



The European Union created Regulation (EC) 1935/2004 to provide a common understanding within the EU marketplace regarding the use of certain materials which come in contact with food and the necessary safety measures that must be in place to ensure protection of human health and the best interests of consumers.

The underlying principle is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from the following:

- Being transferred to food in quantities large enough to endanger human health
- Bringing about an unacceptable change in the composition of the food
- Causing deterioration in its sensory properties. (smell, taste, etc.)

The regulation also directs that materials must be manufactured in compliance with good manufacturing practices. All materials must be traceable through each step of the manufacturing process in the event of product recall. It also provides marketing directives for labelling, advertising, and presentation that is not misleading to consumers.

The regulation covers 17 groups of materials and articles. Rubber, plastics, ceramics, and paper are just some of the materials listed however; there is no specific legislation in Europe for rubber other than that of rubber feeding teats/soothers. In the absence of this law, EC 1935/2004 allows for the member countries to create specific measures/tests for rubber sealing materials that must be passed in order to gain approval for food contact within their nation. As an example, in Germany, the Federal Institute for Risk Assessment (BfR) system is widely followed and well respected for proving rubber food contact credentials in the EU. BfR recommendation XXI covers natural/synthetic rubber.

Some examples of the specific measures that may be considered are:

- A list of substances authorized for use in manufacturing of materials or articles and the purity standards applicable to each.
- Specific and overall limits allowed regarding migration of constituents into or on to food.
- Basic rules for checking compliance of the above and collection of samples to perform analysis.
- Provisions related to traceability of all materials and the duration for retention of records.
- Provisions related to labelling materials and articles including correct use of the wine glass/fork symbol.

In the United States, compounds formulated with the materials listed under the FDA Code of Federal Regulations, Title 21, Part 177.2600 are generally considered acceptable for food contact applications. Compliance with the code is self regulated meaning that the compounder certifies the material was made with the approved ingredients. The FDA does not test or specifically approve rubber compounds.

It should not be assumed that all FDA materials will meet the EC1935/2004 requirements.

EC1935/2004 regulation compliance is more difficult in that compounds themselves must be tested to specific requirements that are determined by each country. Users intending to export products for food contact into Europe, are required to use materials that have been tested and deemed EC1935/2004 compliant.

Precision Associates compound 623717 has been tested and is compliant with EC1935/2004 regulations.

Contact PAI for a detailed Product Data Sheet on this material!