



Information

on Requirements regarding Pigments and Fillers detailed in Guidelines and Laws for Food Contact Materials

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Please note:

The information in this publication is based on the current state of knowledge. It does not exempt users from carrying out their own checks and inquiries. A legally binding assurance cannot be derived from this information! Manufacturers and users are responsible for checking and complying with any industrial property rights as well as existing laws and regulations or amendments thereto.

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Introduction

Legal regulations on commodities, or on goods that may come into contact with foodstuffs, are ultimately always regulations on consumer protection. Here, the protection of human health comes first, even before the protection of consumers against deception. Objects that come into contact with food should ideally not cause any negative change in the appearance, taste, aroma or other enriching properties of the food. To ensure this, the foreseeable and intended application scenarios must be taken into account. Ideally, the aim should be to make sure that no substances at all migrate from the packaging into the food. This is known as the “non-migration principle”. However, should such migration nevertheless take place, this should be a minimum amount that is at a toxicologically acceptable level. The magnitude of such specific migration limits (SML) lies in the trace range and they are therefore expressed in parts per million (ppm), i.e. milligrams of substance per kg of food.

This summary from the Technical Commission for Pigments provides an overview of European and international regulations for pigments and fillers used in food contact materials. The focus is on the regulatory areas for plastics, paper/paperboard, ceramics, glass, coatings, printing inks and elastomers/rubber. It should be noted here that specific regulations, e.g. for the use of substances in food contact materials made of plastic, are also expressly regarded as an overarching standard or drawn upon for toxicological assessment, as they deal in great detail with the evaluation of substances.

European Regulations

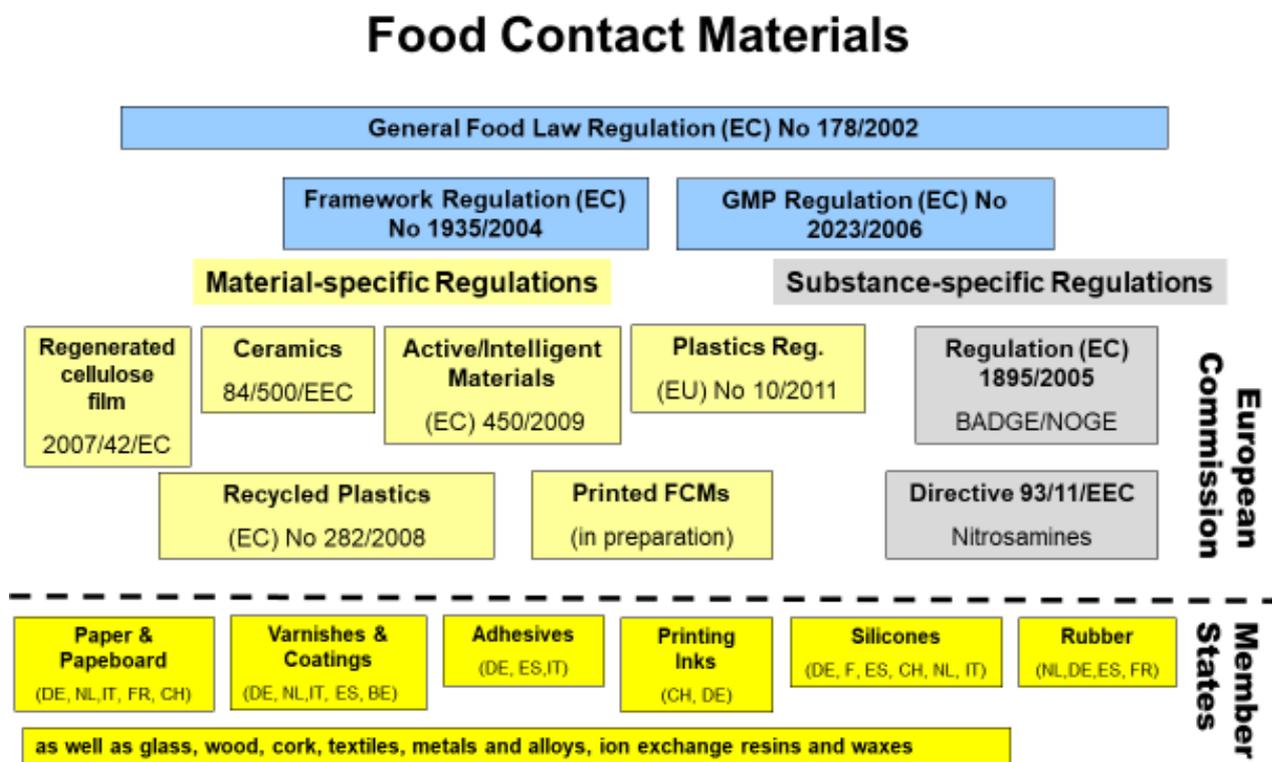


Fig. 1: Overview of European Regulations on commodities

Overview of Regulatory Scope

Within the EU, there is no comprehensive set of rules for all commodities, such as exists in Germany, for instance, via the Food, Commodity and Feed Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch – LFGB). In principle, commodities are “used”, but not “used up” in the way that food or cosmetics are, for example. Thus, commodities are a subgroup of consumer products and are subject to the EU General Product Safety Directive (2001/95/EC). Therefore, each Member State has the possibility to implement the Directive separately. For Germany, this was achieved in the Product Safety Act (Produktsicherheitsgesetz).

Since the establishment of the European Union, work has been underway to harmonise common legislation. As this harmonisation process is time-consuming, some areas have continued to develop in parallel at Member State level. As things stand today, commodities are regulated by uniform EU Regulations, by EU Directives with national implementation or purely by means of national provisions. For food contact materials, the JRC report “*Non-harmonised food contact materials in the EU: regulatory and market situation*” from 2016 summarises the complex situation.

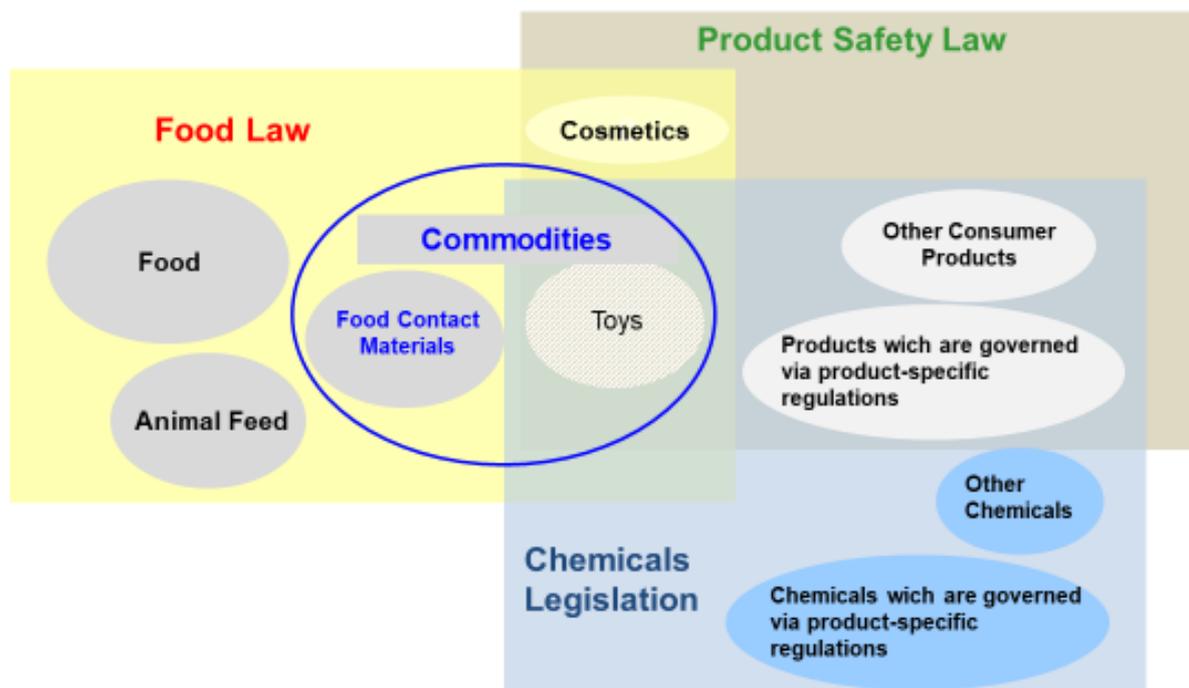


Fig 2: Overlapping legal areas for consumer products (example: Germany)

Among consumer products, commodities for direct human use have a distinctive status, as they are addressed by separate sets of rules:

- Food Contact Materials (Regulation (EC) No 1935/2004)
- Packaging of Cosmetic Products (Regulation (EC) No 1223/2009)
- Toys (Directive 2009/48/EC)

EU Regulations on Food Contact

In contrast to EU Directives, EU Regulations do not have to be transposed into national law first. They apply immediately after their entry into force, with a transitional period usually laid down in the text to allow the industries concerned to adapt to the new situation.

Regulation (EC) No 1935/2004

The Framework Regulation (EC) No 1935/2004 “on materials and articles intended to come into contact with food ...” lays down the requirements for this product class (Art. 3) and, at the same time, establishes the manufacturing conditions to be observed in the production plants.¹

The central point of reference for the evaluation of pigments and fillers is Article 3(1)

(1) ...Materials and articles shall 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.*

The raw materials are thus evaluated in terms of their use in the end product. Decisive here is the release (migration) of substances in respect of subpoints (a), (b) and (c) under **normal and foreseeable** conditions. This forms the basis for the approval practice of raw materials with regard to concrete application conditions, such as temperature and pH value. The wording also indicates that **foreseeable misuse** is not the subject of consideration. Raw material manufacturers define the limit of their responsibility via the intended use.

Example – Aluminium Foil:

The packaging of household aluminium foil usually indicates that the material is not suitable for storing acidic foodstuffs.

Ⓧ Aluminium foils are not suitable for covering food in metal containers. Aluminium foils must not come into contact with food containing acid or salt. The foils can dissolve in those cases, but components released into food are harmless to health. Do not use in the microwave.

Fig 3: User information on an aluminium foil packaging

Annex I of the Framework Regulation lists all materials and articles for which individual measures may be adopted. These 17 categories also include the materials considered here:

- Plastics
- Ceramics
- Coatings
- Elastomers and rubber
- Paper and paperboard
- Glass
- Printing ink

Some areas have already been regulated EU-wide. These areas are plastics for food contact, processes for producing recycled plastics, ceramic articles for food contact, nitrosamines and plasticisers in elastomers. A regulation for printed food contact materials is currently under

¹ Regulation (EC) No 2023/2006 “on good manufacturing practice for materials and articles intended to come into contact with food ...”

discussion at EU level, as is a new version of the regulation for ceramic materials and articles intended to come into contact with food.² However, there are still no concrete drafts that can be evaluated by industry. For the supply chain of materials and articles intended to come into contact with food, the Framework Regulation contains a number of obligations. The prescribed issue of a confirmation of compliance with the general conditions (declaration of conformity) and the maintenance of suitable documentation have far-reaching consequences. The obligation to trace the materials used in the supply chain extends to “all stages of manufacture” and thus also to raw material suppliers, such as manufacturers of pigments and fillers.

Regulation (EC) No 2023/2006 (GMP)



Fig 4: Components of the GMP Regulation

By virtue of its scope, this Regulation is directly linked to Annex I of the Framework Regulation (EC) No 1935/2004. It applies to the materials referred to therein and to combinations of those materials as well as to recycled materials.

Starting substances, such as pigments and fillers, are only indirectly covered by the provision. According to the text of the Regulation, starting substances are not covered by this provision, but the production of them is. For example, the manufacturer of a plastic food packaging must maintain a quality assurance system and select all raw materials in such a way that they comply with the specifications defined in advance.³ For the raw material suppliers, this means that supporting information is available for their customers, and consequently also “GMP-related” documentation.

Plastics: Regulation (EU) No 10/2011

“on plastic materials and articles intended to come into contact with food”

as well as the explanatory Guidance documents:

- Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food;
- Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain;
- JRC Technical Report: Practical guidelines on the application of migration modelling for the estimation of specific migration (2015).

For colorants and fillers used in food contact material made of plastic, the requirements of Article 3 of the Framework Regulation (EC) No 1935/2004 based on a risk assessment

² Status 02/2019

³ 2023/2006 – *Article 2 (Scope)* This Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

according to internationally recognized scientific principles as defined in Article 19 of Regulation (EU) No 10/2011 must be complied with.

Pursuant to Article 5(2)(b) of the Regulation (EU) No 10/2011 “on plastic materials and articles intended to come into contact with food”, colorants, fillers and their components are not classified as additives within the meaning of that Regulation and therefore do not need to be included in the EU list of authorised substances. Article 6(2) of Regulation (EU) No 10/2011 also provides that colorants and fillers may be used in the manufacture of plastic layers in plastic materials and articles subject to national law.

Plastics: Regulation (EU) No 10/2011 – Special case: Dual Use

Regulation (EC) No 1333/2008 refers in its Annex II (EU list of food additives approved for use in foodstuffs, and their conditions of use) to Article 11(3) of the Plastics Regulation (EU) No 10/2011 by also listing some colorants and fillers, classified as chemical substances, as authorised food additives via a common authorisation procedure for food additives, enzymes and flavourings.

The colorants approved for colouring foodstuffs may not be suitable for colouring plastics due to technical reasons. When incorporated into plastics, the colorants used must be stable at temperatures of between 150 and 300 °C and should not decompose during processing of the plastic.⁴

Recycled Plastic as Food Contact Material⁵

This Regulation still refers to Directive 2002/72/EC, the predecessor to Regulation (EU) No 10/2011, but is still in force and is used to regulate food contact materials made of recycled plastic. It mainly deals with suitable recycling processes and the certification thereof. The purity and quality requirements are not set out explicitly, but are dealt with by reference to Article 3 of Regulation (EC) No 1935/2004. This means that there are no defined testing requirements for these goods; instead, proof must be provided that no substances harmful to human health are emitted.

Chemical recycling, production waste from raw materials and materials with a functional barrier are excluded from this Regulation, provided they are manufactured in accordance with GMP and comply with the quality requirements of Directive 2002/72/EC and the successor Regulation (EU) No 10/2011.

Ceramics

Directive 84/500/EEC continues to be in force, although a new version in the form of an EU Regulation has been under preparation since 2012. It includes three categories of ceramic articles which are assessed based on the release of lead and cadmium:

1. Non-fillable and flat articles
2. All other fillable articles
3. Cooking and baking appliances, as well as containers with more than 3 l in volume.

⁴ BfR Recommendation No. IX Colorants for Plastics and other Polymers Used in Commodities, as of 01.02.2015

⁵ Regulation (EC) No 282/2008

Category	Lead	Cadmium
1	0.8 mg/dm ²	0.07 mg/dm ²
2	4.0 mg/l	0.3 mg/l
3	1.5 mg/l	0.1 mg/l

Demands are also indirectly placed on pigments if they contribute to the content of the two elements according to this measurement method.

How the limit values will develop during the course of the revision can only be estimated at present. On the basis of the last draft, the lead and cadmium limit values are to be drastically reduced (Pb 0.01 mg/l and Cd 0.005 mg/l respectively). A correspondingly low limit value for cobalt is also to be introduced. This would reduce the range of available ceramic colours to less than half.

Country	Additional Limit Values
Austria	Ba, Zn, Sb
Netherlands	Ba, As, B, Cr, Co, Hg, Li, Rb, Se, Sr
Norway	Ba
Finland	Cr, Ni

Paper and Paperboard

Currently, at European level, only the publication of the Council of Europe can be cited for this product group. Among the Member States, 11 countries have national regulations in force:

MS	Measure
BE	Arrêté royal du 11 mai 1992
HR	NN125-2009
CZ	Vyhláška č. 38/2001
EE	Käskkiri No. 54 of 09.03.2015
FR	DGCCRF Note d'information 2004/64
	BOCCRF n° 9 du 12 mai 1999
	BOCCRF n°15 du 3 octobre 1996
	BOCCRF n° 16 du 15/12/1995
	BOCCRF n° 20 du 27 octobre 1994
	Instruction 30/11/1987
	L. Circ. du 28 octobre 1980
	L. Circ. du 4/01/1982
	Circulaire du 29 mai 1978
DE	BfR Rec. XXXVI
	BfR Rec. XXXVI/1
	BfR Rec. XXXVI/2
	DE BfR Rec. XXXVI/3
EL	Greek food code (Article 24)
IT	D.M. of 21/03/1973 (and its amendments)
	DPR n.777 23/08/1982 (and its amendment)
NL	Commodities Act (Packagings and Consumer Articles)
PL	Polska Norma PN-P-50430 of 1998
SK	Foodstuffs Code 1799/2003

Glass

Glassware is not regulated uniformly within the EU. The Council of Europe has issued a policy statement on the release of lead from glassware, which is based on the ISO 7086-2 and ISO 6486-2 standards.⁶

Article	Lead Limit Value
Small hollowware	1.5 mg/l
Large hollowware	0.75 mg/l
Very large hollowware	0.5 mg/l
Flatware	0.8 mg/dm ²

The relevant national measures must be taken into account here.

BE	Arrêté royal du 11 mai 1992
BG	Ordinance N° 3 from 4.06.2007
HR	NN125-2009
CZ	Vyhláška č. 38/2001
DK	BEK Nr. 822 of 26/06/2013
FR	DGCCRF Note d'information 2004/64
FR	Arrêté du 15/11/1945
DE	ASU nach §64 LFGB, BVL B 80.03-4:2008-10
IT	D.M. 21/03/1973 (and its amendments)
NL	Commodities Act (Packagings and Consumer Articles)
NO	Regulation 1381-1993
SK	Foodstuffs Code 1799/2003
CH	Ordinanza DFI del 23/11/2005

Coatings

Apart from the Framework Regulation, there are no overarching European regulations in this sector. To evaluate substances, a Council of Europe document is sometimes drawn upon.⁷ This list mainly includes monomers and coating additives.

In addition, national regulations must be consulted for further evaluation.

Printing ink

There are no harmonised regulations within the EU regarding printed food contact materials. In addition to the requirements of the Framework Regulation, reference is made in most cases to the Swiss Ordinance on Materials and Articles.⁸ With over 4500 substances, it covers about 85% of the substances used in printing inks. Of the EU Member States, only France, the Netherlands and Slovakia have regulations in force that affect a further 1% of the substances used. In addition, related regulatory areas such as Directive 2007/42/EC regarding materials and articles made of regenerated cellulose film and Regulation (EU) No 10/2011 are drawn upon for evaluation purposes. Although the Union list is directed at the production of plastics, it does still contain some components from printing inks together with migration limits. The total

⁶ Policy statement concerning lead leaching from glass tableware into foodstuffs, Version 1, 22.9.2004

⁷ CoE policy statement concerning coatings intended to come into contact with foodstuffs, Version 3, 12.2.2009

⁸ EDI Ordinance on Materials and Articles Intended to Come into Contact with Foodstuffs, SR 817.023.21, Section 12: Printing Inks

migration value of 60 mg/kg of food or 10 mg/dm² of contact area is used as the basis for a hazard analysis.

Elastomers and Rubber

The food contact evaluation for this product group is mainly characterised by the possible migration of N-nitrosamines or nitrosatable amines originating from the vulcanisation accelerators used. The only EU-wide regulation on teats and soothers (Directive 93/11/EEC) lays down basic rules for determining the release of this class of substance. In addition, there is a policy statement from the Council of Europe (CoE) concerning rubber products intended to come into contact with foodstuffs. In the packaging sector, elastomers are found at most in seals; large-area applications are reserved for plastic films, which then fall under Regulation (EU) No 10/2011.

Among the Member States with a regulation on rubber goods (CZ, HR, FR, DE, NL and SK), most adopt a categorisation approach similar to that of the Council of Europe.

- (1) Sensitive groups (toddlers, infants)
- (2) Long contact (>24 h or hot)
- (3) Medium contact (10 min - 24 h)
- (4) Short-term contact (<10 min)

Other

Resolutions of the Council of Europe

AP(89) 1 – Purity Requirements for Colorants⁹

The use of colorants is not yet regulated by a dedicated EU Directive or Regulation. In preparation for a common regulation, the Council of Europe adopted Resolution AP(89) 1 containing purity requirements for colorants in plastic materials intended to come into contact with foodstuffs. AP(89) 1 itself has no legal force, but the limit values have since been incorporated into most national provisions. However, it is one of the few regulations that relate directly to the pigment and not to a migration limit with respect to the end product.

AP(89) 1 lists the maximum contents of the following metals and metalloids soluble in 0.1M of hydrochloric acid:

Sb :	0.05 %	Cr :	0.1 %
As :	0.01 %	Pb:	0.01 %
Ba:	0.01 %	Hg:	0.005 %
Cd:	0.01%	Se:	0.01 %

⁹ AP(89) 1: On the use of colorants in plastic materials coming into contact with food, 13.09.1989

Other limit values:

Aromatic amines:	500mg/kg
Sulphonated aromatic amines:	500 mg /kg
Carbon black: Toluene extract:	<0.15%
Polychlorinated biphenyls:	extractable PCBs <25 mg/kg
Inorganic Cd pigments:	no use, only in justified exceptions

ResAp (2002) 1: Paper and Board Materials in Contact with Foodstuffs¹⁰

This Resolution is based on the 2002 framework document and five technical documents on detailed aspects. It deals with paper and board materials made of cellulose-based natural fibres as well as recycled fibres. It includes post-treatment substances, polymeric binders as well as organic and inorganic pigments.

Substance	QM Limit Value (mg/dm²)
Cd	0.002
Pb	0.003
Hg	0.002

In addition to the QM values (maximum permitted quantity), the resolution also refers to valid SML limit values for plastics in contact with foodstuffs. The conventional ratio of 6 dm² of material coming into contact with 1 kg of foodstuffs and assuming 100% migration is also used here for the migration assessment. For specific details, the tables in the technical documents from the Resolution should be consulted.

ResAP (2004) 1: Coatings in Contact with Foodstuffs¹¹

This Resolution is based on the 2004 framework document and a technical document on detailed aspects. It deals with coatings for metal packaging, flexible packaging and heavy-duty coatings. The technical document lists authorised substances as well as restrictions, where applicable. The list essentially contains organic polymer components, but also some inorganic compounds such as titanium dioxide, carbon black or sodium tetraborate.

A separate limit value list for heavy metals is not defined in it.

ResAp (2004) 4: Rubber Products in Contact with Foodstuffs¹²

This Resolution is based on the 2004 framework document and two technical documents on detailed aspects. It deals with finished materials and articles made of rubber (elastomers) as well as mixtures of rubber with plastics or other materials. The technical document lists authorised substances as well as any restrictions. These substances are largely organic compounds for rubber production, but also include some inorganic compounds such as titanium dioxide or carbon black. With regard to colorants, reference is made to the requirements of AP(89) 1.

¹⁰ Paper and board materials and articles intended to come in contact with foodstuffs, Version 4, 12.02.2009

¹¹ Coatings intended to come into contact with foodstuffs, Version 3, 12.2.2009

¹² Rubber products intended to come into contact with foodstuffs, Version 1, 10.6.2004

ResAp (2005) 2: Inks for Printing on the Non-food Contact Surface of Packaging¹³

This resolution is based on the 2005 framework document and three technical documents on detailed aspects. It deals with printing inks and varnishes for printing on the non-food contact surface of packaging materials and articles. For the fundamental requirements, it refers to Article 3 of Framework Regulation (EC) No 1935/2004. In addition, there are also several lists of dyes (Section 3.3) and pigments (Section 3.4). At least for colorants no restrictions have been stated in the first version of this document, so that the current legislation or evaluation by authorities should be drawn upon. The purity requirements of the colorants used must comply with AP(89) 1.

Technical Document on Lead Leaching from Glass Tableware (2004)¹⁴

This document deals with lead glass tableware containing 6-32% PbO. It does not apply to ceramics and glass ceramics. According to the test procedures described therein, the relevant product must comply with the specified limit value for lead.

Size / Type	Number of Samples	Test Criterion	Limit Value
Small (< 600 ml)	4	All \leq Limit Value	1.5 mg/litre
Large (600-3000 ml)	4	All \leq Limit Value	0.75 mg/litre
Very large (>3000 ml)	4	All \leq Limit Value	0.5 mg/litre
Flatware	4	$\bar{x} \leq$ Limit Value	0.8 mg/dm ²

¹³ Packaging inks applied to the non-food contact surface of food packaging, Version 2, 10.10.2007

¹⁴ Lead leaching from glass tableware into foodstuffs, Version 1, 22.09.2004

Differences in Regulations

The following list is intended to show the main differences between European and national regulations, although there are exceptions on both sides:

Regulation (EU) No 10/2011	FCN (US)*
Limit values refer to extractable fractions (SML)	Limit values refer to maximum usage quantities
Limit values (SML) are toxicologically justified	Limit values (maximum usage quantity) are based on the technically required usage quantities
Pigments are excluded from the listing in the Annex of Regulation (EU) No 10/2011. However, they must be evaluated in accordance with Article 19	Pigments must be listed according to § 178.3297 in 21 CFR. Since 2000, Food Contact Notifications (FCN) can also be submitted which are only valid for the submitter

* FCN: Food Contact Notification

- SML = Specific Migration Limit
- SML = TDI x 60 (60 = average body weight)
- TDI = Tolerable Daily Intake (toxicological evaluation x safety factor of 100)

The problem here is that manufacturers of food packaging can only check the finished packaging for components with an SML for compliance with regulations. Testing may only be waived if exceedance of the SML can be ruled out based on the ratio of packaging to content mass and assuming total transfer of the substance. According to the national regulations, the manufacturer can assume that the packaging complies with the foodstuff regulations if the permissible usage quantities are not exceeded. In this case, only the relatively high limit value of global migration (10 mg/dm² or 60 mg/kg) has to be observed. The limit value of global migration has no toxicological justification but serves exclusively to maintain the purity of the foodstuff.

National Regulations

In this section, national regulations of the individual EU Member States shall be described with regard to their relevance for pigments and fillers.

Germany

In Germany, the production of food contact materials and articles is regulated by the German Food and Feed Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch – LFGB), the German Consumer Goods Ordinance (Bedarfsgegenständeverordnung – BedGgstV) and the recommendations of the Federal Institute for Consumer Health Protection and Veterinary Medicine (BgVV).

Food and Feed Code (LFGB)

Essential components of the European Regulation (EC) No 1935/2004 have been implemented in the LFGB. The LFGB contains the definition of terms for commodities, the scope as well as the bans for the protection of health. In addition, it authorises the BgVV (formerly BGA) to issue regulations.

German Consumer Goods Ordinance

This regulation serves the implementation of various EU Directives. It was last amended with regard to the restriction of the use of bisphenol A in plastic infant bottles.

Other Regulations

Recommendations of the German Federal Institute for Risk Assessment (Bundesinstitut für Risikobewertung – BfR)¹⁵

The recommendations of the Federal Institute for Risk Assessment (BfR) on materials for food contact are practically parallel to the German Consumer Goods Ordinance (BedGgstV). In the polymer-specific recommendations, the monomers, additives and other starting substances admissible in the manufacture of commodities are listed with their maximum permissible contents in the end product. In the supply chain, the “BfR Recommendation IX – Colorants for Plastics and other Polymers used in commodities” is widely used. With its latest revision, it was largely linked to the evaluation concept of the Plastics Regulation (EU) No 10/2011. This means that the migration limits and restrictions specified therein are to be applied to the evaluation of the polymer components. Fortunately, the purity requirements for colorants have been maintained, so that pigment manufacturers can check the suitability directly on their product.¹⁶

Lead	0.01 %	Barium	0.01 %
Arsenic	0.01 %	Chromium	0.1 %
Mercury	0.005 %	Cadmium	0.01 %
Selenium	0.01 %	Antimony	0.05 %

¹⁵ See VdMi Position Paper on the Revised Version of BfR Recommendation IX
<https://www.vdmi.de/englisch/media-library/food-contact.html>

¹⁶ Maximum soluble fractions in 0.07 N of hydrochloric acid (according to DIN 53770)

Overview of BfR recommendations with references to colorants and pigments:

II. Plasticizer-free polyvinyl chloride, ... content of vinyl chloride in the total mixture
IX. Colorants for Plastics and other Polymers Used in Commodities
XXI. Commodities based on Natural and Synthetic Rubber
XXXVI. Paper and Board for Food Contact
XXXVI/1. Cooking Papers, Hot Filter Papers and Filter Layers
XXXVI/2. Paper and Paperboard for Baking Purposes
XXXIX. Commodities Based on Polyurethanes
XLIV. Artificial Sausage Casings
XLVII. Toys Made from Plastics and other Polymers, and from Paper and Paperboard
LI. Temperature Resistant Polymer Coating Systems for Frying, Cooking and Baking Utensils
LII. Fillers

France

The numerous circulars (Circulaires), decrees and decisions of the State are contained in the brochure “**Matériaux au contact des denrées alimentaires produits de nettoyage de ces matériaux**”, also known as “Brochure No 1227”. (Brochure No 1227, Journal officiel de la République Française).

Worthy of special mention is **Circulaire 176**, in which the permitted colorants are listed and which is therefore referred to as the “**French Positive List**”. France is thus the only EU country to have a positive list for pigments. In June 2000, France also incorporated the limit values for heavy metals and aromatic amines of AP(89) 1 into its regulations.

The DGCCRF (Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes) has issued a general guideline dealing with food contact materials (Note d'information n°2014-108). However, as with almost all regulations, the focus here is on the definition of requirements for the finished materials. In the case of drinking water, special regulations apply.

Alongside the reference to the relevant EU Directives for plastics and ceramics, a number of French decrees are also cited that deal with the following materials:

- Rubber (Caoutchouc, Arrêté du 9 novembre 1994)
- Silicone elastomers (Élastomère de silicone, Arrêté du 25 novembre 1992)
- Aluminium (Aluminium, Arrêté du 27 août 1987)
- Stainless steel (Acier inoxydable, Arrêté du 13 janvier 1976)

Pigments are only mentioned in the directives for silicone elastomers and aluminium, and explicit reference is made to the Positive List.

Furthermore, the materials used to manufacture silicone elastomers, including pigments, should also meet the following requirements:

The fraction soluble in 0.1 N of HCl shall not exceed

- 0.01% lead,
- 0.01% arsenic,
- 0.0005 % mercury,
- 0.01% cadmium,
- 0.005 % antimony and
- 0.01 % barium.

In the case of carbon blacks, the component extractable in toluene shall not exceed 0.15 % and the content of 3,4-benzpyrene shall not exceed 30 mg/kg.

Other Member States of the European Union have also established national standards which essentially concentrate on purity criteria such as heavy metal contents and/or general exclusion of substances/compounds of concern.

Switzerland

In SR 817.032.21¹⁷ the following terms, among others, are defined in Article 2:

f. *Additive*: a substance intentionally added to a material in order to produce a physical or chemical effect during its manufacture or in the finished commodity; this substance is intended to be present in the finished commodity;

g. *Auxiliary* substance in the manufacture of plastics: any substance used as a suitable medium for the manufacture of polymers or plastics; it may be present in the finished commodities but is neither intended for this purpose nor does it have any physical or chemical effect in the finished commodity;

*Colorants*¹⁸: coloured powders, pastes or liquids intentionally added to commodities in order to add colour to them; they include dyes (soluble colorants) as well as organic and inorganic pigments;

In addition to the subject matter and scope (Article 1), labelling (Article 3) and quality assurance (Articles 4-7), Articles 8 and 9 contain requirements for metal or metal alloy commodities. The articles relevant for pigments and fillers are then described.

Product Groups

Plastics (Definition of Terms in Article 10)

The requirements for pigments and fillers in plastics are set out in Articles 11, 12 and 13. Article 11 describes substances that are listed in Annex 2 and also substances whose use does not endanger the health of consumers: e.g. colorants¹⁸ (b). Article 12 describes both the overall migration limit and the specific migration limit for additives: According to the Additives Ordinance (SR 817.022.31), additives are likewise permitted, provided that they do not migrate into final food products in quantities that alter their technical properties; furthermore, they must

¹⁷ Swiss Ordinance about materials and articles intended to come into contact with food

¹⁸ In the original Version (German) the term „Farbstoffe“ is used incorrectly because the definition means colorants („Farbmittel“)

not violate the restrictions for their use as authorised food additives or flavourings provided for in the Additives Ordinance. Article 15 sets out the requirements for a corresponding declaration of conformity.

Note: Other specifications apply to recycled plastics (Articles 17 to 20). Articles 21 to 25 describe the requirements for commodities based on regenerated cellulose film.

Paper and Paperboard

The requirements for pigments and fillers in paper are set out in Article 27.

Ceramic and Glass

The requirements for pigments and fillers in ceramics, glass, enamel and similar materials are set out in Article 26. There, the maximum amount of lead and cadmium is specified, which can also be found in Annex 8.

Coatings

There is no information on varnishes and coatings in the Swiss Ordinance.

Article 28 describes the requirements for commodities based on paraffins and waxes; Article 29 describes the requirements for commodities based on colorants.

Printing Ink

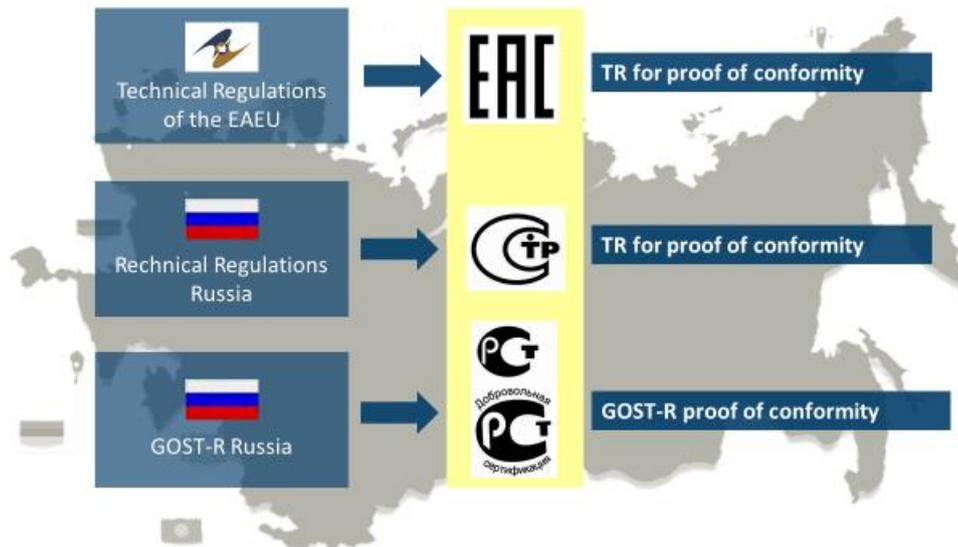
The requirements for pigments and fillers in printing inks are set out in Articles 33, 34 and 35. Article 33 describes the scope: (a) no direct contact with foodstuffs, (b) migration of substances from printing inks into foodstuffs impossible and (c) leakage of substances or escape as gas excluded. Article 34 also defines the term “printing ink”: (1) no direct contact with food, (2) manufacture with binders, dyes, pigments, plasticisers, solvents, drying agents and other additives, and application by appropriate printing or coating processes, and (3) finished condition. Finally, Article 35 names the authorised substances, namely those listed in Annexes 2 and 10 (subject to compliance with the conditions laid down therein) and certain salts.

Elastomers and Rubber (Commodities based on Silicone)

The requirements for pigments and fillers used as elastomers and rubber, i.e. commodities based on silicone, are set out in Articles 30 to 32. Article 32 names all authorised substances, namely those listed in Annexes 2 and 9, subject to compliance with the conditions laid down therein, and certain salts.

Russia/Eurasian Economic Union

Since the establishment of the Eurasian Customs Union and the subsequent merger into the Eurasian Economic Union¹⁹, coordinating and monitoring the formulation and drafting of Technical Regulations has taken place at this level. The aim is to harmonise the Technical Regulations of the countries.



The Technical Regulations are intended to ensure the safety of products placed on the market within the territory of the Union and define binding minimum requirements for the implementation and application of regulated objects (products). The Technical Regulations apply throughout the territory of the Economic Union. For this purpose, the Eurasian Economic Commission has issued 45 Technical Regulations with binding requirements. Compliance or conformity with the Technical Regulations must be demonstrated by means of proof of conformity in the form of certification or declaration. Such products are marked with the uniform EAC mark. With regard to commodities and materials intended to come into contact with foodstuffs, the following Technical Regulations have been issued by the Eurasian Economic Commission:

1. TR CU 005/2010 "On the safety of packaging"
2. TR CU 007/2011 "On the safety of products intended for children and adolescents"
3. TR CU 008/2011 "On the safety of toys"
4. TR CU 009/2011 "On the safety of cosmetics and perfumes"
5. TR CU 017/2011 "On the safety of light industry products"
6. TR EAEU 041/2017 "On the safety of chemical products" from 2.07.2021

Since 2014, work has continued on an overarching regulation "On the safety of materials in contact with foodstuffs". A public draft is not yet available.

Similar to the EU Framework Regulation 8 (EC) No 1935/2004 or Regulation (EU) No 10/2011, the Technical Regulations of the Eurasian Economic Union contain both general provisions and specific requirements for the regulated objects.

¹⁹ Armenia, Belarus, Kazakhstan, Kyrgyzstan and the Russian Federation, Treaty on the Eurasian Economic Union of 29 May 2014, Astana

Overview of the partially interconnected regulations on commodities

Controlled Substance	TR CU 005/2011 (1,2,3,4,5,7)	TR CU 007/2011 (1,2,3,4)	Hygiene Requirements, Section 16 (1,2,3,4,5)
	SML, mg/l	SML, mg/dm ³	SML, mg/l
Zinc (Zn)	1.000 (1,7,3,2,5)	1.00 (4,3,2)	1.000 (1,2,3,5,7)
Tin (Sn)	- (1)	2.00 (1)*	- (1)
Boron (B)	0.500 (3,4,5)	not allowed	0.500 (3,4,5)
Lead (Pb)	0.030 (3,2,4,5)	not allowed	0.030 (2, in the case of 3,4**,5)
Arsenic (As)	0.050 (2,4,5)	not allowed	0.050 (2,4,5)
Chromium Cr (III)	In total 0.100 (3,2,4,5)	not differentiated 0.100 (4,3,2)	In total 0.100 (3,2,4,5)
Chromium Cr (VI)			
Titanium (Ti)	0.100 (3,2,5)	0.100 (4.3)	0.100 (2,3,4,5)
Aluminium (Al)	0.500 (3,2,4,5)	not allowed	0.500 (3,2,4,5)
Barium (Ba)	0.100 (3,2,4,5)	not allowed	0.100 (3,2,4,5)
Cadmium	0.001 (3,2,4,5)	not allowed	0.001 (2, in the case of 3,4**,5)
Copper (Cu)	1.000 (3,2,4,5)	1.000 (4.3)	1.000 (3,2,4,5)
Manganese (Mn)	0.100 (3,4,5)	0.100 (4.3)	0.100 (2,3,4,5)
Cobalt (Co)	0.100 (3,4,5)	not allowed	0.100 (3,4,5)
Lithium (Li)	- (3)	not allowed	- (3)
Iron (Fe)	0.300 (2.5)		0.300 (2.5)
Nickel (Ni)	0.100 (5)		0.100 (5)
Hexamethylene diamine	0.010 (1)	not allowed	0.010 (1)
Benz(o)pyrene	not allowed (2)	not allowed	not allowed (2)
Benzene ²⁰	- (1,2)	not allowed (1,2)	- (1,2)
		* Migration into the simulant, no more than	
		** Different values depending on type and size of tableware	

Legend

1	Plastics
2	Paper and paperboard
3	Ceramics
4	Glass
5	Coatings
6	Printing ink
7	Elastomers/Rubber

²⁰ The same values also apply to dichlorobenzene, ethylbenzene and chlorobenzene.

North America

USA

Structure of Rules and Regulations on Commodities/Consumer Products

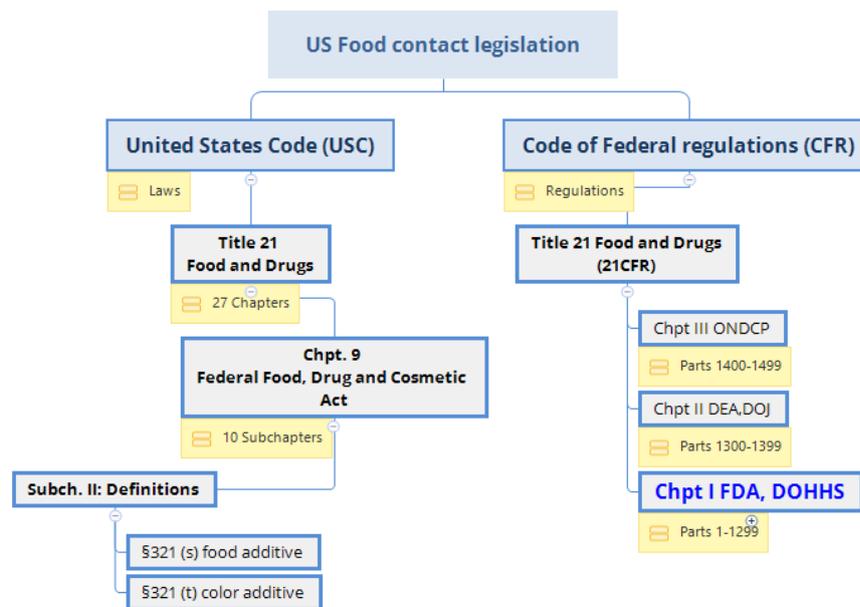


Fig 5: US Food Contact - Legislation

Regulations/Recommendations for Goods Traffic

As in most food contact regulations around the world, food packaging in the USA should not adversely affect food composition, appearance, odour and other relevant properties, including health, i.e. toxicological aspects. Ideally, no substances should migrate from the packaging into the food or, if they do, only in toxicologically harmless quantities. Manufacturers are responsible for the safety of the packaging. They must ensure that all components are approved by the FDA for the intended use and quantity and that the finished packaging meets the general requirements.

Substances which are not classified as carcinogenic or toxic and which do not migrate or only migrate up to a max. of 50 ppm, or which do not reach the food due to an efficient barrier (“Functional Barrier Doctrine”) do not require approval. This is also referred to as “No Migration Exemption”. Substances which are used in a concentration below 1% for the production of a polymer (catalysts, plasticisers, colorants, etc.) are defined as polymer components and are therefore also excluded from independent regulatory consideration (“Basic Polymer Doctrine”). Housewares that are intended to come into contact with food are generally exempt from

approval procedures in the USA (“Housewares Exemption”). The responsibility for the composition of food contact materials lies solely with the manufacturer.²¹

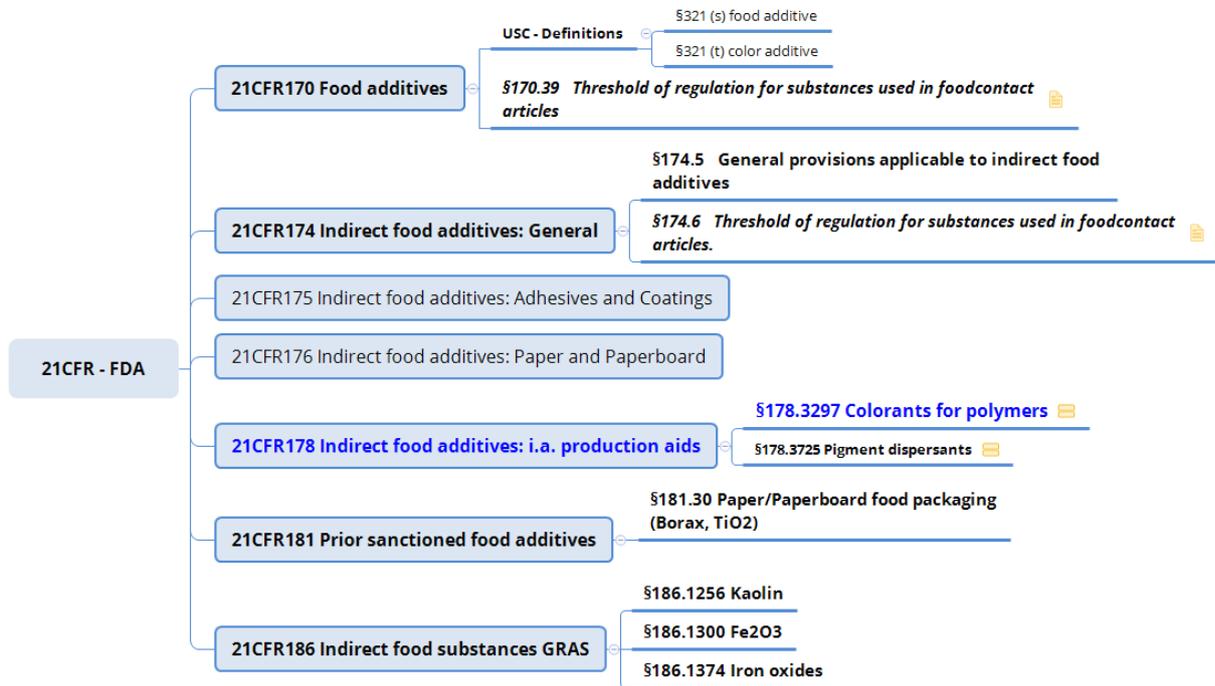


Fig 6: Consideration of colorants in the Code of Federal Regulations (CFR)

Many substances have already been classified as safe by the FDA and, depending on the area of application, are included in the positive lists of the above-mentioned paragraphs §§174 - 189 (21 CFR). This inclusion in the positive lists is to be regarded as approval of the substance in compliance with the named purity requirements and quantity restrictions. Most of the substances listed in Title 21 can also be viewed in alphabetical order in the “Food Additives Status List”.²²

Colorants are assigned a central role here by §178.3297 (21 CFR), which provides an extensive positive list for colorants in plastics and which is also frequently referred to in the other paragraphs. Therefore, confirmation of compliance with this paragraph by pigment manufacturers has become a kind of industry standard.

Food Contact Notification

If a component of a colorant is not listed there (or in another positive list), the pigment manufacturer can apply for a Food Contact Notification (FCN) directly at the FDA.²³ This will later only be valid for the named manufacturer. When such an FCN is issued, an evaluation is carried out to determine whether there are any concerns regarding migration and toxicology in

²¹ Source <http://www.packaginglaw.com/special-focus/fathoming-food-packaging-regulation-revisited>

²² “Appendix A of the Investigations Operations Manual (IOM)”: <https://www.fda.gov/food/ingredientspackaginglabeling/foodadditivesingredients/ucm091048.htm>

²³ Sample form (FDA Form 3480) <https://www.formsbirds.com/free-form-fda-3479-notification-for-a-food-contact-substance-formulation>

the intended use, including the definition of maximum quantities and any other limitations. If the overall result of the evaluation is good, the FCN can be issued and usually includes information on the exact composition of the pigment tested and the named limitations. Applicants may carry out and submit their own studies or calculations based on current scientific methods to determine relevant data such as migration levels, estimated daily intake levels or environmental exposures. The FDA can request further studies if necessary and makes guidance documents available on its website.

Another safeguard option for pigment manufacturers is known as a “legal opinion”. This involves renowned law firms in the USA, together with toxicologists and analytical laboratories, carrying out an assessment similar to that of the FCN. Usually, reference is made to various approaches that are intended to ensure the safety and harmlessness of the product, such as the “GRAS” status of a component (“Substances Generally Recognized as Safe”), a migration level below a toxicologically critical threshold (“de minimis migration”) or the presence of the above-mentioned efficient barrier that predictably prevents significant migration from packaging into food (“Functional Barrier Doctrine”). Ideally, these law firms will also assume liability for their assessment in the event of feared US law suits.

Recycled Plastics

If the pigment is only to be used in a recycling process to (re)colour a polymer, it is enough to apply for a “letter of no objection” from the FDA.²⁴

²⁴ Further Information:

<http://www.packaginglaw.com/special-focus/lot-digest-us-recycled-plastic-food-contact-regulations>

Canada

Canadian Food and Drugs Act

<https://laws-lois.justice.gc.ca/eng/acts/C-1.68/index.html>

https://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/index.html

(F&D Act) and the Food and Drug Regulations (FDRs)

Structure of Rules and Regulations on Commodities/Consumer Products

Competent authorities:

Health Canada

Health Products and Food Branch (HPFB), Food Directorate (FD)

Canadian Food Inspection Agency (CFIA)

Overarching law:

Canadian Food and Drugs Act (F&D Act), Division 23, Section B.23.001 and the Food and Drug Regulations (FDRs)

Regulations/Recommendations for Goods Traffic

It is prohibited to bring food into circulation in packaging in which substances harmful to the consumer can be transferred to the contents (B.23.001). Ensuring the safety of the packaging material and conformity with B.23.001 is the responsibility of the manufacturer or distributor of the food.

Health Canada only needs to provide specific information on the packaging material for dietary supplements (Division 24), infant formula (Division 25), and designer food (Division 28), where the packaging is part of the evaluation process. Food contact materials such as kitchen utensils and household goods are exempt from the regulations²⁵.

Pre-Market Safety Assessments

Due to the lack of positive lists with approved ingredients, packaging materials intended for foodstuffs can be submitted to the Food Directorate (FD) for a Pre-Market Safety Assessment (also known as a Health Risk Assessment).²⁶ The aim of the Pre-Market Assessment is to evaluate chemical product safety according to B.23.001. It can be used both for the finished packaging product as well as for its starting materials such as plastic granules, dye mixtures and other mixtures.

²⁵ KELLER AND HECKMAN LLP, Regulation of Food Packaging in Canada, Oct 07, 2014

²⁶ <https://www.canada.ca/en/health-canada/corporate/about-health-canada/branches-agencies/health-products-food-branch/food-directorate.html>

For single substances such as pigments, antioxidants, ultraviolet absorbers, etc., the relevant manufacturers can apply to the Food Directorate (FD) for a “letter of no objection” before the substance is sold to further processing companies.

“Letter of no objection” (LONO)

Manufacturers of single substances and formulators of packaging materials may provide their customers with HPFB “letters of no objection” to assure them that the substance or the substances sold by them have been evaluated by the Food Directorate as chemically safe for use in food packaging. These letters of confirmation do not, however, constitute approvals in the legal sense and do not release food packaging manufacturers from their obligation to comply with B.23.001. The “Letter of no objection” (LONO) has no expiry date and is valid for as long as the substance is used in the manner described.

It is the responsibility of the manufacturer to inform the Food Directorate of any change (in composition / use). The FD may revoke its evaluation at any time if a change in formulation has not been disclosed or if a potential health risk to the consumer is suspected.

To apply for a LONO, information on the identity of the product, its proposed use, data on extractability properties and toxicological data are required.²⁷ There is also a diagram (Annex xx) providing an overview of the application process. To speed up the process, it is advisable to submit an application for processing aid to the HPFB and the CFIA at the same time.

Food Packaging used in Public Establishments

Where food contact materials are intended for use in public establishments, which are subject to controls by the CFIA, manufacturers should be aware that since 2 July 2014 the CFIA has released industry from its pre-registration responsibility for inclusion in the Reference Listing of Accepted Construction Materials, Packaging Materials and Non-Food Chemical Products. The operators of public institutions hold responsibility for the use of safe packaging materials that comply with all legal requirements. Manufacturers of food packaging materials can continue to voluntarily request a LONO from Health Canada and make this available.²⁸

Positive List for Polymers from the Food Directorate

To make it easier for manufacturers of packaging materials to identify similarities, the Food Directorate maintains positive lists of polymers on the Health Canada website: “Lists of Acceptable Polymers For Use in Food Packaging Applications”. They include all plastics for which the Food Packaging Materials & Incidental Additives Section of the Chemical Health Hazard Assessment Division (Food Directorate) has already issued a LONO for use as food packaging and other food contact applications. The aim of the list is to eliminate the need to apply for a new LONO if the composition of a packaging material has been changed solely by replacing the type of plastic with a similar one for which a corresponding authorisation already exists. In this case, it is sufficient to inform the FD about the replacement, so that the LONO retains its validity. The FD reserves the right to question the change.

²⁷ Further information: <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/information-requirements-food-packaging-submissions.html>

²⁸ Source: <https://food-nutrition.canada.ca/food-safety/referencelist/index-en.php>

The list includes the trade name, the purity of each polymer, the manufacturer, the date of issue of the LONO and any restrictions. The polymers are divided into 12 groups and one “Others” category (for polymers not belonging to the 12 previous categories).²⁹

Positive Lists for Food Contact Materials Possible in Canada in Future

In July 2017, at the 13th Biennial International Symposium on Worldwide Regulation of Food Packaging in Baltimore, Mr. Anastase Rulibikiye (Section Head of Health Canada’s Health Products and Food Branch) announced that Canada was considering implementing a positive list to regulate food contact materials.³⁰

Recycled Plastics

With respect to their chemical safety, recycled plastics are treated in exactly the same way as that of new plastics. Manufacturers of food packaging should also read the “Guidelines for Determining the Acceptability and Use of Recycled Plastics in Food Packaging Applications”.³¹

²⁹ Further information: <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/lists-acceptable-polymers-use-food-packaging-applications.html>

³⁰ Source <http://www.packaginglaw.com/news/canada-considering-positive-list-system-food-contact-materials>

³¹ Source <https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-determining-acceptability-use-recycled-plastics-food-packaging-applications-1996.html>

In the Technical Committee for Pigments and Fillers of the VdMi, experts from manufacturers of pigments and fillers deal with regulatory questions, interpretations and the potential effects thereof on the use of the products in downstream applications.

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The Verband der Mineralfarbenindustrie e. V. represents German manufacturers of inorganic (e.g. titanium dioxide, iron oxides), organic and metallic pigments, fillers (e.g. silicic acid), carbon black, ceramic paints, food colorants, artists' and school paints, masterbatches and products for applied photocatalysis.