

**Notification of market surveillance programmes
in accordance with Article 18(5) and (6) of Regulation (EC) No 765/2008:**

2014 market surveillance programme for cosmetic products, toys (chemical and toxicological requirements) and tobacco products

1. Products concerned

The information in this document concerns:

- cosmetic products,
- the chemical and toxicological safety of toys (consumer goods),
- tobacco products.

In Germany, these product groups are regulated in the Food and Feed Code (*Lebens- und Futtermittelgesetzbuch*), the provisional Tobacco Act (*Vorläufiges Tabakgesetz*), the Toy Safety Ordinance (*Verordnung über die Sicherheit von Spielzeug*), the Consumer Goods Ordinance (*Bedarfsgegenständeverordnung*) as well as the Tobacco and Tobacco Products Ordinances (*Tabakverordnung, Tabakprodukt-Verordnung*). The relevant European Union rules are contained in Regulation (EC) No 1223/2009 on cosmetic products, Directive 2009/48/EC on the safety of toys, Directive 2001/37/EC concerning the manufacture, presentation and sale of tobacco products, as well as Regulation (EC) No 1907/2006 (REACH).

2. Organisation and procedures

It is the responsibility of the *Länder* to enforce the legislation and to organise the implementation of their surveillance operations independently. Approximately 320 inspectors are employed full-time as part of the market surveillance framework for these product areas.

Market surveillance involves the monitoring of compliance with legal requirements. In accordance with the requirements of the General Administrative Regulation on the principles for carrying out official monitoring of provisions under food and wine legislation (*AVV Rahmen-Überwachung*, § 9), the number of samples of cosmetic, consumer and tobacco products to be taken is, in principle, 0.5 per 1000 inhabitants.

Companies that make cosmetic, consumer or tobacco products available on the market are inspected regularly. The market surveillance authorities are able to monitor products throughout the production and supply chain on a risk-oriented basis. The regularity of inspections is determined according to various criteria, for instance: the type and scale of production at the company; experience of the company's internal monitoring regime; the type and origin of the products (in particular their durability); product, production and personal hygiene; employees' qualifications and size of workforce; whether the products are intended to be used by vulnerable groups; and, where applicable, previous irregularities. Should any acute problems be identified, immediate inspections will take place.

The General Administrative Regulations, enacted by the German Federal Government with the agreement of the *Länder*, ensure a uniform standard for authorities to conduct surveillance. In order for the *Länder* to coordinate their surveillance activities, bodies

such as the Working Group on Food, Wine, Consumables and Cosmetics (*Arbeitsgruppe Lebensmittel, Wein, Bedarfsgegenstände und Kosmetika*) and the Research Group of Experts in Food Chemistry (*Arbeitskreis Lebensmittelchemischer Sachverständiger*) have been established. Additionally, the Federal Office for Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit*) fulfils various coordination tasks.

3. Programmes

Parallel to the routine inspection and sampling activities, two special surveillance programmes are operating at a national level in Germany: the Monitoring Plan (*Monitoring*) and the Nationwide Control Plan (*Bundesweiter Überwachungsplan*).

3.1 Monitoring Plan

Monitoring consists of systematic and repeated observation, measuring and evaluation of levels of undesirable substances in consumer products that pose a health risk. It forms part of the preventive measures protecting consumer health and helps to identify the possible health risks to consumers from undesirable substances such as residues, mycotoxins, heavy metals and other environmental contaminants at an early stage; where appropriate, specific measures to remedy the situation can be investigated. The samples taken are representative of all of Germany. Monitoring is carried out as the independent task of the *Länder* on the basis of sections 50-52 of the Food and Feed Code as part of their official surveillance operations. Monitoring is conducted annually according to a plan drawn up by the Federal Government and the *Länder*, which details the products selected for testing and the substances to be tested for, as well as the distribution of testing among the *Länder*. Selections are based on long-term strategies for obtaining reliable data for risk assessment purposes. In addition to their routine investigative duties, the surveillance authorities in each *Land* are charged with taking and analysing samples for use in the monitoring process. The Federal Office for Consumer Protection and Food Safety captures the extracted data, analyses them and publishes them in the form of an annual report.

In 2014, the following data will be analysed as part of the Monitoring Plan:

- Cosmetic products
 - 154 samples for nitrosamines in oxidative hair dyes
 - 151 samples for nitrosamines in direct dyes (semi-permanent or temporary hair dyes)
 - 213 samples for micro-organisms in plant-based hair colouring products
- Toys
 - 193 samples for the PAH content of products with coated surfaces.

3.2 Nationwide Control Plan

Germany's Nationwide Control Plan is renewed annually and covers the execution of the official controls agreed on by the *Länder* to verify compliance with regulations. This may include programmes to inspect products, factories and other establishments or a combination of the these. The Nationwide Control Plan is a risk-oriented surveillance programme. The selection of samples to be tested and establishments to be inspected will be based on a risk analysis. These investigations may cover chemical and

microbiological parameters, particular manufacturing and treatment processes as well as labelling issues. The aim of the Nationwide Control Plan is to obtain information on compliance with regulations throughout the country. Additionally, data will often be collected in order to provide clarification for any issues that may arise.

Suggestions for programmes to include in the Nationwide Control Plan are made by the *Länder*, the Federal Ministries, the Federal Institute for Risk Assessment as well as the Federal Office for Consumer Protection and Food Safety. The *Länder* and the Federal Office for Consumer Protection and Food Safety agree on which of the suggested programmes will be implemented. As not all issues are of equal relevance to all *Länder*, owing to regional differences, each individual *Land* independently decides which programmes it will participate in and how many samples it will collect.

In 2014, the following data will be analysed as part of the Nationwide Control Plan:

- 705 samples for the determination of panthenol in cosmetic products claiming to increase the skin's ability to retain moisture or stimulate epithelisation.