



News from DG SANTE

Joint EURLs Pesticide Residue Workshop 2023

Fellbach, 18/10/2023

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CONTENTS

➤ The Pesticide Residues Team in DG SANTE

Who we are, what we do

➤ Projects

- ✓ Confirmatory Data (analytical standards)
- ✓ Monitoring of Pesticide Residues
- ✓ Updated/New Guidelines
- ✓ Guidance values for residues of chlorate, BAC, DDAC in fish

➤ Challenges

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

The Pesticide Residues Team in DG SANTE

Who we are, what we do

Who is who in SANTE

DG	01	HRBC	PA	ADV02		
A	1	2	3	4	5	ADV01
R	1	2	3	4		
DDG1	PA01	PA02				
B	1	2	3	4	ADV01	
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

The Pesticide Residues Team in DG SANTE

Who we are, **what we do**

REGULATION (EC) 396/2005

MRL setting (art.6) **EU Monitoring Programme (art.29)**

Analytical methods

Import tolerances Extrapolation Guidance

MRL Review (art.12)

MRLs on fish?

Cumulative Risk Assessment

Mixture Assessment Factors

Extraction Efficiency

EURLs/NRLs/OfLs

Sampling methods

Processing Factors

Codex MRLs (CXLs)

Directive 2002/63/EC

Temporary MRLs (art.16)

Environmental factors

MRL Deletion (art.17)

Emergency measures

Official Controls

Confirmatory data

EU MRL Database



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)

Temporary MRL (art.16)

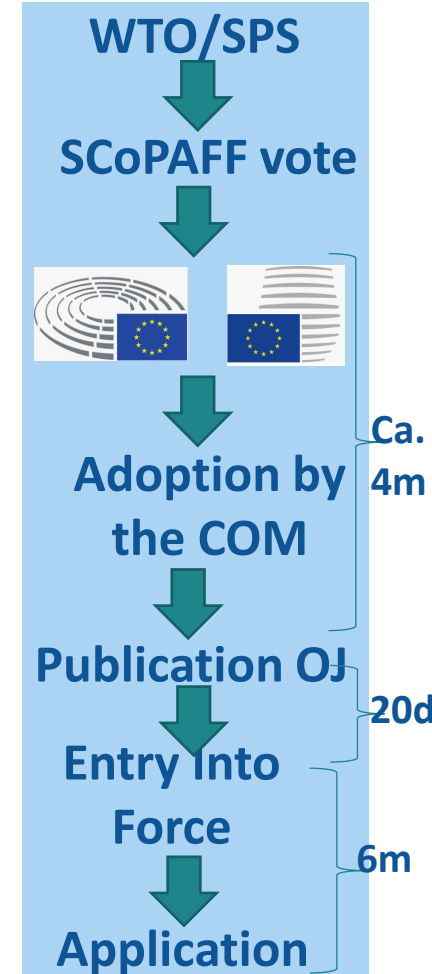
Evaluating
Member
State/RMS

EFSA
Reasoned
Opinion

Consultation
with EURLs
LOQ, RD...

EFSA
Assessment

Draft
Regulation

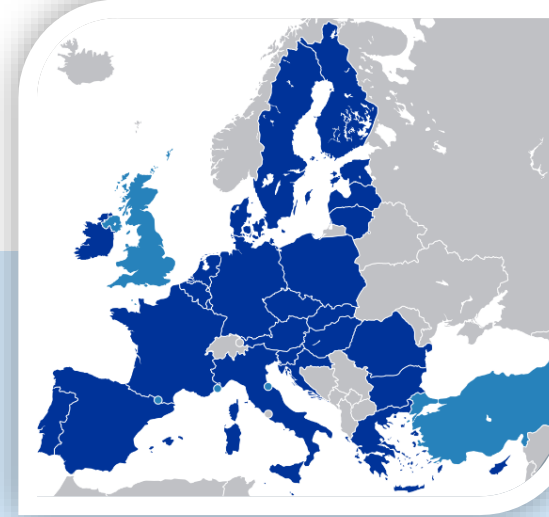


The Pesticide Residues Team in DG SANTE

Who we are, **what we do**

REGULATION (EC) 396/2005

- **EU multi-annual control programme for pesticide residues – MACP (Art.29)**
 - ✓ Aims at assessing consumer exposure and compliance with current legislation
 - ✓ Annually updated through an Implementing Commission Regulation, usually published April-May every year
 - ✓ Takes into account problems identified regarding the compliance with MRLs



The Pesticide Residues Team in DG SANTE

Who we are, **what we do**

REGULATION (EC) 396/2005

- **National Control Programmes (NCPs) (~~Art.30~~)**

REGULATION (EU) 2017/625

- ✓ Article 155: deleted Article 30 of R396/2005 (14/12/2022)
- ✓ Article 110 minimum requirements for MANCPs, no detailed practical arrangements

Implementing Regulation (EU) 2021/1355

- ✓ Providing specific practical arrangements (e.g. risk-based, criteria)



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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

(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

REGULATION (EC) 396/2005

MRL Review (art.12) Procedure

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 batches of substances ongoing in 2023
- ✓ Update of WD SANTE/10235/2016 on risk management decisions in the absence of confirmatory data (e.g. methoxyfenozide/ aubergine)

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**



**Analytical standards
were made commercially
available by
manufacturers**

Projects

Monitoring of Pesticide Residues (1/1)

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

Regulation (EC) 2023/731: EU MACP 2024-2025-2026 **01/01/2024**

Meeting of the Working Group: 13 October 2023

**Regulation
EUMACP
2025-2026-2027**
*For vote at SCoPAFF
Feb2024*



**Working Document
SANCO/12745/2013,
Rev 15**
*For endorsement SCoPAFF
Nov2023*

Projects

Updated /New Guidelines 1/3

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 of R396/2005 (Processing Factors – PFs).
- ✓ Indications for FBOs to prepare and have the necessary information for Competent Authorities (CAs).
- ✓ **Responsibility of CAs to decide if and which PF to use.**
- ✓ EFSA -> Second update of the EU PFs database in collaboration with 3 MSs. New processing studies collected from MSs by 31st August 2023 (not only PFs included in EFSA publications, but also studies by FBOs)
- ✓ **The update will be made publicly available by EFSA in January 2024.**

Projects

Updated /New Guidelines 2/3

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**

SANTE/2017/10632, Rev.5:
SCoPAFF→**10/05/2023**

✓ "Frequent Questions and Answers" section added in Annex 2 of the document. (*e.g. Is the evaluation of extraction efficiency necessary for analytical methods for honey?*)

Projects

Updated / New Guidelines 3/3

SANTE/2020/12830, Rev.1 :

Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes;
SCoPAFF → **24/02/2021**

- ✓ 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).

Chapter 2.3 on the use of hazardous re-agents:

Rev.1 used **by mistake the hazard classification** of R67/548/EEC, thus excluding the use of n-hexane and toluene. But with this is not the case with the numerical designations of the hazard classifications of R1272/2008.

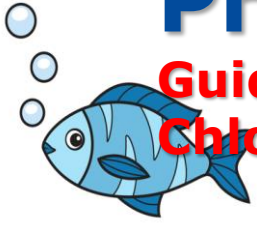
SANTE/2020/12830, Rev.2 :

SCoPAFF → **14/02/2023**

- ✓ Corrected the mistake
- ✓ Excludes use of chlorinated solvents (e.g. chloroform, dichloromethane) due to problematic behavior of such compounds in the environment and the laborious disposal of waste)

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 without inducing any legal liability.

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), didecylmethylammonium 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

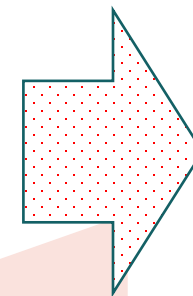
Deadline: 28 April 2023



Projects

Guidance values for Fish Chlorate, BAC, DDAC

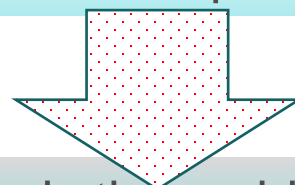
- ✓ EFSA call for data for residues of chlorate, BAC and DDAC on fish and fish products.
- ✓ Data call open to all countries: only few MSs and the United Kingdom submitted data, i.e. limited geographical representativeness → EFSA conclusions indicative



EFSA received
2.296 entries from
MSs (2012-2021)

Results: SCoPAFF 10-11 May 2023

- ✓ **EFSA** did not identify any consumer intake concern for those substances found on fish.
- ✓ Highlighted uncertainties, mainly due to insufficient geographical data representation.
- ✓ Identified narrow margin of safety for the acute exposure for chlorate as it reached 82%ARfD.



Commission: further action as regards the residues of those substances on fish is not needed



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Challenges

Cumulative Risk Assessment 1/3

A European Green Deal

Striving to be the first climate-neutral continent



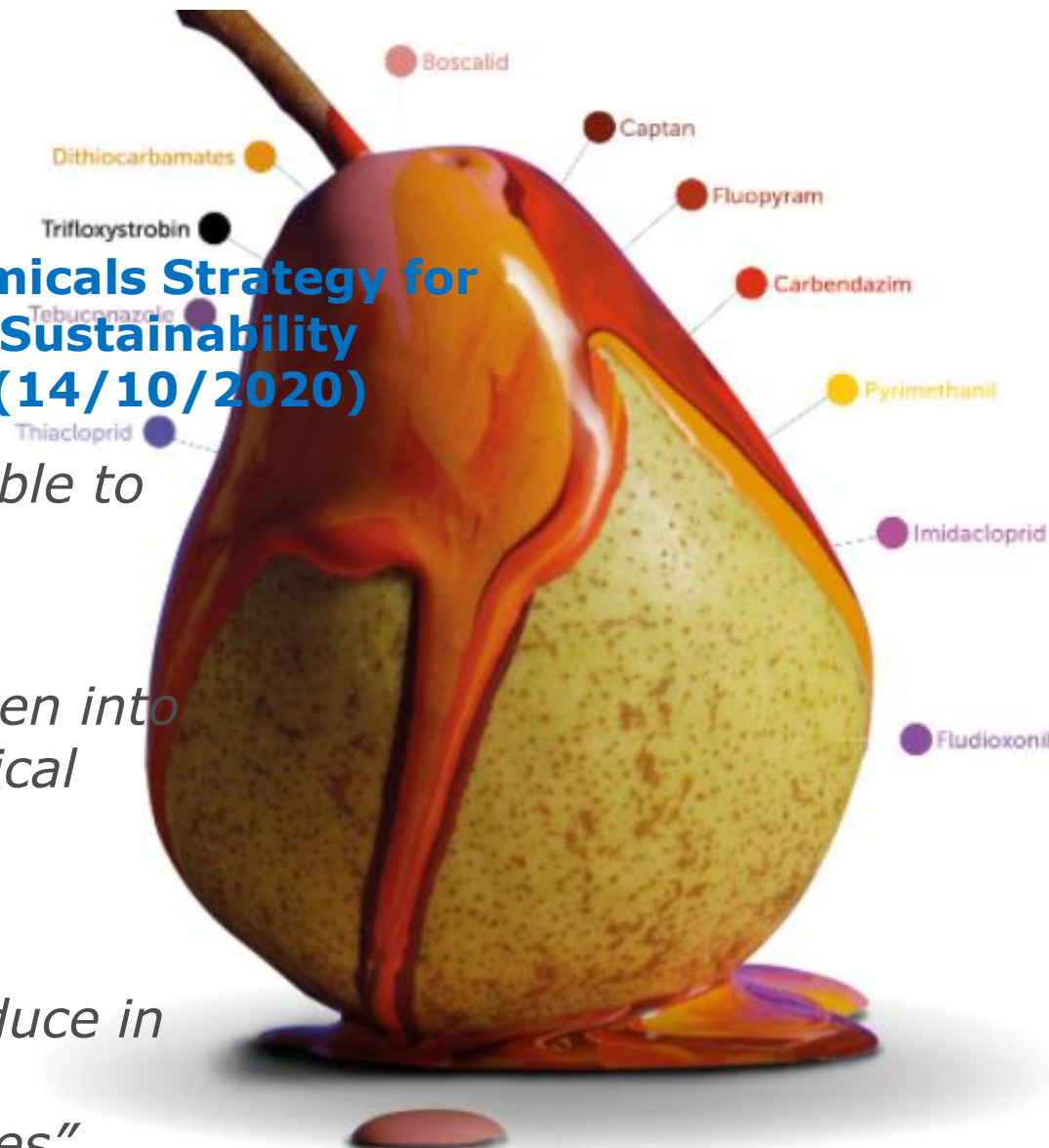
Chemicals Strategy for Sustainability (14/10/2020)

"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.**"*



European
Commission

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 Assessments (acute/chronic)** based on a real MRL applications expected 2023-2024 (EFSA collaboration with ANSES).
- ✓ **SANTE/10216/2015, Rev.8**: proCRA parameters (MSs endorsed 18/09/2023)

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

- ✓ **SCoPAFF Sep2022: COM** → Update and **transform into a Regulation** to include more elements to further support **sampling, analytical methods and enforcement**.

The WG Meeting on 24 April 2023 discussion on PLAN/2023/636:

- ✓ Inclusion of more products to reflect Annex I to R396/2005 (e.g. honey, fish, terrestrial invertebrate animals, amphibians and reptiles)
- ✓ Formalisation in a legal text of certain enforcement elements that are now included in the Guidance Document SANTE/11312/2021 (e.g. measurement uncertainty)
- ✓ Option to provide FBOs possibility to apply same sampling rules as CAs
- ✓ Updating the quantities of laboratory samples, but maintaining Codex requirements

2nd meeting of the WG for further discussion.

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.
- ✓ EFSA assessment of (limited) data on tea 2019 and 2021: **could not conclude on whether the presence of TMS can be linked with the use of Glyphosate or not.**
- ✓ MS / Stakeholders should collect/provide data on different matrices to better understand TMS occurrences on various food products.



SCoPAFF 10-11 May 2023

Substance-Specific Issues

➤ Matrine

- ✓ Reported first time in 2019 by German labs that found residues $>0.01\text{mg/kg}$ 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.

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).

Thank you

