

Food Safety Committee

Date:
18 06 2024

Time:
10h00 - 12h00 CET

Venue: ONLINE TEAMS

Chairmen: Mike Turner (ECMA MD) [MT], Carmine Iuvone (SEDA) [CI]

Participants: Michael Avemarg (Van Genechten Packaging) [MA], Sigrid Gerold (Mayr Melnhof Packaging) [SG], Mathilde Gros (Graphic Packaging) [MG], Paolo Minichini (SEDA) [PM], Elaine Murray (WestRock) [EM], Carola Poggenpohl (Mayr Melnhof Packaging) [CP], Ashleigh Pyatt (Alexir Packaging) [AP], Christian Schiffers (FFI) [CS], Annika Schrimpf (Graphic Packaging) [AS], Caroline Seguin (Mayr Melnhof Packaging) [CSG], Helena Moring Vepsalainen (Mesta Group) [HV], Jan Cardon (ECMA) [JC]

Apologized: Eliza Konecka-Matyjek (WestRock) [EK], Dorien van den Helm (Acket) [DH]

1. Introduction and welcome.

Mike Turner welcomed all participants and opened the meeting around 10h00. According to good legal practice, reference is made to the ECMA Antitrust Guidelines which had been prepared by ECMA's legal attorneys. The proceedings of this meeting would be in accordance with these guidelines. A statement summarizing these Guidelines was read out. They are designed to ensure ECMA meetings' compliance with the legal framework as set out in article 101 of the Treaty on the Functioning of the European Union ("TFEU"), which prohibits all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market. It was stressed that individual company data other than those publicly available will, under no circumstances, be made public during the meeting. The purpose of the discussions would not be to identify market related information regarding a particular company but to identify general trends and market developments to the benefit of all those concerned.

2. Update on the bio assays screening methods to avoid genotoxicity in FCMs.

See meeting preparation p 4-5

Peter Behnisch (Director BioDetection Systems) [PB] joined the meeting for sharing what can be expected in the next 5 years from bio assays in the perspective of the EU Green Deal.

See presentation Peter Behnisch "Sustainable & safer materials".

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 the current thinking of the Commission, the safety of recycled materials is an issue to be monitored and toxic substances need to be phased out.

Comments made in relation to the numbered slides of the BDS presentation:

- (1) BDS is using human cells and is one of the most modern laboratories using high super dot screen.



- (4) Bio assays bring added value in assessing the hidden part of the iceberg.
- (5) Article “Hidden cocktails uncovered” (2012). The table gives an overview of bioactive pollutants, the available bio assays and the mode of action.
- (6) Different as for analytical testing with just 1 injection, the high-through-put screening is working with 6 concentrations that are measured 3 times, means 18 measurements. High capacity available.
- (10) Industry (e.g. AkzoNobel) came with the request to look for safe alternatives for BPA. Alternatives were compared to BPA, with the bioassays ER- α -Calux (female hormones), AR Calux (male hormones), Anti-AR Calux (inhibition male hormones) and Anti-TR β -Calux (Thyroid). The endocrine disruptors are a hot topic and there is in this context in the next 5 years the need to tackle also the thyroid impact. Test methods are being developed.
- (11) Questions related to the metal packaging coatings, by e.g. Nestlé and PPG. The method developed with Nestlé combines both bioassays and analytical testing. Is well described and can be used for other materials.
- (12) Safety by design. Partners come typically with different FCM alternatives to identify the safest material to use.
- (13) Interlaboratory comparison made, demonstrates good concordance.
- (14-15) Toxicological profiling of plastic additives for safe recycling practices. Comparison made for many phthalates, parabens ...
Typically, there is for the plastic additives a high activity for ER α , AR-anti ... Genotoxicity is not that relevant for the plastic additives (Bio assay P53).
In a green chemistry approach, it has been possible to identify the compound furan dicarboxylate as a biobased alternative for the phthalates, with little or no endocrine effects.
[FDCA: 2,5-furandicarboxylic acid]
- (16) For the unknown chemicals “features” in a non-targeted analysis, the combination of the chemical compound specification analysis with the effect-based analysis is a step forward.
- (17-18) Broad bio assays testing of 500 samples by OFI. (Kirchnawy 2019)
Over 70 % of the samples was safe!
The plastic food packaging sector has already worked on introducing compounds with lower estrogen activity. More endocrine activity is found for toys, medical devices ...
- (19-21) Studies done by Prof. Zimmerman (University of Trondheim/Norway).
2020 “Are bioplastics and plant-based materials safer than conventional plastics? In vitro toxicity and chemical composition.”
43 products were evaluated: biobased biodegradable, petroleum-based biodegradable, plant based (starch, cellulose, bamboo) and biobased non-biodegradable.
In the chemical analysis 186-20965 features were found in individual samples. Extracts from cellulose and starch-based materials triggered strong in vitro toxicity. Bioplastics and plant-based materials are similarly toxic compared with conventional plastics.
2021 “Plastic products leach chemicals that induce in vitro toxicity under realistic use conditions”.
24 products were analysed.
- (22) Recent study done using the BDS bioassays. “Migration of endocrine and metabolism disrupting chemicals from plastic food packaging.” (2024 Stevens et al.)
Different plastic materials were tested (HDPE, LDPE, PET, PP, PS, PUR, PVC), starting with methanol, ethanol and water extracts.
In the next 5 years it will not only be about cyto- and genotoxicity, but also about EDCs generating obesity (PPAR γ bioassay) ...
PXR is an early warning bioassay.
- (23) In total 14000 - 16000 PFAS exist. The screening in the Promiscues project is limited to 45 PFAS. Bio assays allow to assess PFAS containing disposable food



packaging and tableware.

Samples taken from, DE Germany, ... the fast-food chains KFC, MCD ...

Also, according to the German government, the TTR activity is most concerning, is an indicator for the transport of PFAS from the blood into the brain ...

The publication "Throwaway packaging, forever chemicals" (2021) gives an overview of the available assessment methods from cheap to more expensive.

- (24-28) IPCP UN Environmental programme. International Panel on Chemical Pollutants.

The IPCP consulted BDS, 3 years ago on appropriate approaches.

The different BDS in vitro bioassays are recognised.

A global study was done for plastic pellets, with samples from 9 low- and medium-income countries. The methods used were discussed with Fraunhofer.

The capacity for analytical testing (10 days ...) is simply not available, faster and cheaper methods are needed, high through-put extractions of plastic in THF/Hexane, 50% ethanol/water and 20% ethanol/water.

Some results are presented in the slides 27-28.

BDS is also quantifying the results, which is different from Martin Wagner and OFI. Quantification allows the authorities to monitor and industry to work on process improvement.

PVC is the most toxic. More endpoints are needed. ...

- (29-30) BDS is directly involved in current important Green Deal EU projects.

Riskhunter 3R www.risk-hunt3R.eu "Safe & sustainable by design."

Champion www.champion-project.eu "Circular bio-based polymers."

- (31) High throughput bioassays have been used for decades by leading companies as BASF for chemical testing, for medicines ... why not for materials to a much larger extent?

Questions raised

- [SG] questions to which extent the bioassays approach is applicable for cartons, extraction is not representative for the conditions of use of cartonboard packaging. When testing cardboard, recycled cardboard, you will always find suspicious substances. The question is how much is migrating into the food.

[PB] For recycled paper and board, MOSH/MOAH are typically an issue and those compounds are active in bioassays (EDC ...). The whole bioassays assessment is however going further as just food contact, it is about the full LCA circle, the safety of recycling, the presence of PFAS, MO ... in the recycling loops. It is not just about migration, but about what is happening with the present substances in the recycling process. This broader focus will become more prominent in policy making in the coming 5-7 years.

[SG] We know already MOSH/MOAH and other chemicals are present in the recycled grades coming from the incoming printed articles and it is not possible to get rid of those substances. The bio assays technology is interesting but we need more time, to find a reasonable utilisation for the paper and board sector.

- Isn't there value in finding out the adhesives, inks ... and also the virgin board, the sector is using is free of EDCs and genotoxic compounds?

[SG] The sector already aims at avoiding the hazardous substances, but paper and board remains a natural material. Somehow it is easier for the plastic sector to track substances.

[PB] So far, the EDC problems are for paper and board not yet really on the table, but the multinational companies, the front runners, have early warning systems and are in the context of the green deal interested in alternative paper products without toxicity pathways.

BDS is looking for companies which are developing alternatives and will enter the market, e.g. the fast-food segment. The work related to FDCA as an alternative for BPA was one of the first cases of such an approach.

[SG] BPA and PFAS have not intentionally been used in the sector for many years.



[PB] This are just two examples, the broader problem is the testing of NIAS in paper and board. Other technologies are needed. Looking with analytical testing after 10 000 features is simply not possible.

- Already in 2011, at the GMP launch, Sander Koster presented the importance of avoiding genotoxicity for a more reasonable assessment of the peaks on gas chromatograms (above 90 ppb instead of 10 ppb).

[PB] The issue is broader now, not just about genotoxicity. Now also the EDC substances - female, male hormones and "I'm sure also for paper and board" the thyroid impact - are becoming a prominent concern.

BDS is involved in the SAFFI project, which is testing food and when positive responses are found also the sources are/will be investigated.

- Sensitive enough for genotoxicity?

The P 53 bioassay is as sensitive or more sensitive as the other testing approaches (Blue screen, AMES, Mini AMES) and if no activity is found, many toxic impacts can be excluded.

- Costs involved?

[PB] Carton makers have often their own extraction laboratory. If an extract is delivered, there is the cost for making the dilution (105 €) and then a cost of 117 € per bioassay. For the reporting it depends if customers just want the numbers or also the toxicity testing...

Time frame?

[PB] It depends on what you want. For the UN project BDS worked with a short extraction of 1-2 hours up to 8, means the extraction is available in 1 day and the bioassays require 5-10 working days. In 2 weeks, the results are available.

Closing the agenda item, Peter Behnisch is especially thanked for joining the meeting and for the presentation given.

3. Approval minutes and short follow up from the Food Safety Committee 19/04/24.

The minutes are approved without modifications.

What still needs to be organised is the meeting with the analytical experts from EuPIA. In addition to the testing conditions and the Fraunhofer study, we may at that occasion also discuss the NIAS project ECMA has in mind.

4. Tour de table on specific food safety concerns and developments.

- It would be valuable to develop guidelines on testing. When do we need to test FCM's? [MG]

- Customers are unhappy with the unclear status quo in relation to the French mineral oil measure. The document from the PIJITF is for carton makers a helpful holding statement, but the frustration remains. [EM]

- No really new developments. EDCs are a concern and France is regularly coming with new EDC substances. Customers are performing own migration studies. [CP]

- Questions related to the compostability of cartonboard packaging in the PPWR context.

Customers are also ever more focussed on national legislations, France, the Italian Decree ...

The mutual recognition is not always working! [SG]

- Recently PTS was asking FFI, after the English translation of the national legislations in the Netherlands, France, Italy ... This is missing. It would be helpful for the members if even unofficial translations would be available on the members only section of the ECMA website in a kind of legal document library. [CS]

[SG] MM has access to the unofficial translation of the Italian Decree from Decernis, but this is hard to share.

[JC] At the time, the Commission promised to develop in the follow up of the Baseline Study in 2017 such a library with the most relevant national FCM legislations, but this hasn't happened. For the more recent legislations often the translation has been provided in the TRIS notification procedure. (Warenwet NL). If nothing is available or can be found, there is DeepL Pro ...

[CI] will try to help for the Italian Decree.

- Carbon black continues to be an issue. French customers are choosing the design and come afterwards with the question, if carbon black is present? As covered previously, customers are mixing up with the problems related to carbon black in plastic recycling. [CSG]

- PPWR/EUDR[CI]

Customers are also coming with broader requests, not just asking after a CEPI recyclability certificate, but more a full LCA evaluation of the material. [MA]

Valuable to check the pricing when ordering recyclability tests. There are huge differences! [SG]

- German Printing Ink Ordinance. When adopting the ordinance in 2021, a transition period was accorded of 5/6 years. The end of this period is coming closer and the German Printing Ink Association is indicating there are still problems. The substance suppliers further upstream need to run the dossiers ... trade secrets ...

It seems important to put pressure on the ink suppliers and to check if substances are still missing for the own inks. [CS]

- Aside wood, also other natural materials are in scope of the EUDR.

To be checked with the adhesive suppliers, if rubber/rubber derivatives are present in the adhesives used and if so, how the EUDR compliance is assured. [CS]

Even more materials require an EUDR check: wooden pallets, cores for reels, soy beans in inks ...

Recycled materials based on pre- and postconsumer PFR are out of the scope. In case virgin fibres are added, those need to be compliant.

- The recent MOAH notifications are added in the meeting preparation. (p 8-9)

In the course of the Tour de Table [MG] shared with the committee, she will at the end of June leave GPI for a new challenging opportunity with her family in Mexico. In both directions special words of appreciation are expressed.

Ashleigh Pyatt from Alexir Packaging is welcomed as a new member of the Food Safety Committee.

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

See meeting preparation p 10-11.

The outcome of the visit is briefly presented. The notes and presentations used at the meeting are available from the ECMA FS Com Workspace.

- Also, in view of the green transition, appropriate testing methodologies are needed for paper and board.

- FERA is well equipped for methodology development and for NIAS assessments.

- The UK starts to deviate from the EU FCM legislation.

6. Development NIAS Database.

See meeting preparation p 12-14

- [SG] mentioned strong NDAs are in place in the relationship with suppliers, often without carton makers knowing which substances are in.

The information is only shared with the laboratories.

EuPIA stated they could agree with us sharing anonymously information, but also with the ink suppliers there are NDAs in place. Before starting the exercise, the suppliers need to be informed. We need also to take into consideration, the initiative would create an advantage for FERA.

- New FCM legislation will anyway force suppliers to be more open, also on the starting materials, with NDAs ... Useful to start such an initiative. [CSG]

It is all not easy to obtain. As WestRock we get there. Regulation will indeed help. [EM]

The NIAS anyway need already to be addressed in the DOCs of suppliers.

- The project is about the development of NIAS lists per category of materials, not about which substances from which specific products, with often the same substances within material categories from different suppliers. [CSG]

- Many NIAS substances will be not declared, which means the NIAS lists will remain incomplete.

Such an initiative represents a huge workload. Suppliers are often only willing to share information with their laboratory partners, with FERA?

Another way may be, if such a lists would be developed by EuPIA and FEICA and shared with us, and even without our input, FERA has already a lot available on NIAS. [SG]

- [EM] expressed rather support for a - to be further defined - NIAS project at sector level. More input from [EK].

In view of the limited remaining meeting time, it is agreed to have an additional separate call, on this topic, preferably still before the summer holiday period.

7. Testing conditions for cartons in different applications.

See meeting preparation p14-17

As agreed ECMA introduced the topic in the PIJITF (8/11 and 11/04) and in May there have been different mail exchanges with Nestlé.

In summary their comments:

- Harmonised and acknowledged testing conditions for paper and board packaging are drastically missing.

- The Arrhenius theory is not fully applicable for paper and board, because diffusion is for this material not the only driving force for migration ...

- The ECMA statement on LT @ RT is just a start. In case of a research project, Nestlé is interested to participate, with an involvement of their national laboratories and maybe the Lausanne Research Centre.

- Nestlé has not been able so far to develop generic conditions for testing dry and wet fatty food contact.

Comments made in the meeting:

- Develop well accepted generic testing conditions is very much required. [MG]

- Is a long-term project. It will be difficult to find a solution. [SG]

- Every bit helps. This needs to be solved. [CSG]

- [EM] There is a need to reduce the burden, alignment and consistency can help. We must get the information we need and need to avoid the not workable extremes.

- The JRC may be an additional partner in such a testing conditions project, but the JRC has at this moment many priorities. Eddo Hoekstra is aware of the ECMA statement. [JC]

It is agreed to cover also this possible testing conditions project, in the separate call.

8. ILSI Guidance on Best Practices on the risk assessment of NIAS in food contact materials and articles.



See meeting preparation p18-20

In view of questions raised in previous meetings, the existing ILSI publication was added to the agenda.

The included flow chart is providing an overview of the different steps: collection of data, prediction of NIAS, Chemical analysis and Bio assays, Hazard identification and characterisation, Exposure assessment, Risk assessment and Risk Management.

[SG] A new document is available from ILSI “An overview of approaches for analysing NIAS from different FCMs” (05/04/2023). See annexed document.

9. Review FCM legislation.

See meeting preparation p 21-25

EU

The Commission organised the 10/06 a workshop related to policy pillar C “Supporting safer and more sustainable FCM”.

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. On sustainability, reference will be made to existing legislations. A gap analysis will be conducted.

ICF Associate is the involved consultant. The study will take 45 weeks.

BPA/Quality amendment 10/2011/ POPs : see FC update 17/06.

BfR 36

An update of BfR 36 is prepared.

[SG] For the phthalates the official recommendations will be followed. The intention is to reorganise the list of substances, with the names and their correlation with the CAS numbers. Not too much change is expected.

10. Miscellaneous.

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Hereafter, the Chairmen closed the meeting around 12h00.

All participants were thanked for their attendance and contribution in the discussion.

The next plenary meeting is scheduled on the 26/09 10h00-12h00.