



# European stakeholders workshop on New Approach Methodologies (NAMs) for Developmental Neurotoxicity (DNT) and their use in the regulatory risk assessment of chemicals.

Online on Teams 07-08-09 March 2022

## Draft programme

**Overall Chair: Antonio Hernandez Jerez (EFSA)**  
**Overall Rapporteur : Andrea Terron (EFSA)**

**BO Rapporteurs :**

- **BO 1 Rapporteur: Susanne Hougaard, DTU Technical University of Denmark**
- **BO 2 Rapporteur: Antonio Hernandez Jerez, University of Granada, Spain**
- **BO 3 Rapporteur: Martin Wilks, Swiss Centre for Applied Human Toxicology, Switzerland**

### DAY 1: 07<sup>th</sup> March 2022 (13:00-17:30)

| <b>SESSION 1   Overview on DNT</b>  |  |  |
|---|--|--|
| <b>Chair : Antonio Hernandez Jerez (EFSA PPR Panel Chair, Prof. Toxicology University of Granada)</b><br><b>Rapporteur : Andrea Terron (EFSA, Pesticide Peer Review Unit)</b> |  |  |
| 13:00-13:10   | <b>Overview Welcome and Introduction to the event NT</b>   | Manuela Tiramani /Andrea Terron, EFSA, Parma, Italy    |
| 13:10-13:25   | <b>Testing for DNT, a scientific and societal need (e.g. Consensus paper, 2018)</b>  | Karin Kilian, DG ENV., Brussels, Belgium               |
| 13:25-14:00   | <b>Is the current paradigm suitable for testing the overall chemical universe?</b>   | Martin Paparella, University of Innsbruck, Austria     |
| <b>SESSION 2   Overview of the DNT-IVB; scientific backgrounds, assay methods, added value and limitations</b>  |  |  |
| <b>Chair : Antonio Hernandez Jerez (EFSA PPR Panel Chair, Prof. Toxicology University of Granada)</b><br><b>Rapporteur : Andrea Terron (EFSA, Pesticide Peer Review Unit)</b> |  |  |
| 14:00-14:30   | <b>Testing for key neurodevelopmental processes</b>  | Marcel Leist, University of Konstanz, Germany          |
| 14:30-15:00   | <b>Coffee break</b>  |  |
| 15:00-15:40   | <b>The DNT IVB: assays methods and data gaps.</b><br>- <b>Identification and explanation of which aspects of in vivo nervous system development these in vitro tests do cover and which aspects they do not cover.</b> | Ellen Fritsche, IUF, University of Dusseldorf, Germany |
| 15:40-16:00   | <b>EFSA DNT in-vivo database. In-vivo in-vitro preliminary concordance analysis and limitations</b>  | Iris Mangas, EFSA, Parma, Italy                        |



### SESSION 3 | The OECD Guidance

**Chair : Antonio Hernandez Jerez (EFSA PPR Panel Chair, Prof. Toxicology University of Granada)**  
**Rapporteur : Andrea Terron (EFSA, Pesticide Peer Review Unit)**

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|-------------|--|---|
| 16:00-17:00 | <b>Interpretation and integration of Data from the Developmental Neurotoxicity (DNT) In-Vitro Testing; the OECD Guidance</b> <ul style="list-style-type: none"> <li>- <b>Scope of the guidance Interpretation and integration of Data from the Developmental Neurotoxicity (DNT) In-Vitro Testing; the OECD Guidance, regulatory application, IATA case studies, uncertainties analysis, tiered approaches.</b></li> </ul> | Kevin Crofton, R3Fellows LLC, United States |
| 17:00-17:30 | <b>Open discussion</b>   | Andrea Terron, EFSA, Parma, Italy           |

### DAY 2: 08<sup>th</sup> March 2022 (13:00-17:30)

#### SESSION 1 | Overview on DNT

**Chair : Manuela Tiramani/Iris Mangas (EFSA)**  
**Rapporteur : Iris Mangas/Magda Sachana (EFSA)**

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|-------------|--|--|
| 13:00-13:30 | <b>Regulatory consideration in EU</b> <ol style="list-style-type: none"> <li>a. <b>Level of information required currently under different regulatory frameworks (e.g. REACH (Annex-dependent), BPR: OECD TG 426 (or equivalent test set) or OECD TG 443 with neuro cohorts and additional investigation for cognitive functions is now a standard data requirement)</b></li> <li>b. <b>Potential uses in hazard and risk assessment</b></li> <li>c. <b>Explain the current CLP criteria for developmental toxicity</b></li> </ol> | Kati Hellsten, ECHA, Helsinki, Finland |
| 13:30-13:45 | <b>EFSA perspective opinion. EFSA Case studies.</b>  | Iris Mangas, Parma, Italy              |
| 13:45-14:00 | <b>US EPA perspective opinion on the use on DNT NAMs</b>   | Liz Mendez, US, EPA                    |
| 14:00-14:15 | <b>Health Canada perspective opinion on the use on DNT NAMs</b>  | Stephanie Watson, Health Canada        |
| 14:15-14:30 | <b>Industry perspective opinion on the use on DNT NAMs</b>   | Kathrin Bothe, Bayer Crop Science      |
| 14:30-14:45 | <b>Decision tree, a case for pesticides</b>  | Andrea Terron, EFSA, Parma, Italy      |
| 14:45-15:15 | <b>Discussion</b>  | Andrea Terron, EFSA, Parma, Italy      |
| 15:15-15:45 | <b>Coffee break</b>  |  |



## SESSION 2 | breakout sessions

Chair : Iris Mangas, Andrea Terron (EFSA, Pesticide Peer Review Unit)

Rapporteurs : Andrea Terron/Iris Mangas (EFSA)

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|-------------|---|--|
| 15:45-16:00 | <p><b>Presentation of the breakout sessions:</b></p> <ul style="list-style-type: none"> <li>- <b>What is necessary for the inclusion of the DNT-IVB as data requirement in different EU legislations (REACH, BPR, pesticides) identification of critical gaps, next steps?</b></li> <li>- <b>What could be potential option(s), in the context of the IATA, for the use of DNT-IVB in DNT hazard and risk assessment?</b></li> <li>- <b>What would be a suitable tiered approach for using the DNT-IVB in the different regulatory legislations?</b> <ul style="list-style-type: none"> <li>▪ <b>one approach may not fit to all regulatory frameworks</b></li> <li>▪ <b>a need to update the current approaches.</b></li> </ul> </li> <li>- <b>Road map proposal for the integration of the DNT IV-B in the Chemical Risk Assessment in Europe.</b></li> </ul> | Iris Mangas, EFSA, Parma, Italy                                      |
| 16:00-17:30 | <b>Break out session 1</b>  | Susanne Hougaard, DTU Technical University of Denmark                |
|             | <b>Break out session 2</b>  | Antonio Hernandez Jerez, University of Granada, Spain                |
|             | <b>Break out session 3</b>  | Martin Wilks, Swiss Centre for Applied Human Toxicology, Switzerland |

## DAY 3: 09<sup>th</sup> March 2022 (13:00-17:00)

### SESSION 1 | Breakout sessions

Chair : Kevin Crofton

Rapporteurs : Andrea Terron/Iris Mangas (EFSA)

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|-------------|---|--|
| 13:00-13:05 | <b>Welcome and introduction to the BO</b> | Andrea Terron, EFSA, Parma, Italy                                    |
| 13:05-14:00 | <b>Break out session 1</b>                | Susanne Hougaard, DTU Technical University of Denmark                |
|             | <b>Break out session 2</b>                | Antonio Hernandez Jerez, University of Granada, Spain                |
|             | <b>Break out session 3</b>                | Martin Wilks, Swiss Centre for Applied Human Toxicology, Switzerland |



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|--|-------------------------------------|--|
| 14:00-14:45  | <b>Coffee break</b>                 |  |
| <b>SESSION 2   Feedback from the breakout sessions</b><br><b>Chair : Kevin Crofton</b><br><br><b>Rapporteurs : Andrea Terron/Iris Mangas</b> |                                     |  |
| 14:45-15:15  | <b>Discussion group 1</b>           | Susanne Hougaard, DTU<br>Technical University of<br>Denmark                              |
| 15:15-15:45  | <b>Discussion group 2</b>           | Antonio Hernandez Jerez,<br>University of Granada,<br>Spain                              |
| 15.45-16:15  | <b>Discussion group 3</b>           | Martin Wilks,<br>Swiss Centre for Applied<br>Human Toxicology,<br>Switzerland            |
| 16:15-17.00  | <b>Final discussion and remarks</b> | Andrea Terron EFSA,<br>Parma, Italy and Kevin<br>Crofton R3Fellows LLC,<br>United States |