SWISS ORDINANCE ON MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SR 817.023.21)

Permitted Substances for Packaging Inks

Questions & Answers

The Swiss Federal Department of Home Affairs (FDHA) recently adopted an amendment to the Ordinance of 23rd November 2005 on Materials and Articles (SR 817.023.21) detailing certain provisions relating to packaging inks. Within this amendment, introduced on 7th March 2008 and coming into force on 1st April 2010, Article 26g details the requirement that only permitted substances should be used in the manufacture of Packaging Inks.

Permitted Substances are defined as those which are listed in Annex 1 Lists I and II and in Annex 6.

As this piece of legislation is quite complex and can be prone to misinterpretation, the following guidance to addressing the most frequently posed questions, according to the understanding of EuPIA, is provided. Please note that this guidance is provided in good faith and should not be considered as a legally validated position.

Question 1

Is it true that Substances listed as B 'status' (unevaluated) in the individual substance lists cannot be used in Packaging Inks?
No, this statement is incorrect. Substances listed as B 'status' can be used, providing that the final packaging complies with the requirements of the Ordinance, i.e. migration of the listed substances is not detectable using an officially validated analytical method. In any case, migration must not exceed 0.01 mg/kg.

Question 2

Is there a requirement for the printing ink itself to comply with the SML's and QM's shown in the Ordinance?
No. The SML's and QM's apply to the individual substances present in the final food contact article (i.e. the packaging) of which the dried printed ink layer is a component.

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Question 3

If a substance or substances is/are listed in the Ordinance, does it mean that packaging inks using these substances are safe?
No. Listing on the Ordinance simply provides verification that the substance may be used in the manufacture of packaging inks. To ensure safety according to the law, in end-use the migration limit(s) applicable to the substance(s) must not be exceeded and Good Manufacturing Practices (GMP) for printing inks manufacturing and printing must be used.

Question 4

Are substances listed as 'A' status the 'good' ones and those listed in 'B' status the 'bad' ones?
No. Substances listed as 'B' status are not necessarily 'bad' but remain unevaluated. Available toxicological and migration data may not have been considered by EFSA or other regulatory bodies due to the fact that they have not been previously used in regulated food contact materials such as food contact plastics. 'B' status can also mean that there is insufficient data currently available for the substance and as a result an assessment cannot yet be made or, as the substance has never been petitioned for use in food contact materials, no toxicological data is available.

Question 5

If new technologies (substances) are developed, will they automatically be considered a high risk resulting in related substances being listed as 'B' status?
No. Applications for inclusion of any new substance into the Ordinance must be supported by a dossier of toxicological and migratory information. If the data is found to be sufficient, a limit for migration of that substance will be set, the new substance will be added to the correct substance list and it will be given 'A' status (evaluated). If the data is insufficient, the substance will be given 'B' status (unevaluated), the migration limit of 0.01 mg/kg (10 ppb) will apply for the substance and additional information will be requested.

New substances may also be given 'B' status (unevaluated) if the initial dossier of submitted data indicates that there is no migration. In such cases the Swiss authorities may wish to run confirmatory tests before the substance is granted 'A' status (evaluated).

Furthermore, if the new technology involves the use of substances which already have evaluation data, such substances may already be listed in the lists in the Ordinance with 'A' (evaluated) status. They will not necessarily be 'B' status ones.

Question 6

Will the Ordinance restrict new developments in printing inks?
Possibly yes. However in the course of the REACH registration process toxicological data gaps for many substances will be filled.

Question 7

Will new technologies see long delays to full implementation?
Possibly yes, some new technologies could be delayed if new, unevaluated substances are to be used. Before such substances can be used, the required toxicological evaluation will have to be completed, the dossier of information submitted for evaluation, and approval obtained.

Question 8

Does the Ordinance apply to every food contact article?
Yes – the Ordinance applies to every food contact article. The list of permitted substances in Annex 6 only applies, however, to printing inks for printing on the non-food contact side of materials that are in contact with foodstuffs. There are some other applications excluded, but not relevant for the purpose of this paper.

Question 9

Will the Ordinance kill some ink technologies?
There is a risk that this may happen, however this is clearly not the objective of the Ordinance. In extreme cases where substance manufacturers have no interest in developing toxicological dossiers for specific substances that are key to a particular technology, the consequence might be discontinuation of that technology.

Question 10

Will Non Governmental Organizations make use of the Swiss Ordinance?
Possibly yes – the Ordinance is a public document and everyone with an interest will make use of it in whatever way they require. The Ordinance does however only apply to Switzerland and is only legally binding in Switzerland. Toxicological evaluations made by the Swiss authorities may not therefore be recognized by other national authorities or toxicologists.

Question 11

Are there substances exempt from being listed?
Some printing ink components are currently not required to be listed in Annex 6, such as polymers (if component monomers are listed), pigment additives and certain salts of listed acids. Similarly some application scenarios are also not covered by Ordinance, e.g. where the packaging ink layer is in direct contact with the foodstuff. It is not known whether such substances and applications will continue to be “exempted“, but EuPIA continues to have a close dialogue with FOPH regarding the future direction and scope of the Ordinance.

Question 12

Who will submit new substances to the Swiss authorities?
The manufacturers of new substances, to effect that the substances can be used by ink manufacturers as raw materials in the manufacture of food packaging inks.

Question 13

Will the Swiss Ordinance have an impact on legislation in other countries outside of Switzerland?
Not directly. The Swiss Ordinance has no legal status outside of Switzerland. However the European Commission may consider the Ordinance when further developing EU food contact legislation.

Question 14

How will 'Not Intentionally Added Substances' (NIAS) be handled?
This is not known as yet. The question about NIAS is still not resolved after many years for established food contact materials such as plastics, so it is probably premature to consider how this issue might be considered for packaging inks.

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