



Guideline for Interpretation of the Swiss Ordinance on Printing Inks

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Joint Industry Group (JIG) on Packaging for Packaging Safty Swiss Packaging Institute (SVI)

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Guideline for Interpretation of the Swiss Ordinance on Printing Inks



The following Guideline was developed by the

Joint Industry Group (JIG) on Packaging of the Swiss Packaging Institute (SVI)

The JIG is an association of interest groups along the value chain, in particular the packaging industries as well as industry associations with the participation of Government officials. Led by the Swiss Packaging Institute (SVI) the JIG is trying to promote the work in the field of safety packaging.

Scope & background

The updated Swiss Ordinance 817.023.21 (Revision February 1st 2024, AS 2023 836 ff.) will enter into force on February 1, 2026. The new article 35a requires at all marketing stages, except for retail sales, a Declaration of Compliance (DoC) for printing ink layers as a component of a consumer product, for printing inks, and for the materials used in the manufacture of printing inks. The Declaration of Compliance must be issued by a responsible person and contain the information specified in Annex 15 of 817.023.21.

This guideline aims to support the legal requirements by giving advice how all stakeholders could fulfil the set-out criteria, especially of Annex 15 of 817.023.21. It is not a legal advice nor legally binding but the outcome of exchanges in the value chain. This is especially valid for the DoC template in the annex.

To harmonise the information-flow, a standardized SoC – information from ink supplier to converter – and a standardized DoC – information from converter to food industry – is needed [1]. In this, the revision of the SIO does not impose fundamental changes in the responsibilities within the supply chain. Printing ink manufacturers cannot take (legal) responsibility for processes they do not control. An SoC is part of the compliance work needed for issuing a DoC on the next stage of the value chain. However, the suppliers' DoCs belong to the 'supporting documents' (documents in accordance with Art. 35b). [10]

This SoC guidance in the annex was developed by a working group of the Swiss Packaging Institute (SVI), including the FSVO and industry representatives, to avoid any misinterpretations of the legislation based on examples. The backbone of the current template is the FAQ document, published on the web page of Swiss Federal Food Safety and Veterinary Office (FSVO/BLV) [2]. A SoC or a DoC can never cover all possible usage cases. Therefore, the proposals are always linked to defined application conditions in terms of surface-to-volume ratio, printing film weight, ink coverage amount, etc, which are under control of the converter. Concepts and examples for calculations are provided with this guideline.

Substance definitions:

The Swiss ordinance is based on a positive list allowing a differentiation:

- 1) IAS: Intentionally added substances

This group can be separated into:

- a. Listed substances (**LS**): meaning substances which are intentionally added to the ink formulation and listed either in Annex 2 (equivalent to Regulation (EU) 10/2011) or 10 of the Swiss Regulation
- b. Non-Listed substances (**NLS**): meaning substances which are part of the ink formulation but not listed in Annex 2 or 10 of the Swiss Regulation.

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- 2) NIAS: non-intentionally added substances
meaning substances which may occur as contaminations of the raw materials used or degradation or reaction products when processing the ink. Raw material mixtures may also contain impurities, residual starting substances etc., which are NIAS. This definition is based on the EUPIA NIAS definition [2].
Risk assessments can be performed according to the guidance and opinions issued by EFSA, depending on the extent of available toxicity data. NIAS classified and/or known as being genotoxic and/or non-threshold carcinogens (CM-substances) or should not migrate above 0.15 µg/kg food. For reprotoxic substances (R) and threshold-carcinogens (C), higher threshold values can typically be derived through a toxicological risk assessment.
- 3) CMR: carcinogenic, mutagenic, toxic for reproduction
A CMR substance is not allowed to be intentionally used as NLS. If a CMR is a NIAS, it needs to be risk-assessed (see above 2).

Trade Secrets

It may happen, that certain substances are not disclosed due to trade reasons. This can be accepted if further information is given in terms of substance classification (e.g. CMR, IAS, NLS, NIAS) and an action is defined. If delegation to converter is foreseen, the way of disclosure and to whom should be described.

CMR Assessment of NLS

For CMR assessment two possibilities have to be differentiated

- 1) Check the harmonized classification of the substance according to ChemV. However, the CMR info in a Safety Data Sheet according to the GCL of CLP starts only from a concentration > 0.1 % (for CM) and >0.3 % (for R)- this might conflict with the limit based on the calculation model and might not be sufficient for the assessment.
- 2) no harmonized classification for the substance exists.

At first check available toxicological data, if no data is available, then:

- a. Clarify the endpoint “M” via read-across and/ or in silico (with suitable SAR or QSAR models).
- b. Clarify the endpoint “C” by read across or literature research (“expert judgement”), where possible, while for threshold carcinogens the limit of 10 µg/kg food can be accepted for NIAS
- c. Clarify the endpoint “R” by calculating a threshold, where possible.
If no tox-based threshold can be achieved, the limit of 10 µg/kg food can be accepted for NIAS. (see pragmatic assessment approach in the latest EuPIA document [4])

Expert Judgement- As Key Legal Criteria for Experts the following could be used:

- i. Qualification: Demonstrated expertise in a relevant field
- ii. Relevance: Their opinion must relate directly to the issue in question
- iii. Reliability: Based on accepted scientific or technical principles

DoC of Converter

In the best case: the information received from the ink supplier, in the proposed SoC/DoC format – to the extent

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applicable for the ink supplier – already estimates the compliance for many substances. Nevertheless, compliance for these substances must be verified at the converter stage. Additionally, it is the obligation of the converter to check if the applied model calculations, assumptions, and testing approaches are applicable for the final application. Converters must verify the compliance for substances, for which the information received via the SOC from the printing ink manufacturer is not sufficient/100% applicable (e.g. WCC of ink supplier needs recalculation on real case; migration test necessary) or for substances which may also occur from other sources of the final printed material. The compliance verification can be based, as mentioned, on further worst-case calculations, modelling principles, and/or migration testing.

A similar template format could be used for this purpose, but this is not subject to this current guidance document. NIAS formed during the converting step (including printing) must be assessed for the final printed food contact material.

General Considerations for the assessment of the printed article compliance

(specifically to be considered by testing laboratories, converters and brand owners)

The following general considerations give some ideas to the converters how to act in case NIAS results are questionable. The considerations are not conclusive but offer a guidance.

NIAS Assessment

For the assessment of NIAS in a printed article, the EFSA Note for Guidance (2008) and the subsequent EFSA publications on this topic are decisive for the FSVO. [3]

Important to note: NIAS from a printed article may come as result of e.g. degradation, contamination or impurities from any of the packaging components (substrate, adhesives, primers, inks, etc) or from the printing process. So, what happens if a NIAS cannot be identified – the so-called “unknowns” in analytical reports? In this case it is worthwhile to do the following:

- a) Repeat the analysis to find out if the finding is systematic. In case of random findings, it might be impossible to run a root cause, or
- b) Revise the test conditions – selecting a more appropriate simulant instead of running a worst-case scenario, or
- c) Try to collect NIAS out of migration simulants (which is a rather scientific approach and may not be applicable in a day-to-day business).
- d) Change the packaging system, e.g. include a barrier.

Migration Tests

For migration tests, especially for non-plastic applications like paper and board no harmonised conditions are set out in relevant food contact legislation addressing especially potential migrants from print layers. This may lead to many discussions in case of findings that are exceeding limits. In that case it is highly recommended to discuss upfront, what might be relevant testing conditions. Just simply applying conditions taken from Regulation (EU) 10/2011 for plastics to non-plastics should be avoided – see also EUPIA Testing guideline [5]

Generally, it is worthwhile to verify migration test results exceeding a limit as follows:

When failing in migration tests (result > SML or for NLS >0.01 mg/kg), it is possible albeit expensive to perform tests in real food applications as the simulants might be overestimating (see also Regulation (EU) 10/2011, article 18/6). This advice may be given in the SoC, if suitable conditions are known.

The alternative to food testing is to implement a suitable barrier. However, the effectiveness of a barrier itself needs

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to be demonstrated on the final printed article (this is responsibility of the Business Operator as defined in Reg. 1935/2004). If known, the printing material supplier may provide data regarding which barrier material may be suitable, e.g. material type, thickness, time/temperature conditions, etc.

References:

- [1] Please refer to PIJITF GUIDANCE Information and Transparency in the Printed Food Packaging Supply Chain and PIJITF GUIDANCE Information and Transparency in the Printed Food Packaging Supply Chain [PIJITF (Packaging ink joint industry task force) – EuPIA].
<https://www.eupia.org/key-topics/food-contact-materials/pijif-packaging-ink-joint-industry-task-force/>
- [2] FAQ of FSVO
<https://www.blv.admin.ch/blv/en/home/gebrauchsgegenstaende/materialien-in-kontakt-mit-lebensmitteln/verpackungen.html>
- [3] 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
- [4] EuPIA SIO Guidance:
www.eupia.org/wp-content/uploads/2025/12/20251202_VSLF-EuPIA_Guidance_SIO-1.pdf
- [5] EuPIA Guidance on Migration – Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials, 4th amendment 2023-05-03
- [6] Customer Guidance Note for using ink Statements of Composition when considering compliance of food packaging
https://www.eupia.org/wp-content/uploads/2022/09/2021-09-03_EuPIA_Customer_Guidance_Note_for_Using_Statements_of_Composition.pdf
- [7] Explanatory note for suppliers of ink raw materials regarding regulatory compliance of printed food packaging
https://www.eupia.org/wp-content/uploads/2025/08/33_2025-08-05_EuPIA-Explanatory-Note-for-raw-material-sup.-reg.-compliance-of-printed-food-packaging.pdf
- [8] Position of the Packaging Inks Joint Industry Task Force (PIJITF) on the review of Framework Regulation on Food Contact Materials & Articles
<https://www.eupia.org/key-topics/food-contact-materials/pijif-packaging-ink-joint-industry-task-force/>
- [9] PIJITF GUIDANCE Information and Transparency in the Printed Food Packaging Supply Chain
<https://www.eupia.org/key-topics/food-contact-materials/pijif-packaging-ink-joint-industry-task-force/>
- [10] Technical guide on documentation supporting compliance and safety of food contact materials and articles (in accordance with the principles laid out in the Council of Europe Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food.) – 1st edition, 2024

Annex I: Elements that should be included in an ink SoC/DoC

A SoC should address the following points. Generally, information can be given in additional documents like technical data sheets or statements. However, clear references are needed. Therefore, the proposed format is a recommendation to harmonise the information flow, but it can be individually adapted.

1) Requirements of Annex 15 – point 8 of SIO

The SoC should address the following SIO requirements:

8.1 the groups of consumer goods on which the printing ink may be used

Examples:

- PET, PE, PP, cardboard
- Refer to TDS.

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

Examples:

- All kinds of food acc. to 10/2011 resp. CH-legislation
- All food types, depending on packaging structure.
- Exclusions / No exclusions known. Packaging designer should conduct proper suitability assessment.
- Reference to TDS

8.2.2 duration and temperature of treatment and storage in contact with the foodstuff

Examples:

- long-term indirect
- Exclusions: high temperature applications (oven, microwave, sterilization, etc)

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

Examples:

- $S/V \leq 6 \text{ dm}^2/\text{kg}$ with a maximum ink load of $xyz \text{ g/m}^2$

8.3 the conditions of use that must be complied with to achieve the desired function

Examples:

- Process conditions
- Reference to TDS
- Barrier is needed (e.g. PE 20 μm)
- Ink load (dry) not more than 1.5 g/m^2

2) SoC-Template – Version 2025

The format is a proposal; each ink supplier may choose to give the additional information that it is thought of being of importance. However, the amount should be given.

The following table contains information from the printing ink manufacturer to the downstream users on substances used (IAS) or known to be present (NIAS) with the potential to migrate (at concentrations of regulatory relevance), including indication whether the substances are restricted:

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CAS-No	PM/FCM Ref-No	Name	Restrictions and specific migration limits (SML) [mg/kg]			For non-volatile/ non-reactive substances: Maximum amount in dried ink film [%]	Comments	
			Regulation (EU) No 10/20115	Swiss Ordinance 817.023.21	German Consumer Goods Ordinance (GIO)		Substances Status	Restriction
	A		OML (60)			20	LS	
	B		1			2	LS	
	C		0.05			1	LS	
	D		0.05			> 1	LS	Under Converter testing
	E		0.01			2	NLS	Under Converter testing
	F		0.01			0.5	NLS	
	G		0.09 (self-derived)			0.5	NIAS* (non CMR)	Under Converter testing
	H		0.05 (self-derived)			0.3	NIAS* (non CMR)	Model migrations showed no exceeding of SML
	I		0.00015			> 0.00017	NIAS* (CM)	Under Converter testing
	J		10 (expert judgement)			0.09	NIAS* (R)	
	K		Not known			0.1	NIAS* (unidentified)	Excluded by WCC or model migration
	L		Not known			0.2	NIAS* (unidentified)	Under Converter testing
	Trade secret						IAS/NLS/NIAS	Under Converter testing

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Annex II: Calculation Model

As the information to be forwarded for substances is always concentration dependent, it is difficult to create a threshold valid for all possible applications. So far, most calculations are based on standardized surface-to-volume (S/V) ratio of 6 dm²/kg (“EU-cube”).

Therefore, it is highly recommended, that the issuer of the SoC/DoC clearly describes on which model basis the calculation has been performed. The model allows the user/converter to check if this model fits with his application or not. In case of significant deviations with respect to the final application, the converter must re-calculate. Printing ink manufacturers cannot be held responsible for uses of their products that they are not aware of, that are outside the scope of the printing ink manufacturers’ recommendations, or that violate the conditions of use defined in the SoC/DoC or the Technical Data Sheets (TDS) referenced therein [6] [7]. For energy-curing systems, no concentration in the wet ink film can be given in the SoC.

Example Model: Worst Case Calculation for substances with a potential to migrate:

Target Concentration in Food	CM Substance as NIAS*	Non-Listed Substance
Limit in Food	0.15 µg/kg	10 µg/kg
Packaging Surface/Volume	6 dm ² /kg	
Concentration per surface	0.025 µg/dm ²	1.67 µg/dm ²
Ink Coverage	100%	
Ink film weight	1.5 g/m ²	
Ink film weight	0.015 g/dm ²	
Concentration surface per film weight	1.67 µg/g	111.1 µg/g
Equal to	1.67 mg/kg	111.1 mg/kg
Decision Limit for Reporting	0.00017%	0.011%

*for “R” (reprotoxic calculation) a threshold may be calculated

As calculated in the example, applying an ink coverage of 100 %, an ink film of 1.5 g/m² and a S/V of 6 dm²/kg food, any non-listed substance with a potential to migrate above 0.011 % (111.1 mg/kg) in the dry ink film needs to be addressed in the SoC.

For NIAS in a first instance the same reporting limit of 0.01% should be applied as far as known. For “CM” classified” NIAS a reporting limit of 0.00017 % according to above model calculation should be considered to ensure that the migration limit of 0.15 µg/kg cannot be exceeded.

- Note 1: For listed substances, a quantitative reporting limit should be in the range of 10 % of the SML.
- Note 2: The model approach used is based on knowing and communicating the level of constituents in the wet and dried ink. This is only feasible for non-energy cured inks. Therefore, for energy cured inks further work is needed to develop a way to manage risk assessment and management

If the default calculation model does not cover the final application, a re-calculation might be required by the converter. The reporting limit of the migratable substances present in the ink composition are in the responsibility of each individual ink manufacturer, by considering the worst-case scenarios and specific evaluations (e.g. analytical results, model calculations etc.) of the recommended applications as required by Annex 15.8 of the SIO.

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Become a member of the Joint Industry Group for Packaging Safety

Definition of the JIG The Joint Industry Group for Packaging Safety (JIG) of the Swiss Packaging Institute (SVI) is a packaging-neutral association of various interest groups with the aim of promoting work in the field of packaging safety and implementing regulations. The relevant interest groups, in particular the packaging industry along the value chain, authorities and enforcement agencies, as well as industry associations, work together to develop economically viable solutions and concepts for the entire packaging industry. Goal of the JIG We want to provide our industry with the necessary information and tools to enable it to guarantee the safety of packaging efficiently and sustainably.

5 reasons to join the JIG

1. The topics covered by the JIG are relevant to everyone involved in packaging.
2. Gain broad market acceptance by participating in projects (developing methods).
3. Contribute your own questions and develop efficient solutions.
4. Benefit from the exchange of information and experience with proven experts and thus also gain a knowledge advantage.
5. Build up a comprehensive network in the field of conformity work.

5 advantages of working with JIG

1. Together we can achieve more.
2. Broad-based discussion leads to holistic solutions that are accepted by all, such as industry standards.
3. The JIG acts as an intermediary between science, legislation, enforcement, and practice in the value chain.
4. Receive JIG publications free of charge.
5. Special conditions for JIG events and JIG training courses, and much more.

How much is secure packaging worth?

1. JIG membership
2. Individual membership costs CHF 360 per year.
3. Membership lasts for at least one year.

Members (individual membership) are invited to a general meeting at least twice a year and are encouraged to contribute project ideas and help shape projects. The funds paid in are used to maintain the group (project managers, experts, events, and administration).

The membership fee of CHF 360 per year is charged by invoice. Unless written notice of termination is given, membership is automatically renewed.

Membership cannot be transferred to other persons.

Further information can be found at:

<https://new.svi-verpackung.ch/jig-finanzierung/>



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