Answers to the questions left open at the VdL web seminar "conformity of printed food contact materials in Germany" on April 7th 2022

Q: Regarding the definitions of DFC and non-DFC. A printing ink applied to the outside of a packaging is considered a non-DFC. But a paper for example does not provide a functional barrier and substances might be transferred from the outside to the food contact side thereby becoming a direct food contact. Is the ink still defined as a non-DFC then?

A: For the differentiation between DFC and non-DFC the contact scenario is relevant and not the barrier properties The ordinance distinguishes between the following contact scenarios FCMs:

- the printing ink is intended to come into direct contact with foodstuff
- the printing ink does come into direct contact with food during normal, foreseeable use of the FCMs, although the FCM is not intended for this purpose
- The ink layer does not come into contact with food.

For FCMs for which a transfer of substances from the printing ink to the food can be excluded (a barrier being typically a necessary, but not sufficient condition to achieve this) several requirements of the GIO do not apply.

Q: Are products where contact of ink and food is not probable also in scope of this law, e.g. glass bottle is FCM on which the paper label is applied, but the label will hardly migrate through glass to the product?

A: The GIO states (working translation): "*Paragraphs 5 to 9 do not apply to printed food contact materials and articles for which the transfer of substances, including those in the form of nanomaterials, from the printing ink to the food is excluded*." Hence, the relevant criterion is, whether a transfer can be excluded or not. A barrier is typically a necessary but not sufficient condition, as effects such as set-off or gas-phase migration need to be controlled, as well.

Q: Does the current ordinance lay down the mechanism for changes from EU CLP? Is there a transition timeline? For example, should a Table 14.1 listed substance undergo C&L update per REACH that adds a CMR category.

A: Substances listed in table 14.1 can be used subject to the conditions laid down in the table, irrespective of the CLP classification. The CLP criterion is only relevant for non-listed substances. Here the GIO just refers to the CLP regulation (working translation): "*Furthermore, the substances referred to in the first sentence may only be used if they do not meet the requirements of sections 3.5, 3.6 and 3.7 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006 (OJ L 353, 31.12.2008, p. 1; L 16, 20.1.2011, p. 1; L 94, 10.4.2015, p. 9; L 349, 21.12.2016, p. 1; L 190, 27.7.2018, p. 20; L 55, 25.2.2019, p. 18; L 117, 3.5.2019, p. 8), as last amended by Delegated Regulation (EU) 2021/643 (OJ L 133, 20.4.2021, p. 5), are classified as "mutagenic", "carcinogenic" or "toxic for reproduction"*."

Q: Do I understand correctly that EU PIM authorised substances with a group restriction will not be allowed after the transition period? If yes, does that only apply to substances not currently listed in Table 14.1? Or is it including even those substances in Table 14.1 with a group restriction in column 7?

A: Substances listed in table 14.1 can be used subject to the conditions laid down in the table, irrespective of any listing or group restriction in regulation (EU) No. 10/2011 (PIM). If a group limit value is specified in column 7 of table 14.1 then this limit value needs to be observed, but the substance can in principle be used. The gliding reference to the PIM is only relevant for substances not listed in table 14.1 and is only applicable if there are no restrictions in column 9 or 10 of the PIM.

Q: Do you have any indications that for example BfR will "endorse" the EuPIA guidances for assessing printed FCMs?

A: BfR is of course aware of the EuPIA guidelines and VdL/EuPIA have been discussing many of the concepts with the BfR. An endorsement by the BfR is, however, not to be expected. Although the EuPIA guideline follows the EFSA principles as well, the BfR usually only accepts the official EFSA guidelines.

Q: Regarding metallic 3pieces cans, does the side stripe lacquer used to protect the weld area fall under GIO scope?

A: The official justification of the ordinance refers to the PIJITF definition. According to the PIJITF definition printing inks “do not include coatings which are applied with the prime objective of enabling the material or article to achieve a technical function such as heat sealing, barrier, corrosion resistance etc., as opposed to a graphic effect.” If the stripe lacquer’s sole purpose is to protect the weld, then its function seems to be of a technical nature and would hence not fall under the GIO scope.

Q: What about polymeric additives, in 10/2011 this is clearly described?

A: Polymeric additives are intentionally added during the manufacture of the polymer dispersion. However, if they have no function in the final ink, they would be NIAS in the production of the printing ink. The GIO defines “use of substances in printing inks” as (working translation) “*the planned use of substances in the manufacture of printing inks that serve at least one of the following purposes: Monomers or other starting materials, colorants, solvents, photoinitiators or other additives*.”

Q: Does the GIO describe which migration testing conditions need to be used? anything specific for set-off pre-incubation?

A: The GIO does not provide any details on migration testing. Hence, the same conditions remain applicable that are used under the EU law.

Q: The absolute barrier rule has a minimum thickness for metals... correct? Can you remind what that thickness is?

A: The GIO does not define the term "barrier". However, it says (working translation) "*Paragraphs 5 to 9 do not apply to printed food contact materials and articles for which a transfer of substances, including those in the form of nanomaterials, from the printing ink to the food is excluded*".

Hence, it lies in the responsibility of the person placing the FCM on the market to make sure that the transfer is excluded. A barrier with a sufficient thickness is only part of the solution, as it only prevents migration through the packaging. Effects such as set-off or gas-phase migration need to be controlled, as well.

Q: You expect raw material suppliers to prepare dossiers. However, there is no provision to collaborate together with competitors (like under REACH) or with other parties to perform migration testing. Are you working on some kind of collaboration platform?

A: Indeed, this is a deficiency of the ordinance, which has been addressed during the political process many times: Collaboration is possible and to our understanding even encouraged by authorities, however, no legal provisions exist. At the moment, the only option is to get in touch with the BfR at an early stage to inquire, whether another party has already submitted a dossier. Sometimes the relevant trade associations representing the raw materials in question can serve as platform to bring interested companies together.

Q: What is the status with two component printing inks based on aromatic Isocyanate and in which aromatic Amines may be still detectable?

A: As for all types of inks, the positive lists, the SMLs defined therein and the requirements for non-listed substances need to be observed. Concerning primary aromatic amines table 14.4 provides additional requirements (working translation) "*A transfer to food must not be detectable. A transfer of up to 0.01 milligrams of the sum of primary aromatic amines per kilogram of the foodstuff is deemed to be undetectable. For the primary aromatic amines mentioned in Annex 1 No. 7, the detection limit is additionally 0.002 milligrams per kilogram of the food per individual substance*."

Q: Ethyl acetate and ethanol which are usual solvents used in printing inks are not listed in Table 14.1- why?

A: Ethyl acetate and Ethanol are listed in regulation (EU) 10/2011 and are hence covered by the gliding reference to the PIM.

Q: How is unintended but foreseeable food contact defined?

A: The ordinance does not give a definition, however, the official justification provides the following clarification (working translation): "*This may be the case, for example, with napkins, tray liners and the like. As a general rule, these may not necessarily be intended for foodstuffs to be placed on them and thus come into direct contact. However, it is undoubtedly foreseeable in the course of normal use that napkins, for example, will also be used for these purposes."*

Q: Is there a way of co-ordinating registrations, so that multiple suppliers are not duplicating costs/testing

A: Collaboration is possible and to our understanding even encouraged by authorities, however, no legal provisions exist. At the moment, the only option is to get in touch with the BfR at an early stage to inquire, whether another party has already submitted a dossier. Sometimes the relevant trade associations representing the raw materials in question can serve as platform to bring interested companies together.

Q: Is the Migration testing done on the final FCM or the ink? If substances are present in a functional coating and the ink, is a differentiation possible?

A: Migration testing is typically done on the final FCM, as testing the ink as such without a substrate makes no sense. Indeed, if a substance is present in different components of an FCM, it is hardly possible to differentiate, which component contributed to the migration. However, the ordinance states (working translation): "*In the case of printed food contact materials and articles, the substances listed in Tables 1 and 2 of Annex 14 must not exceed the transfer limits specified for them in columns 6 or 7 in conjunction with Table 3 of Annex 14.*" Hence, the migration limits apply to the printed FCM regardless of the origin of the migrant. As SMLs are derived from toxicological data they are in principle applicable regardless of the origin of the migrant.

Q: How do we have to consider residual monomers present in a polymer used to produce a printing ink? And especially for these monomers with a group restriction number in the positive list of regulation (EU) 10/2011 and not listed in Table 14.1 of GIO?

A: Polymers may be used for the formulation of FCM inks, if the monomers are either listed in table 14.1 or covered by the reference to the PIM. In the first case, the migration limit set in table 14.1 are relevant for residual monomers and in the second case the limits defined in the PIM. Polymers made from non-listed monomers (and this includes monomers that are listed with a group restriction in the PIM and not listed in the GIO) may only be used, if the monomers are not CMR and migrate below 10 ppb.

Disclaimer:

Answers to the questions have been compiled based on the current understanding of VdL's experts of the legal text. However, the information is provided for informational purposes only and should not be construed as legal advice.