

Consumers have the right to purchase, use and consume foodstuffs, including drinks and water incorporated in foodstuffs, that are safe from a health and hygiene standpoint.

The factors which can compromise the wholesomeness, conformity and shelf life of foodstuffs are dependent upon many variables or aspects, starting from their formation, composition, conservation and preparation methods, and also involving the characteristics of the environments in which these operations are performed as well as, for the purposes of this document, the characteristics of the equipment and machinery used in the preparation and conservation of the foodstuffs, their raw materials and semi-finished products, their design, the composition and means of operation and the maintenance of said objects and especially of the materials of which they are composed, which could alter the foodstuffs in various ways, depending also on their intended use and their usage limits.

In what follows, for the sake of simplicity, we shall call all these items and their components as a whole, "MOCA/FCM", an acronym now in common usage in the agro-food sector meaning *"Materiali od Oggetti destinati al Contatto con Alimenti/Food Contact Materials"*.

Manufacturers and users of MOCA/FCM have every interest in ensuring compliance with the requirements set out in existing regulations in order to avoid a situation in which the items they manufacture are found to be non-compliant or, as a result of them, foodstuffs are found to be non-compliant, leading to civil litigation or, even worse, giving rise to criminal liability in the event of a risk to consumer health.

And it is also worth bearing in mind that any non-conformity with these recommendations may lead to the seizure, recall or withdrawal of non-conforming products: situations which easily create a domino effect of suspicion and distrust amongst consumers, not only of the specific item or product shown to be non-conforming but, as unfortunately has already happened on many occasions, of entire sectors to which the product belongs and, in some cases, of every product coming from a certain country.

The damage thus caused is not immediately quantifiable, but it can be presumed to be orders of magnitude greater than that which might reasonably have been expected for the specific triggering events and such effects can be felt for a long time, affecting even companies or countries unrelated to the incriminating event, compromising, at least in part, the investments and efforts made by companies to ensure and maintain the quality and the compliance of their products and imposing additional costs to promote informational campaigns aimed at bringing the commonly held conception of quality into line with reality.

As a response to the request and urging from both the scientific world and possible stakeholders (clients, suppliers, users, sector operators, food industry workers, etc.), the Legislator has focused its attention on the transfer of undesirable substances from unfit MOCA/FCM into foodstuffs, defining rules aimed at preventing said risk, regulating and defining the classes and types of materials that may come into contact with foodstuffs and establishing the founding principles of good manufacturing practices, or GMP, that must characterise the management of the phases of production, manufacture, and "in general, the use of MOCA/FCM".

In summary, to increase the level of food safety, preventing, as far as possible, foodstuffs from containing undesirable substances (including Not Intentionally Added Substances, NIAS) derived from contact with unfit materials, preventative action is extended to the definition of positive lists of materials that may be used and the characteristics that they must be shown to possess, under operating conditions, in order to avoid the possibility of this type of contamination.

2 - SCOPE AND FIELD OF APPLICATION

All of this is made possible through the systemic introduction and application of a quality assurance and control system based on the principles of self-regulation and working methods based on Good Manufacturing Practices (GMP), able to manage and monitor the proper performance of each critical phase of manufacture, ensuring that any deviation from interval or safety values is dealt with promptly. It will thus be possible to provide the end user of the MOCA/FCM suitable proof of food contact compliance with reference to set usage scenarios.

On the other hand, the proper interpretation of the aforementioned proof by users of the MOCA/FCM derives both from an understanding of the principles and criteria by which each declaration of conformity is bound, however that may be expressed, and from an assessment of the impact that the actual usage of the MOCA/FCM might have on the components, structure and performance of the latter.

The documentation attesting to conformity, if correctly formulated and accompanied by the usage conditions together with any appropriate recommendations, should facilitate the identification of a boundary between the respective skills and responsibility of the supplier and the client.

Finally, this document aims to present itself as a common basis of reference for other, more specific guidance documents for the manufacture and use of particular types of object, equipment and machinery intended to come into contact with foodstuffs.

3 - LEGISLATIVE REFERENCES

MOCA/FCM are governed at both a European and national level by regulations whose structure is closely integrated with and correlated to that of regulations on the safety of foodstuffs and drinks; the concept of food safety has, in fact, been logically extended to everything that can, in whatever way, affect the composition of the foodstuff itself.

In the introductory part of Regulation (EC) no. 1935/2004, under recital (3), we find the key principle to refer to in the rationale governing MOCA/FCM:

"The principle underlying this Regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties. Also relevant is Regulation (EC) no. 178/2002, which establishes the principles and general requirements for food legislation, instituting the European body for food safety and establishing procedures in the field of food safety."

Consequently, Regulation (EC) no. 852/2004 and Regulation (EC) :1. 853/2004 establish the means through which Food Business Operators (FBO) ensure the implementation of the food safety principles and Regulation (EC) no. 854/2004 establishes specific regulations for the organisation of official controls on products of animal origin destined for human consumption. Finally, Regulation (EC) no. 882/2004 defines the means used to plan and execute the official controls aimed at verifying conformity with the regulations on feed and foodstuffs and the regulations on the health and well-being of animals. Other regulations have subsequently identified the compliance requirements for certain types of foodstuffs, with reference to specific microbiological and chemical parameters: an implementation process in regulations regarding food security destined to continue and improve in the future.

To date, having been returned to the national level, the definition, on the basis of the respective regulations, of the sanctioning regimes to EU regulations, Italian Legislative Decree no. 193 of 6 November 2007, performs this function in terms of food safety regulations relative to the foodstuffs and feed mentioned above in Italy.

These regulations constitute the cohesive set of the so-called EU "hygiene package" in the food sector, which is completed by the regulatory framework regarding MOCA/FCM: Regulation (EC) no. 1935/2004, establishing the general requirements which must be met by the materials and items intended to come into contact with foodstuffs, and Regulation (EC) no. 2023/2006, which, integrating the previous regulation, establishes the regulations for good manufacturing practices for the entire MOCA/FCM production chain.

Even in the case of the MOCA/FCM, as per foodstuffs, other specific regulations are added that contain detailed provisions for certain types of materials. In any case, for the materials for which no EU regulation exists, the Member States may establish national regulations.

The sanctioning system, too, due to the failure or incomplete application of that established by EU regulations, has a national nature: Italy recently passed Italian Legislative Decree no. 29 of 10 February 2017 which defines and governs the sanctioning framework for breaches of the provisions referred to in Regulations (EC) no. 1935/2004, no. 1895/2005, no. 2023/2006, no. 282/2008, no. 450/2009 and no. 10/2011, regarding materials and items intended to come into contact with food products and foods.