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EuPIA

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

Guidance Document

What is the Swiss Ink Ordinance (SIO)?

The term SIO refers to the "Ordinance of the FDHA on materials and articles intended to come into contact with food". Thus, the SIO is not a separate law – it's part of this FCM Ordinance. Specifically, Chapter 12 (articles 33–35), respectively the Annexes 10 (positive list) and 15 (Declaration of compliance for inks – ink Stage DoC) are addressing printing inks. It is issued by the Swiss Federal Department of Home Affairs (FDHA) and is referred to by the Systematic Compilation of Federal Law Number (SR) 817.023.21. The SIO is only applicable to p-FCM (printed Food Contact Materials) with indirect food contact, i.e. the SIO does not regulate DFC (Direct Food Contact) – unlike the German Ink Ordinance.

In the manufacture of printing inks the following substances are allowed to be used: Substances listed in Annexes 2 and 10 and substances that do not exhibit CMR properties and do not migrate into food (NIAS and NLS).
A declaration of conformity (Stage DoC) is mandatory to be issued for printing inks and printed materials.
Substances listed in former Part B of the SIO until 2023 may continue to be used provided the following requirements are met: Migration of the substance into food or food simulants is not measurable with statistical significance by an analytical method with a detection limit of 0.01 mg/kg and the substance does not show carcinogenic, mutagenic or reprotoxic properties nor is classified as "mutagenic", "carcinogenic" or "reprotoxic" (CMR substances) in category 1A, 1B or 2 according to the criteria in Art. 6 of the Swiss Ordinance on Protection against Dangerous Substances and Preparations (ChemO, 813.11, self-monitoring). It is important to note that missing data on the toxicological properties of a substance cannot justify its use.

Definition of terms

For a list of acronyms, please refer to the end of this document. For detailed definitions of the terms IAS, NIAS, NLS etc., please refer to the relevant EuPIA documents:

- EuPIA Guideline on Printing Inks applied to Food Contact Materials
- EuPIA NIAS Guidance
- EuPIA GMP

For further information, the Swiss Federal Food Safety and Veterinary Office (FSVO)

offers a FAQ page which can also be consulted (Link BLV FAQ).

Definition of "Printing inks"

In addition to the official definition within the SIO, the official explanatory memorandum to the German Printing Inks Regulation (GIO) 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 included. Functional coatings are not considered as printing inks and therefore not in scope of the above definition.

Definition of 'not detectable' (ND)

For substances other than those in the form of nanomaterials, a migration of up to 0.01 mg/kg (10 µg/kg, 10 ppb) into food is considered undetectable. Nevertheless, the detection of such substances might be technically possible. The definition introduces only an arbitrary limit which is not depending on the analytical methods used, available or developed in the future.

Polymers and Polymeric Additives

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."

Polymeric materials are used in printing inks in various functions. The main area of application is binders. Binders form the polymer matrix in which other additives, pigments, etc. are embedded. In addition, additives are also used, which can also be polymeric (e.g. for coating pigment surfaces and/or as dispersants). This means that these additives have a polymeric structure with a molecular weight >> 1000 g/mol. Polymer additives, as well as polymer binders, may only consist of approved monomers. Unlisted monomers can only be used if they are not classified as CMR. Residual monomers may only migrate up to the maximum amount as stated by the SML in Annex 10 or, if not listed, 10 ppb.

The assessment of non-listed polymers is always based on the monomers. So, if non-

listed monomers are to be used, the criteria of non-migration and non-CMR apply.

Use of CMR Substances in the Supply Chain

Case: A manufacturer of additives for printing inks uses a prepolymer containing <1 ppm of a residual carcinogenic monomer to produce a polymer. Together with other ingredients, this forms the printing ink additive. According to a worst-case calculation of an application, a maximum of 0.0015 ppb of the monomer can migrate into the food through the gradual dilution. TTC approach yields: 0.15 ppb migration into food would be permissible.

This example raises several questions:
How far back in the supply chain do you need to go? What applies to the prepolymer, the monomer rule in the regulation (i.e. either listed or not CMR)? In this case, is the monomer a NIAS according to the SIO?

Answer: Yes, the CMR monomer in this case is considered a NIAS. In the upcoming updated FAQ of the FSVO it will also be made clear that precursor substances which are used in the production of the IAS used in printing inks are regarded as NIAS.

Distinction between NIAS and IAS

Intentionally Added Substances (IAS): This covers all chemical substances which are intentionally used in the production and use of the printing ink, and which have an intended and specific function within the final ink and without which the performance of the ink would change. These substances may be added as single components or as mixtures of various substances. The term “use” of raw materials or substances in inks in this paper means always that these raw materials or substances are added intentionally (IAS).

Non-Intentionally Added Substances (NIAS): Raw materials (single chemical substance or mixture of substances with defined technical properties) used in the manufacture of printing inks may contain other substances originating from the manufacturing or extraction process. These substances are non-intentionally added but present in the raw material which is intentionally used in the manufacture of the printing ink. Further, during the manufacture and use of printing inks, reaction and degradation products of used substances can be formed. These reaction and degradation products are, as well, non-intentionally present in the printing ink (NIAS). As far as these NIAS are relevant for the risk assessment for the final printed FCM, they should be considered and risk assessed.

There is no distinction between NIAS from *assessed substances (“listed”)* and NIAS from *unassessed substances (NLS).*

Risk Assessment (NIAS/NLS)

A risk assessment is applicable for NLS and NIAS. The following exemplary case can

be considered: Azo Pigment Yellow 83 (PY83) – previously A listed without SML, No. 1662.
Azo pigments are produced by coupling a paA with other components. The pigments contain residues of these coupling components (paA being regulated) which are used by the pigment manufacturer, but not by the ink manufacturer.

	PY83	**Coupling Components**
Pigment Manufacturer	reaction product	IAS
Ink Manufacturer	IAS	Residues are NIAS
Annex 10	Listed No. 1662, no SML	Not listed

The same substance can therefore come as an impurity from both listed and non-listed substances (depending on the manufacturing stage), a distinction is not possible in the finished printing ink, the printed product or in migration measurements. Regardless of the source, such a NIAS should always be evaluated in the same way (e.g. via TTC, *threshold of toxicological concern*).
General approach: Every NIAS must be evaluated, and EFSA Note for Guidance is applied to determine a self-derived SML.

It is sometimes confusing, that according to Art. 11 of the Swiss Consumer Goods Ordinance, plastic consumer goods may contain unintentionally present substances if these do not endanger the health of consumers. Whereas Art. 35 for printing inks (SIO) does not contain this passage.
But, **Art. 35** regulates the application/utilisation of substances, which is synonymous with intentional use (**IAS**). The FAQ on the FSVO website (vide supra) also makes a clear distinction:

> *- [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.

Polymer Processing Aids (PPA)
This applies to process aids and catalysts, "Aids to Polymerization". PPA are exempt from the requirements (i.e. self-assessment analogous to NIAS must be done), see Chapter 1.3 of Annex 10 and the FSVO FAQ.

Important point: this exemption applies only to PPA used for polymers that are used for the manufacture of printing inks. Substances that have such a function during the curing of the ink, e.g. photoinitiators, are regarded as IAS.

Use of Non-Listed Substances, Assessment of CMR-Properties

Non-listed substances can be used as IAS

- if a harmonized classification as not CMR in accordance with ChemO exists *OR*
- if a CMR self-assessment with negative outcome has been performed

AND in both cases the non-listed substances do not migrate above 10 ppb.

Caution: A missing harmonised classification of the substance in accordance with ChemO can be based on data gaps. Therefore, not only a harmonised classification as CMR but also a positive outcome of a CMR self-assessment can lead to a substance being excluded as IAS.

Self-Assessment of CMR-Properties

Important: Self-assessment cannot be used to overrule a harmonized CMR classification and should always be done by a qualified expert/toxicologist!

Former requirements by the FSVO that for the **endpoint "M"** both gene mutations and clastogenicity/aneugenicity would have to be tested *experimentally* were challenged by EuPIA toxicologists with the following arguments:

- A REACH-registered substance in the 1–10 t volume range only requires testing for gene mutation, not testing for chromosomal damage
- EFSA's Note for Guidance calls for both tests for an SML of 50 ppb. The effort required by the FSVO would have been equivalent to that required for a dossier on substance listing.
- In the absence of experimental data for endpoint "M" (gene mutations), EuPIA argued that at 10 ppb, *in silico* statements (using e.g. two independent QSAR models) on mutagenicity should be completely sufficient.

For **endpoint 'C'** (genotoxic carcinogens), a distinction can be made between genotoxic carcinogens and epigenetically acting carcinogens. The latter have a toxicological effect threshold above 10 ppb. These are therefore not to be considered further in the CMR assessment. Therefore, if the endpoint 'M' is negative, the 'C' assessment is already covered.

For **endpoint "R"**: Reprotoxic substances have a threshold that is practically always well above 10 ppb. So why investigate R?

After discussion with EuPIA toxicologists the following was accepted by the FSVO:

C	In case of genotoxic carcinogens see M In case of non-genotoxic carcinogens: 10 ppb limit applies, but no further tox assessment is necessary

M	Use of existing experimental toxicological data (gene mutations), if not available use of *in Silico*
R	10 ppb limit applies, but no further tox assessment is necessary

The FAQ on the FSVO homepage now states:

"To clarify the possible CMR properties of a substance, we recommend the following procedure:

1. Review of the harmonized classification of the substance according to ChemO.
2. If there is no harmonised classification for the substance:

A) Clarification of the endpoint "M" in silico (with suitable SAR or QSAR models);
B) Clarification of the endpoint "C" by read-across or literature search ("expert judgement")."

On November 14, 2024, we received the following response from the FSVO: "The point of considering experimental data is taken into account. The point that the data can also come from suppliers is mentioned…"
According to FSVO, Point A is going to be changed in the upcoming FAQ update to:

A) Clarification of the endpoint "M":
i. Evaluation of toxicity data in the REACH registration dossier or data from other toxicological studies
ii. If no toxicity data is available: in silico (with suitable SAR or QSAR models)

If a substance is newly classified as CMR, such a classification generally has no effect on listed substances. In the case of non-listed substances, there are no transitional periods under food law, but the corresponding provisions of chemicals law apply (1.5–2 years). Specifically, 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.

Statement of Composition SoC/Stage Declaration of Conformity (Stage DoC)
There has been some confusion over the differences SoC vs. DoC and the implementation in practice. E.g. which information and confirmations exactly must be in the DoC.

First, a definition of terms:

- Statement of Composition SoC: This is the current document according to EUPIA recommendations
- Stage Declaration of Conformity DoC: This is the document required for printing

inks according to the SIO. Apart from some additional information or references this mainly contains the same information as a SoC prepared according to the EUPIA recommendations.

- Final article Declaration of Conformity DoC: This is the DoC made by the converter for the final article, taking into account all information compiled from the supply chain.

According to SIO Annex 15 a Stage DoC shall contain the following information:

8. Specifications for the use of the printing inks, such as:
8.1 The groups of consumer goods on which the printing ink may be used,
8.2 The foodstuffs that come into contact with the printed consumer goods:
8.2.1 Types of foodstuffs that may come into contact with it,
8.2.2 Duration and temperature of treatment and storage in contact with the foodstuff,
8.2.3 The maximum ratio of the surface area in contact with foodstuffs to the volume on the basis of which the conformity of the consumer goods was established, or equivalent information,
8.3 The conditions of use that must be complied with to achieve the desired function.

As discussed on multiple occasion with the FSVO it is also feasible to refer to Technical Documents (TDS) within the ink Stage DoC. Moreover, specific disclaimers are also possible. This means that the requirement to deliver an ink Stage DoC will lead to no elevated level of responsibility for the ink producers/suppliers.

The standard Statement of Composition (SoC) according to EuPIA recommendations lists all substances with migration potential contained in a formulation as well as all volatile or reactive substances. Based on the EU Cube Model, the calculated amount of dry film of the formulation is given at which the migration limit to be considered is exceeded. Substances without SML should also be included in the ink Stage DoC, i.e. all migratable substances must be listed, as the overall migration limit (OML = 60 mg/kg food) must also be complied with. An ink Stage DoC must contain all the information that the converter needs for compliance work, i.e. at least maximum concentrations for these substances need to be included in the information.

However, a statement regarding compliance with the migration limits is only possible for the printed material. In addition to the composition of an ink, many factors beyond the control of the ink manufacturer influence the migration: nature and thickness of the substrate, application weight, printing parameters, storage conditions, etc.

The definition of a standard application within the ink Stage DoC can be useful. For a standardised application, this would specify the grammages and surface area:volume ratios assumed by the printing ink manufacturer when creating the DoC.

Regarding Annex 15, point 8: The printing ink manufacturer often does not have the complete details about the structure and use of the printed consumer goods: e.g. in the case of flexible packaging (8.1), which films are used to make a composite, which foodstuffs are packaged (8.2.1), storage conditions of the packaged foodstuffs (8.2.2), but also the ratio of the area of the consumer goods to the volume of the foodstuff (8.2.3).

The requirements listed under Annex 15, point 8 are therefore tailored to the finished consumer item and cannot be fully met by printing inks in delivery form or the raw materials used.

As part of the consultation, the FSVO made clear: Of course, conditions may be included in the DoC and the previous fundamental responsibilities along the supply chain remain unchanged, see FSVO FAQ "How are responsibilities organised along the supply chain?: […] *Upstream operators cannot issue declarations of compliance covering the legal responsibility of manufacturers of packaging or other FCM and fillers.*" Also, the SIO does not 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.

If a printing ink manufacturer concludes, based on the recommended application conditions of a 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 and reference to the decision model should be given. 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.

Summary

A "well-made SoC can be used as ink Stage DoC". As there is also no formal requirement that the document must be named DoC, a SoC prepared according to the recommendations and standards of EuPIA provides all information that has to be communicated for the stage of the ink production as set out in Annex 15 and hence equals an ink Stage DoC.

For clarification within SoC documents, EuPIA recommends using the following sentence: "This Statement of Composition also serves as a Declaration of Compliance (ink Stage DoC) in accordance with Article 35a of the Swiss Ordinance on Materials and Articles in Contact with Food (SR 817.023.21) for printing inks, confirming compliance with the applicable requirements."

VSLF/EuPIA, 2 December 2025

List of Acronyms

ChemO	Swiss Chemicals Ordinance, «Chemikalienverordnung»
CMR	Carcinogenic, Mutagenic (causing genetic mutations), and toxic to Reproduction
D	Dalton (g/mol)
DFC	Direct Food Contact
DoC	Declaration of Conformity
EFSA	European Food Safety Authority
EuPIA	European Printing Ink Association
FCM	Food Contact Material
FDHA	Swiss Federal Department of Home Affairs/Innenministerium
FSVO	Swiss Federal Food Safety and Veterinary Office/Bundesamt für Lebensmittelsicherheit und Veterinärwesen
GIO	German Printing Inks Ordinance/Bedarfsgegenständeverordnung
GMP	Good Manufacturing Practice
IAS	Intentionally Added Substances
ink stage DoC	Declaration of Conformity issued for printing inks
LGV	Swiss Foodstuffs and Utility Articles Ordinance/Lebensmittel- und Gebrauchsgegenständeverordnung SR 817.2
ND	Not Detectable
NIAS	Non-Intentionally Added Substances
NLS	Non-Listed Substances
OML	Overall Migration Limit
paA	primary aromatic Amine
p-FCM	printed Food Contact Materials
PIJITF	Packaging Ink Joint Industry Task Force
PPA	Polymer Processing Aids
ppb	parts per billion (1 µg/kg, 1E-9)
ppm	parts per million (1 mg/kg,1E-6)
SIO	Swiss Printing Inks Ordinance
SML	Specific Migration Limit
SoC	Statement of Composition
TDS	Technical Data Sheet
TTC	Threshold of Toxicological Concern

References

- EuPIA Guideline on Printing Inks applied to Food Contact Materials
- 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
- EuPIA Good Manufacturing Practice (GMP) Printing Inks for Food Contact Materials
- German Consumer Goods Ordinance ("German ink Ordinance", GIO)
- Swiss Ordinance on Materials and Articles in Contact With Food (SR 817.023.21)
- Regulation (EU) No 10/2011
- Position of the Packaging Inks Joint Industry Task Force (PIJITF) on the review of Framework Regulation on Food Contact Materials &
- PIJITF GUIDANCE Information and Transparency in the Printed Food Packaging Supply Chain
- Articles EuPIA Information Note: Scoping Paper on Functional Coatings