Customer Guidance Note for using ink Statements of Composition when considering compliance of food packaging

This guidance note concerns printing inks, which are applied on Food Contact Materials (FCMs). It is intended to help printing converters and end users assess the compliance of printed FCM using the information provided by the ink supplier.

Regulation (EC) No 1935/2004 requires that food contact materials and articles in their finished state must not transfer any components to the packed foodstuff in quantities which could endanger human health or bring about an unacceptable change in the composition or deterioration in organoleptic properties.

FCM inks may be one source of substances with the potential to migrate. To allow the assessment of the levels of potential migration from printed FCMs, EuPIA members may supply converters with a Statement of Composition (SoC) of a printing ink. This SoC will list those substances with the potential to migrate along with the applicable migration limits and the amount of that substance in the print. The migration limits for a substance may come from the Plastics Regulation (EU) No 10/2011, from the Swiss Ordinance SR 817.023.21 or from another recognised authority such as an EFSA opinion. In the case where Non-Intentionally Added Substances (NIAS) or substances that are intentionally added but which are not required to be positively listed (NLS) are included in the SoC then the migration limit may have been derived from toxicological data or by following a threshold of toxicological concern (TTC) approach.

For more information about regulations related to FCM inks and how regulatory information should be communicated along the supply chain please refer to the EuPIA document "Good Manufacturing Practices (GMP): Printing Inks for Food Contact Materials" which can be found on the EuPIA website.

In order to determine compliance for a specific printed food packaging the converter will need to recalculate the amounts of potentially migrating substances based on their actual usage of the printing ink. This will include:

1. The applied ink dry coating weight.
2. The % coverage of the printing ink.
3. The actual packaging surface area and packaged food weight[1].
4. How well the converter has dried / cured the ink[2].
5. Press side additions introduced by the converter.

The converter then needs to collate this data together with data of potentially migrating substances provided by suppliers for other components of the food packaging (example plastic films, adhesives, coatings).

For some types of substances, the amount in the applied (liquid) ink and the remaining amount in the dry ink film are completely different. This is typically the case for all volatile substances (which should

[1] According to article 17 of the Plastics Regulation (EU) No 10/2011 migration results may in specific cases be expressed in mg/kg, applying a surface to volume ratio of 6 dm² per kg of food. This "EU cube" assumption is typically used when the exact surface to volume ratio of the final food contact article is not known. However, actual packaging geometries may vary significantly from this model. The regulations require that the actual packaging geometry is considered.

[2] These process steps are under control of the converter. Inks must be completely cured/dried according to the instructions of the ink supplier.

be removed during the drying process) and for substances which should react during the drying/curing of the ink (reactive dilutants and photoinitiators, crosslinkers). Hence the residual amount of such substances in the dry ink layer needs to be controlled by the converter (for example by head-space solvent retention measurements), and the worst-case migration calculation cannot be based on the initial amount in the (liquid) inks.

For each potentially migrating substance, the calculations may show that even if all of the potentially migrating substance were to migrate into the food that this would still be below the specific migration limit. If that is the case, then for this substance no further action is required. If the calculations show that the migration limit would be exceeded if all of the substance migrated into the food, then migration assessment would be recommended to measure the extent of migration. This migration assessment could be migration modelling or migration testing. The modelled or measured migration value should be compared to the applicable migration limit to determine compliance.

For energy curing products (UV or EB curing), the SoC represents a list of materials which can potentially migrate. This information is given to allow those carrying out migration studies to target these for quantification. The data given is not suitable for carrying out worst case migration calculations, as the chemical state of the cured product is not the same as that of the uncured one.

For risk assessed substances there is the option of refining the risk assessment by adjusting the exposure assessment to match the end use of the printed FCM. This is covered in the EuPIA document "Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Evaluated or Non-Listed Substances (NLS) in printing inks for food contact materials" which can be found on the EuPIA website.

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The following schematic represents the suggested process flow involved in risk assessing the migration of substances from inks into food from packaging.