News from DG SANTE

Joint EURL/NRLs (SRM-FV) Pesticide Residue Workshop 2022

Almeria, 13/10/2022 (Zoom)

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Stephanos Kirkagaslis, DG SANTE E.4

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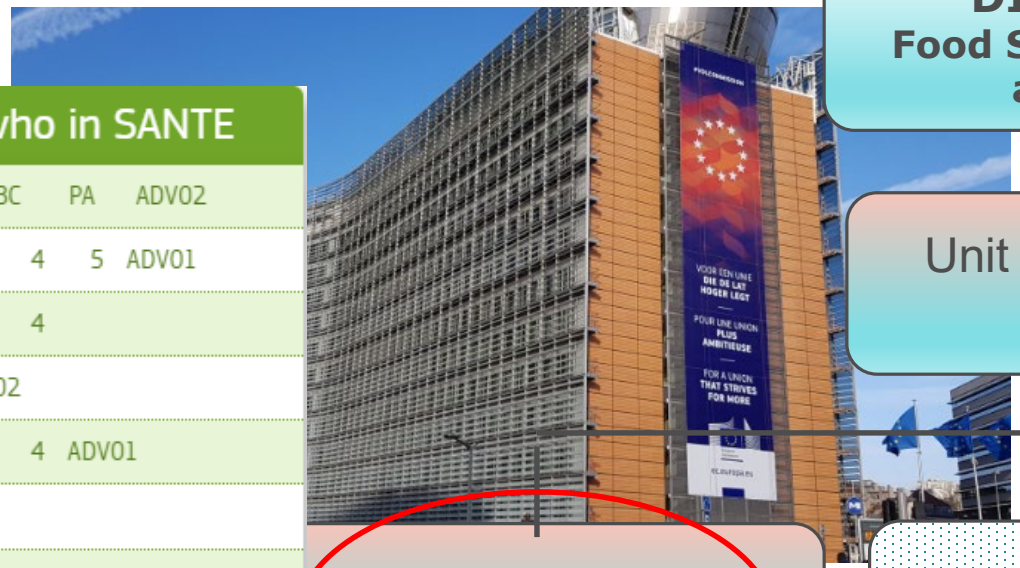
The Pesticide Residues Team in DG SANTE

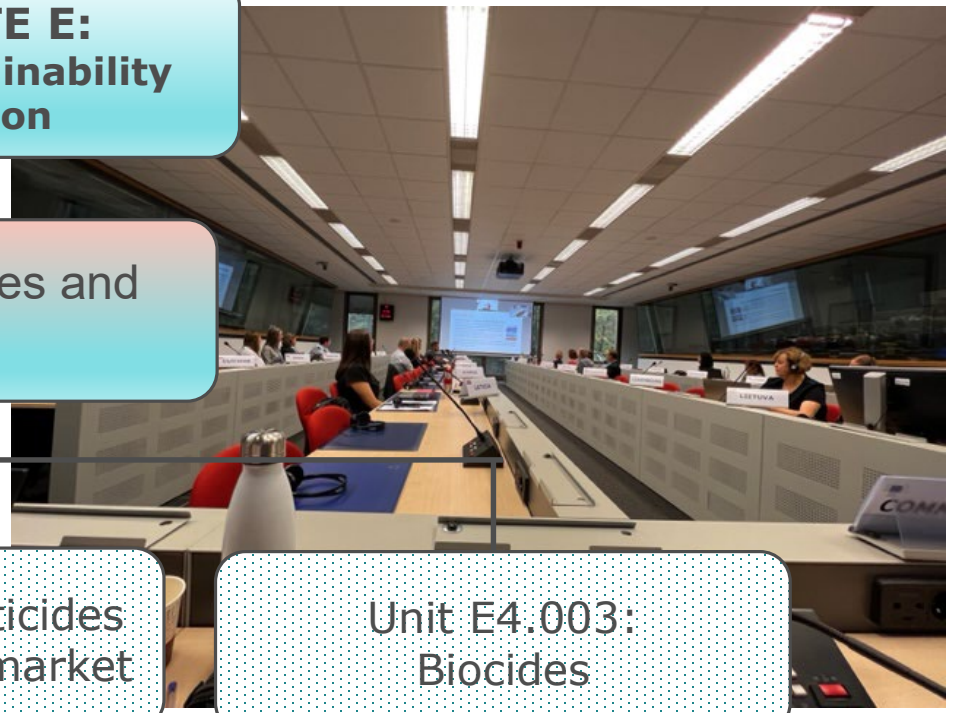
Who we are, what we do

Who is who in SANTE						
DG	01	HRBC	PA	ADVO2		
A	1	2	3	4	5	ADVO1
R	1	2	3	4		
DDG1	PA01	PA02				
B	1	2	3	4	ADVO1	
C	1	2	3			
D	1	2	3	4		
DDG2						
E	1	2	3	4		
F	1	2	3	4	5	6
G	1	2	3	4	5	



DIRECTORATE E:
Food Safety, Sustainability and Innovation

Unit E4: Pesticides and Biocides



Unit E4.001: Pesticide Residues

Unit E4.002: Pesticides – Placing on the market

Unit E4.003: Biocides

Standing Committee on Plants, Animals, Food and Feed – SECTION: Phytopharmaceuticals Pesticide Residues

Standing Committee on Plants, Animals, Food and Feed – SECTION: Phytopharmaceuticals Legislation

Standing Committee on Biocidal Products

European Commission

The Pesticide Residues Team in DG SANTE

Who we are, what we do

Stefano Messori

Almut Bitterhof

Maria Tabernero

Siret Surva

Anne Latrive

Stephanos Kirkagaslis

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The Pesticide Residues Team in DG SANTE

Who we are, what we do

REGULATION (EC) 396/2005

MRL setting (art.6)

Analytical methods

MRL Review (art.12)

MRLs on fish?

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Cumulative Risk Assessment

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Processing Factors

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Codex MRLs (CXLs)

Emergency measures

Directive 2002/63/EC

EU MRL Database

Official Controls

European Commission

The Pesticide Residues Team in DG SANTE

Who we are, what we do

REGULATION (EC) 396/2005

MRL setting (art.6)

EU application
Import tolerances
Codex MRLs (CXLs)

MRL Review (art.12)

MRL Deletion (art.17)

Evaluating Member State/RMS

Consultation with EURLs

EFSA Reasoned Opinion

Consultation with EURLs

Draft Regulation

WTO/SPS

SCoPAFF

Adoption by the COM

Publication OJ

Entry into Force

Application

Ca. 4m

20d

6m

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  - ✓ Cumulative Risk Assessment
  - ✓ Directive 2002/63/EC
  - ✓ Substance-Specific Issues

Projects
Confirmatory Data 1/3

REGULATION (EC) 396/2005
MRL Review (art.12) Procedure

EFSA Reasoned Opinion

- Recommended MRL: fully supported by data

- Tentative MRL: some information is missing*, further consideration from risk managers, safe for consumers

**e.g. residue trials, metabolism studies, analytical methods*

Regulation

The applicant is invited to submit data by deadline otherwise MRL → LOQ

(+) The European Food Safety Authority identified some information on crop metabolism as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 August 2015, or, if that information is not submitted by that date, the lack of it.

0251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)
0251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)
0251060	Rocket, Rucola (Wild rocket)

Projects
Confirmatory Data 2/3

REGULATION (EC) 396/2005
MRL Review (art.12) Procedure

(a) applicant submits confirmatory data → EFSA Reasoned Opinion evaluates data → COM prepares Regulation, accordingly:

i) Data not sufficient to support MRL, ->LOQ
ii) Data sufficient to support MRL, ->MRL
iii) Data sufficient to support a lower MRL

(b) applicant does not submit confirmatory data → MRLs lowered to LOQs

i) EFSA Statement confirming no data
ii) EURLs consultation for LOQ

Commission Regulation (EU) 2022/1363:

2,4-D, azoxystrobin, cyhalofop-butyl, cymoxanil, fenhexamid, flazasulfuron, florasulam, fluroxypyr, iprovalicarb and silthiofam

e.g. MRL iprovalicarb/lettuces, data gap on crop metabolism, deadline 17Aug2015

↓

EFSA Statment: no data received

↓

MRL: 0.8mg/kg →0,01*mg/kg deleted the footnote.

Next batch of substances will be included in one Regulation to be prepared in 2023

European Commission

Projects
Confirmatory Data 3/3

REGULATION (EC) 396/2005
MRL Review (art.12) Procedure

What about footnote (A)?

Missing analytical standards

E.g. next to the RD for cyflufenamid, footnote (A) reads:

- (A) The EU reference laboratories identified the reference standard for the E-isomer and for metabolite 149-F1 as commercially not available. When reviewing the MRLs, the Commission will take into account the commercial availability of the reference standard referred to it in the first sentence by 17 September 2020, or, if that reference standard is not commercially available by that date, the unavailability of it.

Reminder letters for the commercial availability of:

>spiroxamine carboxylic acid metabolite M06
>cyflufenamid (E-isomer)
>fluroxypyr conjugates

Next batch of letters will be sent after the deadline in 2023

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Projects

Monitoring of Pesticide Residues

Regulation (EC) 2021/601: EU multi-annual control programme (EU MACP) **2022-2023-2024** **01/01/2022**

Regulation (EC) 2022/741: EU MACP 2023-2024-2025 **01/01/2023**

Meeting of the Working Group: 17 October 2022

Regulation EUMACP 2024-2025-2026

For vote at SCoPAFF Feb2023

Working Document SANCO/12745/2013, Rev 14

For endorsement SCoPAFF Nov2022

Projects

Updated /New Guidelines 1/2

SANTE/2021/10704: Information Note on Article 20 as regards processing factors (PFs); SCoPAFF→**22/02/2022**

- ✓ Guidance to MSs including OfLs on how to implement article 20 (PFs).
- ✓ Indications for FBOs to prepare and have the necessary information for Competent Authorities.
- ✓ **Responsibility of CAs to decide if and which PF to use.**
- ✓ EFSA -> Second update of the EU database of processing factors in collaboration with BfR. New processing studies will be collected from MSs until the 31st August 2023

SANTE/2017/10632, Rev.4: Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods; SCoPAFF→**23/02/2022**

- ✓ Chapter 7 was revised to clarify applicability of the TG, e.g. how does the lack of data on extraction efficiency affect the results of residue trials in art.6 MRL applications
- ✓ **During the SCoPAFF Sep 2022, a MS requested a more substantial update of this TG and volunteered to lead**

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Projects

Updated / New Guidelines 2/2

SANTE/2020/12830, Rev.1 :
Residues Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes; SCoPAFF
→ **24/02/2021**

- ✓ **Applicable since 01/03/2021**
- ✓ **Raised Many questions from stakeholders:**

> E.g. if it applies on studies that started prior the application date or not.

> E.g. Chapter 2.3 on the use of hazardous re-agents, now excludes not only the use carcinogens, mutagens and substances toxic for reproduction. This seems to have challenged some labs.

- ✓ Merged and updated **SANCO/3029/99** *(Guidance on generating and reporting methods of analysis in support of pre-registration data requirements)* and **SANCO/825/00** (Guidance Document on pesticide residue analytical methods).

All these documents are meant to support all parties involved in the pre- and post-registration processes by providing the grounds for a common understanding, but <u>without inducing any legal liability</u>.

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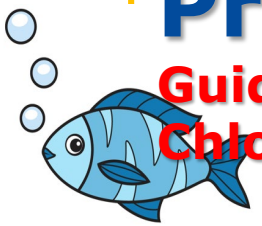
Projects

Guidance values for Fish
Chlorate, BAC, DDAC



✓ Footnote (8) of Annex I of R396/2005: "*no MRLs are applicable until individual products have been identified and listed within this category*". I.e. when the first product is listed, the default MRL 0.01 mg/kg will apply for all fish and fish products.

✓ A MS submitted monitoring results for high levels of benzalkonium chloride (BAC), didecyldmethylammonium chloride (DDAC) and chlorate in fish.

✓ Proposed to establish MRLs for those substances under Regulation (EC) 396/2005.

✓ We invited MSs to submit data for pesticide residues (including chlorate, BAC/DDAC) with an aim to Explore the possibility to establish indicative values for further enforcement action by national authorities under Article 14 of R178/2002

✓Presented the results of the statistical evaluation of ca. 800.000 determinations submitted by EFSA, MSs, NO, CH at the WG_Mo 21 and proposed guidance values for chlorates, BAC, DDAC

✓However, a Member State indicated possible health risks for its population and, therefore, called for an EU consumer exposure assessment by EFSA.

✓We mandated EFSA to collect data, perform statistical evaluation and exposure assessment

Deadline: 28 April 2023

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  - ✓ Cumulative Risk Assessment
  - ✓ Directive 2002/63/EC
  - ✓ Substance-Specific Issues

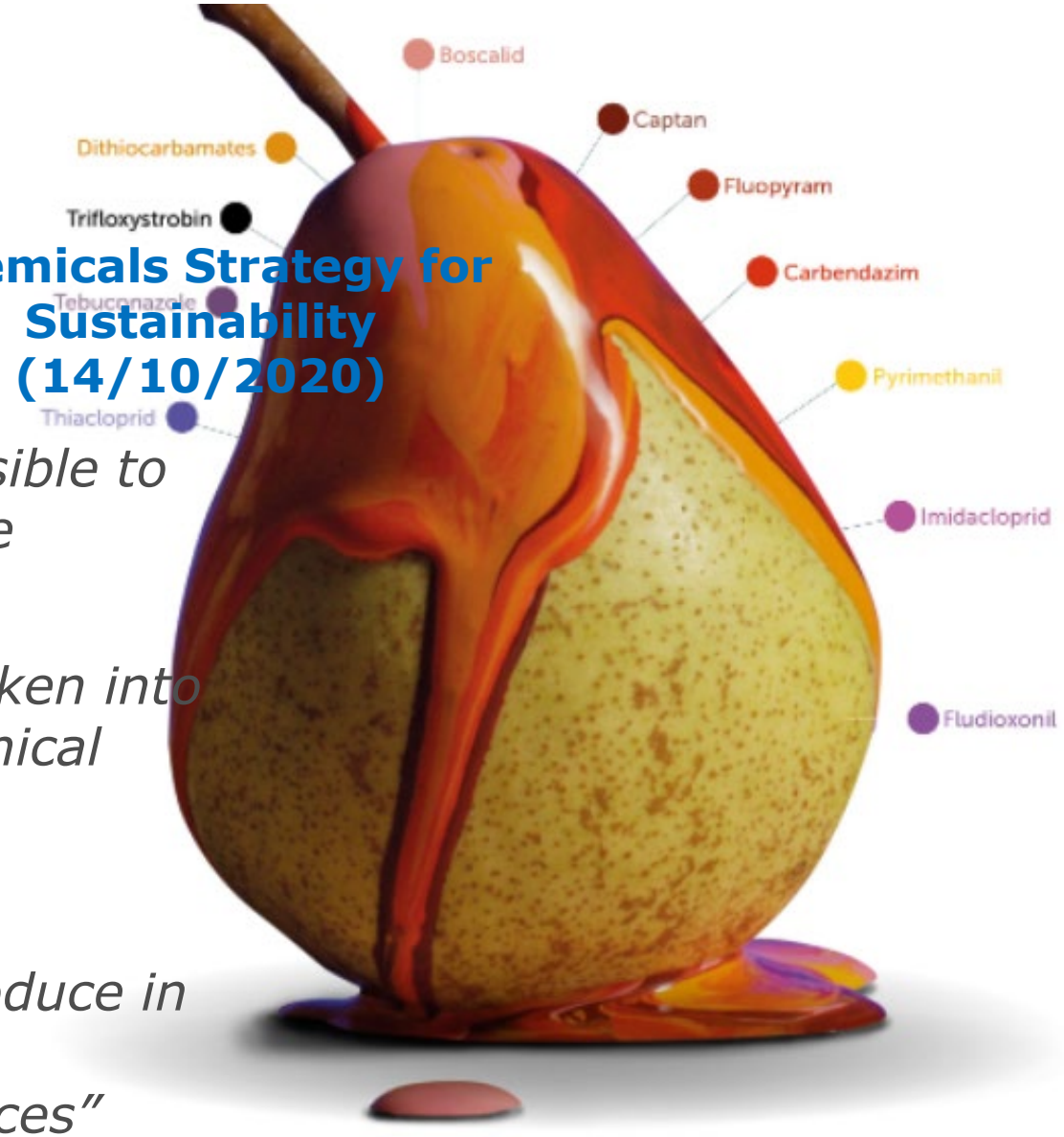
Challenges

Cumulative Risk Assessment 1/3

A European Green Deal

Striving to be the first climate-neutral continent

Chemicals Strategy for Sustainability (14/10/2020)



"It is currently not realistic nor economically feasible to specifically assess and regulate an almost infinite number of possible combinations of chemicals".

"…the effect of chemical mixtures needs to be taken into account and integrated more generally into chemical risk assessment."

"On the combination effects of chemicals, the Commission commits to assess how to best introduce in REACH (Reg.1907/2006) ***Mixture Assessment Factors*** *for the chemical assessment of substances"*

"In parallel, ***targeted methodologies*** *could be further developed and explored for* ***specific policy areas****."*

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Challenges

Cumulative Risk Assessment 2/3

- ✓ CRA is included in pesticides' legislation (R1107/2009, R396/2005)
- ✓ EFSA has been working on a targeted methodology.
- ✓ The methodology starts with grouping substances with similar health effects into Cumulative Assessment Groups. We have CAGs for the nervous system, the thyroid and craniofacial alterations.
- ✓ Then we have a probabilistic exposure assessment based on monitoring data, i.e. all occurrences of pesticide residues are combined with all consumption data for 10 available diets → **Retrospective CRA**
- ✓ **Methodology was developed with the help of a WG that started in 2015**
- ✓ **Parameters for retro-CRA agreed in the SCoPAFF of Sep2018**

Challenges

Cumulative Risk Assessment 3/3

- ✓ Currently, the COM work focuses on **prospective CRA,** i.e. the exposure assessment that is carried out to decide whether a new MRL application is considered to be safe for consumers and can be established in legislation.
- ✓ 2021: 2 WGs on pro-CRA, 15 acute + 15 chronic case studies (RIVM)
- ✓ 2021: EFSA/RIVM report on prospective scenarios
- ✓ **Mock Assessment based on a real MRL application expected 2023-2024. EFSA will cooperate with ANSES.**

Hint: pro-CRA has one limitation. In a MRL application, the pesticide must be part of a CAG, the product must be included in the EU MACP.

Challenges
Directive 2002/63/EC

- ✓ During the SCoPAFF of Sep2022 a MS expressed concerns on the legal status of the Directive, because in its Article 1 it refers to Directives 76/895/EEC, 86/362/EEC, 86/363/EEC and 90/642/EEC which are repealed by R396/2005.
- ✓ We confirmed that this repeal has no impact on the validity of the sampling Directive and it still applies. It is also mentioned in the Monitoring Regulation.

- ✓ We informed that we envisage to update it and **transform it into a Regulation** that would include more elements to further support **sampling, analytical methods and enforcement**.

Substance-Specific Issues

Glyphosate

- ✓ The procedure for the further elaboration of the draft Regulation for the review of the MRLs of Glyphosate will be kept on hold until there is further clarity on the renewal process of the substance.

Trimethyl sulfonium cation

- ✓ RD: "...resulting from the use of Glyphosate".
- ✓ According to industry, findings of trimesium on teas and herbal infusions are due to the drying process and not due to the use of Gly. The two substances should be decoupled from the RD.

- ✓ The discussion will benefit from the outcome of Gly renewal process.
- ✓ Meanwhile, MS / Stakeholders should collect/provide data on different matrices to better understand Trimesium's occurrences on various food products.

Substance-Specific Issues

➢ Matrine

- ✓ Reported first time in 2019 by German labs that found residues >0.01mg/kg in EU organic mandarins, tomatoes and lettuces.

- ✓ Since then it was reported in Honey from China and in Licorice from Iran.
- ✓ China: its presence is un-avoidable due to co-blossoming of Sophora flowers (naturally containing matrine) with Acacia flowers, so bees are contaminating the honey.
- ✓ Industry: its presence is un-avoidable due to co-collection of Sophora roots (naturally containing matrine) licorice roots and it is impossible to distinguish the roots.

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Substance-Specific Issues

➢ Matrine

✓ Matrine is a pesticide in SE Asian countries, e.g China.

Industry: Licorice grows in the wild in Iran

✓ Since it is a pesticide, R396/2005 applies.

✓ Matrine has never been assessed in the EU, i.e. we have no indication if it is harmful or not for human. We don't know how much human can consume before it becomes toxic.

✓ In application of the Precautionary Principle, which ensures a high level of consumer protection in the EU, the default MRL 0,01mg/kg applies.

✓ Stakeholders can apply for a MRL or import tolerance (art.6, R396/2005).

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Thank you

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