



HARRPA

Hydrocarbon Resins, Rosin Resins and Pine Chemicals
Producers Association

HARRPA STATEMENT ON Resins and EU Food Contact Legislation

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The products manufactured by the HARRPA (Hydrocarbon Resins, Rosin Resins and Pine Chemicals Producers Association) members are used in many applications, e.g. (hot melt) adhesives, rubber, chewing gum, cosmetics, paints, tyres and food contact applications. Usually the resins do not represent the major component of the article or material. More information on products can be found on the HARRPA website¹.

General

Food contact materials are regulated by law in most countries. These laws and regulations have in common the intent to protect human health by only allowing on the market safe foodstuffs and that the food itself is not adulterated.

For food contact materials the situation in the EU is very complex. Harmonisation has not yet been completed and for most applications not even a start has been made. Therefore, EU Member States may have legislation in place that differs from one another. E.g., The Netherlands has so-called positive lists in place, whereas Germany only has a generic statement in its legislation. In addition, not every country covers all types of food contact materials.

At the EU level, the process of harmonising all food contact materials was started a long time ago. Currently the so-called Framework Regulation 1935/2004² is the starting point for all legislation regarding food contact materials. The Framework Regulation states in Article 3 that food contact *"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 deterioration in the organoleptic characteristics thereof."*

Annex I to the Framework Regulation gives a list of groups of materials and articles that may be covered by specific measures. This document focuses on Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food³ and further amendments.

The Framework Regulation stipulates that *all* food contact materials on the EU market, also those that are not covered by a specific Directive or Regulation, have to be manufactured according to Good Manufacturing Practice. This means that the business operator establishes, implements and ensures adherence to an effective and documented quality assurance system. The EU Regulation on GMP 2023/2006⁴ in force as per 1 August 2008 applies to the manufacturing of the materials and articles.

¹ <http://www.cefic.org/About-us/How-Cefic-is-organised/Fine-Speciality-and-Consumer-Chemicals/Hydrocarbon-Resins-Rosin-Resins-And-Pine-Chemicals-Producers-Association-HARRPA/HARRPA-Applications/>

² <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:338:0004:0017:EN:PDF>

³ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>

⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:384:0075:0078:EN:PDF>

The EU established the European Food Safety Authority (EFSA) as the legal body to evaluate the dossiers submitted by companies seeking approval for, amongst others, food contact materials.

Principle of Mutual Recognition

As a move towards removing barriers to trade (i.e. creating a level playing field) the principle of mutual recognition was developed.

Basically this means that a product legally marketed in one Member State can be legally marketed in all other Member States. If a product complies with the applicable legislation in one EU Member State, then all other Member States must allow that same product to be marketed in their area of jurisdiction. The product must not be shown to pose a hazard to health. This has been embodied in an EU Regulation 764/2008⁵.

To put this into perspective, if for example a chemical substance is approved for use in a food contact material, such as a coating in Dutch law, then that same substance must be allowed to be used in the same application in all other EU Member States..

Food contact materials

At a European level only the European Food Safety Authority (EFSA) has the authority to evaluate direct food additives, food contact materials and investigate specific issues concerning food safety.

In the case of food contact materials, EFSA only accepts petitions only for substances that have been extensively tested. In most cases these petitions have been submitted for substances used in the manufacture of food contact plastics. The approved substances are listed in the Union List.

Not only manufacturers of food contact plastics make use of the Union List. For other applications than plastics, manufacturers use the EFSA evaluations for their risk assessment of materials and articles other than plastics, e.g. adhesives, coatings or printing inks.

The Association of the European Adhesive and Sealants Industry (FEICA) has published a significant paper on food contact matters⁶. Even though the paper was written for adhesives, the regulatory environment as well as the principles for risk assessment are valuable for other types of applications as well.

CONCLUSIONS

All products on the EU market intended to come into contact with foodstuffs are subject to Framework Regulation 1935/2004, regardless the type of food or the type of food contact material. Depending on the type of food contact material, either regulations specific for a country apply or a regulation that is subject to harmonisation through an EU Directive or Regulation.

⁵ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0021:0029:EN:PDF>

⁶ <http://www.feica.com/ehs-sustainability/food-contact>

The FEICA document on food contact materials is a good starting point to learn about the regulatory aspects of food contact materials, but also helpful for the principles of risk assessment of food contact materials.