

Stakeholder workshop “Biomarkers of effect: from principles to a cross-sectoral guidance on the use in regulatory risk assessment of chemicals”

24-25 June 2024

Agenda and workshop description

Last update: 21 Jun 2024



CONTEXT

The workshop is organised in the context of the ongoing activities related to biomarkers of effect and their use in risk assessment. In a previous workshop organised by the European Food Safety Authority (EFSA) in September 2022, it has been concluded that ‘*guidance for the use of biomarkers of effects which are intermediate events in the toxicological pathway leading to apical adverse effects*’, needs to be developed. The opportunities for collaboration with regulatory bodies within and outside the EU and international organisations have also been emphasised, acknowledging the importance of a constructive dialogue between stakeholders for the alignment of the methodologies developed and applied.

In this context, EFSA has initiated a project towards developing a “*guidance on the use of biomarkers of effect in regulatory risk assessment of chemicals*”, implemented with the support of a Working Group of experts established under EFSA’s Scientific Committee¹.

In a first phase of this project (ongoing), EFSA has been working on a scientific report, with the intention to look closer at the definitions, description and other important aspects related to biomarkers of effect and that need to be considered in the development of such guidance. In addition, relevant activities, initiatives and knowledge in this area are collected and analysed within a mapping study, complemented by a survey shared with stakeholders. The aim was also to create a structured basis for the future guidance, identify challenges and recommend a way forward for the guidance development.

The **draft scientific report** related to this phase is currently under **public consultation**².

For the second phase, the aim is to co-develop the guidance on the use of biomarkers of effect in risk assessment of chemicals.

OBJECTIVES

Considering the need of a cross-sectorial guidance in this area, the aim is to further discuss on the challenges, opportunities and options for the co-creation of the guidance:

1. Discuss on scientific and technical challenges regarding the use of biomarkers of effect in risk assessment, including experiences from ongoing initiatives in this area.
2. Identify the main components/aspects of the future guidance and discuss on the next steps, including the feasible mechanisms and stakeholders’ interest to contribute to the guidance development.

¹ <https://open.efsa.europa.eu/questions/EFSA-Q-2023-00583>

² Draft Scientific Report on the ‘*Conceptual basis for the development of guidance for the use of biomarkers of effect in regulatory risk assessment of chemicals*’
<https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0lTk000001FW5R/pc1003>



AGENDA

24 JUN 2024

Chair: **Guilhem DE SEZE** (Head of ASSESS Department, EFSA)

Time (CET)	Duration	Item	Presenter
14:00	15 min	Opening and introduction of Day 1 activities Welcome speech Objectives of the workshop	Guilhem DE SEZE and Carlos DAS NEVES (Chief Scientist, EFSA)
14:15	15 min	<u>Presentation #1</u> : Overview of EFSA’s initiative on biomarkers of effect	Lucian Farcas , EFSA
14:30	20 min	<u>Presentation #2</u> : Latest developments of PARC Effect Markers Group (EMG)	Eva Cecilie Bonefild-Jørgensen , Aarhus University, DK
14:50	20 min	<u>Presentation #3</u> : Effect biomarkers used for the mixture risk assessment of toxic metals inducing nephrotoxicity in humans	Marcel Mengelers , RIVM, NL
15:10	20 min	<u>Presentation #4</u> : Biomarkers of effects - from scientific discovery to regulatory applications	Tomasz Sobanski , ECHA
15:30	30 min	<i>Coffee break</i>	
16:00	20 min	<u>Presentation #5</u> : Overview of OECD’s project on effect-biomarker guiding principles	Robert Pasanen , SECO, CH
16:20	20 min	<u>Presentation #6</u> : Food and biomarkers - updates on activities of FDA’s Center for Food Safety and Applied Nutrition	William B. Mattes , US FDA
16:40	45 min	Open discussion	Moderator: Lucian FARCAL, EFSA
17:25	5 min	Concluding remarks and future work	Chair
17:30	-	<i>End of Day 1</i>	

25 JUN 2024

Chair: **Nik KRIZ** (Head of ENABLE Department, EFSA)

Time (CET)	Duration	Item	Presenter
09:00	10 min	Welcome and introduction of Day 2 activities	Nik KRIZ , EFSA
09:10	10 min	Introduction and objectives of the break-out session	Antonio Hernández-Jerez (WG member)
09:20	70 min	<u>Break-out session</u> : Guidance approach and workflow (<i>working groups</i>)	Facilitators of the break-out session
10:30	30 min	<i>Coffee break</i>	
11:00	45 min	<u>Reporting from break-out session</u> groups	Rapporteurs of the break-out session
11:45	60 min	<u>Panel discussion</u> : Co-creation of guidance - challenges, opportunities and options for the way forward	Moderator: Claudia RONCANCIO-PEÑA, EFSA
12:45	15 min	Conclusions and wrap-up of the workshop	Nik KRIZ , EFSA
13:00	-	<i>End of the workshop</i>	



SESSIONS DESCRIPTION

SCIENTIFIC PRESENTATIONS AND DISCUSSION (DAY 1)

This session will be dedicated to presentations and discussion related to different EU or international initiatives, looking at scientific and technical aspects, issues or other limitations in this area.

BREAK-OUT SESSION (DAY 2)

In this session, the participants will work in smaller groups on an approach to be taken and the main components/aspects to be considered in the development of the guidance. The outcome of the session will include a draft workflow applicable to risk assessment of chemicals and that could be further used and implemented for the guidance development.

PANEL DISCUSSION (DAY 2)

In this session, the next steps on the guidance development, including challenges/blockers, opportunities and options for the co-creation/collaboration in the preparation of guidance will be discussed. The outcome should include a better understanding on the feasible mechanisms that could be implemented towards the co-creation/collaboration in the preparation of the guidance, involving different organisations performing risk assessment.

HOW TO CONNECT

- **Workshop (Day 1 and 2):** [Teams link](#)
- **Break-out session (Day 2):** *see details below*

CONTACT

For any questions related to the event please contact mese@efsa.europa.eu



BREAK-OUT SESSION GROUPS

	Group 1	Group 2	Group 3	Group 4
Teams link	(the same link used for the workshop)	Link	Link	Link
Facilitator	Henk van Loveren (p)	Ron Hoogenboom (p)	Harry McArdle (p)	Susanne Hougaard Bennekou (p)
Rapporteur	Chantra ESKEs (p)	Cristina CROERA (p)	Silvia VALTUENA MARTINEZ (p)	Agnès DE SESMAISONS (p)
Support	Daniela MAURICI (p) Daniela.MAURICI@efsa.europa.eu	Georgia BOMPOLA (p) Georgia.BOMPOLA@efsa.europa.eu	Sara LEVORATO (p) Sara.LEVORATO@efsa.europa.eu	Lucian FARCAL (p) Lucian.FARCAL@efsa.europa.eu
Group members	<ul style="list-style-type: none"> • Kriz Nikolaus Georg (p) • Guilhem De Seze (p) • Rocancio-Peña Claudia (p) • Binaglia Marco (p) • Schwerdtle Tanja (o) • Pieper Christina (o) • Mengelers Marcel (o) • Sarigiannis Dimosthenis (o) • Bonefild-Jørgensen Eva (o) • Mattes William (o) • Pasanen Robert (o) • Wilks Martin (o) • Sobanski Tomasz (o) • van Doesum-Wolters Ciska (o) • Rivière Gilles (o) • Raikos Athanasios (o) • Briggs Jonathan (o) • Percivaldi Cinzia (o) • Manini Paola (o) • Paini Alicia (o) • Bastaki Maria (o) 	<ul style="list-style-type: none"> • Christodoulidou Anna (p) • Al Harraq Zainab (o) • van den Bran Annick (o) • Sycova Milada (o) • Viegas Susana (o) • Koivisto Pertti (o) • Chaideftou Evgenia (o) • Weikert Cornelia (o) • Rühl Isabel (o) • Beal Marc (o) • Gkana Eleni (o) • Fitzpatrick Suzanne (o) • Schmeisser Sebastian (o) • Scattareggia Marchese Adriana (o) 	<ul style="list-style-type: none"> • Hernández-Jerez Antonio (p) • Abraham Klaus (o) • Kudász Ferenc (o) • Lemke Nora (o) • Houben Ken (o) • Diaconu Daniela Ivona (o) • Long Manhai (o) • Gannon Anne (o) • Zanni Francesca (o) • MacMahon Shaun (o) • Baert Katleen (o) • Steffensen Inger-Lise (o) • Steinkellner Hans (o) • Cattaneo Irene (o) 	<ul style="list-style-type: none"> • Mangas Iris (p) • Silva Maria João (o) • Hauzenberger Ingrid (o) • Rusko Janis (o) • Tietz Thomas (o) • Mielke Hans (o) • Zugravu Corina (o) • Georgieva Tzveta (o) • Wielsøe Maria (o) • Verstraete Frans (o) • Barrett Gordon (o) • Schuler Matthieu (o) • Soares Jorge (o) • Astuto Maria Chiara (o)

(p) = in presence

(o) = online



REGISTERED PARTICIPANTS

Last name	First name	Affiliation	Country	Participation
HERNÁNDEZ-JEREZ	Antonio	University of Granada	SP	In presence
VAN LOVEREN	Hendrik	Maastricht University	NL	In presence
HOUGAARD BENNEKOU	Susanne	Danish Patient Safety Authority	DK	In presence
HOOGENBOOM	Laurentius (Ron)	Wageningen University	NL	In presence
MCARDLE	Harry	Rowett Institute, University of Aberdeen	UK	In presence
SCHWERDTLE	Tanja	German Federal Institute for Risk Assessment (BfR)	DE	Online
MENGLERS	Marcel	National Institute for Public Health and the Environment (RIVM)	NL	Online
VAN DEN BRAND	Annick	National Institute for Public Health and the Environment (RIVM)	NL	Online
SYCOVA	Milada	Public Health Authority	SK	Online
VIEGAS	Susana	NOVA National School of Public Health	PT	Online
SILVA	Maria João	National Institute of Health Dr. Ricardo Jorge (INSA)	PT	Online
SOARES	Jorge	ISA Expert	PT	Online
KOIVISTO	Pertti	Finnish Food Authority	FI	Online
HAUZENBERGER	Ingrid	Environment Agency Austria	AT	Online
CHAIDEFTOU	Evgenia	Medical University Innsbruck (MUI)	AT	Online
RUSKO	Janis	Institute of Food Safety, Animal Health and Environment BIOR	LV	Online
PIEPER	Christina	German Federal Institute for Risk Assessment (BfR)	DE	Online
WEIKERT	Cornelia	German Federal Institute for Risk Assessment (BfR)	DE	Online
ABRAHAM	Klaus	German Federal Institute for Risk Assessment (BfR)	DE	Online
TIETZ	Thomas	German Federal Institute for Risk Assessment (BfR)	DE	Online
MIELKE	Hans	German Federal Institute for Risk Assessment (BfR)	DE	Online
SCHMEISSER	Sebastian	German Federal Institute for Risk Assessment (BfR)	DE	Online
RÜHL	Isabel	German Environment Agency (UBA)	DE	Online
LEMKE	Nora	German Environment Agency (UBA)	DE	Online
HOUBEN	Ken	Federal Agency for the Safety of the Food Chain (FASFC)	BE	Online
DIACONU	Daniela Ivona	National Institute of Public Health (NIPH)	RO	Online
ZUGRAVU	Corina	National Institute of Public Health (NIPH)	RO	Online
KUDÁSZ	Ferenc	National Center for Public Health and Pharmacy	HU	Online
GEORGIEVA	Tzveta	National Centre of Public Health and Analyses	BG	Online
SARIGIANNIS	Dimosthenis	National Hellenic Research Foundation	GR	Online
RIVIÈRE	Gilles	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)	FR	Online
SCHULER	Matthieu	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)	FR	Online
BONEFLD-JØRGENSEN	Eva Cecilie	Aarhus University	DK	Online
LONG	Manhai	Aarhus University	DK	Online
WIELSØE	Maria	Aarhus University	DK	Online
STEFFENSEN	Inger-Lise	Norwegian Institute of Public Health and Norwegian Scientific Committee for Food and Environment	NO	Online
MACMAHON	Shaun	US FDA (Center for Food Safety and Applied Nutrition)	USA	Online
MATTES	William	US FDA (Center for Food Safety and Applied Nutrition)	USA	Online
FITZPATRICK	Suzanne	US FDA	USA	Online
BARRETT	Gordon	Health Canada	CA	Online

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BEAL	Marc	Health Canada	CA	Online
GANNON	Anne	Health Canada	CA	Online
PASANEN	Robert	State Secretariat for Economic Affairs SECO	CH	Online
WILKS	Martin	University of Basel (UNIBAS)	CH	Online
SOBANSKI	Tomasz	European Chemicals Agency (ECHA)		Online
VAN DOESUM-WOLTERS	Ciska	European Medicines Agency (EMA)		Online
RAIKOS	Athanasios	EC, DG SANTE		Online
GKANA	Eleni	EC, DG SANTE		Online
ZANNI	Francesca	EC, DG SANTE		Online
VERSTRAETE	Frans	EC, DG SANTE		Online
BAERT	Katleen	EC, DG SANTE		Online
BRIGGS	Jonathan	EC, DG SANTE		Online
FARCAL	Lucian	EFSA/MESE		In presence
LEVORATO	Sara	EFSA/MESE		In presence
BOMPOLA	Georgia	EFSA/MESE		In presence
RONCANCIO PEÑA	Claudia	EFSA/MESE		In presence
MAURICI	Daniela	EFSA/MESE		In presence
CROERA	Cristina	EFSA/FIP		In presence
AL HARRAQ	Zainab	EFSA/FIP		In presence
VALTUEÑA MARTINEZ	Silvia	EFSA/NIF		In presence
DE SESMAISONS	Agnès	EFSA/NIF		In presence
CHRISTODOULIDOU	Anna	EFSA/FEEDCO		In presence
ESKES	Chantra	EFSA/FEEDCO		In presence
STEINKELLNER	Hans	EFSA/FEEDCO		Online
PERCIVALDI	Cinzia	EFSA/ENREL		Online
MANGAS	Iris	EFSA/PREV		In presence
BINAGLIA	Marco	EFSA/PREV		In presence
DAS NEVES	Carlos	EFSA/CSO		Online
DE SEZE	Guilhem	EFSA/ASSESS		In presence
KRIZ	Nikolaus Georg	EFSA/ENABLE		In presence
PAINI	Alicia	EFSA/MESE		Online
MANINI	Paola	EFSA/FEEDCO		Online
BASTAKI	Maria	EFSA/MESE		Online
ASTUTO	Maria Chiara	EFSA/MESE		Online
CATTANEO	Irene	EFSA/MESE		Online
SCATTAREGGIA MARCHESI	Adriana	EFSA/MESE		Online