

**Food Contact.** Many plastics have various applications in the food sector. But before they can be used in the most diverse applications, such as food packaging or coffee machines and household appliances, they must meet a range of requirements. The specifications are laid down in EU directives and regulations, and particularly in Germany, in the Regulation on Commodities.

# Economies here Can Be Harmful

#### RUTH ZSCHIESCHE ET AL.

o meet their consumer protection responsibilities, the Council and the Commission of the European Community, have enshrined EU food law in the form of regulations, directives and decisions.

The basic regulatory framework, Regulation (EC) No. 1935/2004, sets out the basic requirements for materials and articles intended to come into contact with food. The main requirements are found in Article 3 of the regulation, which states that the materials 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 a deterioration in the organoleptic characteristics thereof."

The details of this good manufacturing practice are specified in Regulation (EC) No. 2023/2006: It provides information on "good manufacturing practice (GMP) for materials and articles intend-

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ed to come into contact with food". This GMP regulation came into force in the European Union on 1 August 2008 and should not be confused with that GMP which has long applied in the medical field. The GMP regulation for food-contact materials calls for a quality assurance system and a quality control system that applies to every stage of the supply chain to rule out impairment to food-contact materials - and thus to food - that could harm consumers. Further implementing provisions are not described in the regulation. Meanwhile, however, various organizations, including PlasticsEurope, have drawn up instructions on how to implement GMP. A draft guideline of a DIN/CEN GMP standard is being pre-

The third key regulation in this context, which deals specifically with plas-

### Manufacturer

BASF SE Fachpresse Kunststoffe D-67056 Ludwigshafen Germany Tel. +49 621 60-43348 Fax +49 621 60-49497 www.plasticsportal.net Fig. 1. This spatula is made of Ultramid A3EG6 FC, the latest addition to the polyamide range

tics only, is EU Directive 2002/72/EC (and its amendments). It contains specific rules on foodcontact materials made of plastic and also takes into account its predecessor directive, which has already been in force for 20 years. This

directive specifies that only listed monomers and additives are approved for the manufacture of plastics. They may be subject to additional restrictions on the maximum permitted quantity in the article and/or the specific migration level for the monomers and additives into food. In Germany, this directive has been enacted as part of the Commodities Regulation.

All three of these regulations or directives must be observed and respected where plastics are used for food contact.

### Importance to the Plastics Industry

Ever since the EU's GMP regulation on food-contact materials came into force on 1 August 2008, plastics manufacturers and plastics processors who are active in Europe must ensure that an enhanced quality assurance and process control system for their plastics or plastic products in this application segment is in place. Even greater responsibility is therefore being placed on all members in the added-value chain, with liability resting on the company marketing the products. In the past, ignorance or a misunderstanding of cost management has caused substantial reputational damage to many

reputable end-product manufacturers.

BASF makes plastics for the food sector that have long since satisfied high safety standards. The new regulation, however, forces plastic manufacturers to select and qualify specific materials as well as to implement more comprehensive measures on documentation and quality assurance. BASF provides its customers with the relevant, written confirmation of EU compliance. Categorized by product type and industry, on one hand there are products, such as polystyrene and Styrolux (styrene-butadiene block copolymer, SBS), which have long been used for food contact. On the other, these are being increasingly joined by polymers, e.g. Ultramid (PA) and Ultradur (PBT), that were hitherto more common in the automotive and electronics sectors. Only recently have they found application in coffee machines and storage jars. For such products, BASF has now launched special GMP grades, which bear the label FC (for "food contact"). Almost all these FC grades also have FDA approval, which is needed for the U.S. market.

## Recently Approved: Polyamide Compounds and PBT

BASF's Ultramid range has recently been extended to include several nylon 66 grades which are produced in compliance with the new GMP regulation. Bearing the suffix FC, to signify suitability for food contact, the grades in question are Ultramid A3K and Ultramid A3EG6 and A3EG7, which are non-reinforced and glass fiber-reinforced (30 and 35 %) grades respectively. Grade A3EG7 is now

Fig. 2. Me.g. ged. & Co. K mater co

Fig. 2. Many toy manufacturers, e.g. geobra Brandstätter GmbH & Co. KG, insist that the raw materials comply with foodcontact legislation; toys in Germany are also subject to a commodities regulation (the yellow face, ears and neck of this Playmobil monkey are made of Ultradur B2550 FC)

available not only in unpigmented form, but also in black. The consequence for inhouse quality and control structures is that, in addition to the plastics and the glass fibers, the black pigments must be subjected to GMP – by no means all commercially available colorants meet this demand. Application areas include kettles, coffee machines, stirrer attachments and spatulas (Fig. 1). All these require materials with high heat resistance, even in contact with water and fats.

Several of the partially aromatic, heatresistant Ultramid T brands have been added to the FC range as well. The PA 6/6T grades marketed under this name are currently available as a 40 % glass fiber FC version, but other fiber contents can be made on request. Compared with Ultramid A, Ultramid T offers greater dimensional stability, higher short-term heat resistance (for temperatures up to 250°C) and its mechanical properties are less influenced by humidity changes. These attributes and its good surface quality render the product suitable for all kinds of kitchen utensils that come into contact with food and high temperatures. Producers and users of conveyor belts, too, should bear FC materials in mind because, if their machines are in contact with food, they must follow GMP rules.

BASF Leuna GmbH's Miramid (PA 6 and PA 66) grades, which can be manufactured in small quantities and to custom formulations on request, were recently joined by the FC brands Miramid A3F FC (unreinforced) and Miramid A3EG6 FC (black).

Aside from applications in the automotive sector, PBT possesses an interest-

ing combination of properties which are enabling it to tap into new everyday applications, such as household appliances, packaging films and food-contact coatings. For this reason, ever since the GMP regulation came into force in early August 2008, BASF's PBT range has included several new grades specifically designed for contact with food. Specifically, these are three non-reinforced and unpigmented base polymers (Ultradur B2550 FC, Ultradur B4500 FC and Ultradur B6550 FC) and compounded PBT brands for injection molding applications, including the unreinforced Ultradur B4520 FC with demolding agent and fiber glass-reinforced Ultradur B4300 G6 FC (30 % glass fibers), which can also be obtained with 20 % glass fibers. A highly reinforced version containing 50 % glass fibers (G10) is still an experimental product and is currently undergoing registration. All products are obtainable unpigmented or in black. Like PA, their typical application areas are those components of coffee machines which are exposed briefly to high temperature and pressure; electric kettles; lids of deep-fat fryers; packaging containers for kitchens; and, in unreinforced form, fibers for toothbrushes. Consideration must also be given to the valves of toilet cisterns. The reason is that even products and components which are part of the water cycle must meet all regulations for food-contact materials. Consequently, all BASF's Ultradur FC come with the necessary certificates (Fig. 2). Uncompounded Ultradur can serve as one of several components in multi-layer laminated films for beverage cartons, but it is also used together with PP, for example, to package chocolate bars. It af-

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fords customers a way of selectively reducing the transparency of the packaging film. Another possible application is the coating of aluminum coils with PBT in the production of beverage and food cans. Again, since August 2008, only GMP-certified PBT grades may be used.

The production of materials such as Ultramid FC and Ultradur FC, which are GMP-compliant, is costly. The outcome of the shift to GMP is that a plastics manufacturer such as BASF must go to greater lengths during production processes, and this is reflected not only in increased logistics and warehousing but also in specific production sequences and process monitoring. The production operation must be specifically set up, kept particularly clean, the staff specifically trained, the process documented and the risk of process variations be regularly reviewed against a GMP checklist. Thanks to BASF's vertically integrated process for manufacturing polyamide and PBT polymers, it has the advantage of being in a position to constantly monitor all the raw materials. Similarly, the number of suppliers has to be restricted: only those additives are permitted which also demonstrate compliance with food-contact and the GMP regulation. Intensive cleaning of production lines - sometimes even their disassembly - is just as necessary for GMP production as the use of fresh water for the cooling tanks used in pelletization. It should therefore come as no surprise to customers of Ultradur or Ultramid FC products that these increased production costs are reflected in the price of the materials. In return, all Ultramid FC and Ultradur FC products are produced to GMP standard and furnished with all quality



Fig. 4. Baby bottles are often made of Ultrason E (PESU) nowadays

SBS polymers are widely employed in the form of drinking cups, eating utensils for aircraft and daily-food boxes

and therefore have approval across the board for food contact. In the case of polystyrene or Styropor as well as polyamides for extrusion, this approval applies only to selected brands. The basic point to remember is that food-con-

tact certification is required for both direct and indirect food contact: for elastic, transparent Styroflex film in direct contact with raw meat and for Styrolux shrink sleeves for wrapping drinking-yoghurt bottles. BASF introduced a customized product, Styrolux HS 70, especially for this application in 2007 (Fig. 5).

Among the styrenic specialties, the following three types should be mentioned in the context of food contact: Luran, the SAN range of products from BASF, has long found application in salad bowls, mixers and storage jars on account of its transparency and dish-washer safety. Terlux, a transparent MABS, fulfills the requirements for food-contact materials, too. Its specialty lies in medical technology, diagnostics and cosmetics. Both product families have longstanding approval for food contact, and so there has been no need to develop special FC brands. Not so with Luran S, the ASA from BASF. In the past, this was mostly employed in automotive construction and in the sports and leisure sector, but for some time now has been enjoying growing popularity in food-contact applications due to its thermal resistance, good chemical resistance and high color stability (Fig. 6). These ap-



assurance documents demanded by legislators

### Already Established in the Food Sector

Marketing of products Ultrason (PSU, PESU, PPSU) and Ultraform (POM) has traditionally focused on the food sector, and they also come with the necessary quality certificates. The bulk of the BASF Ultraform range has long been approved for food contact. These include the unpigmented and pigmented products as well as glass fiber-reinforced and tribologically optimized variants. Typical applications are brewing units for fully automated coffee machines, conveyor belts in the food industry, grinders for salt cellars (Title picture) and other functional parts, such as gears in metering devices which come into contact with food. Many POM grades are also compliant with the even more stringent regulations concerning contact with potable water. Such products are required, e.g. in shower heads and in functional parts inside drinking water fittings. Ultrason, BASF's high-temperature product line, already has approval for all core products intended for the food sector and for many grades intended for potable-water contact. The core products of the Ultrason E (PESU) and Ultrason P (PPSU) ranges are also approved for packaging. Their wide range of applications includes microwave dishes, baby bottles, as well as filter membranes for drinking-water treatment (Figures 3 and 4).

Besides PA, PBT, and many commodity plastics, BASF has long been offering styrenic polymers for food packaging that meet the high safety standards imposed. BASF's Styroflex and Styrolux ranges of



Fig. 5. The new Styrolux HS 70, designed specifically for shrink sleeves has food-contact approval, which is necessary for even indirect food contact



Fig. 6. Luran S, an ASA, is no longer found just in the automotive industry. Owing to its thermal resistance and color stability, it is used in household appliances — a typical application for this styrenic is that of juicer sieve, as shown here in the MP 80 variant from Braun

plications include housings of household appliances which are exposed to high heat stress, e.g. in microwave ovens. The grades specially developed for these are called Luran S 757 G FC, Luran S 797 S FC and Luran S 777 K FC. Nor should we forget Ecoflex and Ecovio, which are biodegradable polymers that were developed from the outset for direct contact with food, e.g. in the form of packaging film.

#### Summary

To protect the consumer, legislators impose high demands on the safety of food-contact materials. To ensure this safety, the plastics manufacturers must have an extensive knowledge of regulatory aspects and implement these in the form of quality assurance measures. Only those producers which can demonstrate compli-

ance with the rules will prevail in this market. ■

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