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UNION SUISSE DE L'INDUSTRIE
DES VERNIS ET PEINTURES

Consolidated Q&A on
RS 817.023.21 "Swiss Ordinance"

In April and May 2025, the Association of the Swiss Paint and Varnish Industry (VSLF) and the Association of the German Paint and Printing Ink Industry (VdL) organised joint webinars dedicated entirely to the topic of printing inks for food packaging and their regulatory requirements.

In one webinar in German and one in English with several hundred participants, the legal framework and current developments in Switzerland and Germany were examined - in particular the *Ordinance of the Federal Department of the Interior on Materials and Articles Intended to Come into Contact with Food* (SR 817.023.21). The "Swiss Ink Ordinance" (SIO) is not a separate law – it's part of this FCM Ordinance, specifically Chapter 12 (articles 33–35) and the Annexes 10 (positive list) and 15 (ink Stage DoC) that deal with printing inks.

Experts from authorities, industry and associations provided practical information on the requirements for printing inks in contact with food (p-FCM) and how those affected can prepare for future changes. The direct comparison of the regulatory approaches of both countries and details of data exchange within the supply chain were particularly valuable.

The lively participation and great interest showed that the need for information in this area is high and the exchange within Europe is more important than ever. The speakers therefore wrote answers to the open questions from the events and coordinated these with the Swiss Federal Food Safety and Veterinary Office (FSVO) and the German Federal Ministry of Agriculture, Food and Regional Identity (BMLEH) and distributed them to the participants and within the respective associations.

The questions regarding general topics and the SIO of both language versions as well as the Q&A still applicable from an older Q&A document were compiled into this document. Answers to the questions have been compiled based on the current understanding of the legal text. However, the information is provided for informational purposes only and should not be construed as legal advice.

Q1: What is the limit for 'not detectable' (ND)?

A: For substances other than those in the form of nanomaterials, a migration of up to 0.01 milligrams per kilogram (10 ppb) of food is considered undetectable.

Q2: The term 'printing inks' has not been defined. The PIJITF position paper has provided a proposed definition here, which also includes primers under 'printing inks'. The explanatory memorandum to the legislation makes loose reference to this. What is the status here? Do primers, coatings, adhesion promoters, basecoats and overprint varnishes etc. belong to 'printing inks' or not?

A: The official explanatory memorandum to the Printing Inks Regulation explains that printing inks are a fixed term in the supply chain and refers to the definition of the PIJITF:

Printing inks are:

a. Mixtures of colourants with other substances applied to substrates to form a graphic or decorative pattern, in combination with or without

b. other coloured or uncoloured overprint varnishes/coatings or primers normally applied in combination with a) to give the printed design certain functions such as ink adhesion, rub resistance, gloss, slip/friction, durability, etc.

Coatings that are applied with the primary aim of providing the substrate or object with a technical function such as heat sealability, barrier properties, corrosion resistance, etc., as opposed to a graphic effect, are not covered by the term 'printing inks', even though they may be coloured.

Hence, e.g. primers and overprint varnishes described under point b are therefore considered included.

Q3: What about substances that are contained as NIAS in printing inks but are not detectable after processing? Should they be listed in the ink stage DoC?

If a printing ink manufacturer concludes, based on the recommended application conditions of its product and after careful examination, that a NIAS does not need to be mentioned in the ink stage DoC, e.g. because a certain quantity threshold cannot be exceeded, then this NIAS can be omitted from the list of migratable substances. The decisive factor is that substances may only be transferred from FCMs to food in quantities that do not jeopardise human health (Article 49 of the Foodstuffs and Utility Articles Ordinance (LGV) SR 817.2). This general requirement includes NIAS.

For the FSVO, the EFSA Note for Guidance (2008) and the subsequent EFSA publications on this topic are authoritative for the assessment of NIAS.

Q4: What about substances without SML, do they also have to be included in the ink stage DoC?

Yes, all migratable substances must be listed, and the overall migration limit (OML = 60 mg/kg food) must also be complied with.

Q5: According to Art. 11 of the Swiss Ordinance, plastic consumer goods may contain unintentionally present substances if these do not endanger the health of consumers. Art. 35 for printing inks does not contain this passage. Why is a distinction made here?

A: Art. 35 regulates the application/utilisation, which is synonymous with intentional use (IAS). The FAQ on the FSVO website also makes a clear distinction. It states [https://www.blv.admin.ch/blv/de/home/gebrauchsgegenstaende/materialien-in-kontakt-mit-lebensmitteln/verpackungen.html]:

- [2] Which substances are permitted in printing inks [IAS]? => Substances listed in Annex 2 without restriction of use (column 10)...

- [12] How are unintentionally added substances, the so-called 'NIAS' (Non-Intentionally Added Substances), treated? => This is not explicitly addressed in the Regulation.

NIAS fall under the provisions of general health protection regarding FCMs (Art. 49 LGV and Art. 3 1935/2004) and must be assessed by experts on a case-by-case basis as part of self-regulation. In this context, even CMR properties are currently not an exclusion criterion for substances that occur as NIAS in printing inks.

Q6**:** Regarding the ink stage DoC in Switzerland: must a quantification of the substances be included?

A: An ink stage DoC must contain all the information that the converter needs for compliance work, i.e. at least maximum quantities.

Q7**:** The German and Swiss ordinances are not available as official documents in English. Are there plans to publish these regulations in English as well? This would make discussions along the supply chain much easier.

A: Both the German and Swiss authorities are examining whether an English version can be made available.

Q8**:** Are there plans to publish the attachments in machine-readable form? This would considerably simplify digital distribution and integration into companies' IT systems.

A: Both the German and Swiss authorities are checking whether a machine-readable version can be made available.

Q9**:** Are you also planning a future webinar on the French specifications for printing inks individually or in comparison to the German specifications?

A: According to our information, there are no regulations on printed consumer goods of a comparable scope in France. Therefore, no webinar is currently planned. Information on the regulations on mineral oils in France is available from EuPIA and the French printing ink association AFEI.

Q10**:** According to CM/Res(2020)9 (Council of Europe Resolution on the safety and quality of materials and articles for contact with food), printing ink manufacturers must submit declarations of conformity for printing inks from 2026 (e.g. freedom from BPA and BPA derivatives (e.g. epoxy resins)). Isn't the 'Statement of Composition' already dead?

A: On the contrary, the Statement of Composition is a very sustainable concept. The resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food contains legally non-binding recommendations. In principle, each actor in the supply chain must fulfil their level of responsibility and provide the information required for compliance work at the next point in the supply chain. This is also reflected in the requirements of the resolution. The Statement of Composition fulfils precisely this purpose. As the specific regulations under Community law relate to the final product, no compliance can be declared at the level of printing inks, as there are no specific requirements for printing inks against which compliance could be certified. The situation is different if, as in the case of Switzerland, there are specific requirements. An ink stage DoC is possible and required here, but the content is almost

identical to the Statement of Composition. The Statement of Composition will also be highly relevant in the context of the German Printing Ink Ordinance in order to pass on the relevant information in the supply chain.

Q11**:** NLS (not CMR) have a 'migration limit' of 10 ppb. At the same time, is it the case that a NIAS that is not CMR/genotoxic is allowed to migrate 90 ppb in a separate risk assessment for Cramer Class III according to the TTC? Or does the 50 ppb limit of 10/2011 also apply?

A: The 10 ppb for NLS is a regulatory limit that regulates the listing requirement to obtain a practicable regulation. The general requirements of the Framework Regulation, in particular Article 3, remain unaffected. NIAS must be tested by the responsible operator in accordance with internationally recognised scientific principles of risk assessment. This provision takes up the previous procedure in EU law regarding the use of substances not assessed for health reasons in food contact materials and articles (see Regulation (EC) No. 450/2009 and Regulation (EU) No. 10/2011). The EuPIA 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 should be referred to for assistance.

Q12**:** I find it very confusing that so many different limits are set here that concern identical substances. Or to put it another way, why does it make a difference whether I use a substance intentionally or whether it is present as an impurity?

A: In principle, IAS and NIAS must equally fulfil the requirements of the Framework Regulation (in particular Article 3). However, NIAS pose a particular challenge both from a regulatory perspective and for the business practice of risk assessment: A first hurdle is the chemical-analytical identification and quantification of an often large number of unknown chemical structures. In addition, the provision of sufficient test materials for toxicological tests can be problematic. To take this into account, a differentiation of the specific requirements at EU level, as implemented in Article 3 for IAS and NIAS, has so far proven to be appropriate. However, it should also be noted that the EU Commission is currently reconsidering this approach in its long-term plans to revise the framework regulation.

Q13**:** Will the ink manufacturers also provide standards and analysis methods for the final tests so that the converter can also ensure compliance with the limit values/assessment values?

A: Neither VSLF nor EuPIA intend to specify how converters must carry out compliance tests. Although EuPIA has published the EuPIA Guidance on Migration Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials, this is intended for indicative migration tests at the level of the printing ink manufacturer (e.g. as part of NIAS screening). Corresponding standards for the converters would have to be developed at the level of the relevant converter associations. It should also be noted that the need to prove the compliance of the final food contact material by means of appropriate migration tests has not only existed since the German or Swiss Printing Inks Ordinance but may already be required by current Community law.

Q14**:** Is it possible to check compliance with the SML using a model calculation or is a migration analysis necessary before placing the product on the market?

A: Neither the Swiss nor the German regulation stipulate how compliance is to be ensured. This is the responsibility of the person placing the final food contact material or article on the market. In principle, it is also possible to demonstrate compliance using suitable worst-case calculations.

Q15**:** By mentioning no CMR substances - do you mean category 1A, 1B and 2? And - what is the approved tool which should be used to evaluate CMRs? Is CLP regulation enough to exclude CMR?

A: It is indeed category 1 and 2 and refers to CLP regulation. Please refer to *SIO Guidance* for details.

Q16**:** Can non-listed pigments be used for non-DFC applications?

A: It depends, whether they are not CMR and do not migrate above 10 ppb. For pigments this is very often the case but needs to be checked individually. Also, please consider that pigments that are not recommended for food contact applications may contain significant amounts of NIAS that may migrate into food. Also, pigments should at least fulfil the requirements of BfR recommendation IX or AP(89)1.

Q17**:** If the CMR substance is a NIAS in indirect food contact, what migration limit would apply ? (10 ppb, 150 ppt ?)

A: NIAS shall be assessed in accordance with internationally recognised scientific principles on risk assessment. Hence the SML depends on the outcome of this assessment. More details can be found in the EuPIA 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 (https://www.eupia.org/wp-content/uploads/2022/09/2021-05-11-EuPIA_NIAS_Guidance.pdf).

Q18**:** In the past polymers were only excluded if they were solid. So that has changed now?

Yes, the FAQ on the FSVO website state: "Listing in Annex 10 is currently not required for some components of printing inks. These include polymers (provided the monomers they contain are listed) and polymerisation auxiliaries." For more details, please refer to *SIO Guidance*.

Q19**:** For Swiss Ordinance Annex 10, use as additive: are non-listed polymers considered substances on their own (usable even if not listed provided no migration and no CMR properties)? Or are rather the building monomers to be assessed in the same way (usable even if not listed provided no migration and no CMR properties)?

Yes, the assessment always bases on the monomers. So, if non-listed monomers are to be used, the criteria of non-migration and non-CMR apply.

Q20: If a substance is newly classified as CMR, is there a transition period to phase out this substance from printing inks according to SIO?

In Switzerland, the same applies to the reclassification of substances as in Germany/EU. Such a classification generally has no effect on listed substances. In the case of non-listed substances (IAS), there are no transitional periods under food law, but the corresponding provisions of chemicals law apply (1.5–2 years). In concrete terms, this is regulated in Switzerland as follows: A revision of the ChemO refers 'statically' to a delegated regulation of the EU "x. ATP". The same transitional periods apply as in the EU.

As an example, the transitional provisions for substances according to the '21st ATP':

- EU: Art. 2 of Regulation (EU) 2024/197: Delegated Regulation - EU - 2024/197 - EN - EUR-Lex
- Switzerland: Annex 2 of the ChemO, section 15.3 https://www.fedlex.admin.ch/eli/cc/2015/366/de#annex_2/lvl_u1/lvl_15

Q21**:** According to Commission Regulation (EC) No 2023/2006, food is not allowed to get in contact with the printed side. Quote from the Annex: ' 3. The printed surfaces shall not come into direct contact with food.' Will this be amended for inks suitable for direct food contact?

A: This is a common misconception: The annex of regulation (EC) No 2023/2006 only has indirect food contact in scope. Accordingly, it foresees that such a non-DFC ink should not come into direct contact with the food. However, this does not mean that direct food contact is forbidden. This has also been confirmed by the Commission several times.

Q22**:** Is there a requirement for the printing ink itself to comply with the SMLs shown in the Ordinance?

A: No. The SMLs apply to the individual substances present in the final food contact article (e.g. the packaging) of which the dried printed ink layer is a component.

Q23**:** If a substance or substances is/are listed in the Ordinance, does it mean that non-DFC FCM inks using these substances are safe?

A: No. Listing on the Ordinance simply provides verification that the substance may be used in the manufacture of non-DFC FCM 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.

Q24**:** Will the Ordinance restrict new developments in printing inks?

A: Possibly yes. However, during the REACH registration process toxicological data gaps for many substances will be filled.

Q25: Will new technologies see long delays to full implementation?

A: 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.

Q26: Does the Ordinance apply to every food contact article?

A: Yes – the Ordinance applies to every food contact article. The list of permitted substances in Annex 10 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.

Q27: Will the Ordinance hinder some ink technologies?

A: 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.

Q28: Will Non-Governmental Organizations make use of the Swiss Ordinance?

A: 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.

Q29: Are there substances exempt from being listed?

A: Some printing ink components are currently not required to be listed in Annex 10, 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 the 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 FSVO regarding the future direction and scope of the Ordinance.

Q30: Who will submit new substances to the Swiss authorities?

A: 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.

Q31**:** Will the Swiss Ordinance have an impact on legislation in other countries outside of Switzerland?

A: Not directly. The Swiss Ordinance has no legal status outside of Switzerland. However, the European Commission and the EU member states may consider the Ordinance when further developing EU food contact legislation.

VSLF/EuPIA, 2 December 2025