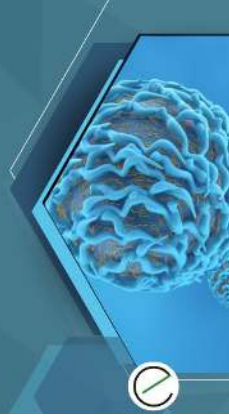
# IMMUNOTOXICITY ASSESSMENT
## ADDRESSING CHALLENGES AND ADVANCING METHODOLOGIES



Open Workshop on **July 9-10**, 2025, Brussels, Belgium to take place in the '**Le Louise Hotel Brussels**'. Immunotoxicity assessment: Addressing Challenges and Advancing Methodologies

## Objectives

The primary goal of this workshop is to develop guidance for relevant triggers and parameters to assess immunotoxicity. ECETOC suggests that such guidance takes into account a tiered approach (Ball et al., 2022) which can include additional assessment of the immune system in existing regulatory studies to limit the need for further animal testing. To this aim we hope to bring together industry, academic and regulatory stakeholders, including representatives from European Agencies, competent national authorities and international organizations, to brainstorm and discuss the current status and challenges in the field of assessing immunotoxicology and developmental immunotoxicity (DIT).

## Background

The regulatory assessment of immunotoxic properties of chemicals is a complex and challenging task. Limited regulatory guidance on in vivo assessment is available, for example in OECD 407 and 443, and there is also emerging OECD guidance on in vitro assessment in a Detailed Review Paper (DRP) which focusses on immunosuppression. However, there is no general consensus under the REACH regulation on how to address relevant early markers of either adult or developmental immunotoxicity, for example through ex vivo analysis of tissues from animals used in repeat dose toxicity studies such as OECD 407, 421 or 422. Additionally, there is a significant lack of industry and regulatory-wide expertise to propose fit-for-purpose methodologies.

## Workshop Goals

1. **Collaboration:** Create a platform for authorities, industry representatives, and immunologists to come together.
2. **Methodology Discussion:** Discuss current methodologies and identify opportunities to enhance testing methods.
3. **Task Force Formation:** Identify candidates for an ECETOC Task Force and define its scope.
4. **Knowledge Assessment:** Assess the current state of knowledge about immuntoxicology and DIT methods.
5. **Strategy Development:** Develop a roadmap for a testing strategy on immunotoxicity and DIT.
6. **3Rs Implementation:** Implement the principles of Replacement, Reduction, and Refinement (3Rs) in current testing programs.
7. **Stakeholder Mapping:** Map out interested stakeholders and plan follow-up actions via the task force.

## Conclusion

This workshop aims to foster collaboration and innovation in the field of immunotoxicology, addressing the current gaps and challenges. By bringing together key stakeholders and experts, we can develop more effective and harmonized approaches to the regulatory assessment of immunotoxic properties of chemicals.

**References**:

Ball N, Bars R, Botham PA, et al. (2022) A framework for chemical safety assessment incorporating new approach methodologies within REACH. Archives of Toxicology 96(3):743-766 doi:https://doi.org/10.1007/s00204-021-03215-9

# Workshop programme

| Day 1: Immunotoxicity assessment: Addressing Challenges and Advancing Methodologies – 9 July [Onsite and online participants] | | | | |
|---|---|---|---|---|
| **Item** | **Start** | **End** | **Agenda item** | **Who** |
| 1 | 11:30 AM | 12:00 PM | Arrival and registration | Organising committee |
| 2 | 12:00 PM | 12:30 PM | **Welcome Lunch** (Registration to continue through lunch) | |
| 3 | 12:30 PM | 12:40 PM | **Welcome, introduction and WS objectives** | |
| 4 | 12:40 PM | 1:05 PM | **REACH and immunotoxicological tests** | Laura Rossi (ECHA) – Online |
| 5 | 1:05 PM | 1:30 PM | **Immunotoxicity from a regulatory perspective - challenges and opportunities** | Melanie Flach (BASF) |
| 6 | 1:30 PM | 1:55 PM | **Practical considerations for the inclusion of additional immunotoxicity studies in existing regulatory guidelines** | Kirsten van Dycke (Charles Rivers) |
| 7 | 1:55 PM | 2:20 PM | **Overview of *in vitro* methodologies for immunotoxicity assessment** | Emanuela Corsini (University of Milan) |
| 8 | 2:20 PM | 2:45 PM | **Transition from *in vivo* to *in vitro* immunotoxicity prediction: methodology, practical insights, and *in vivo* implementation opportunities** | Raymond Pieters (Utrecht University) |
| 9 | 2:45 PM | 3:05 PM | ***Coffee break*** | |
| 10 | 3:05 PM | 3:30 PM | **Experimental and mechanistic in vitro/in vivo evaluation of immune effects** | Marc Pallardy (University of Paris-Saclay) |
| 11 | 3:30 PM | 3:55 PM | **Application of alternative methods for immunotoxicity assessment** | Dori Germolec (NIEHS) & Victor J. Johnson (NIEHS) – Online |
| 12 | 3:55 PM | 4:20 PM | **NC3Rs *In vitro* TDAR CRACK IT challenge: Development of a human *in vitro* T-cell dependent antibody response (TDAR) assay** | Sofie Pattyn (IQVIA) & Lenie van den Broek (Mimetas) |
| 13 | 4:20 PM | 4:45 PM | **(Developmental) Immunotoxicity: A Perspective from Agrochemical Safety** | Christian Strupp (Gowan) & Joseph Henriquez (Corteva) |
| 14 | 4:45 PM | 5:10 PM | **Alignment with the ECETOC Staged Assessment Proposal** | Bennard van Ravenzwaay (ECETOC) & Phil Botham (Syngenta) |
| 15 | 5:10 PM | 5:35 PM | **General discussion, extended Q&A** | |
| 16 | 5:35 PM | 5:50 PM | **Summarise and closing remarks - Assess the state of immunotox in regulations, & early scoping for follow-up ECETOC activities.** | |

| Day 1: Immunotoxicity assessment: Addressing Challenges and Advancing Methodologies – 9 July [Onsite and online participants] | | | | |
|---|---|---|---|---|
| **Item** | **Start** | **End** | **Agenda item** | **Who** |
| 17 | 7:15 PM | 10:00 PM | **Networking Dinner –**<br>**Les Larmes du Tigre** (Palais de justice)<br>**21 rue de Wynants - 1000 Brussels**<br>**02/512.18.77** | Onsite attendees registered for the networking dinner |

| Day 2: Developing practical, actionable recommendations for stakeholders - 10 July [Mainly Onsite participants] | | | | |
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| **Item** | **Start** | **End** | **Agenda item** | **Who** |
| 1 | 9:00 AM | 9:20 AM | **Welcome Coffee and Breakfast** | |
| 2 | 9:20 AM | 9:30 AM | *Welcome and recap, introduction on the sessions (objectives and what we want to achieve)* | Organising committee |
| 4 | 9:30 AM | 9:40 AM | **Onsite attendees to proceed to their designated team breakout rooms** | |
| 3 | 9:40 AM | 10:20 AM | 1st Session: Assessment of adult immunotoxicity | Team 1, Team 2 and Team 3 |
| 4 | 10:20 AM | 10:40 AM | ***Coffee break*** | |
| 5 | 10:40 AM | 11:40 PM | 2nd Session Assessment of DIT | Team 1, Team 2 and Team 3 |
| 6 | 11:40 AM | 12:00 PM | ***Coffee break*** | |
| 7 | 12:00 PM | 1:00 PM | 3rd Session Opportunities for a tiered testing approach including NAMs | Team 1, Team 2 and Team 3 |
| 8 | 1:00 PM | 2:15 PM | **Lunch** | |
| 9 | 2:15 PM | 3:00 PM | Plenary feedback from the sessions | |
| 10 | 3:00 PM | 3:15 PM | **Summarise and closing remarks** | |
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## Organising Committee

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|---|---|---|
| Phil | Botham | Syngenta, UK |
| Roland | Buesen | BASF, DE |
| Juan Carlos | Carrillo | Shell, NL |
| Erik | Van Miert | Dsm-firmenich, CH |
| Bennard | van Ravenzwaay | Wageningen University, DE |
| Sergio | León Pérez | ECETOC, BE |
| Francesca | Uguccioni | ECETOC, BE |

## Venue

Le Louise Hotel Brussels - MGallery Collection

40 Avenue de la Toison d Or
1050 BRUSSELS
Belgium

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## Organisers information

ECETOC is a not-for-profit scientific association that provides a collaborative space for leading scientists from academia, governments and industry to develop and promote trusted and practical scientific solutions which ensure a safe, sustainable and healthy world. For more information please visit https://www.ecetoc.org/

ECETOC has significant experience organising workshops and conferences to facilitate the communication of science.