

FOOD MACHINERY

SAFE SUSTAINABLE SOLUTIONS



The UE Commission has enacted the so called **Machinery Directive** 2006/42/EC, which stipulates that equipments intended to be used for foodstuffs or cosmetic or pharmaceutical products must be designed and constructed in such a way as to avoid any risk of infection, disease and contagion, according to the applicable dispositions for the finished product. On June 29, 2023, the new **Machinery Regulation** (EU) 2023/1230 was published, which will replace the current directive; the new Machinery Regulation will apply from January 20, 2027.

The Directive has been accompanied by several technical application standards, such as EN 1672: Food-processing machines - General Principles of Design, and ISO 14159: Hygiene Requirements on the Design of Machines; within these we find definitions of machinery: "A set of connected parts or components, at least one of which is movable, with the appropriate actuators, control circuits and machine power supply, connected for a specific application, in particular for the processing, treatment, handling or packaging of a material."

For food machineries it is needed to apply all the relevant legislation for the components, according to framework Regulation. In regards of Europe, i.e., since the 15th amendment of Framework Regulation 10/2011, a new approach for risk assessment of food machinery was allowed.

(iv) if the plastic material or article intended to come into contact with food of which the compliance must be verified becomes in its final application part of a food processing equipment or an appliance, or a part thereof, the migration tests may be carried out by determining the specific migration into the food or food simulant produced or processed by the whole equipment or appliance, or the part thereof, as appropriate, subject to the following conditions:

- the food or food simulant is processed during testing by the equipment or part thereof in accordance with the worst foreseeable conditions that can be achieved if the equipment or its part is operated in accordance with its operating instructions, and
- the migration from parts used for storage such as from reservoirs, containers, or capsules or pads which are part of the equipment during the processing of the food, is determined using conditions representative for their use, unless the applied testing conditions for the whole tested equipment or appliance are representative also of their use.

When migration testing is done under the above conditions, and the transfer of constituents from the equipment or appliance as a whole does not exceed the migration limits, the plastic parts or materials present in the equipment or appliance shall be considered to comply with Article 11(1).

This approach is applicable for all enabling legislation in the world



OUR SOLUTION

Food Contact Center & Services work together to **carry out risk assessment through tests and supporting documentation aimed at demonstrating compliance of the various components and thus the machinery**, after careful evaluation of the materials in contact and their potential contaminants that may migrate under conditions of use based on specific foods, contact times and temperatures.

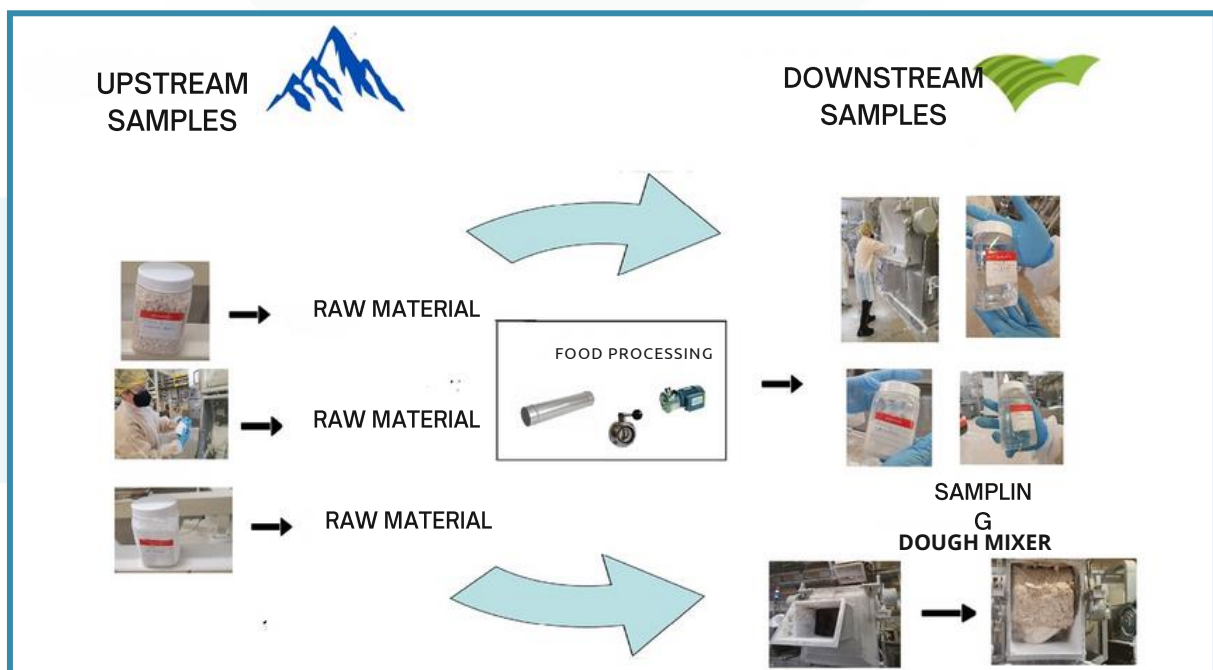
Three different strategies can be adopted according to different situations:

- **A: Testing is performed in part by component suppliers, or to be performed by the machinery manufacturer.** In these cases, it may be appropriate and cost-effective to perform compliance testing by simulant testing to be performed on individual components.
- **B: Newly assembled machinery.** It is possible to perform tests with the "Real Use" approach, using food simulants that are processed by the machinery like the food in its real production process.
- **C: New or existing machinery.** It is possible to perform the specific migration testing in food after validation of the methods of migration analysis in the specific foods of the contaminants identified by the documentary study of the components. Approach C can thus be carried out in accordance with legal requirements by laboratories highly specialized in the topic and validation of specific migration of MOCA contaminants in food. In fact, EU Regulation 10/2011 specifies that "The manufacturer of individual plastic parts shall ensure the absence of migration of substances for which the regulation indicates that migration should not be detectable at a given appropriate level of detection."

Beforehand, a thorough mapping of the machinery should be carried out to identify potential contaminants.

The analytical data must be robust and obtained from reliable analyses; for this reason, the Food Contact Center in March 2021 brought under accreditation analysis of some MOCA contaminants performed in food matrices (flour, pizza, meat and fish products) to prove the reliability of the sample preparation, including an appropriate purification and detection..

For industrial installations already in use, after a thorough study of the production processes, mapping each of them and assigning a related risk assessment, upstream and downstream sampling of the identified segments is performed, then testing the samples for potential contaminants highlighted in the preliminary study. The end of the evaluation is obtained with a technical report which collects all the findings and the strategy used for the segmentation of the risk.



La Direzione del laboratorio

