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**1 Scope of validity**

This leaflet contains explanations of the legal regulations on the use of thermally sprayed coatings for products in contact with food. It also provides general procedural instructions for certifying an application with a thermally sprayed coating in accordance with German and international law.

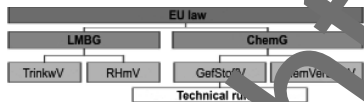
**2 Introduction**

The use of thermally sprayed coatings in contact with food involves technological, medical and toxicological issues, and can only be considered in the context of the legal regulations. The technological aspects most importantly concern the use for which the coating is applied based on its specific function. Medicinal and toxicological aspects are rooted in the materials of the coating, its impurities and adherent chemicals, and ultimately in its effect on the human organism. The legal regulations define the reference values and limit values that are permitted for a food, the measures to be taken when these values are exceeded, and when a proof of harmlessness must be provided for an application.

**3 Legal structure**

The legal regulations to which foods or items that come into contact with food are subject are defined in an interaction between national and international laws. EU guidelines form the basis for national legislation [1 ... 4].

Products that are created using a thermally sprayed coating and come into contact with food should be regarded as commodities. The most important applicable laws are shown in Fig. 1.



**Figure 1.** Extract from relevant laws for thermally sprayed applications that come into contact with food.

**3.1 Laws**

EU law as a superordinate jurisdiction tries to harmonise legislation throughout Europe. National regulations are shaped in the form of guidelines that specify testing methods, positive lists or lists of prohibited chemicals.

The definitive law in Germany on items that come into contact with foods is the German Food Law (LMBG) [5]. It regulates the scope of validity, the permitted and prohibited chemicals, the test

requirements, the monitoring of commodities and the measures for infringement of the law.

LMBG § 5 Para. 1 Item 1 defines as commodities items in general that are intended to be used for the production, treatment, marketing or consumption of food products, and therefore to come into contact with the food. Additional inclusions and parameters for the definition are contained in the law.

In the interest of protecting human health, LMBG § 30 Item 1 prohibits the manufacture or treatment of commodities in such a way that, in intended or foreseeable use, they are able to damage health by their material composition, specifically by toxic substances, or by contaminations.

LMBG § 31 Para. 1 prohibits the commercial use of items as commodities as defined in § 5 Para. 1 Item 1 in such a way or for such purposes that matter is allowed to migrate from them onto food or its surface except on a technically inevitable scale that does not harm health, smell, or taste.

The German Chemicals Act (ChemG) represents the main law for protecting against hazardous substances [6]. This law defines the basic classification that is used to assess the dangerousness of chemicals. It also legislates on registration of a new substance, i.e. it defines regulations that must be observed before a manufacturer brings a chemical or a recipe into commercial use.

**3.2 Regulations**

As a general rule, laws only define the objectives and fundamental principles. The subsequent associated regulations formulate more specific stipulations and definitions of limit values. For instance, the German Ordinance on Hazardous Substances (GefStoffV), which follows on logically from the Chemicals Act, formulates a list of prohibited chemical substances and basic principles for the safe handling of hazardous substances [7].

Ordinances can also apply specifically to individual products. For instance, the German Drinking Water Ordinance (TrinkwV) specifically formulates the limit values that must be observed and the monitoring requirements for the public drinking water supply. For mineral and spring water, the German Mineral and Table Water Ordinance (Min/TafelWV) is applicable.

**3.3 Technical rules**

Specific practical instructions and limit values for individual substances are contained in the technical rules. The Technical Rules for Hazardous Substances 900 (TRGS 900) include permissible workplace limit values [8].

**4 Proof of harmlessness for commodities**

The reason for obtaining proof of harmlessness („certification“) for a commodity is the requirement to ensure before a product is brought into commercial use that it satisfies LMBG criteria. Random sampling is carried out to check that this requirement is met.

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DVS, Technical Committee, Working Group „Thermal spraying and thermally sprayed coatings“

### 4.1 German proof of harmlessness

A proof of harmlessness is issued by an officially recognised testing institute. Before such proof can be issued, the manufacturer must submit detailed information on the product, see Fig. 2. If the product in question has a thermally sprayed coating, then the testing institute may need access to information from the firm that applied the coating and/or the powder supplier. Based on the above details, the test conditions (temperature management, duration of test, etc.) and the simulant food can be decided. The simulant food is a generic material that represents a type of food. Depending on the application, the test conditions and simulant food to be used may be listed in EU directives (85/572/EEC, 82/711/EEC 90/128/EEC, 2004/19/EU, EU Resolution AP (96) 5) [9]. If the product to be tested contains chemical substances that are not listed in a directive, then the testing institute must devise an appropriate test procedure.

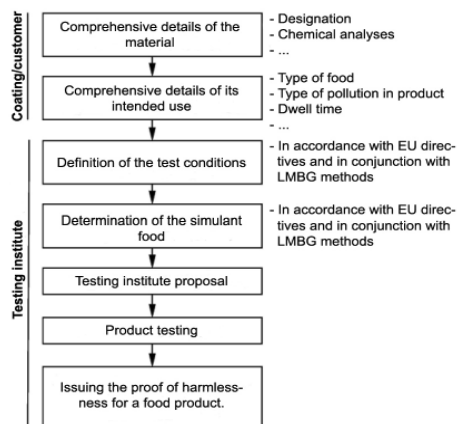


Figure 2. Procedure for issuing a proof of harmlessness for a food product.

It is the responsibility of the testing institute to carry out testing and also to issue the certificate. Another option is to commission a certified foodstuffs laboratory or a trade chemist to perform the tests and then request that the testing institute issues the certificate based on the test results so obtained.

Testing institutes in Germany that are authorised to issue a proof of harmlessness include the Fresenius Institute [10], regional authorities such as the Lower Saxony Regional Authority for Consumer Protection and Food Safety [11] or TÜV Nord Cert GmbH [12]. A list of accredited testing laboratories for carrying out chemical tests and their specified catchment areas can be obtained from the German Accreditation Council (DAR) [13].

### 4.2 German proof of harmlessness in accordance with FDA

Proof based on EU directives is also recognised internationally. Nonetheless, in particular instances additional proof may be required in accordance with the provisions of the US Food and Drug Administration (FDA) [14]. The procedure for this is similar to that for obtaining a certificate in Germany. A test procedure can be determined, based on comprehensive information on the application, the material that comes into contact with the food, the food itself and the purpose of use. If the material and its application are listed in the 'Code of Federal Regulations' (CFR), this means that known test specifications exist for them [15]. Otherwise a test specification must be formulated by the FDA. For this purpose, a new registration for the material (Food Contact Substance, FCS) must be submitted. The registration can be in the form of a 'Notification' (FCN) or a petition depending on whether or not maximum values for ingestion of the substance are known (Cumulative Estimated Daily Intake, CEDI) or Acceptable Daily Intake, ADI). Where a CEDI or ADI value already exists, the situation is more straightforward and a notification can be submitted. In this case, Form 3480 should be completed for a single substance or Form 3479 for a combinati-

on of substances; when the form is submitted it should be accompanied by samples. If no CEDI or ADI values are available, then the process becomes more prolonged and complicated. Medical toxicology tests then need to be carried out or evidence of such tests must be presented to demonstrate the potential effects of the substance on humans or its absorption in the gastro-intestinal tract.

### 5 Terms and abbreviations

LMBG	– Lebensmittel- und Bedarfsgegenstände-gesetz [German Food Law]
ChemG	– Chemikaliengesetz [German Chemicals Act]
GefStoffV	– German Hazardous Substances Directive
ChemVerbotsV	– Chemikalien-Verbots-Verordnung [German Chemicals Prohibition Ordinance]
RHmV	– Rückstand-Höchstwertverordnung [German Maximum Residue Level Regulation]
TrinkwV	– Trinkwasserverordnung [German Drinking Water Ordinance]
TRGS	– Technische Regeln Gefahrstoffe [German Technical Rules for Hazardous Substances]
AGW	– Arbeitsplatzgrenzwert [Occupational Exposure Limit]
BGW	– Biologischer Grenzwert [Biological Limit Value]
FDA	– U.S. Food and Drug Administration
CFR	– Code of Federal Regulations
FCS	– Food Contact Substance
FCN	– Food Contact Notification
CEDI	– Cumulative Estimated Daily Intake
ADI	– Acceptable Daily Intake
DAR	– Deutscher Akkreditierungsrat [German Accreditation Council]
LNAES	– Niedersächsisches Landesamt für Verbraucherschutz und Lebensmittelsicherheit [Lower Saxony Regional Authority for Consumer Protection and Food Safety]

### 6 References

- [1] Chemistry-related information; <http://www.chemlin.de>
- [2] UWS Umweltmanagement GmbH; <http://www.umweltrecht.de>
- [3] German Federal Ministry of Justice; <http://bundesrecht.juris.de>
- [4] German Federal Environment Agency; <http://www.umweltbundesamt.de>
- [5] LMBG: Law concerning the trading of food, tobacco products, cosmetic products and other commodities, version dated 9 September 1997, BGBl. I S. 2296, modified on 8 August 2002, BGBl. I S. 3116
- [6] ChemG: Law for protecting against hazardous substances
- [7] GefStoffV: Verordnung zum Schutz vor gefährlichen Stoffen [German Ordinance for Protecting against Hazardous Substances]
- [8] TRGS 900: Technische Regeln für Gefahrstoffe [German Technical Rules for Hazardous Substances] Limit values in the air at the workplace
- [9] European Union; [http://europa.eu.int/index\\_de.htm](http://europa.eu.int/index_de.htm)
- [10] Fresenius Institute; <http://www.institut-fresenius.de>
- [11] Lower Saxony Regional Authority for Consumer Protection and Food Safety, Institut für Bedarfsgegenstände [Institute for