ENSURING KITCHEN UTENSILS COMPLY TO FOOD CONTACT SAFETY STANDARDS

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There are a handful of trends in the food contact and water safety markets today—sustainability, globalization and safety, which is of utmost importance. Since these markets are global, food and water contact industries are diverse and driven by different regulations in different regions—some being stricter than others. Currently, PA66 is under a microscope because of the exposure of cyclic oligomers exceeding the newly advised surface migration limit of 5 mg/kg food.

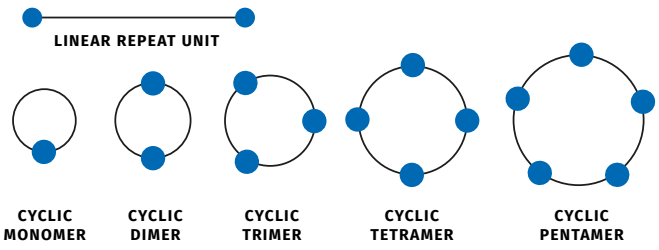
Many kitchen utensils, such as spatulas, tongs, spoons and ladles, are made of PA66 and used during baking and cooking. Cyclic oligomers (cPAO) of these polyamides are considered as non-intended added substances (NIAS) and can migrate into the food.

Since the introduction of Commission Regulation (EU) No 10/2011, there has been discussion on the imposed level of 90 µg/person/day or 90 µg/kg food as exposure limit on PA66 oligomers. Data from 2016/2017 showed that the amounts of cPAO migrating from kitchen utensils into food is far above 90 µg/person/day.

To perform a conclusive risk assessment, the German Federal Institute for Risk Assessment (BfR) in 2018 recommends manufacturers of food contact materials compile toxicological data and make them available to BfR. Consequently, national enforcement bodies warned producers of critical PA66 food contact components on non-compliancy and indicated potential product recalls unless toxicological data shows that a higher exposure is safe.

As brands are liable for determining food contact compliance, and they need to prove they are compliant to the local food contact regulations, this stirred up the European food contact market quite a bit. Also supported by recent PA66 shortage, many companies proactively started looking for replacement materials as a mitigation plan, to prevent their brand value from being at risk when exposed to potential product recalls.

FIGURE 1 – SCHEMATIC CYCLIC OLIGOMERS



As a side product of the polymerization, cPAO containing several repeat units are formed and represent a significantly higher concentration versus the linear oligomers. When these oligomers have a molecular weight above 1,000 Dalton (up to cyclic pentamer), they are not expected to pass the gastrointestinal tract.

THE BPA-BADGE CASE OF 2016

Concern from the brand owners is justified by the BPA-Badge case of 2016—a good example of what can happen when there is no toxicology data available. BPA-Badge is ofted used in coatings of canned oily products and creates oligomers. These oligomers were extracted over the 90 µg/person/day. Toxicological data could not be generated as it requires 6 kg of pure BPA-Badge side-product for oral rat studies. Therefore, the industry banned BPA-Badge for this particular use[1].

CPAO SAFE FOR USE ASSESSMENT REVISITED

In the meantime, BfR continued collecting information and opened the discussion with the plastics industry. Based on a recently updated toxicological assessment of PA66 cPAO conducted by BfR, the exposure no longer needs to be below 90µg/person/day, but now a surface migration limit of 5 mg/kg food is considered safe[2].

Unfortunately, this only helps a bit as approximately 30% of the utensils are still above the 5 mg/kg food, and according to BfR, pose possible health problems.

In the BfR report Polyamide Kitchen Utensils, it is therefore recommended to keep contact of PA66 and PA6 with hot food as brief as possible. They even recommend consumers to keep food contact of current PA6 and PA66 utensils limited, especially at temperatures above 70°C.

Brands that sell kitchen utensils on the European market are clearly not yet off the hook and need to accept that they need to change the material or run the risk of publicly being challenged on differing from the opinion of an expert body. When considering alternative solutions, it is good to understand how BfR came to their conclusions, and to see if other materials assessed similarly can comply.

HOW DID THE BFR ASSESS THE EXPOSURE OF CPAO?

Typical food contact is simulated with extraction testing on the polyamide article, using a simulant at a given time and temperature mimicking the actual exposure in line with the European Food Safety Authority (EFSA) guidelines. The amount of cPAO in the extract per dm^2 of the polyamide component can be quantified and the exposure can be calculated according to the general exposure in mg/dm^2 for 1 kg food or exposure based on measuring the surface area of the part (S) on 1 kg food.

Using the general exposure approach, almost all PA66 utensils are far above the 5 mg/kg food. BfR also uses the S/V approach to come to a specific exposure for the article. Using this approach, 70% of the tested PA66 articles comply and only the articles with a high S/V, such as ladles and spoons have a migration above the 5 mg/kg food.

WHAT HAPPENS WHEN THERE IS NO AVAILABLE TOXICOLOGY DATA ON THE NIAS?

When there is no toxicological data available and it cannot be derived, the risk of exposure to the extracted substance can be assessed according to the threshold of toxicological concern (TTC)[3]. The TTC concept proposes that a de minimis value can be identified for many chemicals, including those of unknown toxicity, based on consideration of their chemical structures. The chemical structure is first screened for structural alerts on potential carcinogenicity and other adverse effects. If no structural alerts, as with most cPAO, the substance can be allowed daily exposure of 90, 540 or 1,800 µg/person/day depending on the Cramer class. Most cPAO have an allowable exposure of <90µg/person/day. Safe for use can then be assessed with scientifically proven exposure calculation methods on extraction values.

There is a lot of debate on what exposure calculation is acceptable for the brands, but perhaps more importantly also for the national enforcement bodies. Currently, there are different approaches used in the market; a plastics consumption factor, a usage factor, daily average food consumption factor, or surface to food weight factor. BfR generally assumes the worst case use of the article and only accepts the surface area to volume food exposure assessment.

For cPAO of partially aromatic polyamides (PPA) which are known for much lower extractable levels, this TTC approach with a threshold of 90 µg/person/day still needs to be applied as toxicological data is not available. Even if the customers would accept PPA, it does not provide a solution for all parts; tools

FIGURE 2 – MEASURING EXPOSURE

Typical simulations mimic soups, sauces and fried foods

1 https://www.foodpackagingforum.org/fpf-2016/wp-content/uploads/2016/12/FPF_Dossier11_can-coatings-1.pdf

2 https://www.bfr.bund.de/cm/349/polyamide-kitchen-utensils-keep-contact-with-hot-food-as-brief-as-possible.pdf

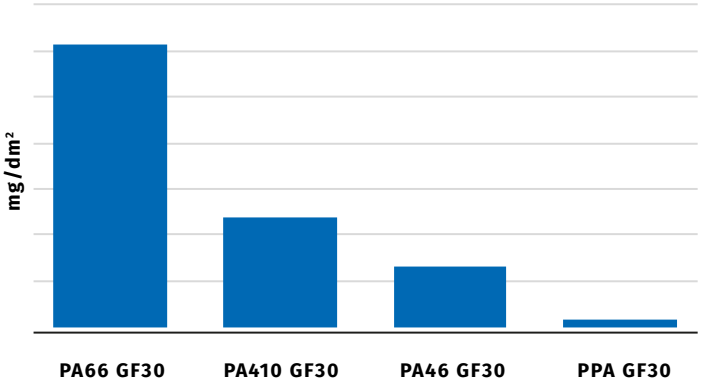
3 https://www.efsa.europa.eu/sites/default/files/event/160524a/160524a-p16a.pdf

need to be changed, the ductility is much lower, the feel of the utensils is clearly different, and most importantly, although there are significantly lower cPAO being extracted, most ladles and spoons still do not comply.

There is another way to assess safe for use when no toxicological data is available—the BfR has also applied for the cPAO and is called a "read across" to derive the surface migration limit. The read across is a scientific method applied to predict toxicological properties of a substance from another similar substance(s) and is based on the experimental observation that similar substances have the same reactivity and thus the same toxicological profile[3].

When applied to cyclic oligomers of PPAs, the specific migration limits (SML) unfortunately cannot be derived yet in a way that it is scientifically accepted. For a lot of other aliphatic polyamides read across is possible and an SML can be derived.

FIGURE 3 – CYCLIC OLIGOMER EXTRACTABLES



Total cPAO content determined on the third extract on 2 mm plaques for 2 hours in 3% acetic acid at 100°C.

WHAT MATERIAL OPTIONS ARE STILL AVAILABLE FOR KITCHEN UTENSILS?

When it comes to thermoplastic kitchen utensils, not all materials are suitable to withstand the dishwasher, have the right property profile or are economic solutions. Of course, there are still the traditional metal and wooden kitchen utensils that can be applied. However, for different reasons, these are not always desired. Most PA66 utensils use PA66 for the high peak temperature, and a polyamide material with at least a melting temperature of 240°C is required. Often alternatives lead to an unacceptable cost increase and a major change in the production process or the tooling.

DSM can offer two thermoplastic solutions that can be used in the tools of PA66. Our polyamides EcoPaXX® PA410 and Stanyl® PA46 have a relatively similar property profile as PA66 and have a high enough melting temperature of 250°C and 295°C, respectively. Because of our unique and patented technology, these polymers have significantly lower levels of extractable cPAO.

When applying read across, our glass filled Stanyl grades are fully cleared for use in kitchen utensils and the EcoPaXX grades are cleared up to a very high S/V. These relatively affordable materials allow brand owners to replace the most critical utensils, and also all PA66 kitchen utensils to simplify the supply chain.

A big value of Stanyl is that even higher peak temperatures or oil temperature can be dealt with when compared to PA66, and it has a higher stiffness allowing thinner parts. A big value of the partially bio-based EcoPaXX is the high amount of measurable bio content. For both products it is optional to significantly improve the sustainability by International Sustainability and Carbon Certification (ISCC) certified feedstock used in the production of Stanyl and EcoPaXX, allowing brands to show they are improving their ecological footprint[4].

EXPERTISE IN FOOD/WATER CONTACT APPLICATIONS

DSM is in a unique global position for food and water contact applications and is the only supplier offering IcPA, PPA and Polyphenylene Sulfide (PPS). DSM's experts understand the global and local requirements and work with customers to figure out the best course of action and can help customers assess safety for use of their articles.

Currently, PA66 does not always comply to safety standards that government bodies are recommending. DSM has alternatives in place that can replace PA66, e.g. Stanyl® TE200F6-FC and EcoPAXX® Q-KG6-FC.

To learn more about these products, or to request test samples, contact us or visit plasticsfinder.com for additional information, including technical data sheets.

4 *www.iscc-system.org.*