FLASH REPORT

Background

This joint workshop was organized as a follow up to similar past initiatives which highlighted **a knowledge gap between the number of substances** claimed to be used in plastics and what is used and provided **ranking of potential exposure but showed challenges to correctly evaluate** quantities of substances (impurities, non-intentional added substances, additives, etc.). **Pressure from authorities and civil society to better know the actual exposure** not only at consumer level but also to the environment has increased in the recent years.

The main question is not, if migration occurs, but to **what extent Non-intentionally/Intentionally added substances** become bio accessible (our own body and in environment) by leaving their original matrix.

As industry, while **we are ensuring compliance and safe use of our products**, we need address societal concerns and propose tools to better evaluate and risk assess exposure to substances that are potentially released from polymer matrices and/or are ending up in the environment. If we do not address this and communicate good science, we may see **more publications** that have a tendency to largely overestimate exposure as a result of incomplete or inaccurate data.

Workshop participation

The workshop took place in Brussels (and online) on the 31st May and 1st June. A well-balanced profile of approximately 40 participants (regulatory, academia, industry), and the mix of in-person and online format contributed to the rich exchange during the workshop, catalyzing constructive discussions and proposals for the next steps.

Presentations and Discussions

Following a brief scene setting introduction from the ECETOC Secretary General, Blanca Ramon Serrano, day 1 continued with a series of presentations and case studies. The second day gave the participants the opportunity to attend break-out group discussions around the following questions:

- Is the current state of "exposure-science" on the migration of Low Molecular Weight Compounds (LMWC) from (polymer) matrices sufficient to address the concerns of all stakeholders?
- What is the broader applicability of the "exposure-science" currently developed for specific regulatory or risk assessment purposes?
- Is the current state of "exposure-science" on the migration of Low Molecular Weight Compounds (LMWC) from (polymer) matrices sufficient to meet existing, new and emerging regulatory or risk assessment needs and if not, what are the knowledge gaps and research needs?

A panel group formed of regulators, industry and academia members reflected on the ideas circulated earlier in the two days and reflected on the future needs.

Key messages

The following high-level messages were highlighted through the presentations and the discussions that took place in the break-out groups and the panel:

Advances in modelling

- It is possible to simplify migration modelling (in liquids/solids) by focusing on the diffusion coefficient (Brandsch)
- The Piringer equation is mostly conservative and may be overconservative in some cases. Furthermore, it does not adequately represent diffusion mechanisms into low diffusivity polymers especially at different T° as well as underestimating exposure under repeated use conditions. New advances in determining activation energy (Welle) may facilitate more realistic modelling.
- More parameters are needed to understand emissions to air (evaporation)/volatility of compound (Brandsch /Certech)
- For the time being the control (regulatory or voluntary) for VOC and VVOC indoor air is still based on standardized tests, not modelling (construction articles, automotive) (Certech)
- For assessment of exposure to tissues, partitioning into tissues might be a driver (FDA)

Bio accessibility

- Bio accessibility (leaching into fluid matrices) describes a simple experimental approach developed by the metals sector for estimation of the number of ions becoming available for leaching into biological tissues
- Valuable learnings about the long process to get acceptability and agreement on useability of the test were shared

Regulatory use

- Need to understand release potential for prioritizing regulatory action. There is precedence for such approaches in the food contact and medical device regulations, so that opportunities to leverage should be assessed
- Assessment of articles needs a more « differentiated approach » based on exposure
- How to get this information available to regulators for prioritization?
- How to get this information to enable recycling?

Areas for future collaboration

Several questions were raised during the workshop:

- Do we see the opportunity for a common research program with buy in from all stakeholders?
- What should be the priority focus?
- Should we further develop a database on substances used in plastics with content range?
- Are there simple ways to evaluate exposure to substances leaching from polymeric matrices and what is the contribution of such leaching in global exposure?
- How will modeling exposure assessment be used for future regulatory development?

The breakout groups identified the following research needs:

- Migration modelling (plastic additives types and concentrations, more data on additives diffusion, activation energy, evaporation/vapour tension)
- Better understanding the presence of polymer contaminants / process aids (e.g. for food contact materials)
- Developing a framework for screening purposes of exposure routes (evaluate all exposure routes or key ones depending on safety thresholds/regulatory requirements)

There clearly remains a significant amount of effort required to build a robust and regulatory acceptable approach in this domain. ECETOC will remain mobilized to provide a platform for fruitful dialogue between interested parties with the aim of advancing the scientific aspects in polymers exposure science. The Organizing Committee together with the ECETOC Secretariat will work on drafting a proposal for the next steps and the relevant stakeholders (including participants to the workshop) will be contacted after the summer break.

WORKSHOP PROGRAMME

Advancing the science of exposure assessment of low molecular weight components in polymer matrices Day 1		
12:00 – 12:10	Welcome & setting the scene of the workshop	ECETOC (Moderation of the day: Blanca & Miguel)
12:10 – 12:35	For which purposes are exposure assessments of LMWC released from matrices necessary?	Mark Pemberton
12:35 – 13:00	Prediction of diffusion in polymers based on activation energies	Dr Frank Welle (Fraunhofer)
13:00 – 13:25	Modelling migration risk and consumer exposure related to short term repeated use food contact applications	Dr Rainer Brandsch (SAFE+ Algorithmics GmbH, Germany)
13:25 – 13:50	Physics-based exposure models for medical device leachables	David Saylor (US FDA)
13:50 – 14:15	Reference methods for the assessment of material emissions and the resulting AIRBORNE exposure	Dr. Olivier Noiset (Certech)
Coffee break		
14:45 – 15:10	The Plastic Additives Initiative (PLASI) - What impact did it have on ECHA's work?	Andreas Ahrens, Stefano Frattini (ECHA)
15:10 – 15:35	Developing a Test Guideline for measuring release from metal matrices: some learning lessons	Violaine Verougstraete (Eurometaux)
15:35 – 16:00	Case study 1: The Cefic LRI ECO58 project: Development of a comprehensive polymer additive release and bio accessibility model for micro- and nano-plastics	Lee Ferguson (Duke Uni)
Coffee break		
16:20 – 16:45	Case study 2: Estimating microplastics releases during service life in construction applications: a presentation of the MiRA project (Microplastics Releases from Article Service Life)	Geoffroy Tillieux (EuPC / EuMBC)
16:45 – 17:10	Case study 3: Refined exposure assessment of migrated styrene from repeat-use ABS kitchen articles	James Doyle (Creme Global)
17:10 - 17:35	Discussion of Learnings from Day 1 and take away messages	EuPC

17:35 – 17:45	Outlook to next day & dinner instructions	ECETOC
19:30	Networking Dinner	

Advancing the science of exposure assessment of low molecular weight components in polymer matrices **Day 2**		
12h00 – 12h30	Lunch	
12h30 – 12:45	Recap of day 1 and breakout group instructions	Plastics Europe
12:45 – 14:15	Break out groups: Strengths of science, broader applicability, knowledge gaps and research needs.	Moderators and rapporteurs
Coffee break		
14:45 – 15:45	Reporting back from the breakout groups & Discussion	Moderators and rapporteurs
Coffee break		
16:00 – 16:30	Polymers, registration requirements and exposure science	Heli Hollnagel (Dow, representing OC)
16:30 – 17:15	Panel discussion: What are the concerns of regulators and stakeholders? How can they be addressed through research?	Moderator: Blanca Serrano (ECETOC) Panel members: Bart Koelmans (Wageningen University & Research), Katrin Schutte (European Commission), Michel Cassart (Plastics Europe), Miguel Arranz Prieto (Cefic)
17:15 – 17.30	Summary of research opportunities to address knowledge gaps	Bruno Hubesch (Cefic LRI)
17:30 – 17.45	Wrap-up and close of workshop	ECETOC

WORKSHOP ORGANISING COMMITTEE

Marcel Bosma	Ziggo
Michel Cassart	PlasticsEurope
Heli Hollnagel	Dow
Chris Howick	Inovyn
Bruno Hubesch	Cefic LRI
Mark Pemberton	Systox
Miguel Arranz Prieto	Cefic
Erik Rushton	Lyondellbasell
Geoffroy Tillieux	EuPC
Blanca Serrano Ramon	ECETOC
Andreea Cuciureanu	ECETOC
Andrea Salvadori	ECETOC
Francesca Uguccioni	ECETOC
Lucy Wilmot	ECETOC