How Metal Can Coatings intended to come into contact with Food in Europe Comply with Art. 3 of Regulation (EC) 1935/2004 and other relevant food contact regulations

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1. Introduction

1.1. Description of metal packaging coatings for food contact applications

ORGANIC COATINGS FOR RIGID METAL PACKAGING, PAILS AND DRUMS[1] :

Organic coatings are mainly prepared from one or more predominantly organic substances (raw materials), which in their finished state do not form a self-supporting layer or film, but when applied onto a substrate form a partial or an integral layer, which has certain intended technological effects in the material or article.

Organic coatings are typically applied in a liquid (solution or dispersion) or powder state and need to dry, cure or solidify to reach their finished state.

With few exceptions, organic coatings for rigid metal food packaging are transformed into the food contact layer at elevated temperatures.
Most organic coatings for rigid metal packaging are thermoset in nature, although some primarily thermoplastic ones are used.
Organic coatings can be applied to the fabricated rigid metal packaging article or most likely at some stage during the manufacture of the rigid metal packaging article.
For example, they can be used on Beer and beverage cans and ends, Food cans and ends, Drums and pails, Aerosol containers, tubes and Caps and closures (e.g. lids on glass jars and bottle tops) [2]

Inorganic coatings, largely based on inorganic materials including metals and oxides, are excluded from this definition as they are not used for the same applications as organic coatings.
Further details are available in the ILSI Monograph on Metal Packaging for Foodstuffs[3].

1.2. Compliance work and legal framework

1.2.1. Legal framework

Metal packaging for foodstuff falls under the scope of framework Regulation (EC) 1935/2004 on materials and articles intended to come into contact with food and Regulation (EC) 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food. Both Regulations are part of EU food law.
Any material or article intended to come into contact with food according to Art. 3 of Regulation (EC) 1935/2004 has to be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

a) endanger human health or
b) bring about an unacceptable change in the composition of the food or
c) bring about a deterioration in the organoleptic characteristics thereof.

[1] Source: TSC34[10]
[2] Description of metal packagings in "MPE FC WG - How Metal Packaging Manufacturers in Europe Comply with Art 3 Reg (EC) No 1935/2004"
[3] ILSI Monograph on Metal Packaging for Foodstuffs

The framework Regulation (EC) 1935/2004, being generic by nature, doesn't specify how compliance should be achieved for metal packaging coatings. At EU level, there is currently no specific harmonized legal measure on metal packaging coatings intended to come into contact with food. Some EU countries have national regulations which apply in addition to Regulation (EC) 1935/2004. In order to demonstrate compliance with the framework requirements for coatings for metal packaging at EU level, those national regulations can be used.

To date, EU Food contact compliance of coatings intended to come into contact with Food is determined according to following rules:

- Regulation (EC) 1935/2004
- Commission Regulation (EC) 2023/2006 on good manufacturing practice
- Commission Regulation (EC) 1895/2005 [Epoxy][4]
- Commission Regulation (EU) 2018/213 [BPA][5]
- Commission Regulation (EU) 10/2011 for specific substances (eg: metals, Primary Aromatic Amines, Vinyl Chloride Monomer)
- EU Member States National regulations on Coatings, where relevant:
    - The Netherlands: Dutch Warenwet, Chapter X Deklagen and framework Chapter 0[6]
    - Belgium: Arrêté Royal concernant les Vernis et Revêtements Destinés à Entrer en Contact avec les Denrées Alimentaires, 25.09.2016
    - Spain: Real Decreto 847/2011, de 17 de junio, por el que se establece la lista positiva de sustancias permitidas para la fabricación de materiales poliméricos destinados a entrar en contacto con los alimentos
    - Italy: Decreto Ministeriale del 21/03/1973 , Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale (and amendments)

1.2.2. Demonstration of Compliance with Framework Regulation

It is the responsibility of the coating manufacturer to ensure compliance of their coatings with relevant legal requirements for their position in the supply chain (see Annex 1 for flowchart of overview of supply chain).
Food contact coatings take on their properties once correctly applied and cured on the metal packaging. Consequently, compliance work for metal packaging is the achievement of joint efforts of a complex supply chain and the different actors in this supply chain have a shared due diligence.
Coating manufacturers rely on the responsible compliance work and transparent communication of their suppliers as well as on sufficient information provided by downstream users.
The following can be used to demonstrate compliance with Framework Regulation (EU) 1935/2004 and ensure the safety of the coatings:

- Commission Regulation (EU) 10/2011 and amendments [Plastics]. Whilst intended to regulate plastics, some parts can help demonstrate compliance for coatings.
- Member States measures on coatings
- Framework Resolution ResAP(2004)1[7] on coatings intended to come into contact with foodstuffs

[4] Commission Regulation (EC) 1895/2005 limits the migration of BADGE and its reaction products and bans the use of BFDGE and NOGE in food contact materials.
[5] With Commission Regulation (EU) 2018/213 the use of Bisphenol A in plastic food contact materials as well as in food contact coatings is limited according to the latest toxicological evaluation of the substance.
[6] Under revision
[7] Published by the Council of Europe (CoE) (Vers. 3, 2009).

- Due to the absence of EU-wide specific legislation, industry developed its own guidelines for its members. These include CEPE Code of Practice[8] (food contact compliance demonstration), TSC33 (NIAS)[9] and TSC34 (migration)[10] reports.

1.2.3. Risk Assessment/Risk Management principles

Risk assessments and risk management measures that are developed as part of the compliance work for metal packaging intended to come into contact with food are in accordance with internationally recognized scientific principles.
Risk assessments and determination of risk management measures shall be required for all migrating substances.

1.2.4. Technical information provided through professional organizations

As part of due diligence, Coating manufacturers have the responsibility to update themselves on evolving regulations.
Coating manufacturers have access to information concerning the latest technical and legal developments through their professional organizations, in particular through CEPE (European Council of the Paint, Printing Ink and Artists' Colours Industry) and its Can sector group. Professional organizations stay in close contact with legislators and enforcement authorities and are involved in the consultation on legislative initiatives at a European and national level. Through CEPE, coating manufacturers in Europe participate in technical working groups which cover the whole value chain from raw material suppliers to food packers. CEPE was a founding member of the Technical Joint Industry Group (T-JIG[11]) and the Cross-Sector Group[12].
The following national coating industry associations are members of CEPE and usually have their own national food contact working groups:

- France: FIPEC
- Germany: VdL
- Italy: Assovernici, Federchimica AVISA
- United Kingdom: BCF
- Spain: Asefapi
- The Netherlands: VVVF
- Switzerland: VSLF

To date, the following specific technical information has been developed by CEPE and/or T-JIG and is available for all coating manufacturers:

- CEPE Code of Practice
- NIAS guidelines - TSC33 [9]
- Migration guidelines - TSC34 [10]
- CEPE GMP [13]

[8] As the result of the work of a technical subcommittee of the Joint Industry Group (T-JIG) the professional organisation of the European coatings industry CEPE has published a Code of Practice for Coated Articles where the Food Contact Layer is a Coating, Ed. 4 (2009), which is being updated.
[9] TSC33 NIAS guidelines for coated rigid metal packaging intended for direct food contact - version 1.7.5 - May 2019
[10] TSC34 Migration Testing Guidelines for Rigid Metal Packaging Coated with Organic Coatings Intended for Direct Food Contact for Discussion with Member States and JRC - Version 6.3 - 10 October 2017.
[11] T-JIG: The Technical Joint Industry Group is a working taskforce formed between industry members and associations of manufacturers involved along the coated metal packaging supply chain. Membership of T-JIG is given in Annex 2.
[12] Group formed with all voluntary european associations and industry members in the field of food contact packaging and articles. Membership of the Cross sector group are given in Annex 3.
[13] Code of Practice for Coated Articles where the Food Contact Layer is a Coatings - Annex X(a) : Good Manufacturing Practices (GMP) Food Contact Coatings - September 2010.

1.3. Scope

It is the scope of this report to document the background and current common practices of the European metal packaging coating industry to demonstrate compliance of coatings intended to come into contact with food with the requirements of the framework legislation and in particular with Art. 3 of Regulation (EC) No 1935/2004.

While Art. 3 of the Framework Regulation (EC) No 1935/2004 explains that Industry needs to demonstrate safety of the FCMs put on the market (see §1.2.1) it doesn't specify how to demonstrate safety. Therefore, the metal packaging industry and its supply chain have developed common principles for compliance work. This document demonstrates the common practice of compliance work of the European coating industry for metal packaging.

2. Good Manufacturing Practice

In Europe, coatings for metal packaging are manufactured according to Good Manufacturing Practice (GMP) principles. Regulation (EC) No 2023/2006 is applicable to the manufacturing of coatings for metal packaging intended to come into contact with food.

Coating manufacturers produces according to Good Manufacturing Practices as described below:

a) Commission Regulation (EC) 2023/2006
b) CEPE GMP of 2010[14]

Coating manufacturers have the responsibility to

1. supply according to agreed specifications;
2. comply with relevant food contact regulations;
3. supply Declarations of Compliance; and
4. comply with chemical laws/acts (REACH, and others like TSCA, China IECSC where appropriate)

[14] under revision

3. Material Supply

3.1. Requirements applicable to all Raw materials

3.1.1. Legal requirements and standards

Unless exempt (eg. Polymers), substances have to be registered at ECHA under REACH regulation.

Producers have the responsibility to follow GMP.
For raw materials, which are outside the scope of GMP, constant quality should be ensured by the manufacturer, in order to allow the RA/RM to be valid for every batch.

Specifications need to be agreed between supplier and customer.

3.1.2. Compliance testing and Risk Assessment / Risk Management

The materials need to comply with specifications and any relevant food contact legislation.

3.1.3. Documentation provided to supplier (Documentation upstream):

To allow the producer to establish the information described above, the following information is given by the coating producer to their supplier:

- Information that it is used in food contact;
- which legislation(s) applies; and
- whether there any specification requirements (e.g. purity).

3.2. Resins / intermediates / Pre-polymers (NOTE: prepolymers are reactive polymers or crosslinkers i.e reactive during coating film formation)

3.2.1. Definitions

Resin[15]: describes families of polymers / prepolymers. e.g. phenolic resins, epoxy resins, vinyl resins, polyester resins etc. used as components of coatings.
Intermediate and Pre-polymer [16]: A polymer of relatively low molecular weight, usually an intermediate between the monomer and the final polymer or resin
Crosslinker: refers to a reactive resin which will chemically react with the main resin(s) during coating cure. The role of the crosslinker is to give to the coatings their protective and performance properties.

3.2.2. Legal requirements and standards

Substances which are listed in the following legislation / documents may be used in the manufacture of resins as long as attention is paid to any specification or restrictions associated with the substances or materials.

- Commission Regulation (EU) 10/2011 and its amendments,
- EU Member States National regulations on Coatings, for example Dutch Warenwet, Belgian, Italian, Spanish
- CoE Resolution ResAP(2004)1 on Coatings
- CoE Resolution ResAP92(2) on Polymerization Aids
- CEPE CoP
- US FDA CFR 21 Part 170 to 199[17]

3.2.3. Documentation provided by supplier

- Food Contact information [FCIS - Food Contact Information Sheet is requested under Food law[18]]
- Regulatory datasheet (compliance and/or non-compliance information), [RDS - Regulatory Datasheet is requested under Chemical law]
- Specifications,
- Technical Data Sheet,
- Safety Data Sheet,
- Disclosure of known relevant regulated and restricted monomers and other starting substances - Disclosure of composition can be done under Confidentiality agreements downstream or through third parties.

The supporting documentation (Internal) which are available to support the compliance evaluation comprise:

- Analysis,
- Risk Assessment,
- toxicological data,
- documents to support control according to framework regulation

[this is provided by supplier to competent authorities upon request]

[15] Resins are further described in Annex IV of CEPE CoP.
[16] Union Guidelines on Commission Regulation (EU) 10/2011.
[17] While US FDA doesn't apply in Europe, it is considered as a useful information regarding safety of starting substance for food contact. Generally, in the absence of EU or MS positive lists, Industry self-determination can be used, including information from outside of EU to gather as much information as possible.
[18] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31 p. 1–24.

3.3. Additives

3.3.1. Definitions

Additive[19]: A substance which is incorporated into coatings for direct food contact to achieve a technical effect in the finished material or article; it is intended to be present in the final material or article.
Only non-reactive additives are covered in this section. Reactive additives (incl. pre-polymers) are covered in 3.2.

3.3.2. Legal requirements and standards

Food Contact compliance is generally determined by following the FCA guidelines[20]. In particular, the section about "how to carry out risk assessment" is followed for materials not listed on the plastic positive list (Regulation (EU) No 10/2011).

When the additive is supplied to the plastic industry as well, it complies with Commission Regulation (EU) 10/2011, so in that case, Commission Regulation (EU) 10/2011 is used for the metal packaging sector.

If not listed on Commission Regulation (EU) 10/2011, Additives have to be listed in at least:

- one EU Member States National regulations on Coatings, for example Dutch Warenwet, Belgian, Italian, Spanish;
- the CoE Resolution on Coatings ResAP(2004)1;
- the CEPE CoP; or
- US FDA CFR 21 Part 170 to 199 [17]

3.3.3. Documentation provided by supplier

- *Food Contact information [FCIS - Food Contact Information Sheet is requested under Food law]*
- *Regulatory datasheet (compliance and/or non-compliance information), [RDS - Regulatory Datasheet is requested under Chemical law]*
- *Specifications,*
- *TDS,*
- *SDS,*
- *Disclosure of known relevant regulated and restricted monomers and other starting substances - Disclosure of composition can be done under a Confidentiality agreement downstream or through third parties.*

The supporting documentation (Internal) which is available to support the compliance evaluation comprises:

- documents required for REACH (REACh registration number, tox information)
- Impurities assessment according to FCA guidelines [20]
- Internal Specifications (eg: recipe)
- dossier for petitions (when used in plastics)

For additives (including polymeric) for non-plastics, Risk Management measures have to be communicated (eg: Specific Migration Limits, Tolerable Daily Intake…).
[this is provided by supplier to competent authorities upon request]

[19] CEPE CoP.

[20] "Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under the requirements of Article 3 of the Framework Regulation (EC) 1935/2004", edition 3.0, september 2020.

3.4. Pigments and fillers

3.4.1. Definitions

Pigment and Filler: inorganic particles which are incorporated into coatings for direct food contact to achieve a technical effect (modify the color in the case of pigments) of the finished material or article; it is intended to be present in the final material or article.

3.4.2. Legal requirements and standards

Determine on which of the following lists the substance(s) is(are) listed:

- Commission Regulation (EU) 10/2011,
- EU Member States National regulations on Coatings, for example Dutch Warenwet, Belgian, Italian, Spanish
- CoE Resolution on Coatings ResAP(2004)1
- CoE Resolution ResAP(89)1 on the use of colorants in plastic materials coming into contact with food
- French decree for colorants (Décret n° 2007-766 du 10 mai 2007)
- CEPE CoP
- US FDA CFR 21 Part 170 to 199 [17]

3.4.3. Documentation provided by supplier

- Food Contact information [FCIS - Food Contact Information Sheet is requested under Food law]
- Regulatory datasheet (compliance and/or non-compliance information), [RDS - Regulatory Datasheet is requested under Chemical law]
- Specifications,
- TDS,
- SDS,
- Disclosure of known relevant regulated and restricted monomers and other starting substances - Disclosure of composition can be done under a Confidentiality agreement downstream or through a third party.

The supporting documentation (Internal) which is available to support the compliance evaluation comprises:

- Analysis,
- Risk Assessment,
- toxicological data,
- any other evidence of compliance with framework regulation

[this is provided by supplier to competent authorities under request]

3.5. Monomers and starting substances (reacted during coating's fabrication)

3.5.1. Definitions

Monomer or other starting substance[21]:

- a substance undergoing any type of polymerisation process to manufacture polymers; or
- a natural or synthetic macromolecular substance used in the manufacture of modified macromolecules; or
- a substance used to modify existing natural or synthetic macromolecules

3.5.2. Legal requirements and standards

It is determined on which of the following lists the substance(s) is(are) listed:

- Commission Regulation (EU) 10/2011,
- EU Member States National regulations on Coatings, for example Dutch Warenwet, Belgian, Italian, Spanish
- CoE Resolution on Coatings ResAP(2004)1
- CEPE CoP
- US FDA CFR 21 Part 170 to 199 [17]

3.5.3. Documentation provided by supplier

- Food Contact information [FCIS - Food Contact Information Sheet is requested under Food law]
- Regulatory datasheet (compliance and/or non-compliance information), [RDS - Regulatory Datasheet is requested under Chemical law]
- Specifications,
- TDS,
- SDS,
- Disclosure of known relevant regulated and restricted monomers and other starting substances - Disclosure of composition can be done under Confidentiality agreements downstream or through third parties.

The supporting documentation (Internal) which is available to support the compliance evaluation comprises:

- Analysis,
- Risk Assessment,
- toxicological data,
- documents to support control according to framework regulation

[this is provided by supplier to competent authorities upon request]

[21] Commission Regulation (EU) 10/2011, (Art 3(6)+(7)).

3.6. Solvents

3.6.1. Definitions

"Organic solvents": processing aids, used in the formulation of many coatings to enable them to be applied to the substrate.
In the case of light metal packaging organic solvents evaporate during the curing process, generally performed at high temperatures (i.e. ~ 200°C) and are therefore not expected to remain in the final layer of coating in contact with foods.
It is the responsibility of the converter to ensure that any residual solvent limits are met.

3.6.2. Legal requirements and standards

Because solvents are usually not intended to remain in the final layer of coating in contact with foods, as stated in 3.6.1, they are in general not listed. If listed with restrictions, appropriate information needs to be communicated as stated in 3.6.3.

3.6.3. Documentation provided by supplier

- Regulatory datasheet (compliance and/or non-compliance information), [RDS - Regulatory Datasheet is requested under Chemical law]
- Specifications,
- TDS,
- SDS,

The supporting documentation (Internal) which is available to support the compliance evaluation comprises:

- Analysis,
- Risk Assessment,
- toxicological data,
- documents to support control according to framework regulation

[this is provided by supplier to competent authorities under request]

4. Compliance testing for metal packaging coatings

4.1. Coatings as supplied

Coatings are tested to demonstrate

a) accordance with Specification
b) compliance with food contact requirements/legislation.

Compliance testing is typically carried out on cured coatings, lab applied on a representative substrate and lab cured according to TDS, and tested for all intended foodstuffs (acidic, alcoholic, aqueous, fatty and dry) following TSC33 and TSC34 guidelines.

Coatings follow principles and guidelines in the CEPE CoP.

Compliance testing for the food contact requirements of food contact coatings is usually initiated by the coating manufacturers and often carried out by independent 3rd parties such as institutes, academia or contract laboratories.
The compliance assessment usually includes the following steps:

- Evaluation of the composition for legal status and/or available public risk management measures for all starting substances of the coating
- Overall migration tests
- Specific migration tests and/or tests for residual monomer content
- Organoleptic tests according to the procedures described in German standard DIN 10 955
- Evaluation of the results with regard to legal compliance of the coating under conditions of intended application

In order to assess the suitability for food contact, it is necessary to obtain the compositional data. Much of these data are confidential or proprietary information of the raw material suppliers or their suppliers. In order to allow the compliance work to be done with full relevant information on the material to evaluate, and maintain confidentiality, an independent laboratory can be contracted as a third party; all the data are submitted to them by the owner(s) of the proprietary information under confidentiality or non-disclosure agreements .

For each starting substance, the status with regard to a risk assessment according to EFSA or national requirements is checked. If substances are listed as permitted starting substances for plastics intended to come into contact with food according to Commission Regulation (EU) 10/2011 the risk management measure (e.g. SML) established for plastics is simply adopted for the coating (unless specific restriction on food contact material type). This would also apply for risk management measures according to national legislation of EU member states if the measures are established on the basis of EFSA equivalent principles. If no adoptable risk management measure for a starting substance is available, a risk assessment according to EFSA principles has to be carried out unless the no migration principle can be used: i.e. substance not CMR 1&2, not nanoform and non-detectable migration (currently < 10 µg/kg food).

Specific migration tests are superfluous if, based on quantitative composition data or the results of total extraction tests and the worst case assumption of a total migration of the substance, it can be demonstrated by calculation that the specific migration limit (SML) will not be exceeded.
Migration testing and organoleptic tests for food contact coatings are carried out on coated metal plate. The coating is usually applied according to the Technical Data Sheet (TDS) under laboratory conditions which should reflect the worst case of industrial application conditions when ranges are provided (i.e. highest film weight and lowest curing conditions on TDS).

The principles for migration testing for rigid metal packaging coated with organic coatings intended for direct food contact as well as factors which limit the applicability of migration testing procedures established for plastic when used for rigid metal packaging and organic coatings are laid down in T-JIG TSC 34 Migration Testing Guidelines (2017)[10].

As an additional element of compliance work for coated rigid metal packaging for some resinous coatings a screening for non-intentionally added substances (NIAS) is carried out. There are currently no standardized procedures established, and therefore the testing strategy and principles of evaluation may differ for different contract laboratories and according to customer demands. It is therefore difficult to compare results of different NIAS screening assessments. T-JIG has established TSC33 NIAS Guidelines for Coated Rigid Metal Packaging Intended for Direct Food Contact. The guidelines describe the state of the art at the time of writing for NIAS screenings of coated rigid metal packaging and food contact coatings. There is currently a constant and rapid improvement of analytical techniques[22] and varying opinions regarding toxicological evaluation used for NIAS screenings[23].

5. Risk Assessment/Risk Management

The risk of a substance is a function of hazard and exposure. Therefore, both should be evaluated as part of risk assessment and risk management.
IAS are risk assessed using accepted EFSA/national SMLs or internationally recognized toxicological approaches (eg QSAR, TTC[24]) and migration testing.
The TSC33 NIAS Guidelines[9] describe in more detail how to carry out risk assessment or risk management specifically for NIAS.

6. Documentation

6.1. Specifications for Coatings as supplied

Specifications are defined in agreement between supplier and customer.

6.2. Declaration of compliance DoC

The Declaration of Compliance is usually written in 2 parts, Part A generally available and Part B being shared under confidentiality agreement to specific individuals in the customers' business.
A model DoC is available in the CEPE CoP.

DoCs of Coating manufacturers typically contain:

- Name and address of the company which manufactures or imports the coating
- Trade Name
- Identity of the coatings
- Date of the declaration of compliance
- The confirmation that the coating, applied and cured under the conditions stated in the TDS, complies with the requirements of appropriate EU Regulations and, when appropriate, of national law(s) under the conditions of intentional use.

[22] Forthcoming ILSI publication on "best practices for identifying and quantifying unknown migrants from food contact materials".
[23] ILSI Bioassays paper: Benoit Schilter, Karin Burnett, Chantra Eskes, Lucie Geurts, Mélanie Jacquet, Christian Kirchnawy, Peter Oldring, Gabriele Pieper, Elisabeth Pinter, Manfred Tacker, Heinz Traussnig, Peter Van Herwijnen & Alan Boobis (2019) Value and limitation of in vitro bioassays to support the application of the threshold of toxicological concern to prioritise unidentified chemicals in food contact materials, Food Additives & Contaminants: Part A, 36:12, 1903-1936, DOI: 10.1080/19440049.2019.1664772.
[24] Barlow and al. publication on TTC, ILSI, 2005.

- Adequate information relative to the substances used for which specific restrictions are in place under relevant EU or national legislation to allow the downstream user to ensure compliance with those restrictions and list of substances used for which an SML or other restrictions are established.
- Specifications and limitations on the use of the coated material such as
    - Suitability for type or types of food
    - time and temperature of maximum treatment and storage of the filled metal packaging
    - surface/volume(mass) ratio used for compliance assessment
- A statement whether or not substances which are also dual use additives[25] are intentionally used

Some information, e.g. the chemical identity of substances for which restrictions are in place may be subject to confidentiality agreements. In this case the coating manufacturer can provide anonymized information.
Declarations of compliance are usually replaced or amended on demand if relevant legal requirements have been amended, or new scientific knowledge has been found which is relevant to the legal compliance of the coating.

6.3. Supporting documentation (available for competent authorities on request)

The supporting documentation (Internal) which is available to support the compliance evaluation can comprise:

- documents from suppliers showing compliance with the relevant legislation,
- TDS,
- Specifications,
- test results (to be within individual product specification),
- analytical results,
- Food Contact Approval,
- DoC,
- Third Party Compliance certificate and test reports,
- Use of no-migration principles
- Risk Assessment and Risk Management measures,
- Risk assessment documentation for starting substances for which restrictions have to be complied with
- Reasoning for the selection of migration testing
- Migration (overall and specific) testing reports and reports on organoleptic tests
- NIAS screening and evaluation with risk assessment
- Results of tests for potential cross contamination (e.g. curing oven, set-off of printing ink components)

Supporting documentation is not accessible for customers on a regular basis because it usually contains multiple confidential data. The set of supporting documentation is available to competent authorities on demand.

It has to be noted that in test reports and compliance certificates issued by independent contract laboratories some information, in particular the chemical identity of some starting substances, may remain anonymized if it is confidential to one of the raw material suppliers.

7. Communication with down-stream users

7.1. Information required from down-stream users (from can makers)

Downstream information:
To permit the coating producer to establish and provide the information described above, the following information is typically received by the coating producer from their customer on end uses:

- food contact applications,
- type of packaging,

[25] Food additives which can also be used as starting substances in food contact coatings (Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives [2008] OJ L354, p. 16–33).

- type of foodstuff (eg: acidic, fatty),
- process conditions

7.2. Information provided for down-stream users (to can makers)

Documentation downstream:
The following information is typically given by coating producer to their customer:

- DoC PartA (and Part B under a confidentiality agreement)
- Regulatory datasheet
- TDS
- SDS
- Specifications
- Migration testing report/certificate/food contact assessment by 3rd party institute (often under a confidentiality agreement)
- other regulatory information for example inventory listing (e.g. TSCA letter)

8. Cooperation with Competent Authorities

On request, Coating manufacturers shall supply supporting documentation to Competent Authorities.
Coating manufacturers in Europe offer full cooperation with competent authorities to enable authorities to adequately enforce the legal framework requirements for materials and articles intended to come into contact with food. This cooperation regards access to the entire supporting documentation as well as explanations of technical details of metal packaging manufacture and background of chemical and physical interaction of foodstuffs with different types of metal packaging.
Mainly through their national and European professional associations, coating manufacturers also cooperate with national and EU authorities in order to support the development of adequate specific and framework legislation for metal packaging and coatings intended to come into contact with food by providing technical information, participation in expert working groups and commenting on draft legislation.

Annex (to be completed)

Annex 1: Flowchart of overview of supply chain

Annex 2: Membership of T-JIG

Annex 3: Participants of the Cross sector group