ECMA Food Contact Network Update

EUROPEAN CARTON MAKERS ASSOCIATION

Non-Intentionally added substances (NIAS)

In its recent meetings, the ECMA Food Safety Committee has been covering the challenging issue of making progress in assessing the NIAS substances which can be present in cartons.
In contrast to the intentionally added substances (IAS), the NIAS are unintended and are typically appearing as impurities in the raw materials used upstream or as reaction and degradation products in the processes along the FCM supply chain (the manufacturing of the raw materials, intermediate FCM and the final materials and articles).
According to Article 3 of the Framework Regulation (EC) 1935/2004, all present substances must not migrate in quantities which could endanger human health.
More specifically reference is made to the obligation to assess the present NIAS substances in the Plastics Regulation (EU) No 10/2011 (recitals 18 & 20) and articles 6.4 & 19) and in the Council of Europe Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food (paragraphs 3.1, 4, 8.1 & 8.2).
This is in between common knowledge, but which substances (known and unknown) to look after and how to assess their possible presence remains often an avoided grey area in food safety evaluations.
Valuable in this respect are the ILSI Europe reports :

- Guidance on Best Practices on the Risk Assessment of Non-Intentionally added substances (NIAS) in food contact materials and articles. (January 2016)
  https://ilsi.org/europe/wp-content/uploads/sites/3/2016/04/2015-NIAS_version-January-2016.pdf
- An overview of approaches for analysing NIAS from different FCMs. (April 2023)
  https://ilsi.eu/publication/an-overview-of-approaches-for-analysing-nias-from-different-fcms/

The first report provides an overview of the different steps in the risk assessment of NIAS: the collection of information on NIAS including the prediction of reactions and formation of NIAS, the use of analytical methods and in vitro bioassays, the hazard characterisation followed by an exposure assessment, risk assessment and risk management. (See flow chart p.28)
The ILSI report from last year provides, an interesting overview of the recommendations and industry guidance for various non-harmonised FCMs, covers for paper and board the existing general migration standards and the standards for specific leachables and/or extractables, describes the sampling, the analytical techniques, the data processing and software tools for identification.
In both publications once more the importance of sharing information on the NIAS substances in supply chains is as a start well highlighted, and in the FS Com the decision has been taken to continue the information collection efforts on NIAS towards the supplier associations.

More - not yet reported - items covered in the ECMA Food Safety Committee meeting (18/06)

- Outcome of the FERA visit (23/04).

Following visits to many other expertise centres (Fraunhofer, FABES, Henkel, Fuji APTC, TU Dresden, JRC Ispra, CTP Grenoble) experts from the ECMA FS Com have in April been visiting FERA Science in York (UK), formerly the Food and Environmental Research Agency.
FERA exists 100 years, has a staff of over 400 employees (375 scientists) and is working 60% for the authorities and 40% for the industry. FERA acts as the UK national reference laboratory and food safety represents the majority of the work.
In the presentation by Emma Bradley (Head of the Food integrity and safety department) (available on demand) the vast analytical & research capabilities of FERA and also certain specificities related to new status of the UK since Brexit, were presented.

The “Thompson Suite” at FERA with 19 LCMS, 14 GCMS …

As in many European laboratories, there has been in the past and there still is a strong focus on the testing of plastics. For the paper and board sector there is a serious gap to cover, capacity-wise and also in the development of appropriate testing methodologies.
ECMA experts expressed in the discussion, how especially in the context of the green transition from plastics to paper and board, appropriate well described methods are missing. How to test cartons with layers on …?
The experience and equipment, is now well in place for testing PFAS and mineral oils.
FERA has developed standardised approaches for assessing NIAS. This is however a very complex matter and their laboratory is delivering analytical reports on NIAS ,which are not in the form of a certificate of safety. The only way to make progress on NIAS is to apply best practices and state of the art approaches, with reference to the ILSI publications.
Since Brexit, FERA has regretfully lost access to the EU EFSA Committees.
FSA (UK Food Standards Agency) is now doing at national level the EFSA work.
Advisory Committees have been established and the FSA is e.g., similarly in the process of approving the plastic recycling processes.
The publications from those advisory committees are publicly available.
Position paper on Bisphenol A (May 2024) : https://cot.food.gov.uk/sites/default/files/2024-07/BPA_Position%20Paper%20-%20Final%20V2%20ACC%20V%20SO_0.pdf
Another consequence of Brexit, is the emerging divergence of legislation. Initially, at Brexit all EU food safety regulations were implemented as GB law, with however no changes since the EU exit …

- Peter Behnisch (Director BioDetecton Systems) joined the FS Com meeting for sharing his views on what can be expected in the next 5 years from bio assays in the perspective of the EU Green Deal.

Since his presentation in an FS Com meeting in April 2017, bio assays have greatly improved, from "effect-based methods" into the - now called - "non-animal methods (NAM)" or "new analytical methods for toxicity testing".
In his presentation "Sustainable & safer materials" (available on demand), a few practical applications of the technology were presented.
In a green chemistry approach alternatives for BPA have been assessed, with the bioassays ER-α-Calux (female hormones), AR Calux (male hormones), Anti-AR Calux (inhibition male hormones) and Anti-TRβ-Calux (Thyroid).
Furan based plastic additives were identified as biobased alternatives for the phthalates, with little or no endocrine effects.
From a safety by design perspective different FCMs can be compared to identify the safest material to use.
Bioassays allow also to assess the presence of PFAS in disposable food packaging and tableware.
Initially there has been particular interest in bio assays for excluding genotoxicity - thus allowing the use of the Cramer Class III limit - in NIAS evaluations. Now, many more endpoints can be assessed. Besides the EDC impact on the female and male endocrine system, the thyroid impact and in the next 5 years also the contribution to obesity, will come into focus.
In the presentation it was made clear, the Commission is interested in the high-through-put, cost effective bioassays screening from a broader perspective, going further as just food contact, for monitoring and phasing out toxic substances, also from the recycling loops. According to BDS this "LCA" focus will become more prominent in policy making in the coming 5-7 years.
BDS is involved in several Green Deal EU projects : Riskhunter 3R www.risk-hunt3R.eu "Safe & sustainable by design", Champion www.champion-project.eu "Circular bio-based polymers" and is participating in the SAFFI project, in which food is tested.
Although bioassays can contribute to the development of more sustainability and safety, in the discussion also clear concerns were expressed in relation to their use for assessing finished cartons. From a food safety perspective, the used extraction at the start is not representative for the conditions of use of carton board packaging. The question is how much is migrating into the food.
Certain studies have also been indicating, extracts from cellulose and starch-based materials are triggering strong in vitro toxicity.

It is important, to discuss and establish a reasonable utilisation for the paper and board sector.

- Review of the EU FCM legislation. The 10/06, the Commission organised a workshop related to pillar C "Supporting safer and more sustainable FCM" of their policy objectives. The intention of the Commission to have sustainability also included, is to avoid solutions are introduced for food safety reasons, which are really harmful for other objectives related to the food system. A study has been ordered from ICF Associate, which will take 45 weeks.