

PROTECTING FARM WORKERS AND CITIZENS IN
RURAL AREAS AGAINST PESTICIDES
EUROPEAN PARLIAMENT 25 SEPT 2024

NEUROTOXICITY AND REGULATORY PERSPECTIVES

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NEUROTOXICITY IN EFSA: IN A NUTSHELL

- Since 2015 EFSA has invested/is investing about 10 millions euros for developing testing strategies, testing and assessing pesticides for risk factors for
 - Developmental neurotoxicity (DNT)
 - Parkinson disease (PD)
- EFSA is supporting, collaborating and coordinating scientific international efforts with OECD, ECHA, US EPA, JRC, PARC, FDA, MJFF, US NICEATM.
- Due to the limitations of in vivo testing, the approach is based a paradigm shift towards the application of in vitro testing within integrated approaches to testing and assessment.
- This approach is in line with the state of the science and the current understanding of DNT and PD underlying biology using data to support regulatory decisions .



CHRONIC NEUROTOXICITY EFSA WORK

Since 2015 EFSA

- has engaged with the scientific and international community to contribute to understand the biology of PD, assess whether pesticide exposure can be risk factor
- developed an AOP indicating quantitative correlation between mitochondrial dysfunction at the cellular level and degeneration of dopaminergic neurons of nigrostriatal pathway in vitro*
- plans to validate and implement the methods in the pesticides risk assessment (as did for DNT).
- organised a Stakeholders Workshop to discuss the topic in 2022
- participate in international specialize NT workshops (e.g SCREENING FOR ENVIRONMENTAL EXPOSURES WORKSHOP of **MJFF (Michael Fox Foundation for Parkinson research)**)
- evaluate and collaborate on projects on accelerating the understanding of PD biology with US MJFF grants and Horizon 2020 for example.
- In addition, EFSA is supporting and coordinating scientific international efforts on the topic with OECD, US NICEATM.

**This is the only AOP that exist for PD mechanistic pathways and allows to screen using robust in vitro methods for this toxicological pathway. EFSA testing project is based on establishing an integrated approach to the evaluation of mitochondrial toxicants and screening for this mechanism pathway (100 approved pesticides will be tested).*



WHAT WE ARE DOING NOW FOR ACTIVE SUBSTANCES

During the Peer Review assessment:

standard sentence is included for Complex I, II and III inhibitors:

Peer Review Meeting:

In addition, the potential adversity related to complex I, II and III inhibition of the mitochondria (including SDHI fungicidal MOA) **is considered during Mam Tox Peer Review Meetings since 2019.**

EFSA conclusions: A data gap for testing in an AOP informed IATA

Other:

Introduction of extra Uncertainty factors

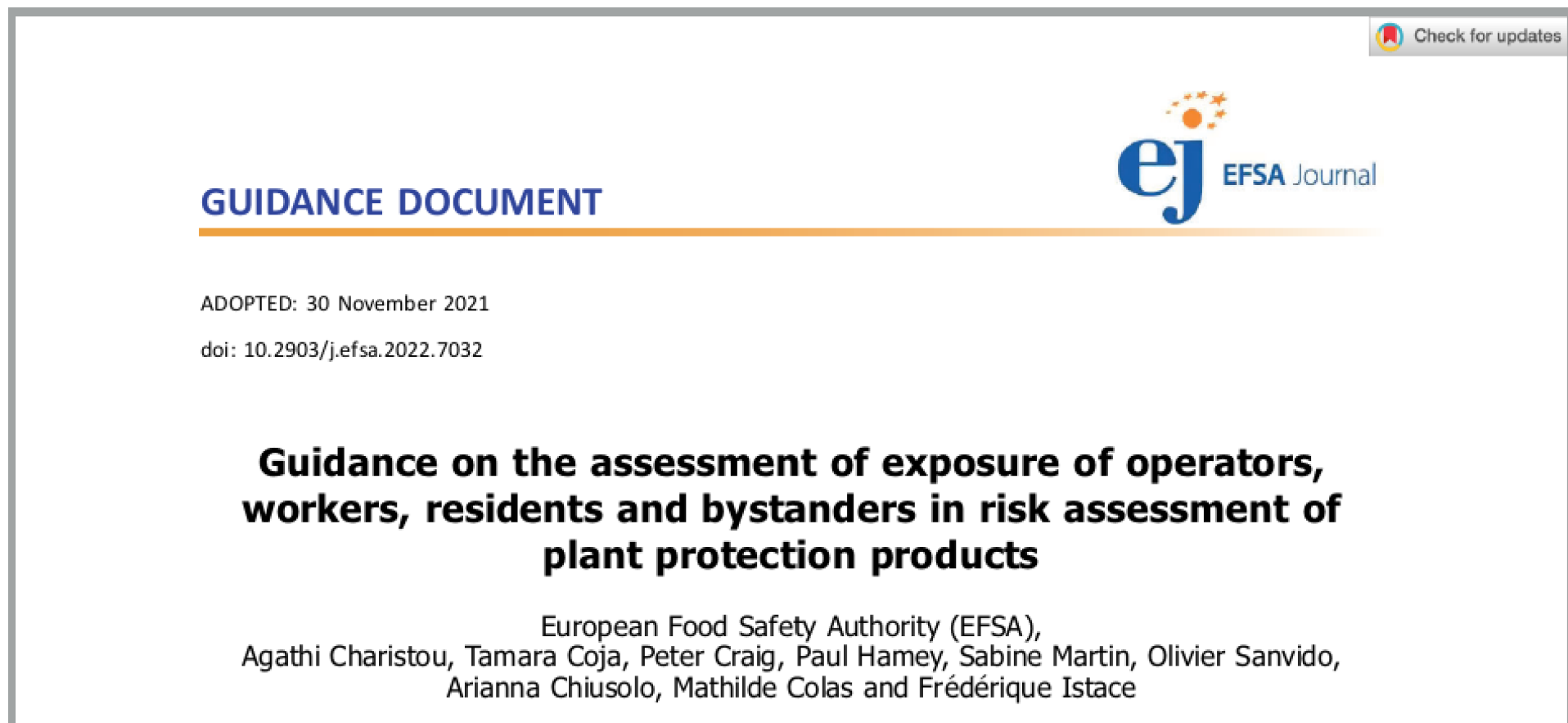
Involvement of stakeholders

Training and communication



NON DIETARY EXPOSURE

- Second [EFSA guidance](#) in 2022, with online calculator



The image shows a screenshot of the EFSA Journal cover page for a guidance document. At the top right, there is a 'Check for updates' button. The title 'GUIDANCE DOCUMENT' is prominently displayed in blue. Below it, the adoption date 'ADOPTED: 30 November 2021' and the DOI 'doi: 10.2903/j.efsa.2022.7032' are listed. The main title of the document is 'Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products'. The authors are listed as the European Food Safety Authority (EFSA) and several individuals: Agathi Charistou, Tamara Coja, Peter Craig, Paul Hamey, Sabine Martin, Olivier Sanvido, Arianna Chiusolo, Mathilde Colas, and Frédérique Istace. The EFSA Journal logo is visible in the top right corner of the document page.

Check for updates

GUIDANCE DOCUMENT

ADOPTED: 30 November 2021
doi: 10.2903/j.efsa.2022.7032

Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products

European Food Safety Authority (EFSA),
Agathi Charistou, Tamara Coja, Peter Craig, Paul Hamey, Sabine Martin, Olivier Sanvido,
Arianna Chiusolo, Mathilde Colas and Frédérique Istace



WHERE ARE WE NOW?

WP* (DC)	3Q2023	4Q2023	1Q2024	2Q2024	3Q2024	4Q2024	1Q2025	2Q2025	3Q2025	4Q2025	1Q2026	2Q2026	3Q2026	4Q2026	1Q2027	2Q2027	3Q2027	4Q2027	1Q2028
Revision Calculator					Calc Contract or + WG	Calc Contract or + WG	Calc Contract or + WG + MS testing(?)												
1) SeedTr opex ^a	0 Prot	0 ID1	0 ID2	0 ID3	0 dFD & FD	GD WG (Annex)	GD WG (Annex)	Calc Contract or +WG	Calc Contract or +WG	dGD (Annex) + dCalc: PC		FGD (Annex) + FCalc							
2) B&R ^a			0 Prot	0 ID1	0 ID2	0 ID3	0 dFD&FD	GD WG	GD WG	GD WG	Calc Contract or +WG	Calc Contract or +WG							
3) W, DFR, DT50					0 Prot	0 ID1	0 ID2	0 ID3	0 dFD & FD	GD WG	GD WG	GD WG	Calc Contract or +WG	Calc Contract or +WG			dGD + dCalc: PC		FG + FCalc

Infosession



MAIN ISSUES/OPPORTUNITIES FOR NDE

- Availability of data!!!
 - Buffer zones
 - Drift
 - Contaminated dust
 - Etc....
- Alignment with academia on research needs
 - Quality of data/usability
- Resources
 - Current contract in place for 820k with a consortium of MSs
- Upcoming non dietary cumulative risk assessment
 - Extremely complex (availability of field data!)



Thanks for your
attention!

#OpenEFSA



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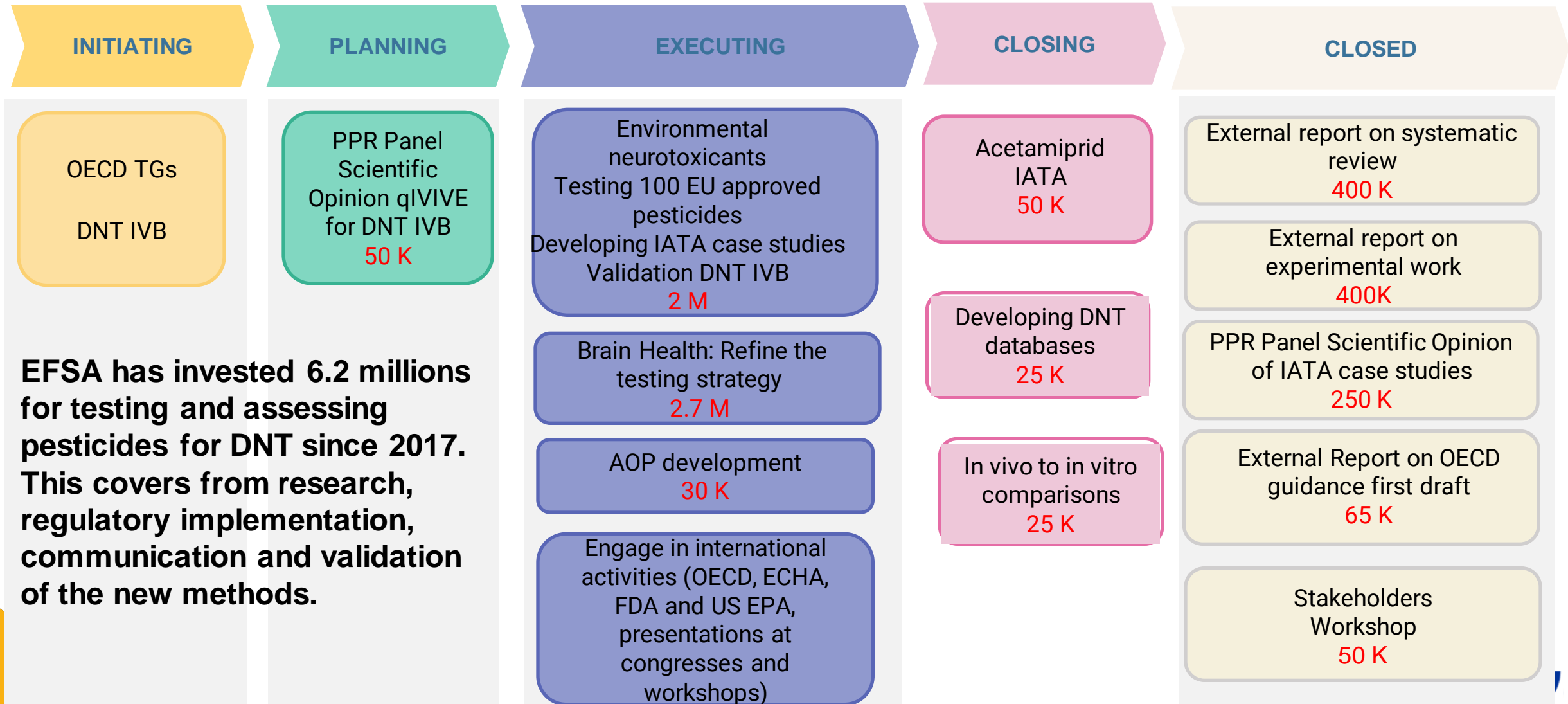


SUPPLEMENTARY SLIDES

- For info

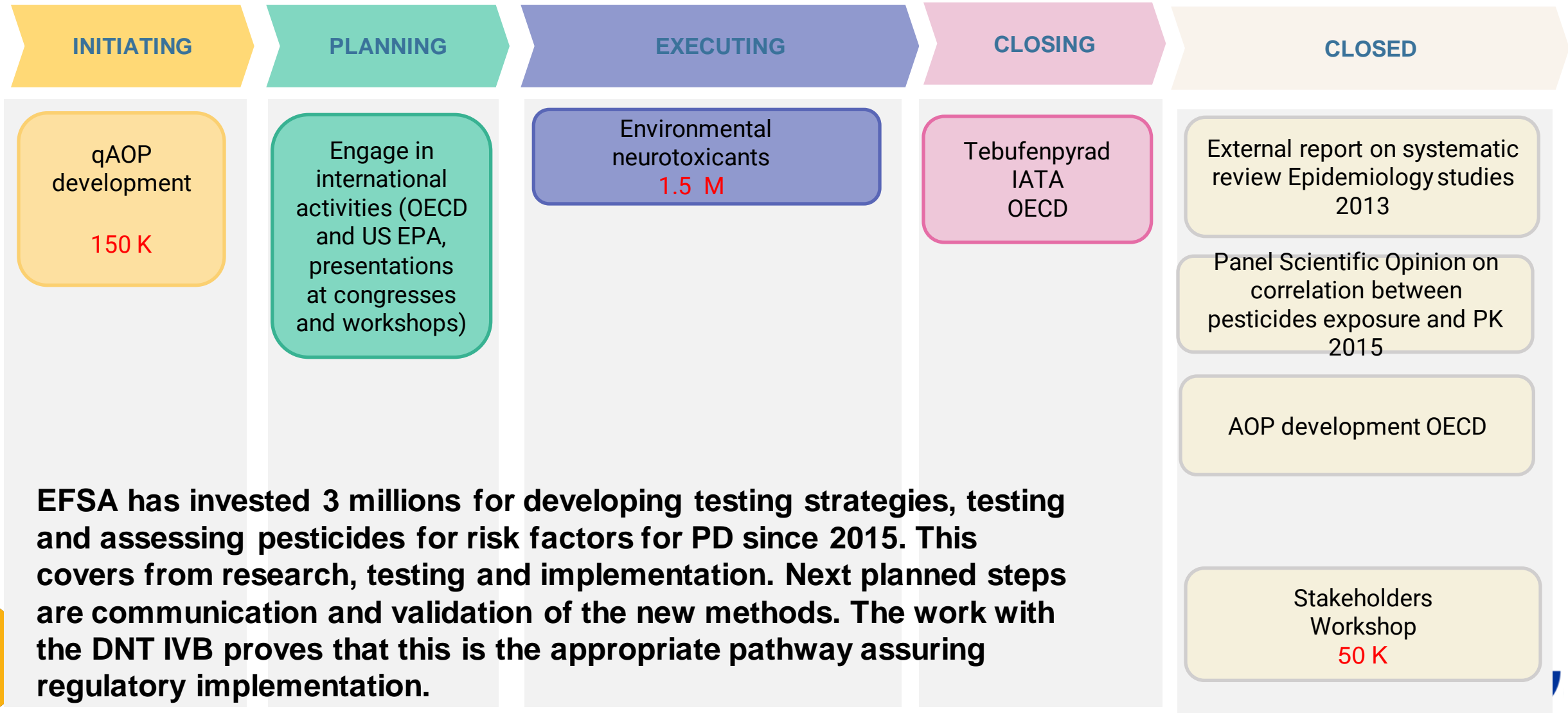


EFSA DNT PROJECTS STATUS AND BUDGET



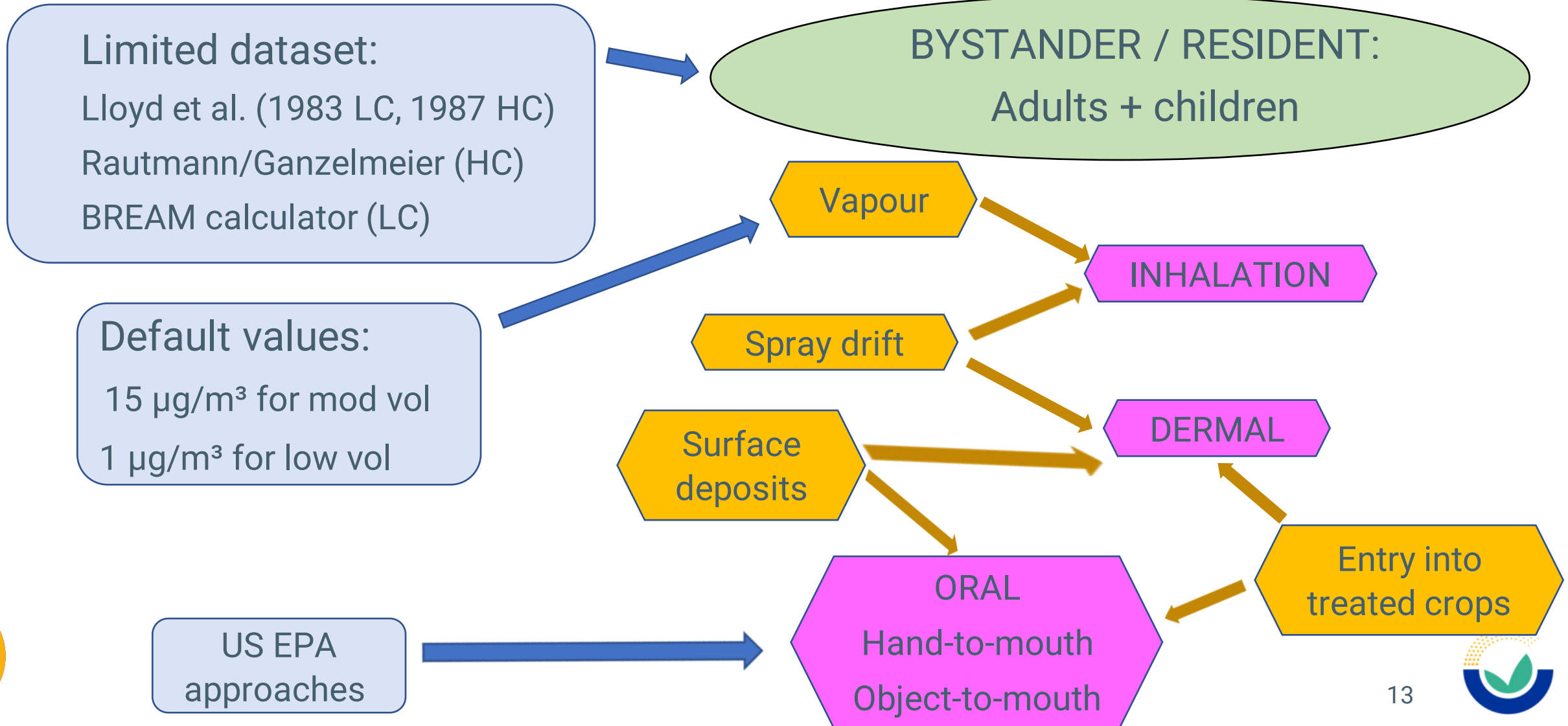
EFSA has invested 6.2 millions for testing and assessing pesticides for DNT since 2017. This covers from research, regulatory implementation, communication and validation of the new methods.

EFSA CHRONIC NT PROJECTS STATUS AND BUDGET



EFSA has invested 3 millions for developing testing strategies, testing and assessing pesticides for risk factors for PD since 2015. This covers from research, testing and implementation. Next planned steps are communication and validation of the new methods. The work with the DNT IVB proves that this is the appropriate pathway assuring regulatory implementation.

BYSTANDER / RESIDENT



WORKSHOP IN 2022 – STATE OF THE ART

- Internal analysis of the future of Non-Dietary Exposure (NDE) to plant protection products
- already received some information/evidence, mainly from industry and public organisations
- also informed about ongoing activities for which final results and raw data could be submitted in the near future
- projects under preparation to be captured with the workshop

Category	Scenario/ parameter* (in grey)	Need* (frequent scenario, info often needed)	Data availability in EFSA	Work ongoing/finalised	Sensitivity* (associated concern)
Operator	Indoor post-harvest treatments	Medium	Yes	Unknown	Low
	Field applications	Low to Medium	No	Unknown	Medium
	Paintbrush	Low (chemicals); medium (basic)	No	Yes (for Biocides)	Low
	Non-professional uses	Low	No	Yes (Ref. from Member States)	Medium
	Seed treatment	Medium to high	No	Ongoing (SeedTropex Task Force)	High
	Closed transfer system	Medium	Partially	Ongoing (field studies)	N.a.
	Drift reduction technologies	High (for refinement purposes)	No	Unknown	N.a.
	Packaging	Low	No	Unknown	N.a.

Category	Scenario/ parameter* (in grey)	Need* (frequent scenario, info often needed)	Data availability in EFSA	Work ongoing/finalised	Sensitivity* (associated concern)
Worker	Non-professional uses	Low	No	Yes (Ref. from Member States)	Medium
	Field applications	Low to Medium	No	Unknown	Medium
	Seed treatment (handling treated seed during loading and sowing)	Medium to high	No	Ongoing (SeedTropex Task Force)	High
	Re-entry in vineyards	High	Yes	Finalised (UK HSE)	High
	DFR studies (meta-analysis)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
	Vapour exposure (literature + field or wind tunnel exposure data)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.

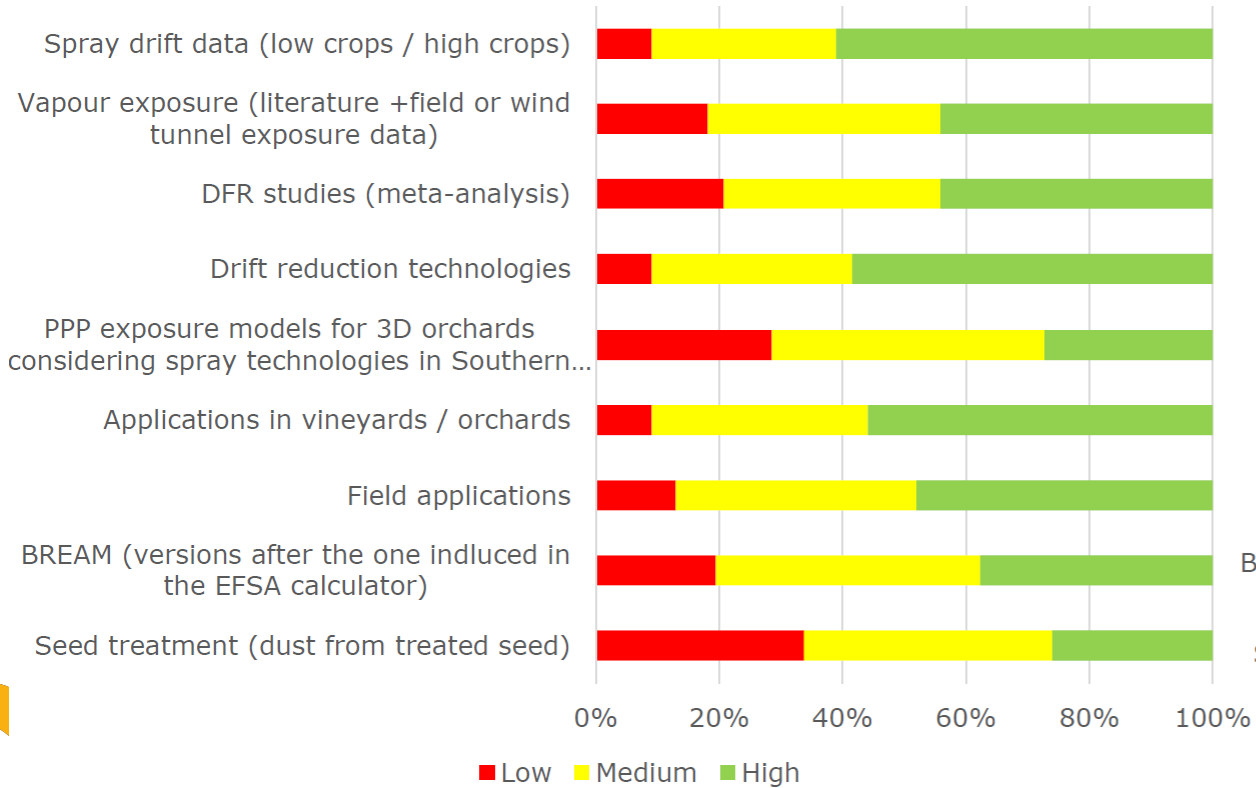
Category	Scenario/ parameter* (in grey)	Need* (frequent scenario, info often needed)	Data availability in EFSA	Work ongoing/finalised	Sensitivity* (associated concern)
Resident	Non-professional uses	Medium	No	Yes (Ref. from Member States)	Medium
	Seed treatment (dust from treated seed)	Medium	No	Ongoing (SeedTropex Task Force)	Medium
	BREAM (versions after the one included in the EFSA calculator)	High	Partially	Version 2 finalised (Silsoe Spray Applications Unit)	Medium
	Field applications	Medium to high	No	Unknown	High
	Applications in vineyards / orchards	High	Yes	Ongoing (Ref. from UK)	High
	Research on exposure of residents to pesticides in the NL	High	No	Finalised (OBO project)	High
	Overview of data and methodologies and data gap identification in exposure assessment for PPPs in residential settings	Low	Partially	Ongoing (LUMIL/RIVM/BPII13)	Medium
	Drift reduction technologies	High (for refinement purposes)	No	Unknown	N.a.
	DFR studies (meta-analysis)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
	Vapour exposure (literature + field or wind tunnel exposure data)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
	Spray drift data (low crops / high crops)	High (for refinement purposes)	No	Finalised (Wageningen University)	N.a.

Category	Scenario/ parameter* (in grey)	Need* (frequent scenario, info often needed)	Data availability in EFSA	Work ongoing/finalised	Sensitivity* (associated concern)
Bystander	Seed treatment (dust from treated seed)	Medium	No	Ongoing (SeedTropex Task Force)	Medium
	BREAM (versions after the one included in the EFSA calculator)	High	Partially	Version 2 finalised (Silsoe Spray Applications Unit)	Medium
	Field applications	Medium to high	No	Unknown	High
	Applications in vineyards / orchards	High	Yes	Ongoing (Ref. from UK)	High
	PPP exposure models for 3D orchards considering spray technologies in Southern Europe	Medium	Partially	Ongoing (LUMIL/UNITO/ELGO GIMITRA/VIAM14)	Medium
	Drift reduction technologies	High (for refinement purposes)	No	Unknown	N.a.
	DFR studies (meta-analysis)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
	Vapour exposure (literature + field or wind tunnel exposure data)	High (for refinement purposes)	No	Ongoing (CLE)	N.a.
	Spray drift data (low crops / high crops)	High (for refinement purposes)	No	Finalised (Wageningen University)	N.a.

*Not developed by EFSA based on received information, not submitted, need/and sensitivity assessed based on EFSA experience in the field

RESULTS OF THE SURVEY

16D Need for Bystander (e.g. frequent scenario, info often needed)



17D Sensitivity for Bystandard (associated concern)

