FCM: Overall Regulatory Framework

Fabiana Vanni, Giorgio Padula, Veruscka Mannoni, Silvia Giamberardini, Marco De Felice, Cinzia Gesumundo

Istituto Superiore di Sanità DAMSA Dipartimento di Ambiente e Salute (Department of Environment and Health) Reparto ECASS (Esposizione a Contaminanti in Aria Suolo e da Stili di vita)

CORRESPONDING AUTHOR:
 Fabiana Vanni
 Email: fabiana.vanni@iss.it
 Viale Regina Elena, 299 – 00161 Roma



Presentato al centenario RISG Sostanze grasse: ricerca, innovazione e scenari futuri

15 novembre 2023

Food Contact Materials (FCM), present at all stages of the food chain (production, processing, storage, consumption), are fully within the scope of Food Safety, as illustrated by the European Union in the White Paper (Brussels 2000). They shall be subject to the Reg. (EC) 178/2002, to the general rules, as well as to the official control procedures established by the Reg. (EU) 2017/625; Member States are required to verify that FCM meets food safety requirements by carrying out appropriate checks at borders and on national territory.

More specifically, the "framework rule" of FCM is the Reg (EC) no. 1935/2004 which establishes general principles of safety and inertia (art. 3), also anticipating a harmonized EU regulatory framework and allowing the Member States to maintain or adopt specific measures where specific EU laws do not exist (art. 6).

Currently the materials covered by EU regulations are plastic [Reg. (EU) 10/2011 as amended and supplemented], polyamide/melamine FCM [Reg. (EU) 284/2011] and materials "Active & Intelligent" [Reg. (EC) 450/2009]. For ceramics and regenerated cellulose, specific directives have been issued.

At the national level, the DM 21/03/1973 as amended and supplemented shall legislate on paper and board, rubber, glass, stainless steel and the non-harmonized part of plastic FCM. Specific provisions are also laid down for aluminium FCM (DM No. 76 of 18/04/2007), tinplate (DM No. 18/02/1984 and DM No. 405 of 13/07/1995) and tin-free steel FCM (DM No. 243 of 01/06/1988).

In addition to the abovementioned Reg. (EC) No 1935/2004, the general regulatory framework also provides national provisions valid for all FCM, regardless of the possible presence of specific provisions for certain materials; they are Presidential Decree No. 777 of 23/08/1982 and Legislative Decree No. 108 of 25/01/1992.

Furthermore, specific provisions regarding recycled plastic FCM are laid down in Reg. (EU) 2022/1616 that repealed the Reg. (EC) 282/2008.

Finally, all FCM shall respond to Reg (EC) 2023/2006 on good manufacturing practices.

1. FCM: GENERAL SAFETY PRINCIPLES

Food Contact Materials (FCM) are ready-to-use materials and objects that could be already in contact with food or would come into contact with food during their lifecycle.

They are present in all stages of the food chain, from production (agricultural harvesting, automatic milking) and processing (contact with equipment, work benches) up to the stages of packaging and storage (canned, sliced, frozen foods). Finally, cooking stages (industrial cooking or cooking pots) and final consumption (cutlery, dishes) are included.

According to the chemical properties of food they are expected to come into contact, FCM need to be projected properly. Infact they could come into contact with acid or alkaline solutions or they may have to withstand thermal shock. To ensure food safety, proper technological suitability and appropriate packaging technologies need to be foreseen.

FCM can be made by a wide type of materials of natural and synthetic origin as well and they are synthetically illustrated in Table I.

 Table I – Materials constituting the FCM

Classes of Materials	Specific Materials
Synthetic polymers	Plastic polymers
	Rubbers
	Non-woven
Cellulosic materials	Papers
	Cardboard
	Wood
	Cork
	Regenerated cellulose
"Silicea" based materials	Ceramics
	Glass
	Crystal
Metallic materials	Coated and uncoated metals and alloys
	Tinplate
	Tin-free steel

They range from synthetic polymers (plastic, rubber, non-woven) to different cellulosic materials (paper, cardboard, wood ecc.). Even "silicea" based materials are also widely used (ceramic, glass and crystal) as well as metallic materials (coated and uncoated metals and alloys, tinplate and tin-free steel). It is important to highlight that the final product could be made by different materials used alone or in combination. All materials have different characteristics but nothing is absolutely inert or insoluble, therefore all materials can be a potential source of food contamination if placed in contact with it. The contaminants might migrate from materials to food and the level of contamination depends on many combined factors. They are the nature of the migrant substance and the nature of the materials, but also the nature of food as well as the contact conditions (time, temperature, surface). From a general point of view, the risk depends on three factors:

- the interaction between material and food, that is the migration from FCM to the food; it is evaluated by experimental tests or calculation through migration models
- the toxicological properties of the migrant substance (hazard) known from toxicological studies or literature data
- the consumer's exposure known through the amount of food consumed and type of consumer (child, adult etc.)

As regards the risk related to the use of the FCM, the normative framework applicable is very complex; the rules apply, as a matter of priority, to producers, importers and distributors, but also end-users are required to comply with the provisions.

2. GENERAL REGULATORY FRAMEWORK

The FCM, present at all stages of the food chain, are fully within the scope of Food Safety, as illustrated by the European Union in the White Paper – Brussels 2000 [1]. The adopted measures laid out the actions needed to modernise European legislation on food, proposing a comprehensive and integrated strategy applicable to the whole food chain "from farm to fork". The provisions regarding "official controls" are also part of this strategy and, as part of a complete and correct management of issues related to food safety, the strategy also contemplates the need to provide correct information to end consumers.

The regulatory structure relating to food contact materials and articles provides for general provisions (summarized in Table II and Table III).

 Table II – General regulatory framework

European legislation	National legislation
Regulation (EC) N. 178/2002	Legislative Decree No. 27 of 02/02/2021
Regulation (EU) N. 2017/625	
Commission Communication (2022/C 467/02)	

Table III – FCM general provisions

European legislation	National legislation
Regulation (EC) No. 1935/2004	Presidential Decree No. 777 of 08/23/1982
Regulation (EC) 2023/2006	Legislative Decree No. 108 of 01/25/1992
	Legislative Decree No. 29 of 10/02/2017

Moreover, provisions are set for certain materials (summarized in Table IV).

Table IV - FCM specific provisions

European legislation	National legislation
Regulation (EU) No. 10/2011	Ministerial Decree 21/03/1973 as amended
Regulation (EU) No. 284/2011	Ministerial Decree 04/04/1985
Regulation (EU) No. 2022/1616	Ministerial Decree 01/02/2007
Regulation (EC) No. 1895/2005	Ministerial Decree No. 76 of 18/04/2007
Regulation (EC) No. 450/2009	Ministerial Decree 18/02/1984
Regulation (EU) No. 2018/213	Ministerial Decree No. 405 del 13/07/1995
Directive 84/500/EEC	Ministerial Decree No. 243 del 01/06/1988
Directive 2005/31/EC	
Directive 2007/42/EC	
Directive 93/11/EEC	

First of all, FCM fall within the scope of Regulation (EC) No 178/2002 [2], as already indicated in the recitals where it is written that "*In order to take a sufficiently comprehensive and integrated approach to food safety, there should be a broad definition of food law covering a wide range of provisions with a direct or indirect effect on the safety of food and feed, including provisions on materials and articles in contact with food, animal feed and other agricultural inputs at the level of primary production*".

Article 6 specifies the concept of Risk Analysis, linked to food safety, and defined as a process consisting of three interconnected components: risk assessment, risk management and risk communication. A key role in the risk assessment phase in all fields related to food safety, including FCM, is played by the European Food Safety Authority (EFSA), established by the Regulation. Indeed, as written in article 22, the Authority, as a primary function, "...shall provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety". In addition, in article 28, in the Description of the Scientific Committee and the Scientific Panel, the Panel on food additives, flavourings, processing aids and materials in contact with food is expressly indicated.

FCM fall within the scope of Regulation (EU) 2017/625 [3] on official controls and other official activities. As indicated in Article 1, "*This Regulation shall apply to the official controls performed for the verification of compliance with the rules, whether established at Union level or by the Member States, to apply Union legislation, in the areas of food and food safety [...omissis...] and the manufacture and use of materials and articles intended to come into contact with food*". The Regulation, in establishing common standards for official controls, also ensures that the legislation is correctly applied and enforced, while specifying the full applicability of both European standards, where existing, and national standards.

In order to assist national authorities in the application of Regulation (EU) 2017/625, the Commission Communication (2022/C 467/02) [4] has been issued. Moreover, the Legislative Decree No. 27 of 02/02/2021 [5] has been issued to adapt national legislation to the provisions of the regulation.

2.1 GENERAL PROVISION FOR FCM

General provisions for FCM are established at EU and national level. As regards the EU regulatory structure, the FCM framework legislation is the Regulation (EC) No. 1935/2004 [6]. The purpose of the Regulation is "to ensure the effective functioning of the internal market for the FCM...securing a high level of protection of human health and the interests of consumers".

However the core of the regulation is represented by the article 3 "Materials and articles, including active and intelligent 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".

All FCM shall comply with the requirements of Article 3, which includes the concept of risk assessment.

The regulatory tools useful for risk management can be, for example, lists of substances authorized, purity standards, specific conditions of use, specific and overall limits on migration etc.

In the absence of specific measures, the Regulation shall not prevent Member States from maintaining or adopting national provisions.

Article 15 contains important indications regarding labelling, it shall be made clear that the object can be intended for food contact and any restrictions on use shall be indicated; while article 17 specifies that the traceability of materials and articles shall be ensured at all stages in order to facilitate control.

It is important to underline what indicated in article 16 about Declaration of Compliance (DoC), a written declaration stating that the products comply with the rules applicable to them. Moreover, a supporting documentation (SD) to demonstrate such compliance shall be made available to the competent authorities on demand.

The DoC and the SD are always present, both in European laws and in our national legislation; although there are differences between EU and national legislation, the fundamental principles and consequences arising from the application of the DoC and SD rules are common.

The DoC constitutes a key point both in the assumption of responsibility of FCM producers and in the correct transfer of information between companies in the supply chain, whereas SD is a mean of demonstrating the compliance of a FCM to the competent authority, in case of inspections or controls.

For the drafting of the DoC there are legislative indications, while for the SD there is only a generic strategy of shared approach. It should have an organized collection, containing the specification of composition and procurement, the certification/declaration of compliance issued by the supplier, when applicable, the test reports on starting material, raw materials, semiprocessed and/or finished articles, or any other documents which enables the business operator to demonstrate to the Competent Authorities that what their company produces comply with the rules on FCM.

The European regulatory framework also provides that the FCM comply with Regulation (EC) 2023/2006 [7]. It means that all companies that produce, market and import FCM shall operate according to Good Manufacturing Practice (GMP) and shall prepare a Quality Assurance System and a Quality Control System.

Since 2009, the Istituto Superiore di Sanità, in collaboration with the Industrial Associations of the FCM sector, has launched the CAST Project (Contatto Alimentare Sicurezza e Tecnologia) and several Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of FCM have been developed and updated over time [8, 9, 10, 11]. Specific documents have also been drawn up to provide information relating to the SD to be made available on demand to the competent authorities [12]. It is important to underline that the guidelines do not have a binding value, but they are a valid tool for a harmonized and shared approach with stakeholders to the abovementioned issues.

The general regulatory framework also provides national provisions valid for all FCM, regardless of the possible presence of specific provisions for certain materials. They are Presidential Decree No. 777 of 23/08/1982 [13] and Legislative Decree No. 108 of 25/01/1992 (constituting an amendment to Presidential Decree no. 777). They contain general provisions, including the mandatory presence of the DoC and the necessary indications on labelling. In these decrees, penalties are also indicated even if the specific Legislative Decree No. 29 of 10/02/2017 [14] is currently in force.

2.2 SPECIFIC PROVISION FOR FCM

Plastic is a material widely used in FCM; it is regulated at European level by Regulation (EU) No. 10/2011 [15], by now in its 17th amendment. It applies to FCM of homogeneous single- and multi-layer plastics (i.e. materials made entirely of plastic, although of different types) held together by adhesives or other means, to plastics whether or not molded or coated, to plastic layers or coatings forming seals

of lids and closures. Instead heterogeneous multi-layer multi-material plastics (FCM consisting of plastics coupled to materials other than plastic) are regulated by national legislation, as falling within the scope of Ministerial Decree 21/03/1973 [16] as amended. In the case of multi-material multi-layer plastics, only the layer that comes into direct contact with food shall comply with the regulatory requirements, provided that it acts as a barrier preventing the migration of material constituents, not directly in contact with the food, to the food itself. For this purpose, the legislation provides for specific migration tests. More generally, European and national regulatory instruments consist primarily of positive lists of monomers and additives, overall and specific migration limits. Other useful instruments are restrictions on use and compliance testing (migration test) as specified in the legislation (food simulants, conditions of contact such as time and temperature). As indicated above, the DoC must be present along all the stages of the supply chain and the SD must be available upon request of the competent authorities. Annex IV of the Regulation (EU) No. 10/2011 highlights nine points with detailed descriptions of the information that must be present in the DoC.

Special conditions apply to polyamide and melamine plastic kitchenware from the People's Republic of China and Hong Kong according to Regulation (EU) No. 284/2011 [17]; these FCM shall be accompanied by a further declaration and test report of the analytical determinations of primary aromatic amines and formaldehyde.

For recycled plastic materials intended to come into contact with food, the Regulation (EU) 2022/1616 [18] is in force; it provides for suitable recycling technologies and processes. The Regulation also states the authorization procedures for recycling technologies and the official controls to be carried out on installations.

Among the European regulations, some are foreseen in more specific areas such as Regulation (EC) No. 1895/2005 for the use of certain epoxy derivatives in FCMs [19]; Regulation (EC) No. 450/2009 on active and intelligent material in FCM [20].

Ceramics is also a material regulated at European level. Directive 84/500/EEC [21], subsequently amended by Directive 2005/31/EC [22] are in force; in Italy they were implemented with the Ministerial Decree 04/04/1985 [23] and the Ministerial Decree 01/02/2007 [24] respectively. Ceramic FCM require maximum levels of cadmium and lead to be met, moreover the presence of DoC up to the retail stage is needed.

Further European directives are foreseen for regenerated cellulose films, Directive 2007/42/EC [25] and for the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber, Directive 93/11/EEC [26]; both are implemented in Italy with specific updates of the Ministerial Decree 21/03/1973.

As required by Regulation (EC) No. 1935/2004, for materials not subject to specific European provisions, national regulations are applicable, where existing. Several FCM fall within the scope of the abovementioned Ministerial Decree 21/03/1973 as amended and they are stainless steel, glass, paper and cardboard, rubber, regenerated cellulose and non-harmonised parts related to plastics (heterogeneous multi-material multi-layer).

As regards stainless steel FCM, the Ministerial Decree 21/03/1973 provides positive lists with the types of stainless steels can be used; they are identified using acronyms provided by international standards or, alternatively, they are identified with chemical cast analysis. These lists may be updated periodically; the last update is Ministerial Decree No. 208 of 25/11/2022 [27]. Overall migration and specific migration limits for chromium, nickel and manganese are also foreseen.

For glass FCM, there are no positive lists, but three categories of glass are indicated with their respective limitations and tolerances of use. For all categories, there are global migration limits; while specific migration limits are provided for lead in crystals.

For paper and board FCM, the Ministerial Decree 21/03/1973 shall include positive lists for fibrous materials, fillers, auxiliary substances, optical whiteners and processing aids. Paper and board FCM shall meet specific composition and purity requirements. All the updates of the Ministerial Decree 21/03/1973 on paper and board flow into the Ministerial Decree no. 217 of 25/09/2007 [28].

Positive lists are also provided for rubber FCM; the compliance shall be verified by migration tests; the Ministerial Decree 21/03/1973 also contains indications for dyes in rubber FCM.

Aluminum FCM are subject to the provisions of Ministerial Decree No. 76 of 18/04/2007 [29]. They shall meet specific purity and composition requirements. No migration tests are foreseen.

Finally, specific provisions are provided for tinplate FCM (Ministerial Decree 18/02/1984 [30], updated by the Ministerial Decree No. 405 del 13/07/1995 [31]) and for tin-free steel (Ministerial Decree No. 243 del 01/06/1988 [32]). In both cases, global migration test and specific migration test of some metals shall be carried out.

On the sidelines of the current legislation, several Notes from the Ministry of Health are also issued. To facilitate their use, DGISAN Note 32249 of 11/10/2011 concerning the DoC of FCM and Note 20072 of 20/05/2014 on objects in metal alloys and objects coated with porcelain enamel are cited.

It is important to underline that the general and specific regulatory framework applicable to FCM, complex and detailed, pursues the aim of the consumer health and it is currently being carefully considered in order to favour updates with primary objectives of safety and sustainability.

3. REFERENCES

- [1] White Paper on Food Safety, COM (99) 719 final, 12 January 2000
- [2] 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, Official Journal of the European Communities L31/1-24, February 2, 2002
- [3] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/ EC and Council Decision 92/438/EEC (Official Controls Regulation), Official Journal of the European Union L95/1-142, April 7, 2017
- [4] Commission Notice on the implementation of Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation), Official Journal of the European Union C467/2-32, December 8, 2022
- [5] Decreto Legislativo 2 febbraio 2021, n.27 Disposizioni per l'adeguamento della normativa nazionale alle disposizioni del Regolamento (UE) 2017/625 ai sensi dell'articolo 12, lettere a), b), c), d) ed e) della legge 4 ottobre 2019, n.117, *Gazzetta Ufficiale* Serie Generale n.60, 11 marzo 2021
- [6] Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, Official Journal of the European Union L338/4-17, November 13, 2004
- [7] Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, Official Journal of the European Union L384/75-78, December 29, 2006
- [8] M.R. Milana, M. Denaro, R. Feliciani, A. Maggio, A, Maini, G. Padula, CAST Project, Guidelines for the application of the Regulation (EC) 2023/2006 to the supply chain of materials and articles intended to come into contact with food, Rapporti ISTISAN 11/37
- [9] M.R. Milana, M. Denaro, R. Feliciani, C. Gesumundo, A. Maggio, V. Mannoni, O. Panico, G. Padula, Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia), Linee guida per il riscontro documentale sull'applicazione del Regolamento (CE) n. 2023/2006, Rapporti ISTISAN 13/14
- [10] M.R. Milana, M. Denaro, R. Feliciani, C. Gesumundo, A. Maggio, V. Mannoni, O. Panico, G. Padula, Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia), Linee guida per il riscontro documentale sull'applicazione del Regolamento (CE) 2023/2006. Vernici, adesivi e inchiostri da stampa, Rapporti ISTISAN 16/43

- [11] C. Gesumundo, M.R. Milana, V. Mannoni, S. Giamberardini, F. Vanni, M. De Felice, M. Denaro, R. Feliciani, M. Massara, G. Padula, Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia), Linee guida per l'applicazione del Regolamento (CE) 2023/2006 alla filiera dei materiali e oggetti destinati al contatto con gli alimenti. Edizione 2023, Rapporti ISTISAN 23/4 Rev.
- [12] M.R. Milana, M. Denaro, R. Feliciani, C. Gesumundo, A. Maggio, V. Mannoni, O. Panico, G. Padula, Progetto CAST (Contatto Alimentare Sicurezza e Tecnologia), Linee guida sulla documentazione di supporto per la dichiarazione di conformità alla legislazione sui materiali e oggetti a contatto con alimenti, Rapporti ISTISAN 18/24
- [13] Decreto del Presidente della Repubblica 23 agosto 1982, n.777, Attuazione della direttiva (CEE) n. 76/893 relativa ai materiali e agli oggetti destinati a venire a contatto con i prodotti alimentari, Gazzetta Ufficiale Serie Generale n.298, 28 ottobre 1982
- [14] Decreto Legislativo 10 febbraio 2017, n. 29, Disciplina sanzionatoria per la violazione di disposizioni di cui ai regolamenti (CE) n. 1935/2004, n. 1895/2005, n. 2023/2006, n. 282/2008, n. 450/2009 e n. 10/2011, in materia di materiali e oggetti destinati a venire a contatto con prodotti alimentari e alimenti, *Gazzetta Ufficiale* Serie Generale n.65, 18 marzo 2017
- [15] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, *Official Journal of the European Union* L12/1-89, January 15, 2011
- [16] Decreto Ministeriale 21 marzo 1973, Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale, *Supplemento Ordinario alla Gazzetta Ufficiale* n.104, 20 aprile 1973
- [17] Commission Regulation (EU) No 284/2011 of 14 January 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China, Official Journal of the European Union L77/25-29, March 23, 2011
- [18] Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008, Official Journal of the European Union L243/3-46, September 20, 2022
- [19] Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food, Official Journal of the European Union L302/28-32, November 19, 2005
- [20] Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food, *Official Journal of the European Union* L135/3-11, May 30, 2009
- [21] Council Directive of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs (84/500/EEC), *Official Journal of the European Communities* L277/12-16, October 20, 1984
- [22] Commission Directive 2005/31/EC of 29 April 2005 amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs, *Official Journal of the European Union* L110/36-39, April 30, 2005
- [23] Decreto Ministeriale 4 aprile 1985, Disciplina degli oggetti di ceramica destinati ad entrare in contatto con i prodotti alimentari, *Gazzetta Ufficiale* Serie Generale n.98, 26 aprile 1985
- [24] Decreto 1 febbraio 2007. Recepimento della direttiva n. 2005/31/CE della Commissione del 29 aprile 2005, che modifica la direttiva n. 84/500/ CEE del Consiglio, per quanto riguarda una dichiarazione di conformità e i criteri di efficienza dei metodi di analisi per gli oggetti di ceramica, destinati ad entrare in contatto con i prodotti alimentari, *Gazzetta Ufficiale* Serie Generale n.66, 20 marzo 2007
- [25] Commission Directive. 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs, Official Journal of the European Union L172/71-82, June 30, 2007.
- [26] Commission Directive 93/11/EEC of 15 March 1993 concerning the release, of the N-

nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers, *Official Journal of the European Communities* L93/37-38, April 17, 1993

- [27] Decreto 25 novembre 2022, n. 208. Regolamento recante l'aggiornamento al decreto del Ministro della sanità 21 marzo 1973, recante: «Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire a contatto con le sostanze alimentari o con sostanze d'uso personale», limitatamente agli acciai inossidabili, *Gazzetta Ufficiale* Serie Generale n.15, 19 gennaio 2023
- [28] Decreto 25 settembre 2007, n. 217. Regolamento recante aggiornamento del decreto ministeriale 21 marzo 1973, concernente la disciplina igienica degli imballaggi, recipienti, utensili destinati a venire a contatto con le sostanze alimentari o con sostanze d'uso personale, *Gazzetta Ufficiale* Serie Generale n.270, 20 novembre 2007
- [29] Decreto 18 aprile 2007, n. 76. Regolamento recante la disciplina igienica dei materiali e degli oggetti di alluminio e di leghe di alluminio destinati a venire a contatto con gli alimenti, Gazzetta Ufficiale Serie Generale n.141, 20 giugno 2007
- [30] Decreto 18 febbraio 1984, Disciplina dei contenitori in banda stagnata saldati con lega stagnopiombo ed altri mezzi, *Gazzetta Ufficiale* Serie Generale n.76, 16 marzo 1984
- [31] Decreto 13 luglio 1995, n.405 Regolamento recante aggiornamento del decreto ministeriale 18 febbraio 1984 concernente la disciplina dei contenitori in banda stagnata saldati con lega stagno-piombo ed altri mezzi, *Gazzetta Ufficiale* Serie Generale n.228, 29 settembre 1995
- [32] Decreto 1 giugno 1988, n.243 Disciplina degli oggetti in banda cromata verniciata destinati a venire in contatto con gli alimenti, *Gazzetta Ufficiale* Serie Generale n.153, 1 luglio 1988