FEC Information Letter Nº11 November 2019

EDITORIAL *P. Llobregat*

Changes and Trends

It is understandable to feel overwhelmed by the current wealth and pace of changes happening in our regulatory field. We are now discussing the 15th amendment for the harmonized Plastics Regulation 10/2011, an impressive pace for a European Regulation. SVHC lists are updated every six months and new proposals for harmonized classification of substances appear even more frequently.

In the field of food contact regulations, major changes are starting to take shape. The European Commission is progressing through its review of the European Food Contact Regulation. The consultancy firm hired to guide this process has published its draft report in September and the final Staff Working Document should be published by the Commission around spring 2020.

Regarding these recent changes, it is key to understand where regulatory authorities seem to be heading. The latest amendment of the Plastics Regulation 10/2011 calls for stricter limits for non-detection; earlier amendments introduced limitations on oligomers migration. It is also important to understand the influence of other stakeholders: Non-Governmental Organizations call for the assessment of NIAS (non-intentionally added substances) in food contact materials, the evaluation of "cocktail effects", and a closer alignment between ECHA and EFSA.

In the field of chemical regulations, and after six months of stalemate, things are evolving for titanium dioxide and cobalt. Opposition to the harmonized classification of titanium dioxide made the process very lengthy and the Commission has chosen to go to a delegated act and forego committee agreement to advance the proposal. However, the story does not end here and FEC has plans in place to avoid further damaging developments for cobalt as well. Here again it is noteworthy that stakeholders' arguments, including resistance from countries outside the EU, were usually swept away and real life impact of regulatory decisions were not considered as relevant.

In this ever-evolving field, understanding the general direction taken by regulatory Authorities and the arguments brought forward by non-governmental organizations is key to navigate these changes safely and to build effective strategies to promote our position and opinions. It will be our pleasure to welcome you in **Wiesbaden** for our **General Assembly** and our **Business Days** on the **14th and 15th of November**. We will take the opportunity to discuss all these topics and more with our senior experts and our guest speakers.

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BUSINESS DAYS & GENERAL ASSEMBLY 2019 - Last Call !

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NEWS IN A NUTSHELL

Additional information is available on FEC intranet and complete information available upon request to Ms. L. Maginet.

GENERAL UPDATES

1. Glossary

FEC will soon make a glossary available to provide an overview about the technical terms in food contact materials and consumer goods area. The glossary will be presented during the FEC Business Days and will be constantly updated.

2. Ecorys Workshop 9th of September 2019

In order to evaluate the efficiency of the current European Food Contact Regulation, a workshop took place on the 9th of September organised by Ecorys. Their aim was to present their findings, to give stakeholders a chance to comment on these and more importantly for them to ask for more data to support their conclusions. At the round table discussions, stakeholders were divided in groups of similar interest: NGOs, Member States, Industry including downstream users such as FEC, members of the Commission, EFSA. All stakeholders agree that better and more harmonisation would be beneficial.

3. SVHC Database

ECHA and the European Commission are both involved in seemingly independent projects that require setting up databases for SVHC in articles. ECHA needs to establish a database by January 2020 and maintain it, in order to guarantee access to waste treatment operators and consumers. Also, REACH regulation sets out the rules for the information flow within the supply chain.

METALS & ALLOYS UPDATES

4. Work on the Chapter 3 of the Guide on Metals & Alloys underway

In mid-July, the draft of chapter 3 of the Guide on Metals and Alloys was made available to FEC Senior Experts: numerous modifications were identified with various level of impact for the industry. In general, FEC Senior experts have the feeling that there is still not enough precision in the description of tests methods and results measurement, new SRLs have not been detailed and there's still too many uncertainty concerning regulation for silver and silver-plated articles.

5. Ni-Co-Project

The issue has been monitored by FEC Senior Experts: in July, they joined forces with the Cobalt Institute to work on Cobalt studies. A series of tests have been discussed, to be performed by a national referenced laboratory. On the legal side, cobalt has been classified as carcinogen, suspected mutagen and presumed human reprotoxic for all routes (including oral). A generic concentration limit of 0,1% will apply for cobalt. For food contact materials, an oral intake study is required.

6. Italian Stainless Steel Decree

The Italian Ministerial Decree nr. 72 of 9 May 2019, published in the Official Magazine of 1 August 2019, modifies the Italian food contact legislation concerning stainless steels (SSs) and FCAs made thereof.
It became effective on 19 August 2019.

PLASTICS UPDATES

7. Glymo (3-glycidyloxypropyltrimethoxysilane)

Glymo is used in adhesives, inks and other food contact applications. DG SANTE maintains a complete restriction on its usage.

8. Phthalates

EFSA (European Food Safety Authority) has completed its risk assessment for phthalates.

9. Plastic Recycling

Only mechanical recycling is covered by current legislation, which includes the recycling of PET and some polyolefin. EU legislation must be amended before chemical recycling of plastics for food contact applications can continue.

10. Main points of the draft 15th amendment to Regulation (EC) No 10/2011

The European Commission is currently working on the 15th amendment to the Plastics Regulation. The earliest potential date for adoption is early 2020. Changes will involve the substance list, the limits for the migration of metals/elements, the specific migration of substances already in the positive list.

11. BfR suggests lower PAH values

The BfR believes it is technically possible to lower the PAH Content to 0.2 mg/kg for all consumer products made of rubber materials, elastomers and plastics, and therefore recommends to lower the levels accordingly.

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With the support of FEC Senior Experts:

- Abde Arbaoui, Groupe SEB
- Annika Graul, Kaï Europe
- Michel Mamrot, Amefa
- Fred Pfeifer, Weilburger
- Stephanie Raisch, Industrielack
- Patricia Rickenbach, Kuhn Rikon
- Bettina Schnabel, WMF Group
- Regina Spohr, Zenker Backformen
- Gernot Strehl, Zwilling Group

FEC Information Letter N°11 ANNEX

To go further

GENERAL UPDATES

1. Glossary

Following the proposal of FEC Business Days visitors to have a reference book for technical terms on hand, a first version of a glossary has been developed by the Senior Experts.

Purpose of this glossary is to provide information to the FEC members by giving a comprehensive overview about the most important terminologies in the area of food contact materials and consumer goods.

This glossary serves as an aid and quick reference and contains a list of common product compliance names and it`s abbreviations, like for example ECHA (European Chemicals Agency) or LOD (Limit of Detection) and gives further details and explanations about these terms.

Explanations and definitions may differ slightly from legal definitions but have been prepared and reviewed with the utmost care by the group of Senior Experts.

The glossary will be continuously updated and supplemented; the first version contains more than 130 entries and will be presented during the FEC Business Days in November. It is accessible for FEC members via the FEC intranet.

2. Ecorys Workshop 9th of September 2019

The assessment of the efficiency of the current European Food Contact Regulation is well under way. Ecorys, the consultancy firm hired by the European Commission to lead this study have organised a workshop on the 9th of September. Their aim was to present their findings, to give stakeholders a chance to comment on these and more importantly for them to ask for more data to support their conclusions.

At the round table discussions, stakeholders were divided in groups of similar interest: NGOs, Member States, Industry including downstream users such as FEC, members of the Commission, EFSA.

In general, all stakeholders agree that better and more harmonisation would be beneficial. The draft report from Ecorys is mild. Although it mentions two of the NGOs favourite points (NIAS and ECHA approach to FCM); it is quite supportive of harmonisation.

It is FEC Senior Experts understanding that the Commission already knows what they want to do and are just following protocol. NGOs were particularly quiet; it is understandable given the format and the number of participants from Industry.

Summary of position of each stakeholder category

NGOs want a combined EFSA/ECHA approach; a ban of SVHCs in FCM; an assessment of cocktail effects; an assessment of NIAS (Non Intentionally Added Substances).

Industry focus their message on the need for harmonised regulations for sectors lacking one; the difference in approach between ECHA and EFSA; the need for guidelines and recognition of Risk Assessment and Risk Management done by Industry.

Member States insist on the lack of resources for enforcement and call for harmonisation and collaboration between Member States at EU level.

Commission accepts that there are gaps in harmonisation; it may challenge the 'no migration limit' of 10 ppb.

The workshop in more details

Participants: There were roughly 140 participants, mostly industry.

Industry associations counted 60 participants; NGOs numbered 13; Member States numbered 28; Commission and affiliates numbered 18; and there were 15 consultants, lawyers and laboratories.
Participants were grouped in tables of 10, with very little mix between industry/Member States/NGO.

Objectives

The Commission stressed that supporting data were not always present to support conclusions from Ecorys. The meeting was therefore primarily aimed at gathering more hard data rather than opinions.

Timeline

This is the second workshop on this review. Ecorys have given more time for additional comments by participants and FEC Senior Experts will use this time to emphasize some of their messages.

The European Commission will prepare a Staff Working Document for spring 2020, from the final report by Ecorys.

Main messages from NGOs

- The system is generally not working
- There is a general lack of harmonisation
  - National authorities fill the gap and Member States should be proactive to protect the safety of their consumers (a call to MS to proactively regulate substances of concern based on the precautionary principle)
  - They do not seem to support positive lists; and would rather see a generic risk assessment approach
- They want cocktail effects (toxicological assessment of mixtures rather than individual substances) to be taken into account
- They call for EFSA to take inspiration from ECHA
  - Use ECHA data and approach
  - Group substances to regulate them as groups
  - Charge applicants a fee for petitions for new substances
  - Allow the use of substances for a limited period of time; include new data as they is available
  - Environmental aspects should be considered
  - A dangerous substance should be banned from being used rather than relying on no migration
- The cost of compliance for Industry should be put in perspective with turnover
- The Commission should impose minimum inspection targets for enforcement authorities
- They call for transparency; and deem it not acceptable that expert working groups do not include NGOs but include industry

Main messages from Industry

- Harmonisation
  - Harmonisation of sectors not yet harmonised is needed
  - The positive list from the Plastics Regulation 10/2011 was cited on multiple occasions by other stakeholders as an effective tool – several participants stressed that the harmonised regulation rather than just the positive list was beneficial
  - A positive list is not a requirement for harmonised legislation; the process of getting one is lengthy
  - Positive lists are material specific
  - Non harmonisation means multiple approvals for substances
  - We do not welcome Ecorys comment 'in the absence of legislation' as all FCMs are regulated
  - Harmonisation is a leverage opportunity for Member States and enforcement
  - Needs to be transparent; fully implemented; fully enforced
  - Ecorys draft mentions coatings, ink, adhesives, paper and board – Industry stressed that other materials needed harmonisation such as Metals and Alloys, Rubbers.
- Cost of compliance
  - SMEs would benefit most from harmonisation
  - Research costs to change materials should be considered
  - Some compliance costs are used for inefficient testing
  - Business Operators are involved today in many countries; harmonisation creates a more predictable environment

- ECHA/EFSA
  - Different approaches with exposure and allocation factors for example
  - REACH can include incomplete data
- The interpretation of organoleptic tests in the draft – Industry reminded the organisers that standards were in place for this testing
- Risk Assessment
  - Work done at Cross Sector Group level regarding Risk Assessment
  - DoC should be harmonised and generalised; some countries already make it compulsory
  - Need to share knowledge through the Supply Chain
- There is a risk in revising the FCM Framework Regulation
  - FCM Framework Regulation is part of the General Food Law
  - Proposal in the draft to include/join the GMP Regulation with the Framework Regulation – Industry warned against joining these two for ease of amendment of GMP
  - Article 3 and Risk Assessment cover NIAS
- Consumer safety
  - Safety comes before sustainability or recycling incentives
  - FCM Regulation is about consumer first; environment considerations should be kept separate
  - There should be no difference of safety levels between recycled and virgin materials
- Cocktail effects
  - Industry challenged the audience to bring forward data showing cocktail effect
- Equal level playing field
  - There is a need for enforcement and controls needed at borders for goods from outside the EU

Main messages from Member States

- GMP
  - Application of GMP in countries outside EU is uncertain
  - Member States need GMP audit training
- More information needed for consumer on safe use of FCM; they suggest explaining to consumers what materials are safer especially with the move away from single use plastics
- Lack of resources
  - More funding needed
  - Call for collaboration in enforcement between Member States at EU level
  - Call for harmonisation of enforcement with Centres of Excellence focused on specific materials around Europe
  - Enforcement in other countries is difficult
- There is a political pressure on Member States to act and control FCM
- REACH cannot solve everything; however if there are some data on NIAS, they should be taken into account
- Harmonisation
  - Many Member States look at National Legislations and Council of Europe to increase coherence
  - Some starting points exist for Harmonised Regulations
  - Expert Working Groups and Guidance (i.e. JRC) could bring more clarity on definition such as 'foreseeable conditions of use' for example
  - A harmonised approach with guidelines needed on NIAS and Risk Assessment is needed
  - There is a need for enforcement guidance for specific materials
  - There is a need for more guidance to exchange data (database, DoC) in Supply Chain
- Safety comes before sustainability or recycling incentives

Main messages from Laboratories/consultants/Lawyers

- Harmonisation
  - More harmonisation is needed for materials and enforcement
  - Harmonisation should be applicable and adapted
  - All stakeholders should be involved
  - We need controls for importers: Importers have not been considered
  - Mutual recognition is not working everywhere

- ECHA/EFSA
  - Two groups working on the same substance should come to the same conclusion
  - FCM and environment considerations should be more integrated; through DG SANTE and DG ENV collaboration
- Cost of compliance
  - SMEs are at a disadvantage with regards to compliance cost, but it is not specific of food contact and true for other Regulatory aspects
- Regulation on Active and Intelligent Material (AIM Reg) was disappointing because we are still waiting for a positive list
- They challenged the fact that questions about worries about cocktail effect may not come from consumers

Main messages from Commission

- EFSA challenged some of the budget costs presented by Ecorys as being too low
- They stressed that National Legislations differed but didn't contradict each other
- The no migration limit of 10 ppb is not a severe restriction
- There is cooperation in place between ECHA and EFSA but could be improved (limitation on confidentiality, ownership and different regulations)
- Ecorys challenged the use of dual use additives in the draft – FCM regulation cover dual use additives
- More detailed guidance is needed in some areas
- Harmonisation will not address multiple exposure and cocktail effects

3. SVHC Database

ECHA and the European Commission are both involved in seemingly independent projects that require setting up databases for SVHC in articles.

ECHA SCIP database

The Waste Framework Directive 2008/98/EC and its following amendments tasks ECHA (the European Chemical Agency) with *"establish[ing] a database for the data to be submitted to it (…) by 5 January 2020 and maintain it. The European Chemicals Agency shall provide access to that database to waste treatment operators. It shall also provide access to that database to consumers upon request."*

The database in question shall be filled by article suppliers with information on SVHCs (substances of high concern) in articles above 0.1% by weight.

The submission of data to the SCIP (**S**ubstances of **C**oncern In articles, as such or in complex objects-**P**roducts) database will be a legal requirement although it is doubtful that it will be ready by early 2020. It is more likely that, because of early funding issues, there will be a delay before the database is implemented and can be accessed.

Recent information from ECHA refer to the 5th of January 2021 as the cut-off date for submitting "sufficient information to allow safe use of" articles that contain SVHCs above 0.1% by weight.

The information that might be needed are the following:

- "Information that allows the identification of the article"
- "the name, concentration range and location of the [SVHC] present in the article"
- "other information to allow the safe use of the article" especially information for waste operators

Some of these requirements go beyond what is required in REACH Regulation Article 33.

Life AskREACH

REACH Regulation Article 33 sets out the rules of communication of SVHCs through the supply chain and to consumers.

"*On request by a consumer any supplier of an article containing [an SVHC] in a concentration above 0.1% [by weight] shall provide the consumer with sufficient information (..) to allow safe use of the article including, as a minimum, the name of that substance (…) within 45 days (…).*"

Multiple mobile apps have been developed by third parties to help convey the consumer's request to the supplier of the article, thus raising the level of awareness of consumers.

The European Commission has supported the development of such an app through the Life AskREACH project. The latest news available were that a beta version has been trialled in the summer and that the app could be up and running by the end of the year. Suppliers are already invited to create accounts in order to provide data for the database. However, the user interface remains an empty shell so far.

The database this time is voluntary. However, it is a possibility that information supplied to answer consumers questions on a specific article might be kept in the database to answer future requests.

METALS & ALLOYS UPDATES

4. Work on the Chapter 3 of the Guide on Metals & Alloys underway

The 2nd revision of Chapter 3 of the Guide on Metals and Alloys has resumed.
In mid-July, the draft was made available to FEC Senior Experts for comments.
The comments were sent to the EDQM in due time. The EDQM Secretariat and the President has assured that FEC Senior Experts' comments will be reviewed during the review and taken into account.
In Chapter 3, numerous modifications were identified with various level of impact for the industry.

The most important changes can be summarized as follows:

- **New SRLs** have not been provided (Chapter 1).
  FEC wanted some preliminary information on planned SRLs (Specific Release Limits) to ensure product conformity and the protection of the business in advance.
  Information gathered from competent National Authorities point to modification of SRL for Manganese, Chromium and Thallium; although further modifications might be discussed within the EDQM.
- **Test method "Release testing" (Chapter 3)**: The wording in the description of the test method is very imprecise in some respects and leaves too much room for interpretation for the laboratories. A uniform test procedure and the comparability of the results of the metal release values are therefore not guaranteed. FEC has listed numerous examples where a detailed description of the test procedure and the description of the chemicals and consumables used must be specified.
  - E.g. „…relevant physical changed occur in the test specimen…" A clear definition of "relevant" is necessary.
  - Hydrated citric acid for the simulant or not? The specification" citric acid 5 g/L" is too vague.
  - Do passivation times of different metals and alloys have to be taken into account during the test or not? Passivation times just for stainless steel are known and discussed in previous EDQM Adhoc Working Group meetings. What about the other metals and alloys? It is also relevant for the results of the release testing and the duration time/costs.
  - The precise definition of "short-term" and "long-term" – food contact is necessary. Adaptions needed to the EU plastic regulation if available. New definition for "short-term-food contact" is required.
  - The testing requirements for "hot fills and short-term storage at room temperature" in the Guide are too strict and too complex. Comparison and adjustment to the Plastics regulation were proposed by FEC Senior Experts.
  - A new category of articles was added "Flat materials and articles". Some examples for this kind of articles would be very helpful for the users of the guide.
  - "Care should be taken when using PTFE because of known interactions with metals" PTFE film can be used for closing the containers for release testing. What precautions for the lab practice are recommended and why?
  - For cutlery made from silver or silver-plated cutlery, a reduction factor should be applied to the specific release (see Annex II). It is the opinion of FEC Senior Experts that an extension of the application to other articles made from silver or silver-plated articles with hot fill conditions of use is urgently required.
- **Measurement and reporting (Annex 1):** The description of the measurement, the calculation of "Z" for articles that cannot be filled and the assessment of the calculated SRLs are not precise enough. It leaves too much room for interpretation by the users of the Guide:
  - It should be made clear if compliance relies on third migration (below or equal to SRL) and 1st + 2nd releases (below or equal to 7 times the SRL).
  - The uncertainty of the release testing must be taken into account but the explanation of the calculation example was wrong and must be adapted in the Guide.
  - The calculation of "Z" for example for knifes must be defined in a clearer way. It is not clear how to calculate "Z" for knifes with a bolster for example. The bolster has a foreseeable and intended food contact. The pictures in the Guide may lead to confusion. In accordance with the calculation of "Z" for knifes, the handle is not considered as food contact part (also for knifes without a bolster). This must be clarified in writing in the updated Guide.

- **Silver and silver-plated articles (Annex 2):**
  - The scope (mentioned in Annex 2) included just silver and silver-plated cutlery. FEC Senior Experts believe the scope needs to be extend in order to include further items intended for contact with hot food (such as soup ladles for instance).
  - Under consideration of several mentioned rules, for cutlery made from silver or silver-plated cutlery the specific release can be corrected by a factor. The correction factor is set to 5.
  - An important quote to note regarding labelling: "Guidance should be available from producers of silver utensils to users of their products that the product is not suitable for intensive day to day use, and should not be used for cooking purposes e. g. by "Due to the specific characteristics of silver, higher amounts of silver constituents could be released into food under specific use conditions. Therefore, it is recommended not to use silver articles on a daily basis and to avoid a use for cooking purposes".
    FEC Senior Experts opinion: This requirement would be unacceptable for the silver industry. If we take the example of aluminum, Res(2013)9 reads: "The producer should provide specific labelling of uncoated aluminum for users. With regard to retail packs, the suppliers must ensure that these are labelled with appropriate information for the end consumer.
    Examples of such labels could be: "User information: do not use this utensil for storage and processing of acidic, alkaline or salty food" or "To be used for storing food in refrigerator only". The Guidance should be available from producers of uncoated aluminum utensils regarding the use of their product with strongly acidic, alkaline or salty foodstuffs. There was no mention at the time of "higher amounts of [aluminum] constituents could be released into food under specific use conditions." The justification to introduce this sentence for silver is not clear. In the opinion of FEC Senior Experts, the Guidance should be discussed in more details and in close collaboration with the manufacturers. For silver and silver-plated food contact articles, a solution comparable to that for aluminum articles should be sought.

5. Ni-Co-Project

At the end of 2017, FEC got aware of possible problems with upcoming legislation on Nickel and Cobalt. During the Ambiente meeting 2018, a specific project designed to tackle these issues has been officially started within FEC and funds for possible testing programs have been raised. A contact to the Nickel Institute and to Eurofer has been established in spring 2018.

Two market studies on the exposure of citizens to Nickel – one organized by IVSH and the other one by Zwilling – have been sent in to ECHA early 2018. The level of interest went down during the CARACAL meetings in 2018. The Nickel Institute informed us, that during the CARACAL meeting on 19th of March the preparation of the Nickel guideline by ECHA has been stopped due to the strongly diverging views between the different relevant authorities. This is a great success of the work of FEC and IVSH as Mr. Beckmann pointed out already in a circular letter on 17th of April. Nevertheless, there may be further activities to reduce the exposure to Nickel in skin contact. The FEC Senior Experts will continue to monitor the issue and keep you informed.

In July 2019, we have been asked by the Cobalt Institute to join forces and to work towards an oral intake study for Cobalt. A gap in the literature on the toxicity of Cobalt via oral route exists today; and this puts the materials containing Cobalt as an impurity at risk. Typically, stainless steel alloys for instance will contain traces of Cobalt.

We also discussed possible test series, which could help to support the need of such a study. The most reasonable approach seems to be that FEC could provide data comparing the release of Cobalt into food/food simulants and the content of Cobalt in food contact materials. During the last FEC Senior Experts meeting on 17th of September a draft of the test matrix has been discussed. It has also been concluded, that we should align our test program with DG Sante and perhaps as well with EDQM and the BfR, to optimise our investment in that study. To improve the credibility of the study, the test program should be executed by one of the national reference laboratories.

In the meantime, the situation on the legal side has evolved. Due to an update of the CLP regulation, substances have to be classified under REACH as carcinogenic, mutagenic or reprotoxic via all routes, if only a study via one route exists, which points to such a risk. For cobalt there is only one study showing the carcinogenic character of Cobalt via the inhalation route. Consequently, a harmonised classification for Cobalt as carcinogen (Carc 1B), suspected mutagen (Muta 2) and presumed human reprotoxic (Repro 1B, fertility) has been put forward during the CARACAL meeting on 18th of September for all routes, hence including the oral route. For the time being, a generic concentration limit of 0.1 % as for all Carc 1B substances will apply for cobalt as soon as the proposal is adopted two months from now unless the European Parliament or the European Council oppose it.

It is noteworthy that an initial specific concentration limit of 0.01 % was proposed for the harmonised classification of Cobalt. This has been put on hold until a committee of experts review the methodology used to support this concentration limit. Such a low limit would have affected most stainless steel alloys.

At WTO level, the Commission will have to deal with the objections of USA, Russia, China and some other countries against the proposed classification of cobalt metal.

For food contact materials, an oral intake study is required. FEC will reach out to Eurometaux, who has formed a cobalt task force together with the Cobalt Institute. However, we will need to have a look at cobalt salts as well, because cobalt reacts with acids in the foodstuff and forms cobalt salts. A number of cobalt salts have been classified as CMR substances already. The toxicologists at EFSA will take this into consideration when reviewing the release limit of cobalt.

6. Italian Stainless Steel Decree

The Italian Ministerial Decree nr. 72 of 9th of May 2019, published in the Official Magazine of 1st of August 2019, modifies the Italian food contact legislation concerning stainless steels (SSs) and FCAs made thereof.
It becomes effective on 19th of August 2019.

Art. 1 "Insertion of new steels" says that «Section 6 Stainless steels» of Annex II to the decree of 21st of March 1973 is replaced by Annex 1 of the new decree of 9th of May 2019.
Annex 1 (art 1, § 1) «Section 6 Stainless steels» is the Italian positive list for Food Contact stainless steels, which implies that only stainless steels included in this list are allowed for food contact applications in Italy.
Part A (containing the positive list of SSs) stipulates that each type of steel has to be indicated with an abbreviation that characterises the chemical composition according to UNIEN 10088-1: 2014 and/or the AISI 1985 manual and/or ASTM technical specifications and/or the UNS designations. It contains also use limitations plus test methods and test conditions that have to be applied.
Part B (containing a table with the maximum content of certain elements) stipulates that provided that there is compliance with Part A and with the migration limits referred to in article 36 of the Ministerial Decree of 21.3.1973, other unintentionally added elements may be present in the final casting, for which a percentage limit is not given in the table.

Art 2 "Mutual recognition" says (briefly summarised) that the provisions do not apply to stainless steel objects legally manufactured and marketed, (manufactured or marketed) in a Member State of the European Economic Area (EU+ Norway, Iceland Liechtenstein) or in Turkey provided they guarantee an equivalent level of health protection ". This implies that in principle for food contact articles made of SS the Decree nr. 72 of 9th of May 2019 only applies to Italian producers and to imports from other countries not covered by the Mutual Recognition and that it may be applied to articles made in the EEA or Turkey that do not guarantee an equivalent protection of human health.

PLASTICS UPDATES

7. Glymo (3-glycidyloxypropyltrimethoxysilane)

The problem of using glymo in adhesives, inks and other food contact applications has not yet been solved. DG SANTE maintains a complete restriction on the use of glymo (or any other epoxysilane) to exert pressure on industry. Manufacturers of formulations containing glymo / epoxysilanes must ensure the flow of communication along the supply chain in order to ensure the obligation to inform downstream users.

8. Phthalates

Furthermore, EFSA (European Food Safety Authority) has completed its risk assessment for phthalates. The EFSA opinion will be officially adopted at the end of September 2019. More information will follow.

9. Plastic Recycling

Another update concerns the recycling of food contact plastics for Regulation (EC) No 282/2008. Consequently, only mechanical recycling is covered by current legislation, which includes the recycling of PET and some polyolefin. The law does not yet regulate the mechanical recycling of other food contact plastics.
EU legislation must be amended before chemical recycling of plastics for food contact applications can continue.

10. Main points of the draft 15th amendment to Regulation (EC) No 10/2011

The European Commission (EC) is currently working on the 15th amendment to the Plastics Regulation. The earliest potential date for adoption is early 2020. In its current form, the draft includes the following amendments.

- Update the Plastic Regulation's positive list focusing on the following substances: montmorillonite clay modified with hexadecyltrimethylammonium bromide, phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)],C10-16 alkyl ester, titanium dioxide surface-treated with fluoride-modified alumina, including the nano form.

- Lower the non-detect limit for the specific migration of 1,3-phenylenediamine from 0.01 mg/kg to 0.002 mg/kg food or food simulant.
- Reduce the non-detect limit for the specific migration of primary aromatic amines from 0.01 mg/kg to 0.002 mg/kg food or food simulant. However, there is still discussion about single PAA, which cannot be detected down to that level.
- Based on the most recent scientific opinions issued by EFSA, the list of elements / metals listed with migration limit in Annex II (Restrictions on materials and articles) should be expanded.
- Move the list of authorized salts of authorized acids, phenols and alcohols from Article 6(3) (a) of the Plastics Regulation to Annex II of that Regulation.
- Changes to compliance testing requirements in Annex V.
- Industry proposed to regulate heavy metals issues in an amendment of framework Directive 1935/2004 or in a separate directive rather than in Regulation 10/2011, which is applicable for plastic alone.
- Non-stick coating users and polyamide manufacturers might be impacted by these proposed changes. More information to follow.

In the context of the fact that the draft has not yet been published on the EC website, it may be subject to further changes.

11. BfR suggests lower PAH values

Currently, all consumer products made of rubber materials, Elastomers and Plastics (including household appliances and goods) underlie a Limit for PAH of 1 mg/kg. The BfR believes it is technically possible to lower the PAH Content to 0.2 mg/kg and therefore recommends to lower the Levels accordingly. Background: According to BfR there is no harmless dose rate for consumers for carcinogenic PAH mixtures. By lowering the limit, the contamination for consumers shall be reduced.