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VdMi Position Paper on the Revised Version of BfR Recommendation IX – Colorants for Plastics and other Polymers Used in Commodities

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Recommendations by the BfR (German Federal Institute for Risk Assessment)

Since 1958 there have been recommendations by the BfR (Federal Institute for Risk Assessment). Initially, such recommendations were issued under the name “plastics recommendations” by the then Federal Health Agency. Meanwhile, they are about various materials and uses. Most recommendations include substance lists and define certain analytical requirements. They are meant to ensure consumer protection, in particular regarding the unintended migration of substances to foodstuffs.

The recommendations are revised if necessary, in order to reflect the current state of science and technology. Today the recommendations have achieved wide acceptance, also beyond Germany.

Due to the lack of own rules, also other industry sectors resort to BfR Recommendation IX^[1] as a reference document. This recommendation is deemed an important assessment basis along the entire supply chain: for answering the question whether substances, materials or articles fulfil the purity criteria for use in food contact. BfR Recommendation IX is even more important, as there is no uniform legislation on colorants in Europe. Not least for this reason, Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food^[2] explicitly allows the use of colorants according to national law.

Revision of BfR Recommendation IX

As mentioned in the minutes of the 12th meeting^[3] of the BfR Committee for Consumer Products (Kommission für Bedarfsgegenstände/BeKo), the reason underlying the revision of BfR Recommendation IX was the need to adapt the “old” substance list (status: 1 January 2010) to the requirements of EU Regulation 10/2011. Then, the whole recommendation was reassessed within the revision process. The revised BfR Recommendation IX (status: 01.02.2015) has been published in the Bundesgesetzblatt 2015, 58:1193-1194.

It is worth noting that the associations urged to maintain the basic structure of the recommendation. They also highlighted to the public authorities the practical benefit of limit values for potential contaminants in colorants. As regards the maintaining of the basic structure of the recommendation and the purity requirements for colorants in respect of heavy metal values, the arguments brought forward by the VdMi were taken into account.

^[1] IX Colorants for Plastic and other polymers used in commodities

^[2] „Plastics Regulation“: COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

^[3] 12th meeting of the BfR Committee for Consumer Products, minutes of 2 April 2014

New criteria for primary aromatic amines (PAAs)

The existing limit value for PAAs, which had to be tested directly on the colorant (pigment/dyes), was deleted without substitution. This possibility was discussed during the 13th BfR meeting. The following substantiation was given in the minutes (quote from page 7^[4]): *“... dass aufgrund der unterschiedlichen Anwendungsbereiche von Farbstoffen ein solcher Grenzwert nicht hilfreich ist und es daher besser wäre, darauf zu verzichten“* (due to the different fields of application for colorants such a limit value is not helpful, so that it would be better to give it up). Finally, this proposal was included in the revised version and adopted in this form.

In the now published version, the purity requirements for PAAs refer to a migration value which, per se, can be determined only in the end product. For the future, this means that the total summary detection limit for PAAs in the final article of 0.01 mg/kg (\pm 10 ppb) must not be exceeded. Furthermore, a restriction applies for carcinogenic PAAs (cat 1A and 1B) which, as individual substances, must be each below the detection limit of 0.002 mg/kg (\pm 2 ppb).

So far [and this continues to apply for other rules and provisions^[5]] the content of primary aromatic amines, determined on the colorant, was not permitted to exceed the maximum value of 0.05% (\pm 500 ppm).

Problems with the new criteria

For the topic of „PAAs in colorants“, the following considerations should be borne in mind generally: Usually, several processing steps are carried out on the way from the colorant to the final article. These steps include dispersing or grinding in the production of paints and colors or various processes in plastics production, in most cases connected with shear influences and thermal stress. Frequently, the colorants are incorporated in a binder matrix (e.g. a plastic) with the adding of further auxiliaries. This can impact the range of secondary constituents and thus, for example, result in changes to the original PAA content. Moreover, their incorporation in the binder matrix influences the migration ability of PAAs. Their migration ability is additionally decided by the type of binder and by the nature of the applied extractant (food simulant). Such simulants and the test conditions depend on the use conditions of the material or article (contact with fatty or greasy foodstuffs, duration of contact, temperature range etc). However, at the beginning of the supply chain the intended end use of the raw material is often not known.

It follows from the above that the result of a migration test cannot be simply deduced by way of calculation from the PAA content of the colorant.

Conclusion

In the future, colorant manufacturers will be no longer able to confirm with almost no limitations the compliance with all purity requirements of BfR Recommendation IX. This might cause uncertainty in the supply chain, because the purity of colorants – as the basis for assessing their suitability for use in food contact materials – will remain an important issue also in the time to come.

Due to the above-described factors with an impact on migration - which are largely outside the sphere of influence of colorant manufacturers - the carrying out of migration tests by colorant manufacturers makes little sense; such tests could have the character of orientation at most.

^[4] 13th meeting of the BfR Committee for Consumer Products, minutes of 12 November 2014

^[5] Resolution AP(89)1, Colorants for Polymers

Usually, it would not be possible to give assurance of certain properties on that basis.

Under the BfR recommendation, a meaningful migration testing for a potential migration of PAAs is possible only in the end product.

In the future, a binding confirmation of the above properties in respect of colorant purities can still be given only for heavy metal contents. It remains possible to issue a declaration of compliance according to AP(89)1 as a complementary measure.