

One substance one assessment. (OSOA)

A key concern within the industry associations in relation to the “Chemicals Strategy for Sustainability Towards a Toxic-Free Environment” (CSS) and the review of the Food Contact Materials legislation is an excessive or single focus on the hazardous characteristics of substances, under the authority of ECHA (European Chemicals Agency).

One of the key actions listed in the CSS is to establish a simpler “One substance one assessment process for the risk and hazard assessment of chemicals”. (See update 10/11 2020)

In a context of food safety, risk assessments are typically performed by EFSA (European Food Safety Agency) based on both, the hazard and the exposure to substances, with the well-known equation:

$$\text{Risk} = \text{Hazard} \times \text{Exposure}$$

The Packaging Joint Industry Taskforce developed a discussion paper on this concern, arguing in favour of a Tailored risk assessment for food contact materials and articles.

The PIJITF proposes a well-balanced approach where substances undergo a “one substance - one assessment”, consisting of a first step “one substance - one hazard assessment” in which the hazard is defined by the intrinsic properties of the substance.

This should then be followed by a second step of an FCM specific risk assessment and management for food contact materials and articles, in which the risk resulting from oral exposure is assessed.

As the arguments may be useful in different discussions, you can find annexed, the PIJITF paper endorsed by ECMA, which was shared with DG SANTE, DG Environment, EFSA and ECHA mid-June.

Interesting in this context is the critical online publication by leading staff members of the BfR.

“The EU chemicals strategy for sustainability questions regulatory toxicology as we know it : is it all rooted in sound scientific evidence ?” by Matthias Herzler, Philip Marx-Stoelting, Ralph Pirow, Christian Riebeling, Andreas Luch, Tewes Tralau, Tanja Schwerdtle, Andreas Hensel.

<https://link.springer.com/article/10.1007/s00204-021-03091-3>

Some statements made in the article:

- The current level of protection in the EU against chemical risks is among the highest in the world.
- Existing concerns in the population have to be taken seriously, but it is the moral and professional obligation of scientific governmental authorities to address such concerns by acting on facts and evidence, clearly distinguishing them from anxieties or beliefs.
- Toxic-free? According to the fundamental paradigm of Paracelsus (early 16th C), all things are poison and nothing is without poison; only the dose makes a thing not a poison. It is wrong to conclude that just because a chemical has hazardous properties it is a threat to human health.
- The article contains a plea for a responsible use of the precautionary principle. In the face of uncertainty the application of the principle depends on certain conditions. For instance, in the 1992 Rio Declaration reference was made to threats of serious or irreversible damage. Now the principle is frequently called upon in absence of demonstrated risks.
- The analysis made seems to hint at a rather low likelihood that EU consumers are currently confronted with significant health risks from the exposure to mixtures, present at dose levels below their individual regulatory thresholds.

Toxicologically speaking, for an adverse mixture effect - currently not covered by the existing regulatory system - to become relevant in terms of regulatory risk assessment, a number of aspects need to come together e.g. chemicals need to have a common or interlinked MoA (Mode of action = change mechanism in living organisms due to the exposure to a substance) and the hazard posed by the individual components must be a high concern.



- Certain chemicals are able to cause chronic effects mediated via the endocrine system, e.g., reproductive effects, toxicity to specific target organ systems, or cancer, and this is of high regulatory concern. Member States and international organisations took action, definitions and classifications (CLP, REACH SVHC ...) exist and this work undoubtedly needs to be continued. A further harmonisation is needed. The established system in the EU allows nevertheless to effectively identify and regulate industrial chemicals with ED potential.
- The move to a hazard based generic "shotgun" approach (applicable to groups of chemicals) will create a range of problems and will likely result in, a system that by design would be inherently arbitrary and inconsistent and lead to societally undesired consequences.
- The authors are in full support of any initiative towards a proper enforcement and a "zero tolerance on non-compliance" in relation to the existing legislations.
- To make the EU Chemicals Strategy a success, the CSS needs to be guided by the best science available.

Specific substances of concern

According to the reporting in the ECMA Food Safety Committee the main questions coming from the market remain related to the PFAS, TiO₂ and the mineral oils.

In relation to those substances hereafter some obtained comments and further available information.

PFAS

As covered in previous updates this category of chemicals will need to be phased out for the so-called non-essential uses. The use of those chemicals is - in our sector - not limited to their presence at the surface of carton board as a surfactant. PFAS can also be present in printing inks and in the fibre mass of moulded fibre packaging.

The used analytical method is too invasive. Burning the material, part of the method, has little to do with the real migration and brings no understanding on where the PFAS are coming from.

TiO₂

At the Fresenius conference (24-25/06) EFSA stated they have been assessing the migration from food contact materials and how based on that evaluation no further work on TiO₂ in FCM is considered. (See Q2 FC update 5/08/2021 available from the members only section of the ECMA website).

Ellen Van Haver (EFSA) provided recently further background. The mentioned assessment is included in the latest FCM opinion on surface treated TiO₂, resulting in the authorisation of FCM substance No 1077. <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2019.5737>

This opinion is similar to the outcome of studies made for the ink layers, obtained from EuPIA. When well embedded in the layer (plastic or ink) the release of TiO₂ is negligible.

In another scientific opinion from EFSA on priority setting for substances that are listed without an SML in table 1 of 10/2011, TiO₂ (FCM 610) was classified in the low priority group of substances needing re-evaluation. <https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2020.6124>

ECMA asked CEPI after information on the migration behaviour of TiO₂ used in paper and board coatings.

Mineral oils

The French ministerial decree on mineral oils is still not available.

Based on worrying information obtained from CITEO (French EPR scheme), the text will - related to our sector - most probably cover the inks and adhesives used for any type of P&B packaging.

MOSH will also be included, taking in account the reference to the class of bio-accumulative substances in recent positions from the Commission.

An entry into force at the end of the year is in between of course excluded.

The text requires a notification to the Commission ... and may contain an entry into force after 12 or 18 months.



ECMA GMP

As announced ECMA is now working on the development of specific guidance in relation to the second used certification scheme in the carton sector, "FSSC 22 000".

Below, an overview is given of this scheme and especially the paragraphs in bold against a grey background have so far been identified as areas for which specific guidance needs to be developed.

| FSSC 22000 Requirements Version 5.1 November 2020 | |
|---|---|
| https://www.fssc22000.com/wp-content/uploads/2021/02/FSSC-22000-Scheme-Version-5.1_pdf.pdf | |
| 1. ISO 22000:2018 requirements for any organization in the food chain. (Available from ISO webshop) | |
| Food Safety Management Systems | |
| 1 | Scope |
| 2 | Normative references |
| 3 | Terms and definitions |
| 4 | Context of the organization |
| | 4.1 Understanding the organization in its context |
| | 4.2 Understanding the needs and expectations of interested parties. |
| | 4.3 Determining the scope of the FSMS |
| | 4.4 Food Safety Management System. |
| 5 | The word d |
| | 5.1 Leadership & Commitment |
| | 5.2 Policy |
| | 5.3 Organizational roles, responsibilities & authorities. |
| 6 | Planning |
| | 6.1 Actions to address risks and opportunities. |
| | 6.2 Objectives of the FSMS and planning to achieve them. |
| | 6.3 Planning of changes |
| 7 | Support |
| | 7.1 General, people, infrastructure, work environment, externally developed elements of the FSMS, control of externally provided processes, products or services. |
| | 7.2 Competence |
| | 7.3 Awareness |
| | 7.4 Communication : general, extrenal, internal. |
| | 7.5 Documentation : general documented information, creating and updating, control of documented information. |
| 8 | Operation |
| | 8.1 Operational planning and control |
| | 8.2 Pre-Requisite programs |
| | 8.3 Traceability system |
| | 8.4 Emergency preparedness and response |
| | 8.5 Hazard analysis : preliminary steps to enable HA, HA, Validation, hazard control plan |
| | 8.6 Updating the information specifying the PRP and hazatrd control plan |
| | 8.7 Control of monitoring and measuring |
| | 8.8 Verification related to PRP and hazard control plan. |
| | 8.9 Control of product and process nonconformities |
| 9 | Performance evaluation |
| | 9.1 Monitoring, measuring, analysis and evaluation. |
| | 9.2 Internal audits |
| | 9.3 Management review |
| 10 | Improvement |
| | 10.1 Non conformity and corrective action. |
| | 10.2 Continual improvement |
| | 10.3 Update of the FSMS |



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|---|--------|---|--|--|--|--|--|--|--|--|--|--|
| 2. ISO 9001 requirements (where FSSC 22000 Quality is required) | | | | | | | | | | | | |
| 3. Relevant prerequisite programs (PRPs) based on technical specifications for the sector (Packaging : ISO/TS 22002-4 : 2013) (Available from ISO webshop) | | | | | | | | | | | | |
| | 1 | Scope | | | | | | | | | | |
| | 2 | Normative references | | | | | | | | | | |
| | 3 | Terms and definitions | | | | | | | | | | |
| | 4 | Generic PRPs | | | | | | | | | | |
| | 4.1 | Establishment | | | | | | | | | | |
| | 4.2 | Layout and workspace | | | | | | | | | | |
| | 4.3 | Utilities | | | | | | | | | | |
| | 4.4 | Waste disposal | | | | | | | | | | |
| | 4.5 | Equipment suitability, cleaning and maintenance | | | | | | | | | | |
| | 4.6 | Management of purchased materials and services | | | | | | | | | | |
| | 4.7 | Measures for prevention of contamination | | | | | | | | | | |
| | 4.8 | Cleaning | | | | | | | | | | |
| | 4.9 | Pest control | | | | | | | | | | |
| | 4.10 | Personal hygiene and facilities | | | | | | | | | | |
| | 4.11 | Rework | | | | | | | | | | |
| | 4.12 | Withdrawal procedures | | | | | | | | | | |
| | 4.13 | Storage and transport | | | | | | | | | | |
| | 4.14 | Food packaging information and customer communication | | | | | | | | | | |
| | 4.15 | Food defence and bioterrorism | | | | | | | | | | |
| 4. FSSC 22000 Additional requirements. | | | | | | | | | | | | |
| https://www.fssc22000.com/wp-content/uploads/2021/02/FSSC-22000-Scheme-Version-5.1_pdf.pdf (pages 18-22) | | | | | | | | | | | | |
| | 2.5.1 | Management of services and purchased materials | | | | | | | | | | |
| | 2.5.2 | Product labelling | | | | | | | | | | |
| | 2.5.3 | Food defence | | | | | | | | | | |
| | 2.5.4 | Food fraud mitigation | | | | | | | | | | |
| | 2.5.5 | Logo use | | | | | | | | | | |
| | 2.5.6 | Management of allergens | | | | | | | | | | |
| | 2.5.7 | Environmental monitoring | | | | | | | | | | |
| | 2.5.8 | Formulation of products. (not for packaging) | | | | | | | | | | |
| | 2.5.9 | Transport and delivery (not for packaging) | | | | | | | | | | |
| | 2.5.10 | Storage and warehousing | | | | | | | | | | |
| | 2.5.11 | Hazard control and measures for preventing cross-contamination. | | | | | | | | | | |
| | 2.5.12 | PRP verification | | | | | | | | | | |
| | 2.5.13 | Product development | | | | | | | | | | |
| | 2.5.14 | Health status (not for packaging) | | | | | | | | | | |
| | 2.5.15 | Requirements for organizations with multi-site certification. (not for packaging) | | | | | | | | | | |

Comments in relation to the selected paragraphs and suggestions to cover also other clauses are of course most welcome.

Food Contact Chemicals Database. (FCCdb)

The ECMA Food Safety Committee revisited once more the prioritisation exercise by the Food Packaging Forum. As previously reported (See FC update 22/12 2020) the related scientific publication provides an overview of all lists used in the FPF study.

<https://www.sciencedirect.com/science/article/pii/S0160412020321802?via%3Dihub>



- Authoritative lists used for the prioritisation of the 608 substances, based on Human Health (HH) hazard and the environment (ENV):

Hazards to HH & ENV based on classifications aligned with GHS from 2 sources:

- ECHA-Classification and Labelling inventory.
<https://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database>
- Japanese Government J-GHS https://www.nite.go.jp/chem/english/ghs/ghs_index.html

Endocrine Disrupting Chemicals (EDC)

- ECHA list <http://echa.europa.eu/ed-assessment>
- SVHCs due to ED <http://echa.europa.eu/candidate-list-table>
- Danish EDC list <https://edlists.org>
- United Nations Environmental Programme's report on EDCs
https://wedocs.unep.org/bitstream/handle/20.500.11822/25633/EDC_report1.pdf?sequence=1&isAllowed=y

Persistent, Bio-accumulative, Toxic (PBT)

- ECHA list <http://echa.europa.eu/pbt>
- SVHC due to PBT/vPvB (very Persistent, very Accumulative)
- US Environmental Protection Agency (EPA) PBT substances
- Stockholm Convention on Persistent Organic Pollutants (POPs) <http://www.pops.int>

Consulted Regulatory lists of hazardous substances (Authoritative)

- SVHC <http://echa.europa.eu/candidate-list-table>
- REACH authorisation list <http://echa.europa.eu/authorisation-list>
- REACH restriction list <http://echa.europa.eu/substances-restricted-under-reach>
- California's Proposition 65 list <http://oehha.ca.gov/proposition-65-list>

- Other authoritative hazard information sources (used to obtain reliable information not for prioritisation).

- EU Community Rolling Action Plan (CoRAP) list
<http://echa.europa.eu/web/guest/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>
- OpenFoodTox database (EFSA) <https://zenodo.org/record/3693783#.Xq1dY2gzZaQ>
- US EPA's Safer Chemical Ingredients List of chemicals evaluated under the Safer Choice Program
<https://www.epa.gov/saferchoice/safer-ingredients#searchList>

- The article contains also the links to lists providing predicted hazard classifications. Not used for prioritisation)

- Danish Environmental Protection Agency based on in silico modelling
<https://clp-veilliste.mst.dk/default.aspx>
- Chemsec SIN list <http://chemsec.org/business-tool/sin-list/>
- The Endocrine Disruption Exchange (TEDX) list
<https://endocrinedisruption.org/interactive-tools/tedx-list-of-potential-endocrine-disruptors/>
- Analysis by the German Environment Ministry on PMT(Persistent, Mobile, Toxic) and vPvM substances (Arp and Hale 2019)
- Toxicity Values (ToxVal) database by US EPA http://comptox.epa.gov/dashboard/chemical_lists/TOXVAL_V5

In relation to the prioritised 608 substances ECMA has been writing to CEPI, EuPIA and FEICA, the European federations representing the paper and board, the ink and adhesive manufacturers, to ask after the use and the performed risk assessment for the respectively 256, 377 and 147 substances which may - according to the FCCdb - be present in the FCMs our sector is using.



More topics covered in the ECMA Food Safety Committee

- At EPPA, the European Paper Packaging Alliance, an interesting study is available on the food hygiene challenges in replacing single use food service ware with reusable food service items.

The study found that the transfer of foodborne disease remains a clear and present hazard to consumers and that there are greater risks of cross contamination within circular reuse systems, than in the current linear single use systems. <https://www.eppa-eu.org/safety-and-hygiene/report-professor-david-mcdowell.html>

- In Q4 2021 a new Regulation on plastic recycling will be adopted, replacing (EC) No. 282/2008. One of the objectives is to define what is actually a recycling process.

According to the Commission recycling is not limited to sorting, cleaning and shredding plastics. Also, a decontamination step is a requirement in all recycling processes. (Source: Bastiaan Schupp DG SANTE at Fresenius June 2021)

- The EFSA CEP Panel (Panel on Food Contact Materials, Enzymes and Processing Aids) concluded, a concern for genotoxicity associated with oral exposure to styrene cannot be excluded. Styrene will in all likelihood be covered in a specific measure in autumn. (Source : Ellen Van Haver - EFSA FIP Unit at Fresenius June 2021)

- As reported the Commission may in future develop measures for major groups of FCM's: synthetic, natural, recycled ...

Surprising at the Fresenius conference, were the comments made by Thomas Simat (TU Dresden) and Konrad Grob (Zurich Laboratory) in relation to the safety of virgin paper & board. When processing wood into useful fibres, "the degradation of lignin and hemicellulose is leading to uncontrolled chemicals".

In the ECMA FS Com it was reported how concerns related to the toxicity of natural materials came up last year when EFSA published a risk assessment on using wood flour in FCM's. In view of the EFSA opinion stating there are not enough data to confirm the inertness of wood flour, this material will be delisted from 10/2011. Also, on this topic ECMA asked CEPI for an opinion.

A selection of not previously announced congresses (See overview FC update 10/06 2021):

29-30 September (Online)

International Conference Food Contact Compliance

<https://www.packagingmeeting.it/en/shop/conferences/international-conference-food-contact-compliance-en/>

18-20 October (Online)

EFSA seminar on the Risk Assessment of combined exposure to multiple chemicals.

<https://www.efsa.europa.eu/en/events/register-now-efsa-international-workshop-risk-assessment-combined-exposure-multiple>

14-16 December (Online)

Smithers Plastics & Paper in contact with foodstuffs.

<https://www.smithers.com/services/events/2021-conferences/p-p-2021-online>

