

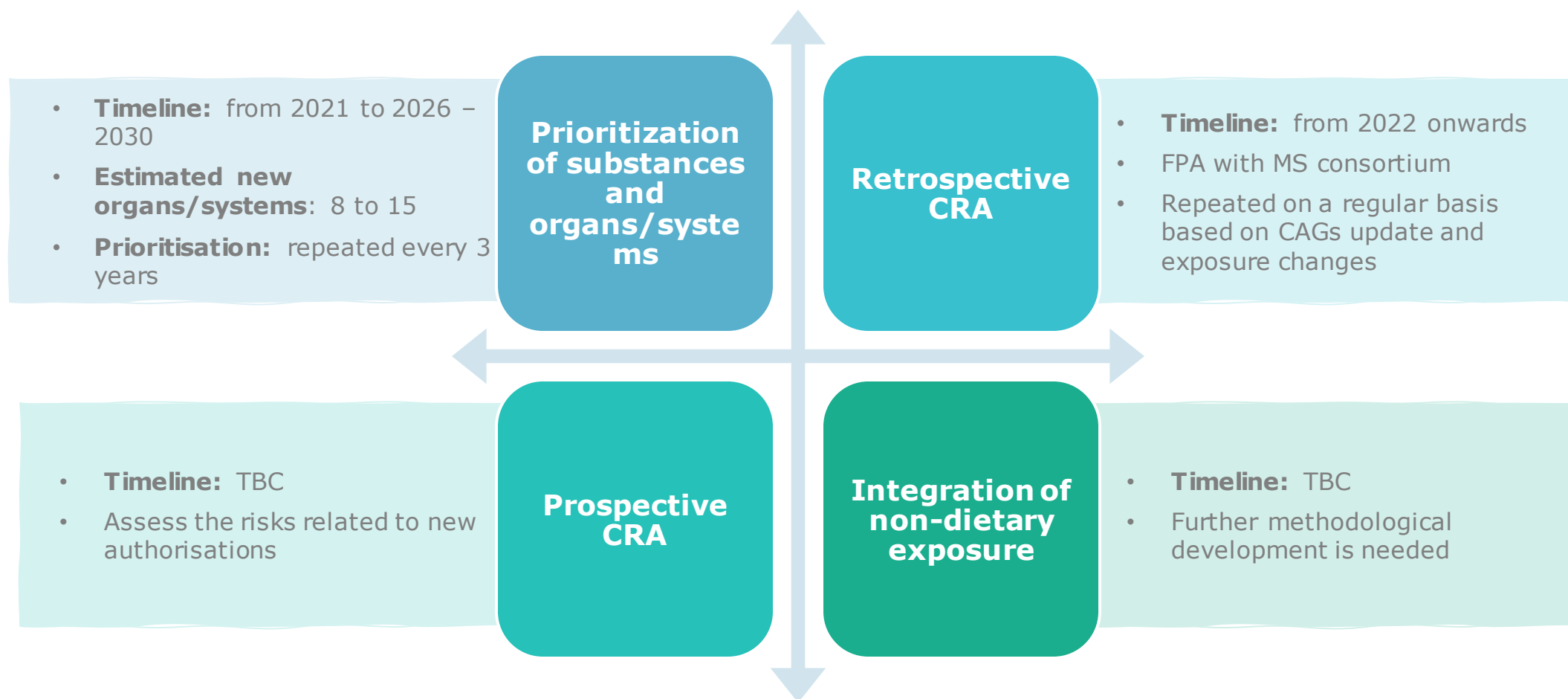
20 October 2022 – Pesticides Steering Network

EFSA update on Cumulative Risk Assessment

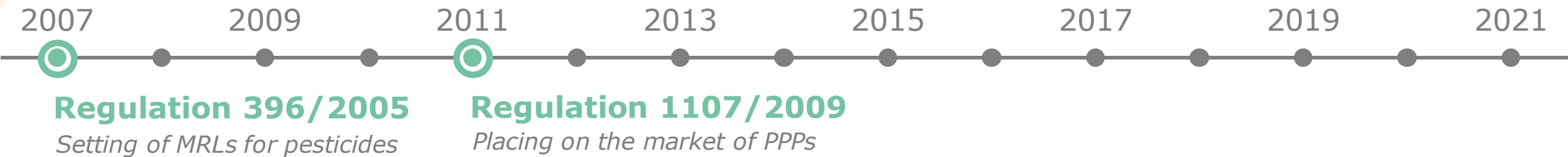
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Plant Health & Pesticide Residues Unit

Trusted science for safe food

- In February 2021, EC and EFSA have published an action plan to accelerate development of the methodology for CRA of pesticides and facilitate its gradual implementation into regulatory practice. https://food.ec.europa.eu/system/files/2021-03/pesticides_mrl_cum-risk-ass_action-plan.pdf



Historical background



Development activities for pesticides

- Tiered methodology for cumulative risk assessment (PPR, 2009)
- Methodology for probabilistic exposure assessment (PPR, 2012)
- Methodology for cumulative assessment groups (PPR, 2013)
- Monte Carlo Risk Assessment software (ACROPOLIS Project, 2013)

"...take into account known cumulative and synergistic effects of pesticides when the methods are available..."

Retrospective CRA (2014-2022)

- Software development
 - ❖ RIVM: MCRA
 - ❖ EFSA: SAS®-based
- Pilot project (2016-2019): Effects on the thyroid and the nervous system
- 2020: chronic AChE inhibition
- 2022: craniofacial alterations



SCIENTIFIC REPORT

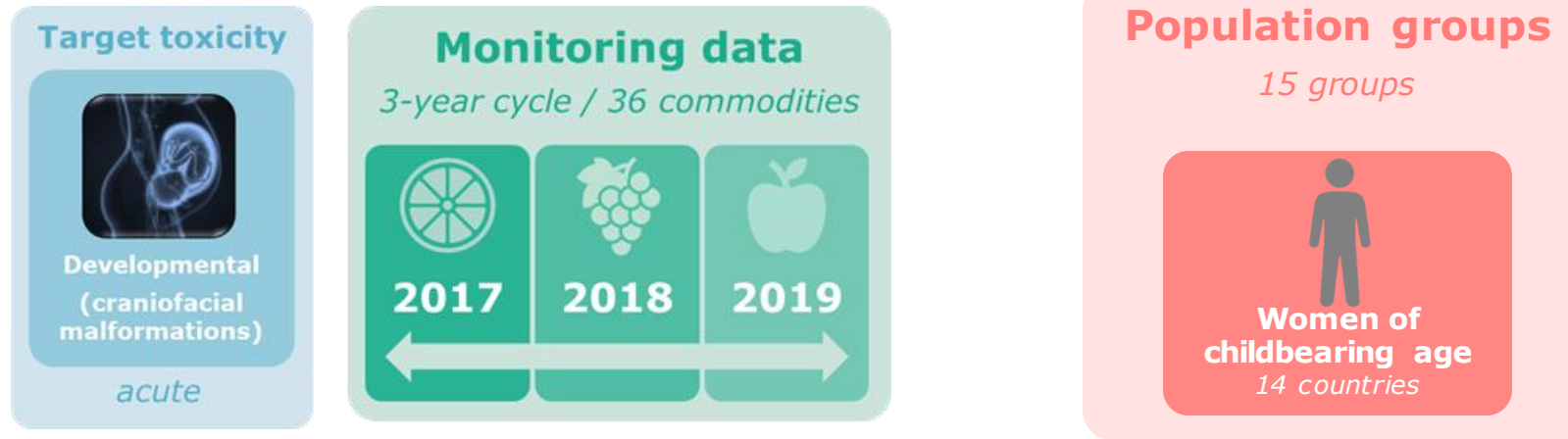
APPROVED: 18 August 2022
doi: 10.2903/j.efsa.2022.7550

Retrospective cumulative dietary risk assessment of craniofacial alterations by residues of pesticides

Cumulative dietary risk assessment of chronic acetylcholinesterase inhibition by residues of pesticides

Retrospective CRA of craniofacial alterations

- EFSA report published on 6th October 2022



2 Cumulative assessment groups (CAG):

- Craniofacial alterations due to abnormal skeletal development (CAG-DAC)
- Head soft tissue alterations and neural tube defects, not due to abnormal skeletal development (CAG-DAH)









CONCLUSION: The threshold for regulatory consideration established by risk managers ($MOET < 100$) is not exceeded.

FPA on retrospective CRA (2nd call)

GP/EFSA/PLANTS/2022/01: Cooperation with EFSA in the area of Cumulative Risk Assessment from dietary exposure to pesticides

Published: 19 January 2022 **Deadline:** 29 April 2022 - 23:59 (CEST)



- [Call for proposals and guide for applicants](#) 
- Annex 1: [Draft framework partnership agreement](#)  and [draft specific agreement](#) 
- [Annex 2: Application form](#) 
- Annex 3: Legal entity form (download template [here](#) )
- Annex 4: Financial identification form (download template [here](#) )
- [Annex 5: Declaration on honour on exclusion criteria and selection criteria](#) 
- [Annex 6: Simplified financial statement](#) 

- 1st call (July 2021) not awarded, followed by market analysis in December 2021
- FPA specific actions: 3 organs (kidney, liver, tbd) + 3 repetitions (thyroid, nervous system, tbd)
- EFSA award letter sent to a consortium by July 2022. FPA still under signature process
- Kidney assessment will be based on work carried out by EFSA WG on the establishment of specific effects on the kidney relevant for CRA

EFSA-SANTE ACTION PLAN for prospective CRA:

- ✓ Development of prospective case studies, under EFSA-RIVM cooperation (2020-2021)
- ✓ Feedback from an expert group of the Standing Committee for Plants, Animal, Food and Feed (PAFF committee) on the case studies (2020-2021)
- **ONGOING:** testing of the selected scenario and possible options in a “mock” assessment (acute and chronic effects) based on a real MRL application. Specific agreement under EFSA Pesticides Tasking Grant.
- Agreement of the PAFF Committee on consolidated methodology
- Gradual implementation of prospective CRA in regulatory MRL-setting
- Partnership EFSA-RIVM for the development and maintenance of an open source MCRA software



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