ministry of Food and Agriculture (BMEL) has presented the so-called “printing ink regulation” in a draft to amend the Consumer Goods Ordinance.

In the following paragraphs, the BfR has compiled some frequently asked questions about the possible health risks of printing inks and primary aromatic amines in food contact materials and products.

How safe is the use of printing inks on products that come into contact with foods?

According to information provided by the European Printing Ink Association, close to 5,000 substances are used in printing inks. As only insufficient toxicological data is available for 90 % of these substances, if at all, it is not currently possible to comprehensively assess the health risk of the use of printing inks on food contact materials.

What health risks are consumers facing?

The possible health risks posed by the transfer of printing inks to food depend on the properties of each substance. For this reason, the substances must be assessed from a health point of view and their transfer to foods regulated accordingly.

For example, primary aromatic amines (PAA) can transfer to foods as impurities of pigments used for printing packaging materials or even paper napkins. Several PAA have carcinogenic and mutagenic properties. If they have contact over longer periods, PAA can transfer to food and then be ingested by humans.

What are primary aromatic amines (PAA)?

The designation “primary aromatic amines (PAA)” describes a group of chemical compounds whose simplest representative is aminobenzene, which is also known as aniline. PAA are substances which are used in the manufacture of certain colourants - so-called azo pigments, for example. The yellow - orange - red colour range can be affected.

How do PAA get into printing inks?

As azo pigments are used as colouring components in printing inks, they are also used to print materials and objects which have contact with food, such as paper napkins and bakery bags. Residues of the PAA used in their manufacture can remain in the finished pigments as impurities.

How do PAA transfer to food?

When printed paper napkins are used to serve or wrap up food, the printed surface can have contact with the food for longer periods, thus allowing the transfer of printing ink ingredients. The same applies if foods are kept in paper packaging for longer periods.

What health risks do PAA pose for consumers?

From a health point of view, attention should be paid to the carcinogenic effect of several representatives of the PAA substance class. While many PAA have not been classified in this regard, several PAA are known human carcinogens. Others are regarded as potentially carcinogenic for humans on the basis of studies involving animal tests. In colourful printed

paper napkins and bakery bags, as well as other food contact materials, several PAA can pose a health risk if they transfer to the food. On the basis of the available information, it has to be assumed that no health-threatening transfer of PAA is to be expected after brief contact with the skin and mucous membrane (lips).

What regulations are there on the transfer of PAA from materials and objects intended for contact with food?

According to Regulation (EU) No. 10/2011 on plastic materials and articles intended to come in contact with food, the transfer of non-specifically assessed PAA shall not be detectable in total. The detection limit for the verification of this requirement has been set at a value of 0.01 milligrams per kilogram of food. This limit value is also used to evaluate the transfer of PAA from other materials.

What does the BfR recommend with regard to PAA in printing inks for food contact materials?

The BfR recommends that the limit value for PAA classified as carcinogenic is reviewed. Consumers should come into as little contact as possible with these substances. From the point of view of the BfR, the ALARA principle should apply to these PAA, i.e. their occurrence in materials that have contact with food should be as low as technically possible. To supplement the existing total limit value for PAA, the BfR recommends an additional restriction of the transfer of the individual substances classified as carcinogenic. The transfer of these PAA to food and/or food simulants should not be detectable with an analytical detection limit of 0.002 milligrams per kilogram of food or food simulant, which is five times less than the current total limit value. This recommendation is followed in the latest draft of a regulation for the amendment of the consumer products regulation ("printing ink regulation").

The BfR also recommends that only pigments are used which do not contain any carcinogenic aromatic amine components.

What does the BfR recommend in general for the printing on food contact materials?

As a basic principle, only substances which have been assessed with regard to health should be used for the printing of food contact materials which do not have a barrier to prevent the possible transfer of printing ink components. The Federal Institute for Risk Assessment has prepared a corresponding positive list which the Federal Ministry of Food and Agriculture has included in the draft amendment of the so-called "printing ink regulation". Only substances for which a risk assessment is available are included in the positive list so that their effects on health can be evaluated and safe limit values for the transfer to foods derived. A comparable legal regulation has existed for quite some time and has proven its value for substances used in the manufacture of plastics intended to have contact with foods.

What can consumers do?

The BfR recommendations to avoid the transfer of PAA from azo pigments to food are aimed primarily at management authorities and manufacturers. Fundamentally, the option exists of avoiding the use of printed paper packagings or napkins (colour range yellow-orange-red) when storing foods in the household over longer periods.

More information on printing inks and primary aromatic amines in food contact materials at the BfR website

<http://www.bfr.bund.de/cm/349/primary-aromatic-amines-from-printed-food-contact-materials-such-as-napkins-or-bakery-bags.pdf>

About the BfR

The Federal Institute for Risk Assessment (BfR) is a scientifically independent institution within the portfolio of the Federal Ministry of Food and Agriculture (BMEL) in Germany. It advises the Federal Government and Federal Laender on questions of food, chemical and product safety. The BfR conducts its own research on topics that are closely linked to its assessment tasks.

This text version is a translation of the original German text which is the only legally binding version.