SVI Joint Industry Group (JIG) on packaging for food contact

Checklist for the evaluation of declarations of compliance

		Yes	No	n/a*
0. Title	0.1. Instructive title such as „declaration of compliance“ or similar?			
	0.2. Title = „declaration of compliance“?			
1. Identification and address of issuer and receiver	1.1. Identification and address of issuer existent?			
	1.2. Identification and address of receiver existent?			
2. Identification of additional companies	2.1. Further indications regarding identification and/or additional addresses existent?			
3. Identification of food contact material (FCM)	3.1. FCM clearly described and identifiable?			
	3.2. Does declaration of compliance encompass all parts of the FCM?			
	3.3. Does composition of the FCM encompass all parts (completeness)?			
4. Date of declaration	4.1. Is the issuance date of declaration mentioned?			
5. Confirmation of observance of regulatory framework	5.1. Is suitability for food contact according to EU 1935/2004 confirmed?			
	5.2. Is confirmed that production observes GMP according to EU 2023/2006?			
	5.3. Confirmation of any quality standard applied during production?			
	5.4. Is compliance with specific measures confirmed, in case such measure is applicable according to EU regulatory framework?			
	5.5. Is the observance of relevant national regulatory frameworks confirmed?			
	5.6. Confirmation of observance of any specific industry sector reference?			
	5.7. Is it clearly stated for what the issuer does accept responsibility?			
6. Sufficient information about substances applied	6.1. Is information provided about substances applied in the FCM sufficient?			
	6.2. Is unequivocal information concerning substances with specific migration limits (SML) available?			
	6.3. Is information about NIAS (non intentionally added substances) available?			
	6.4. If set-off from printed surfaces is possible: is unequivocal information given?			
7. Dual-use additives	7.1. Is information about usage of dual-use additive available?			
8. Specification about the intended usage of the FCM	8.1. Are allowable type or types of foodstuffs (that may get into contact with the FCM) indicated?			
	8.2. Are indications concerning duration and temperature during treatment and storage of food stuffs available?			
	8.3. Is information about surface and volume ratio available?			
	8.4. Are conditions of storage for FCM provided?			
	8.5. In case a restriction of application has to be observed, is it clearly indicated?			
9. Functional barrier	9.1. In case a functional barrier is applied, is a confirmation about its efficacy available?			
10. Date and signature	10.1. Is the document signed with a valid signature?			
	10.2. Is the job description of the signatory indicated?			
	10.3. Has the document been countersigned by the receiver?			
11. Details about compliance work already made	11.1. Are details about compliance work already made available?			
	11.2. Are details about continuative documents (by the issuer) available?			
	11.3. Are details about continuative documents (by third parties) available?			

Summarizing the evaluation: shall the document be accepted?		
The criterion for the acceptance: zero "No"		

* n/a means „not applicable“ and has to be defined by the receiver of the declaration of compliance.

Remarks

Date and signature

This evaluation sheet has always to be used in conjunction with the supplementary instructions.

Supplementary instructions

The structure of the check list follows the structure of the written declaration for plastic products according to art. 15 of EU 10/2011 appendix IV.

In this document the notion „declaration of compliance“ is used in lieu of any kind of document that confirms the suitability of food contact materials.

0. Title

0.1. Does exist in the document an explanatory title such as declaration of compliance or declaration of conformity.

Commentary: a title is needed.

0.2. Has the notion „declaration of compliance“ been used?

Commentary: the term is obligatory in conjunction with materials that are subject to specific measures according to EU rules, such as plastics, ceramics and active and intelligent materials.

1. Identification and address of issuer and receiver

1.1. Is the identification and address of the company known that issued the declaration of compliance?

Commentary: an indication is necessary.

1.2. Is the identification and address of the receiver (the company receiving the declaration of compliance) known?

Commentary: this point is an issue of mutual agreement and not obligatory.

2. Identification of additional companies

2.1. If point 2 is not fully covered by the information submitted in point 1: are further details concerning identification and addresses of companies available that produce materials or products made out of plastic or food contact materials made out of intermediates or produce and/or import substances that are used in the production of materials and products mentioned in point 3?

Commentary: only food contact materials that fall under EU 10/2011 must fulfill this requirement. The requirement only must be met in cases information under point 1 is missing.

3. Identification of food contact material (FCM) covered by this document

3.1. Is it possible to definitely describe and identify the material either by name, by article number, by identification number of production lot or by similar information?

Commentary: the denomination of the material must be traceable in all supporting documents (as found as in company archives) and in analysis reports.

An indication of reference article number of the supplier and/or of the reference article number of the food producer would facilitate the traceability.

3.2. Does the declaration of compliance encompass all parts of the FCM?

Commentary: a declaration of compliance should encompass and describe all parts of the food contact material as delivered. See also 3.3.

3.3. Does the composition of the FCM encompass all parts (completeness)?

Commentary: it must be obvious for which layers the declaration is valid. If necessary a sketch explaining the composition would be helpful.

4. Date of declaration

4.1. Is the issuance date of the declaration mentioned?

5. Confirmation of observance of the regulatory framework

5.1. Does the declaration confirm that the food contact material is fit for use in contact with food stuffs?

Commentary: this requirement is fulfilled if the observance of EU 1935/2004 is confirmed.

In principle it can be assumed that the Swiss regulatory framework is observed if the observance of EU 1935/2004 is declared.

In addition or alternatively a reference can be made to Swiss law (LMG – SR 817.0 and LGV – SR 817.02) in case the food contact material is delivered in Switzerland exclusively.

If the declaration is issued for a non-EU country and/or Switzerland a reference to the regulatory framework of the country of destination should be made.

5.2. Does the declaration confirm that the FCM has been produced according to good manufacturing practice (GMP) following EU 2023/2006.

Commentary: Swiss law does not require observance of EU GMP Regulation but with a view to art. 49 of LGV a demand for quality control procedures can be derived.

5.3. Is a confirmation available stating that any quality standard has been applied during production (such as industry guidelines, ISO procedures)?

Commentary: such quality standards could be ISO 9000, BRC-IoP, hygiene standards (f. e. HACCP).

5.4. If the food contact material is subject to specific measures according to the EU regulatory framework, is observance guaranteed?

Commentary: following materials are subject to EU specific measures:

- Plastic materials: Commission regulation EU 10/2011
- Ceramic articles: Council directive 84/500/EEC
- Active and intelligent materials: Commission regulation EU 450/2009

- Recycled plastic materials: Commission regulation EU 282/2008
- Regenerated cellulose: Commission directive 2007/42/EC

5.5. Is confirmed that the food contact material is in compliance with the national regulatory framework?

Commentary: if there are no harmonised EU rules applicable, a reference to the regulatory framework of the country where the product shall be placed on the market should be made.

F. e. printing inks in Switzerland: Bedarfsgegenstände-Verordnung: 817.023.21 Abschnitt 8b

5.6. Is confirmed that – provided that the above mentioned declaration is valid – the food contact material is complying with specific industry references that have no legal quality?

Commentary: in the absence of national or EU harmonised rules, sector specific industry references may be used subsidiarily, examples are:

- Paper: Recommendations of the Bundesinstituts für Risikobewertung (BfR): Nr. XXXVI
- Metals and alloys: Technical Document Council of Europe, 13.02.2002

5.7. Is it clearly stated for what the issuer of the declaration does accept responsibility?

Commentary: a declaration of compliance without a clear statement about responsibility is problematic. A declaration must clearly state who is responsible for what.

While rejection of responsibility in the small printed bottom paragraph, such as by stating general disclaimers, is possible, the disclaimer is not the basis for a transparent and confidence-building collaboration between the issuer and the receiver of a declaration of compliance. A tacit acceptance of any declaration with a general disclaimer implies that the receiver accepts full responsibility for the product.

It is recommendable to agree on the scope of responsibility as precise as possible on the basis of a bilateral agreement. This agreement should preferably specify criteria relevant for the field of application of the product (see point 8).

For substances mentioned in the declaration both ways are possible: taking on or delegating of the responsibility. For any substance that is not mentioned the issuer takes on the full responsibility anyway.

Unacceptable disclaimers (criteria of exclusion) are those that make no indication to any substance but reject the responsibility globally.

If the issuer does not take on (= does delegate) responsibility (for a specific substance) this means for the receiver of the declaration that he must exert himself for further clarifications in his own compliance work.

6. Sufficient information about substances applied provided

6.1. Does the issuer provide sufficient information about substances applied with no restrictions?

Commentary: indications following the format underneath would facilitate the transfer of information.

CAS No.	name of substance	criteria for purity

By the term „sufficient“ is understood that all necessary information is provided in order that the receiver is enabled to perform his own compliance work.

The limits for allowable migration of any substance with no specific migration limit (SML) for plastic materials (and in case of Switzerland for silicones as well) are defined by the threshold value of global migrate.

Example: Antioxidants Irgafos 168 (CAS 31570-04-4 - Tris(2,4-di-tert-butylphenyl) phosphide - listed in EU 10/2011, but no SML defined.

There are often decomposition products: f. e. 2,4-di-tert-butylphenol (CAS: 96-76-4) (not listed in EU 10/2011) as decomposition product of Irgafos 168

If substances with no SML are not listed it is mostly impossible to allocate decomposition products with the potential to migrate to original substances.

6.2. Is unequivocal information concerning substances with specific migration limits available?

Commentary: the denomination of all substances with specific migration limits is required (provision of sufficient information). A renouncement of mentioning substances (or a single substance) means that the issuer takes on full responsibility.

For every food contact material and for every substances evidence must be given whether the issuer of the declaration has made tests (analysis, modelling, worst-case calculations) by himself. If such tests are available the receiver may exclude these substances from further risk analysis. Consequently, it is understood that the issuer takes on full responsibility for any substance he did not delegate responsibility.

A delegation must be made for a single substance, the format being given in the blueprint underneath.

CAS No.	name of substance	restrictions (such as SML or any other limit applied)	delegation
			☐

If f. e. based on one’s own tests (analysis, modelling, worst-case calculations) a transgression of the restriction can be excluded a delegation would be unnecessary. Abstinence from delegation would minimise unnecessary costs. A documentation about these tests must be

available and is part of the supporting documentation. Whether these documents will be revealed to the customer is a matter of bilateral agreement between issuer and receiver. In any case public authorities have the right to get access to these supporting documents.

6.3. Are any indications concerning NIAS (non intentionally added substances) available?

Commentary: indication in the following format would facilitate the information transfer.

CAS No	Name of substance

A declaration should give evidence whether the issuer has made some research/fact finding about NIAS (non intentionally added substances such as decomposition or reaction products) and preferably gone through the evaluation process as far a possible.

6.4. Are any indication in the declaration in case set-off is possible?

Commentary: set-off is defined as the transfer of substances from the outer side of food contact material to the inner side of the material that is in direct contact with the food. In case the food contact material will be delivered or stocked in reels or in stapled sheets, further indications and/or explanations are expected.

Are there any indications mentioned concerning substances that could migrate as consequence of a set-off process from the food contact side of the packaging.

7. Indication concerning dual-use additives

7.1. Are there any indications concerning dual-use additives?

Commentary: indication is mandatory in case the food contact material is regulated by EU 10/2011, for all other materials indications are desirable and welcomed.

For the time being there is no definitive list of dual-use additives. The EU ordinance on additive substances 1129/2011 may serve as an auxiliary tool meantime.

8. Specifications regarding the utilisation of the food contact material

8.1. Does the declaration make any statement as to what type or classes of foodstuff the food contact material may get into contact with?

Commentary: indication is mandatory in case the food contact material is subject to EU 10/2011. But as a basic rule every declaration should make reference to a specification, independent of the material in use. Specifications are useful to restrict and narrow down the application of the food contact material and the responsibility related to this application. Should the receiver wish to deviate from these specifications he is bound to accept the responsibility and commission further clarifications. In case the receiver has issued specifications that are not compatible with the general specifications issued by the issuer of the declaration (f. e. separate specifications for packaging and/or foodstuff), further comments taking into account these specifications are expected.

8.2. Does the declaration make any statement about duration and temperature during treatment and storage in case of food contact?

Commentary: see 8.1.

8.3. Are there any indications available that take into account the relation of surface of the food contact material and the volume of foodstuff affected, based on which compliance of the material or the product might be assessed?

Commentary: indication is mandatory in case the food contact material is subject to EU 10/2011. For all other materials indications are desirable and welcomed.

8.4. Are conditions for the storage of the food contact material indicated?

Commentary: explanations are necessary especially in cases where materials have been used that are subject to deterioration during storage.

8.5. In case there are prescriptions for the restriction of application fields are these remarks unequivocal?

Commentary: as an example for unequivocal restriction of application may serve: „not to be used for fatty food".

An obligatory remark must be made in case a food contact material is only applicable in combination with a barrier (such as advertising the product as „only fit for indirect food contact“).

9. Indications concerning the application of functional barrier materials

9.1. Is there any conformation available that a functional barrier is effective in case a multilayer material with barrier function is applied?

Commentary: each layer in a multilayer material or product must be compatible with the prescriptions in EU 10/2011.

A deviation from the principle is only allowed in case a plastic material layer does not have direct contact with the food and is separated by a functional barrier. Under these circumstances the plastic material may be produced out of substances that are not part of the EU regulation list or the preliminary directory.

10. Date and signature

10.1. Is the document signed with a legally valid signature?

Commentary: legally valid means in this context that the signatory must be legally entitled according to the authorization list of his company. Declarations without signature are invalid and not accepted for further evaluation.

10.2. Is the function of the signatory indicated?

10.3. Has the document been signed by the receiver?

Commentary: a countersignature is not compelling (i.e. it is part of the agreement between issuer and receiver). A countersignature might be favorable especially in cases of critical combinations of food and packaging, just to underline the mutual responsibility. It will be a guarantee for the issuer too.

11. Indications relating to any compliance work done already

11.1. Are there any indications available regarding compliance work done already?

Commentary: just from the legal perspective there is no need to expose compliance work already done. However, such information will certainly build up confidence in the partnership between issuer and receiver.

It should be possible to derive from the declaration information on what has been done already to gather the essential knowledge in preparing the declaration.

11.2. Are there any indications as to documents available with further information?

Commentary: such documents with further information could be statements of sub-suppliers or statements of innocuousness, expertise and records of analytical tests. These documents do not form part of the declaration but will be part of the supporting documents. In case such documents will be revealed to the receiver, this preferably will be topic of a separate agreement.

11.3. In case there are links mentioned to third-party documents, are there any indications who that might be and what kind of documents they are?

Commentary: it should be possible to establish a reference between food contact material and further third party documents (such as expertise, analytical tests). In case of analytical tests it might be helpful to indicate the type of test and the name of the laboratory.