Joint EURL-FV/SRM Workshop- 27-29 September 2016 Almeria

- Miscellaneous News -

M. Anastassiades



EUPTs-2017

EUPT	Tentative period	Matrix			
FV-19 SM-09	February 2017	Lemon			
SRM-12	March 2017	Strawberry or other high acid content commodity to be decided)			
AO-12	April 2017	Egg			
CF-11	May 2017	Oat flour			

Easter Sunday (both Western and Orthodox): 16 April 2017



Pesticide Reevaluation according to Art. 12 396/2005

Assessment of existing MRLs by the Authority

- 1. The Authority shall, within a period of 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC after the entry into force of this Regulation, submit a reasoned opinion based in particular on the relevant assessment report prepared under Directive 91/414/EEC to the Commission and the Member States on:
- (a) existing MRLs for that active substance set out in Annex II or III to this Regulation;
- (b) the necessity of setting new MRLs for that active substance, or its inclusion in Annex IV to this Regulation;
- (c) specific processing factors as referred to in Article 20(2) of this Regulation that may be needed for that active substance;
- (d) MRLs which the Commission may consider including in Annex II and/or Annex III to this Regulation and on those MRLs which may be deleted related to that active substance.
- 2. For substances included in Annex I to Directive 91/414/EEC before the entry into force of this Regulation, the reasoned opinion referred to in paragraph 1 of this Article shall be delivered within 12 months of the entry into force of this Regulation.



Pesticide Reevaluation according to Art. 12 396/2005

Mechanism to **review existing MRLs** (all appr. + some non-appr. pesticides) Process started 2008 (initially ca. 350 compounds aim ca. 50 per year)

PROCEDURE

"Rapporteur Member State" (RMS) designated for each compound RMS prepares evaluation report

EFSA prepares Reasoned Opinion (RO) based on RMS evaluation report.

Procedure: Completeness Check → review of draftRO → RO (see on-line)

Risk management

COM considering RO and initiates discussion with MSs

COM prepares proposal of legislation with MRL amendments

EURLs consultation

WHO notified 60d to comment

PAFF Votes → Scrutiny (European Council + Parliament) → adoption of §

By June 2016 217 compounds were finalized



Art 12 396/2005 (reevaluation of Pesticides), Ongoing project.

ACTIVE SUBSTANCES TO BE REVIEWED UNDER THE INTERIM PROCESS - LAST REVISION 8 MAR 2016

Compounds to be evaluated by EFSA by Q1 2017

EFSA-Q-number	Active substance	RMS	Current Status
EFSA-Q-2008-511	Cinidon-ethyl	UK	finished
EFSA-Q-2009-00119	Mepiquat	UK	finished
EFSA-Q-2009-00118	Fuberidazole	UK	finished
EFSA-Q-2009-00100	Chloridazon	DE	finished
EFSA-Q-2009-00135	Tralkoxydim	UK	finished
EFSA-Q-2009-00052	Fluazifop-P	FR	finished
EFSA-Q-2009-00116	Fluazinam	AT	finished
EFSA-Q-2008-523	Deltamethrin	SE	in progress
EFSA-Q-2010-00192	Methomyl	UK	finished
EFSA-Q-2009-00191	Sulcotrione	DE	in progress
EFSA-Q-2009-00129	Fenpyroximate	DE	finished
EFSA-Q-2009-00142	Aclonifen	DE	finished
EFSA-Q-2009-00159	Cymoxanil	AT	finished
EFSA-Q-2009-00151	Aluminium phosphide	DE	finished
EFSA-Q-2009-00173	Magnesium phosphide	DE	finished
EFSA-Q-2009-00157	Calcium phosphide	DE	finished
EFSA-Q-2010-00201	Sodium 5-nitroguaiacolate	EL	finished
EFSA-Q-2010-00202	Sodium o-nitrophenolate	EL	finished



Art 12 396/2005 (reevaluation of Pesticides), Ongoing project.

ACTIVE SUBSTANCES TO BE REVIEWED UNDER THE <u>INTERIM</u> PROCESS – LAST REVISION 8 MARCH 2016 (cont.)



ACTIVE SUBSTANCES TO BE REVIEWED UNDER THE <u>INTERIM</u> PROCESS – LAST REVISION 8 MARCH 2016 (cont.)

EFSA-Q-number EFSA-Q-2010-00183 EFSA-Q-2010-00208 EFSA-Q-2010-00197 EFSA-Q-2010-00189 EFSA-Q-2010-00187 EFSA-Q-2010-01068 EFSA-Q-2010-01077 EFSA-Q-2010-01077 EFSA-Q-2010-00209 EFSA-Q-2010-00209 EFSA-Q-2009-00049 EFSA-Q-2009-00049 EFSA-Q-2009-00087 EFSA-Q-2009-00087 EFSA-Q-2009-00038	Active substance Copper compounds Tri-allate Penconazole Etofenprox Dimethachlor 2-Phenylphenol Triflumizole Penoxsulam Bromuconazole Triflumuron Pyridaben Fenbuconazole Carboxin Pencycuron Bromadiolone Clethodim	RMS FR UK DE IT DE ES NL IT BE IT NL UK VL SE NL	Current Status in progress
EFSA-Q-2009-00038 EFSA-Q-2009-00051	Clethodim Fenoxycarb	NL NL	in progress in progress
EFSA-Q-2009-00067	Paclobutrazol	UK	in progress



ACTIVE SUBSTANCES TO BE REVIEWED UNDER THE <u>INTERIM</u> PROCESS – LAST REVISION 8 MARCH 2016 (cont.)

EFSA-Q-number EFSA-Q-2009-00041 EFSA-Q-2009-00059 EFSA-Q-2009-00056 EFSA-Q-2009-00075 EFSA-Q-2009-00064 EFSA-Q-2011-00171 EFSA-Q-2011-00172 EFSA-Q-2012-00450 EFSA-Q-2012-00741 EFSA-Q-2013-00277	Active substance Dazomet Hexythiazox Flurochloridone Tebufenozide Myclobutanil Bispyribac Profoxydim Tefluthrin Metam Fenpyrazamine Mandipropamid	RMS BE FI ES DE BE IT ES DE BE AT AT	Current Status in progress
EFSA-Q-2013-00277 EFSA-Q-2013-00967	Mandipropamid Tembotrione	AT AT	1 0
EFSA-Q-2013-00967 EFSA-Q-2009-00050	Fenbutatin oxide	BE	in progress in progress



ACTIVE SUBSTANCES TO BE REVIEWED UNDER THE FUTURE PROCESS - LAST REVISION 8 MARCH 2016

EFSA Evaluation should will not finish before Q2 2017

EFSA-Q-number EFSA-Q-2008-590 EFSA-Q-2008-638 EFSA-Q-2008-648 EFSA-Q-2008-577 EFSA-Q-2008-578 EFSA-Q-2008-487 EFSA-Q-2008-520 EFSA-Q-2008-613 EFSA-Q-2009-00182 EFSA-Q-2010-00211 EFSA-Q-2008-527 EFSA-Q-2008-527 EFSA-Q-2008-513 EFSA-Q-2008-518 EFSA-Q-2008-535 EFSA-Q-2008-558	Active substance Metiram Thiram Ziram Mancozeb Maneb alpha-Cypermethrin Cypermethrin Propineb Pyrethrins zeta-Cypermethrin Dimethoate beta-Cyfluthrin Clopyralid Cyfluthrin Ethoprophos Fosthiazate Linuron	RMS IT BE BE IT IT BE BE IT IT DE IT DE IT DE IT	in progress
EFSA-Q-2008-575	Linuron	DE IT	in progress in progress
EFSA-Q-2008-579	MCPA	PL	in progress



EESA O number	Active cubetones	DMC	Current Status
EFSA-Q-number	Active substance	RMS	Current Status
EFSA-Q-2008-580	MCPB	PL	in progress
EFSA-Q-2008-588	Methiocarb	UK	in progress
EFSA-Q-2008-592	Metribuzin	EE	in progress
EFSA-Q-2008-605	Phosmet	ES	in progress
EFSA-Q-2008-624	Quinoxyfen	UK	in progress
EFSA-Q-2008-649	Zoxamide	LV	in progress
EFSA-Q-2009-00021	Tricyclazole	ΙΤ	in progress
EFSA-Q-2009-00017	Beauveria brongniartii	DE	in progress
EFSA-Q-2009-00019	Potassium permanganate	ES	in progress
EFSA-Q-2009-00027	Chlorates	FR	in progress
EFSA-Q-2009-00089	Fatty alcohols	ΙΤ	in progress
EFSA-Q-2009-00094	Quassia	ΙΤ	in progress
EFSA-Q-2009-00101	Clofentezine	ES	in progress
EFSA-Q-2009-00102	Dicamba	DK	in progress
EFSA-Q-2009-00103	Difenoconazole	ES	in progress
EFSA-Q-2009-00104	Diflubenzuron	EL	in progress
EFSA-Q-2009-00106	Fenoxaprop-P	AT	in progress
EFSA-Q-2009-00108	Imazaquin	BE	in progress
EFSA-Q-2009-00109	Lenacil	BE	in progress
EFSA-Q-2009-00113	Pyriproxyfen	NL	in progress



EFSA-Q-number	Active substance	RMS	Current status
EFSA-Q-2009-00111	Oxadiazon	ΙΤ	in progress
EFSA-Q-2009-00112	Picloram	PL	in progres
EFSA-Q-2010-00193	Nicotine	UK	in progress
EFSA-Q-2009-00127	Epoxiconazole	DE	in progress
EFSA-Q-2009-00148	2,5-Dichlorobenzoic acid methylester	DE	in progress
EFSA-Q-2009-00160	Denathonium benzoate	PT	in progress
EFSA-Q-2009-00174	Metamitron	UK	in progress
EFSA-Q-2009-00150	Aluminium ammonium sulfate	PT	in progress
EFSA-Q-2009-00152	Aluminium silicate	HU	in progress
EFSA-Q-2009-00189	Sodium aluminium silicate	HU	in progress
EFSA-Q-2009-00190	Sodium hypochlorite	NL	in progress
EFSA-Q-2010-00182	Chlorsulfuron	EL	in progress
EFSA-Q-2010-00186	Difenacoum	FI	in progress
EFSA-Q-2010-00207	Tetraconazole	ΙΤ	in progress
EFSA-Q-2010-01070	Cyflufenamid	UK	in progress
EFSA-Q-2010-01075	Malathion	UK	in progress
EFSA-Q-2010-01073	Fluopicolide	UK	in progress
EFSA-Q-2010-01078	Proquinazid	UK	in progress
EFSA-Q-2010-01079	Spirodiclofen	NL	in progress



EFSA-Q-number EFSA-Q-2010-01080 EFSA-Q-2009-00029 EFSA-Q-2009-00018 EFSA-Q-2009-00072 EFSA-Q-2010-00193 EFSA-Q-2009-00034 EFSA-Q-2009-00047 EFSA-Q-2009-00047 EFSA-Q-2009-00054 EFSA-Q-2009-00074 EFSA-Q-2009-00074 EFSA-Q-2009-00073 EFSA-Q-2009-00073	Active substance Sulfuryl fluoride Napropamide Buprofezin Quinmerac Nicotine Bupirimate Cyproconazole Etridiazole Fenazaquin Fluometuron tau-Fluvalinate Cycloxydim Hymexazol Sintofen	RMS UK UK UK UK UK NL EL EL DK AT FI FR	in progress
EFSA-Q-2009-00060	Hymexazol	FI	in progress





EFSA-Q-2014-00374 Ipconazole UK in progress EFSA-Q-2014-00594 Aminopyralid UK in progress	EFSA-Q-number EFSA-Q-2013-00776 EFSA-Q-2014-00122 EFSA-Q-2014-00204 EFSA-Q-2013-00909 EFSA-Q-2013-00965 EFSA-Q-2013-00777 EFSA-Q-2013-00911 EFSA-Q-2013-00910 EFSA-Q-2014-00212 EFSA-Q-2014-00206 EFSA-Q-2014-00205 EFSA-Q-2014-00207 EFSA-Q-2014-00207 EFSA-Q-2014-00360 EFSA-Q-2014-00360	Active substance Sedaxane Potassium thiocyanate Potassium iodide Benalaxyl-M Chlorantraniliprole Emamectin Penthiopyrad Spirotetramat Pyroxsulam Amisulbrom Pyridalyl Spinetoram Thiencarbazone 1,4-Dimethylnaphthalene Valifenalate Acequinocyl Elubendiamide	RMS FR NL NL PT IE NL UK AT UK NL HU NL FI	in progress
	EFSA-Q-2014-00360 EFSA-Q-2014-00454 EFSA-Q-2014-00374	Flubendiamide Ipconazole	EL UK	in progress in progress in progress



ACTIVE SUBSTANCES TO BE REVIEWED UNDER THE <u>FUTURE</u> PROCESS – LAST REVISION 8 MARCH 2016 (cont.)

EFSA-Q-number	Active substance	RMS	Current Status
EFSA-Q-2014-00596	Metaflumizone	UK	in progress
EFSA-Q-2014-00593	Metobromuron	FR	in progress
EFSA-Q-2015-00080	Meptyldinocap	UK	in progress
EFSA-Q-2015-00068	Chromafenozide	HU	in progress
EFSA-Q-2015-00071	Gamma-cyhalothrin	UK	in progress
EFSA-Q-2015-00476	Halauxyfen-methyl	UK	in progress
EFSA-Q-2015-00485	Sulfoxaflor	ΙE	in progress
Not yet attributed.	3-decen-2-one	NL	in progress
Not yet attributed.	Beta-cypermethrin	UK	?
Not yet attributed.	Cyantraniliprole	UK	in progress
Not yet attributed.	Ethametsulfuron	UK	?
Not yet attributed.	Flumetralin	HU	in progress
Not yet attributed.	Flutianil	UK	?
Not yet attributed.	Orthosulfamuron	ΙΤ	?
Not yet attributed.	Pinoxaden	UK	?
Not yet attributed.	Topramezone	FR	?



Availability of Standards

What does Note [A] in RDs mean?

Fenpropidin (sum of fenpropidin and its salts, expressed as fenpropidin) (R) (A)

Annexes Reg. 396/2005	Annex II
Legislation	Reg. (EU) No 61/2014 Applicable from: 14/08/2014
History ₫	Reg. (EC) No 149/2008 2*
Footnotes	(R) = The residue definition differs for the following combinations pesticide-code number: fenpropidin-code 1000000 except 1040000: sum of fenpropidin, 2-methyl-2-[4-(2-methyl-3- piperidin-1-yl-propyl)-phenyl]propionic acid, and their salts, expressed as fenpropidin (S) = The EU Reference Laboratories for Residues of Pesticides identified the reference standard for 2-methyl-2-[4-(2-methyl-3- piperidin-1-yl-propyl)-phenyl]propionic acid as commercially not available. When re-viewing the MRL, the Commission will take into account the commercial availability of the reference standard referred to in the first sentence by 25 January 2015, or, if that reference standard is not commercially available by that date, the unavailability of it.

If companies do not comply MRLs are dropped to 0.01 mg/kg



Availability of Standards

COM consults EURLs on availability and is also in contact with PPP manufacturers

	Standard	Supplier	Amount	Price (€)
	Plant Origin			
	Bifenazate	Sigma-Aldrich	32504-50MG	88.20
Metabolite	Bifenazate-diazene	HEXONSYNTH		
	Fluensulfone	Chemos GmbH	250 mg	1750 plus freigh
	Guazatine (Guazatine acetate salt)	Sigma-Aldrich	37915-100MG-R	78.50
	Meptyldinocap	Sigma-Aldrich	32098-25MG	93.10
Metabolite	2,4 DNOP ((2,4-dinitro-6-(2-octyl)phenol))	LGC Standards	DER-C14895050	1.7
	Pyriofenone	LGC Standards	10mg	
	Triclopyr	Sigma-Aldrich	32016-250MG	66.40
	Tritosulfuron	Sigma-Aldrich	33873-100MG-R	76.10
Metabolite	AMTT (4-methoxy-6-(trifluoromethyl)-1,3,5-triazin-2-amine)	Alfa Chemistry		
	Animal Origin			
	Aminocyclopyrachlor	Not commercially available		
	Boscalid	Sigma-Aldrich	33875-100MG-R	67.4
Metabolite	M510F01 (2-chloro-N-(4'-chloro-5-hydroxybiphenyl-2-yl)nicotinamide (free and conjugated))	Not commercially available		
	Chlorpropham	Sigma-Aldrich	45393-250MG	46.1
Metabolite	4'-hydroxychlorpropham-O-sulphonic acid (4-HSA)	Not commercially available		
	Fenpropidin	Sigma-Aldrich	46017-50MG	60.7
Metabolite	2-methyl-2-[4-(2-methyl-3- piperidin-1-yl-propyl)-phenyl]propionic acid	Not commercially available		
	Fenpropimorph	Sigma-Aldrich	36772-100MG-R	44.8
Metabolite	Fenpropimorph carboxylic acid (BF 421-2)	Not commercially available		
	Fluopyram	Sigma-Aldrich	32462-50MG	121
Metabolite	Fluopyram-benzamide (M25) (2-(Trifluoromethyl)benzamide)	Sigma-Aldrich	594512-1G	55.7
	Spiroxamine	Sigma-Aldrich	46443-100MG	52.5
Metabolite	Spiroxamine carboxylic acid	Not commercially available		
	Tebuconazole	Sigma-Aldrich	32013-250MG	57.5



MACP meeting in Parma



MONITORING WORKING GROUP MEETING, PARMA 9-10/10/16

- 1) CLASSIFICATION OF RESIDUE DEFINITIONS by EFSA/EURLs (ca. 1000 RDs) gone through:
- COMPLEX RDs: ≥2 compounds determined (e.g. A+B+C expressed as A)
- SIMPLE RDs: 1 result is generated, e.g. :
 - o parent only,
 - sum of isomers determined together,
 - acids following hydrolysis,
 - sums determined as a common moiety
- DUAL RDs: depending on procedure they could be simple or complex,

e.g: RD: A+B+C expressed as A

Simple: Conversion to A and determined as A (e.g. conversion to sulfone)

Complex: Analysis of A, B and C separately

AIM: Close the gaps in SSD to improve and harmonize reporting

MONITORING WORKING GROUP MEETING, PARMA 9-10/10/16

2) CONVERSION FACTORS:

EURLs have provided EFSA with a list of **conversion factors** (based on MW ratios and stoichiometry).

These can be used to calculate the sums of complex residue definitions.

- ❖ Goals: Eventually allow automated calculation of sums by EFSA using the data of individual components provided by MSs.
 - -> practical difficulty (need to stay updated and to keep track of RD history)



MONITORING WORKING GROUP MEETING, PARMA 9-10/10/16

3) Summing LOQs:



SANCO/12574/2014 11-12 June 2015 rev. 3

Main Aim:

Harmonize the way LOQs are reported by MSs when reporting MACP-data

Working document on the summing up of LOQs in case of complex residue definitions.

Application date: 1 January 2016



CASES WHERE LOQ IS USED

1) MRL-Setting

Where pesticide is <u>not used</u> OR where all <u>residues are <LOQ</u>:

EFSA follows the following rules

	EFSA Proposal for MRL*s
Simple RD	MRL*= LOQ
Complex RD	MRL* = Sum of LOQs for all components of RD, as far as they are analysed separately (where indicated considering Molecular Weight based conversion factors) EFSA follows the OECD Guidance (<i>ENV/JM/MONO</i> (2011) 50 of 29 Sept 2011) Note: normally the LOQs should be corrected for but this is not always done

NOTE: in this context LOQs are consensus values to which MSs agree considering capabilities of laboratories



2) Method "Sensitivity Check"

Q: Is the method sensitive enough to allow enforcement of LOQ-MRLs? OR which LOQs should be achieved for the comonents?

SANCO Working Document:

Sum of LOQs of all components within a complex RD that are measured separately should be ≤ MRL.

- LOQs in this context are experimentally verified Reporting Limits of labs
- Molecular weight conversion factors (CFs) need to be considered
 - LOQ is expressed as defined in the residue definition

Example:

Controversial name but agreed at PAFF

"LOQ (legal RD)" = (LOQ1 * CF1) + (LOQ2 * CF2) + (LOQ3 * CF3)

If "LOQ (legal RD)" ≤ MRL → OK
If "LOQ (legal RD)"> MRL → Method not sensitive enough



2) Method "Sensitivity Check" (cont.)

PROBLEMS WITH SOME RDs CONTAINING MANY COMPONENTS:

Example 1: Fenthion

Fenthion (fenthion and its oxygen analogue, their sulfoxides and sulfone expressed as parent) (F) 6 components: Fenthion, Fenthion-Oxon, Fenthion-Oxonsulfone, Fenthion-Oxonsulfoxide, Fenthion-Sulfone, Fenthion-Sulfoxide

Sum of LOQs (assuming LOQ of 0.01 mg/kg and considering CFs): 0.059 mg/kg.

Possible Solutions:

- I) Increase MRL* to 0.06 mg/kg

 Problem: residue levels from normal applications in many cases exceed 0.06 mg/kg
- **2)** Lower LOQ e.g. to 0.003 (resulting in MRL* of 0.02) or 0.005 (MRL* of 0.03) *Disadvantage: Analytically challenging*
- 3) Restrict RD for enforcement to most important components

 Importance Ranking (based on residue findings):

 F-Sulfoxide>Fenthion>F-Oxonsulfoxide >> F-Sulfone>F-Oxonsulfone>F-Oxonsulfoxide



2) Method "Sensitivity Check" (cont.)

PROBLEMS WITH SOME RDs CONTAINING MANY COMPONENTS:

Example 2: HCH

Hexachlorocyclohexane (HCH), sum of isomers, except the gamma isomer

4 components : α -HCH, β -HCH, δ -HCH, ϵ -HCH

Persistent pollutants

Sum of LOQs (assuming LOQ of 0.01 mg/kg and considering CFs): 0.04 mg/kg

Possible Solutions:

- 1) Increase MRL* to 0.04 mg/kg
 Problem: An MRL* of 0.04 would be too high and not in line with the principle of
 minimizing consumer exposure by persistent pollutants
- 2) Lower LOQ e.g. to 0.0025 (MRL* \rightarrow 0.01) or 0.005 (MRL* \rightarrow 0.02) Disadvantage: Analytically challenging
- 3) Regulate each component separately

 Advantage: components with very low findings (<<0.01 mg/kg) do not unnecessarily

 raise the MRL

 Discussion is ongoing ...

 Slide 25

3) Reporting of Monitoring Data:

Requirement in MACP-Regulation:

All individual components of a complex RD, as far as they are measured separately, need to be reported separately together with their individual LOQ

NOTE: No need to apply CFs on results and LOQs of indiv. compounds

EFSA Preference

- → Additionally report LOQ of full RD considering conversion factors
- → Many MSs consider this problematic from the scientific point of view!

Compromize:

- → Report default "99999", indicating that overall LOQ was not calculated OR
- → Report result of sensitivity check "(LOQ (legal RD))".
- **NOTE:** In case 99999 is reported EFSA will calculate an LOQ **for risk assessment purposes** using the sensitivity check algorithm.

4) Mark Results on which Recovery Correction was Applied?

Suggestion by NL → controversially discussed → no agreement → agreed to discuss this issue further by AQC-AdvG and NRLs.

My personal opinion:

Minimizing bias is a general aim of labs (70-120% recovery rule) and can be achieved by e.g. applying approaches that correct for recovery (ILIS etc.) or switching to methods that correct for recovery. Recovery corrected results at least in theory lay in the middle of the acceptable range as far as bias is concerned. Besides this, in most cases correction for recovery (analyte share in final extract) and correction of matrix induced effects (measurement) take place at the same time.

→ Marking of recovery corrected results is not needed and may even lead to confusion

5) Reporting of LODs

For **risk assessment calculations** EFSA currently proceeds as follows (conservative approach):

- > Results of components reported as <LOQ are set at the respective LOQ
- > Results of components reported as ND are set at 0.

EFSA would like to reduce the uncertainty in risk assessment calculations EFSA wish → report LODs for results of components analyzed but not detected.

Controversial discussion → MSs have different understanding of LOD In most cases no LODs are established.

In some cases labs differentiate between ... "<LOQ" (compounds identified but conc. <LOQ (if quantified levels are tentative) and "ND" (comp. not detected)

SDLs (screening detection limits) are currently not considered within SSD

Meeting decision: Discuss issue within the AQC-AdVG and with NRLs at 128



MACP meeting in Brusels



EXPERT GROUP ON MONITORING MEETING, BRUSSELS 21/10/16

DRAFT

MACP-Working Document

Includes compounds and commodities recommended for inclusion in national programs



EUROPEAN COMMISSION DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain. Pesticides and Bincides

> SANCO/12745/2013 30 November 1 December 2015 rev. 7

MACP-Regulation

Mandatory compounds, specified commodities and number of samples and, random sampling ...



Fluopicolide, Prothioconazole and Prosulfocarb

move to MACP-Reg 2018

Working document on pesticides to be considered for inclusion in the national control programmes to ensure compliance with maximum residue levels of pesticides residues in and on food of plant and animal origin. Brussels, XXX SANTE/10913/2016 Rev0 [...](2016) XXX draft

ANNEXES 1 to 2

ANNEXES

to the

COMMISSION IMPLEMENTING REGULATION (EU) .../...

concerning a coordinated multiannual control programme of the Union for 2018, 2019 and 2020 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

Slide 30



CHAPTER 4:

Pesticides to be considered for inclusion in National Control Programmes

Frequent detections, MRL exceedances or RASFF notifications

- Chlorfluazurone (not approved) NEW
- Cyazofamid (decided to be moved to EU MACP 2019)

PLANT origin

- Cyflufenamid (NEW)
- Etoxazole (decided to be moved to EU MACP 2019)
- Fosetyl-Al (SRM)
- Glufosinate ammonium (SRM) EFSA: Check in Soya (food and feed)
- Metrafenone
- Novaluron (not approved) (NEW)
- Phosphines and phosphides (SRM)
- Proquinazid (NEW)
- Pyridalil (NEW)
- Spinetoram (NEW)
- Tricyclazole (not approved)



CHAPTER 4:

Pesticides to be considered for inclusion in National Control Programmes

Recently approved

- Ametoctradin (to be moved to EU MACP 2019)
- Benzovindiflupyr
- Emamectin B1a (to be moved to EU MACP 2019)
- Fenpyrazamine
- Fluxapyroxad
- Isopyrazam
- Penflufen
- Penthiopyrad
- Pyriofenone (moved here from Annex II)
- Spirotetramat (to be included in EU MACP 2019)
- Sulfoxaflor

PLANT origin



CHAPTER 4:

Pesticides to be considered for inclusion in National Control Programmes

Art. 12 priority list

Diquat (SRM)

PLANT origin

Voluntary in Reg. (EU) N° 788/2012

- Amitraz (Not approved) (SRM)
- Prochloraz (SRM)
- Pyrethrins (MRM/SRM)

Originally in MACP-Reg.

but difficult to cover the full RD

→ Moved to WD



CHAPTER 4:

Pesticides to be considered for inclusion in National Control Programmes

Frequent detections, MRL exceedances or RASFF notifications

Azinphos ethyl (Not approved)

Recently approved

- Benzovindiflupyr
- Fenpyrazamine
- Penflufen
- Penthiopyrad
- Sulfoxaflor

Voluntary in Reg. (EU) N° 788/2012

- Bixafen
- Dixalell
- Carbendazim and thiophanate methyl (SRM/SRM)
 Chlormequat (SRM)
- Dichlorprop (Not approved) (SRM)
- Fluazifop-P-butyl (SRM)
- Glufosinate-ammonium (SRM)
- Glyphosate (current RD: 'glyphosate') (SRM)
- Haloxyfop including haloxyfop-R (SRM)

Originally in MACP-Reg.

→ Moved to WD

- loxynil (SRM)
- Maleic hydrazide (SRM)
- Mepiquat (SRM)
 - Metazachlor (Full RD SRM)

ANIMAL

origin

- Prochloraz (SRM)
- Prothioconazole



ANNEX I:

Substances for which information on residues is needed for specific risk management questions

- Anthraquinone, especially relev. for tea, dried herbs and dried spices. (NEW)
- Benzalkonium chloride (MRM/SRM)
- Chlorates (SRM)
- Didecyldimethylammonium chloride (MRM/SRM)
- Glyphosate in soy bean (NEW) (SRM)
- Nicotine (NEW) (SRM)



Annex II:

Substances for which <u>analytical support</u> is requested from the EURLs (no validated analytical method and/or standards available)

Substances relevant for PLANT origin commodities.

PLANT origin

- <u>Bifenazate (MRM/SRM)</u>: No validated method available for the full residue definition. No standard available for bifenazate-diazene.
- Fluensulfone: No method available
- <u>Guazatine (not approved) (SRM)</u>: No method or standards available (standards available but they are mixtures that do not correspond with formulations).
- Glyphosate (future RD 'sum of Gly, AMPA and NAGly) (SRM) A method (QuPPE) that allows analysing the 3 components of the residue definition should be made available to all NRLs and official labs, so they can prepare themselves to enforce the new residue definition once it will become applicable
- <u>Meptyldinocap (approved since 01/04/2015) (MRM/SRM)</u>: No method available for full residue definition



Annex II:

Substances for which <u>analytical support</u> is requested from the EURLs

(no validated analytical method and/or standards available)

PLANT origin

Substances relevant for PLANT origin commodities (cont...).

- Paraquat (SRM): For the analysis of paraquat in soy bean (high fat matrix) it is challenging to enforce the MRL set at the LOQ of 0.02* mg/kg. EURLs requested to validate a method and to circulate it to the labs The analysis of paraquat in soy bean is no candidate for the EU MACP. It can be considered for the national programmes.
- Triclopyr (on hold until Art. 12 Regulation is voted) (SRM): On Art. 12 priority list because it shares the same metabolites as chlorpyriphos and chlorpyriphos-methyl. For these substances new toxicological studies are available requiring the review of certain MRLs... method development should only start once Art. 12 Reg. is voted.
- <u>Tritosulfuron</u> (SRM): New residue definition after Art. 12 review: separate MRLs are set for tritosulfuron and 2-amino-4-methoxy-6-(trifluormethyl)-1,3,5-triazine (AMTT).



Annex II:

Substances for which analytical support is requested from the EURLs

(no validated analytical method and/or standards available)

ANIMAL origin

- Aminocyclopyrachlor (SRM): No method or standard available
- Boscalid; No method available for the full AO residue definition, standard M510F01 is not commercially available
- <u>Chlorpropham (SRM)</u>: No method available for the full AO residue definition, standard 4´-hydroxychlorpropham-O-sulphonic acid (4-HSA) is commercially not available (not needed for the analysis of code 1016000 (poultry) and 1030000 (eggs).
- <u>Fenpropidin (MRM/SRM)</u>: No method available for full AO residue definition, standards of 2-methyl-2-[4-(2-methyl-3- piperidin-1-yl-propyl)phenyl]propionic acid commercially not available
- <u>Fenpropimorph</u> (MRM/SRM): No validated method available for the full AO residue definition (Metab. Fenpropimorph carboxylic acid (BF 421-2))
- <u>Fluopyram</u>: No method available for the full AO RD (Metabolite fluopyram-benzamide (M25) = 2-(Trifluoromethyl)benzamide)



Annex II:

Substances for which analytical support is requested from the EURLs

(no validated analytical method and/or standards available)

ANIMAL origin

- Glyphosate (SRM): (future RD 'sum of glyphosate, AMPA and NAGly): In the upcoming Art. 12 review the residue definition for glyphosate will be changed. A method (QuPPE) that allows analysing the 3 components of the residue definition should be made available to all NRLs and official labs, so they can prepare themselves to enforce the new residue definition once it will become applicable. A solution is needed for dealing with the stability problems for the standard of N-acetylglyphosate. As an alternative approach, a method based on derivatisation or hydrolysis (?) can be proposed.
- <u>Spiroxamine</u> (MRM/SRM): No method available for full AO residue definition, standard spiroxamine carboxylic acid imetabolite M06) is commercially not available
- <u>Tebuconazole</u> (SRM due to conjugates): Standard hydroxy-tebuconazole is commercially not available



Annex III: Substances that are of interest for cumulative risk assessment

- 2,4-DB (SRM, conjugates)
- Amitrole (SRM)
- Cyhalofop-butyl
- Dazomet (SRM –MITC)
- Flufenacet (SRM, common moiety) •
- Glufosinate ammonium (SRM)
- loxynil (MRM/SRM)
- Isoxaflutole
- MCPA and MCPB (SRM, conjug.)
- Milbemectin
- Metconazole
- Molinate
- Oxadiargyl

- Oxasulfuron
- Oxyfluorfen
- Picolinafen
- Propaquizafop
- Proquinazid
- Pyridate (SRM, conjug.)
- Quinoclamine
- Quizalofop (MRM/SRM)*
- Sulfuryl fluoride (SRM)
- Tri-allate

^{*} Quizalofop Propaquizafop likely to be regulated together



Annex IV: Substances with a low level of findings

Compounds with low frequency of findings that were previously in Chapter 4

Previously listed in Chapter 4.1.1 (Frequent detections, MRL exceedances or RASFF notifications)

PLANT origin

- Benalaxayl
- Clomazone
- Heptachlor (Not approved)
- Quintozene (Not approved)

Previously listed in Chapter 4.1.4 (High toxicity)

Ethoprophos (ADI = 0.0004 mg/kg bw/day, ARfD = 0.01 mg/kg bw)

Previously listed in Chapter 4.1.5 (Voluntary in Reg. (EU) N° 788/2012)

- Phenthoate (Not approved)
- Prothiofos (Not approved)
- Rotenone (Not approved)
- Tetramethrin (Not approved)
- Triticonazole



Annex IV: Substances with a low level of findings

Compounds with low frequency of findings that were previously in Chapter 4

Previously listed in Chapter 4.2.3 (Voluntary in Reg. (EU) N° 788/2012)

- Chlorobenzilate (not approved)
- Cyfluthrin
- Cyproconazole
- Epoxiconazole
- Etofenprox
- Fenthion (Not approved)
- Fluquinconazole
- Flusilazole (not approved)
- Metaflumizone
- Methidathion (Not approved)
- Parathion-methyl (Not approved)
- Profenofos (Not approved)
- Resmethrin (Not approved)
- Tau-fluvalinate

ANIMAL origin

- Tetraconazole
- Thiacloprid
- Topramezone (Approval pending)
- Triazophos (Not approved)



Annex V: Evaluation at the end of the evaluation period

Information to be gathered for evaluation at the end of the evaluation period

Pesticide X

Analytical capability (data collection via **EURLs**)

% of samples w. residues / MRL exceedances (data collection by EFSA)

Evaluation summarised by COM in Working Document

Pesticide X

% of labs that is able to analyse the full RD

% of samples with residues > MRL

% of findings

N° of RASSF notifications

- > 60% labs: good capability (-> possible incl. in 2018 EU MACP)
- 40-60% labs: medium capability (-> possible incl. in 2019 EU MACP)
- < 40% labs: poor capability (-> possible inclusion in 2019 EU MACP)

To help decission-making



Annex V: Evaluation at the end of the evaluation period

Online Survey on Analytical capability (EURLs)



NETWORK: 324 OFLs:

286 EU-OFLs; 12 EFTA-OFLs; 23 EU-cand. OFLs

Introduction

Annex V: Evaluation at the end of the evaluation period

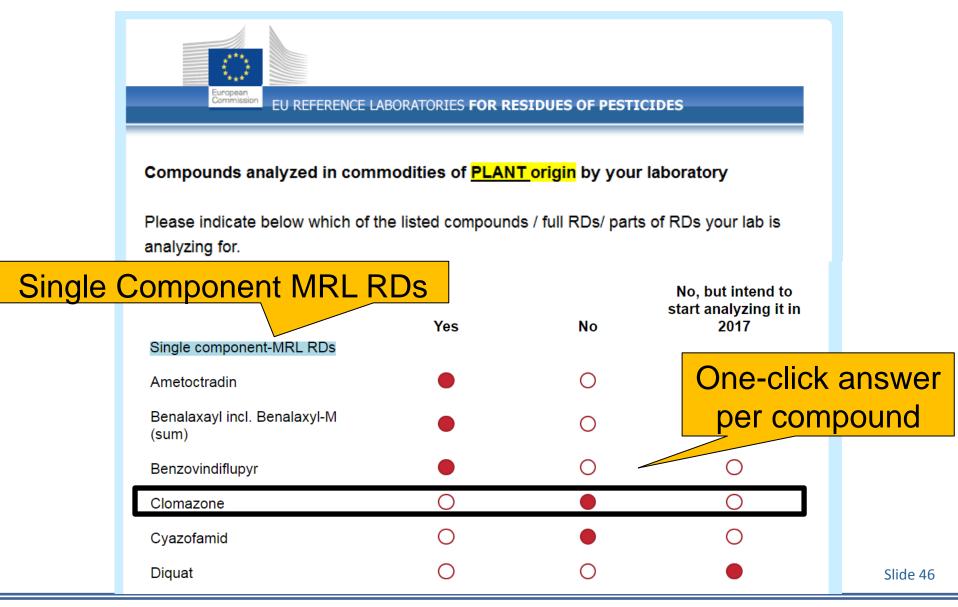
Survey on Analytical capability (EURLs)

- No. of invited OFLs: 263 (only EU)
- →NRLs / OfLs involven in Off. Controls (PLANT / ANIMAL
- No. of participating OFLs: 186 (from 25 MS) (64% participation)
 - PLANT: 125 OFLs (total: 245; participation: 51%)
 - ANIMAL: 84 OFLs (total: 129; participation: 65%)

Start: 12.05.2016 → Deadline: 31.05.2016

Annex V: Evaluation at the end of the evaluation period

Survey on Analytical capability (EURLs)





Questions - Complex RDs

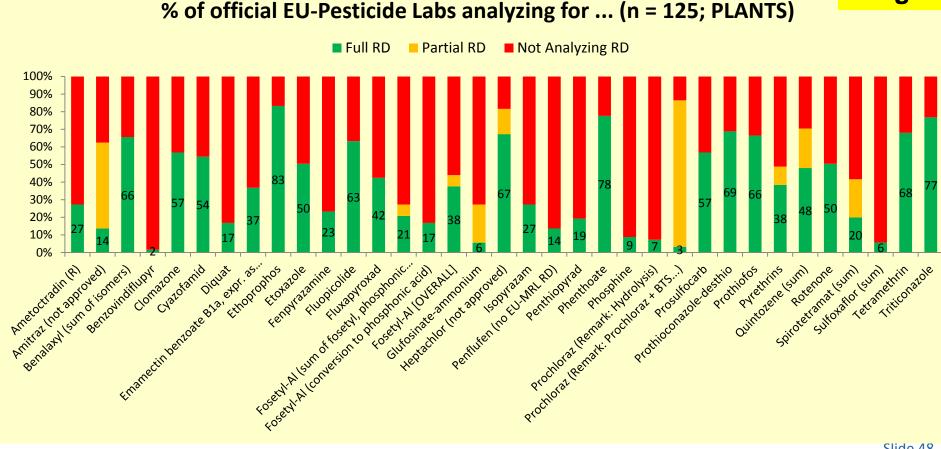
EU MR	L RD				No, but intend to start analyzing it in			
			Yes	No	2017			
	RD: Amitraz (amitraz including the metabolites containing the 2,4 -dimethylaniline moiety expressed as amitraz)							
	Amitraz			0	\circ			
	2,4-Dimethy (DMF)	Iphenylformamide	•	0				
		thylphenyl-N- amidine (DMPF)	0	0	•]			
	Amitraz (sui hydrolysis to dimethylanil	2,4 -	0	•	0			
	RD: F	-Al (sum of fosetyl, phos	phonic acid and their	salts, expressed as fo				
PDc ro	auirina			0	Indivi	dual		
RDs requiring hydrolysis step			0	o comp	ounds			
nyaroiy	•	wing to phosphonic acid)	0		of MF	RLRD		
	RD: Glufosi equivalents)	nate-ammonium (sum of	glufosinate, its salts	, MPP and NAG expres	ssed as glufosinate			
	Glufosinate		0	0	•	Slide 17		

Results

Annex V: Evaluation at the end of the evaluation period

Survey on Analytical capability (EURLs)

PLANT origin



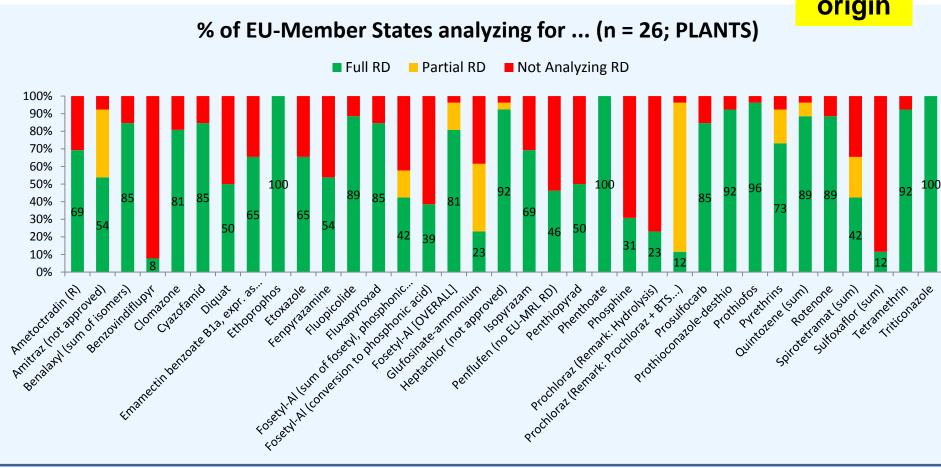


Results (PLANT)

Annex V: Evaluation at the end of the evaluation period

Survey on Analytical capability (EURLs)

PLANT origin

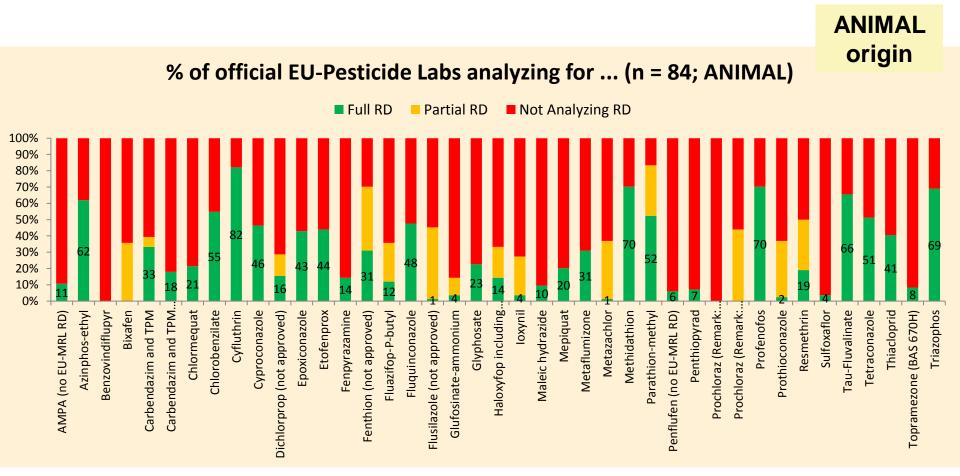




Results (ANIMAL)

Annex V: Evaluation at the end of the evaluation period

Survey on Analytical capability (EURLs)

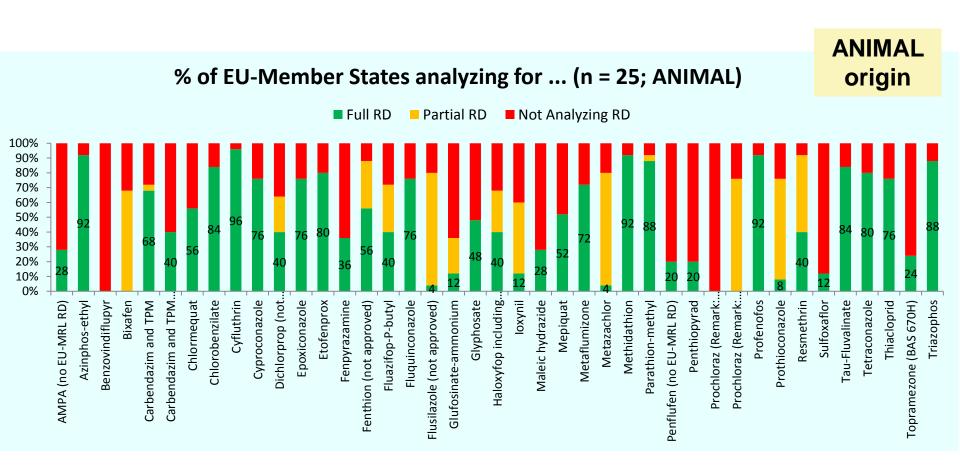




Results (ANIMAL)

Annex V: Evaluation at the end of the evaluation period

Survey on Analytical capability (EURLs)





Annex VI: Proposals for uptake of new substances in Working Document

Proposal sheet to be filled out by COM, EFSA, EURLs or Member States

Proposal made by:

Substance:

Proposed category or annex:

Findings and/or MRL exceedances:

Method:

Toxicity:

Proposed priority:

Proposed evaluation period:

Relevant commodities:

Additional information:



Annex VII: Substances of interest to be analysed in <u>HONEY</u> under the national control programmes

- Acetamiprid
- Amitraz (veterinary medicinal product)
- Azoxystrobin
- Boscalid
- Coumaphos (veterinary medicinal product)
- Dimoxystrobin
- Iprodione
- Lambda-cyhalothrin
- Thiacloprid



Whats next with MACP-Working Document?

By **June 2017** COM, EFSA, the EURLs and Member States can <u>send a</u> <u>proposal to COM for new substances</u> to be included in the working document.

By **August 2017**, the EURLs will gather through a <u>survey the information on % of labs analysing each substance (2016 analyses).</u> By that time the Member States will also submit to EFSA the monitoring data for those substances for which the evaluation timing was set for 10/2017. EFSA will summarise these data for the October/ November expert group.

In **October/ November 2017** <u>decisions</u> will be taken in the expert group on which chapter 4 substances to <u>move to the MACP 2019</u>, which ones to be <u>deleted from WD</u>, which ones to be evaluated for an additional period. During this meeting also new substances that are proposed for inclusion in the working document will be discussed.



Method Finder List

Portal

Fruits and Vegetables | Cereals and Feeding Stuff

EURL for

EURL for Food of Animal Origin | Single Residue Methods

Topics

General Info

DG SANTE About EURLs

Control Programs

AQC Procedures

AQC Documents AQC Panel

Proficiency Tests

About EUPTs General Protocol Annual EUPT-Calendars Obliged Labs 2016 EUPT-FV18 EUPT-FV-SM08 EUPT-CF10

Workshops Workshop Overview

EUPT-A011

EUPT-SRM11

a Library News Archive Surveys List of Methods

Network **EU Contact Points** Lab Contact Data Network News

Control Programs for Pesticide Residues

To ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin Multiannual Control Programmes for Pesticide Residues (MACP) are run within the EU and EFTA. In addition every country runs its national control programs that are complementary to the MACP. The MACP scope is redesigned every year and updated regulations are published that cover a period of three years with the last two years being provisional.

A list of the MACP-Regulations and EFSA annual reports is listed below.

To help the member states in the design of their national control programs and give them persepctive as regards the potential inclusion of pesticides in future MACP-regulations the Commission anually publishes a non-binding Pesticides Working Document (WD, see below).

An overview of the Methods developed or validated by the EURLS on compounds included in the MACP-Regulations or the MACP-WDs can be found in the EURL Method Finder List (see below).

The LOQ Working Document gives recommendations on the summing up of LOQs in case of complex residue definitions: LOQ Working Document.

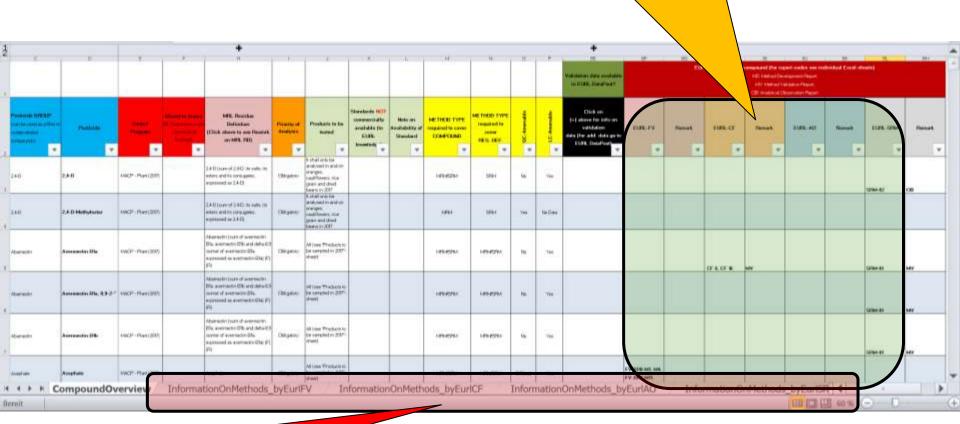
List:

MACP Regulation for	Working Document (WD)	EURL Method Finder List	Annual Report (FVO / EFSA)
2017 - 2019		List 2017	
2016 - 2018	SANCO/12745/2013 rev. 6(3)	List 2016	
2015 - 2017		List 2015	
2013 - 2015			Report 2014, Report 2013
2012-2014			Report 2012
2011-2013			Report 2011
2010-2012			Report 2010



Method Finder List

Codes of available
Methods, Validation reports,
Observation reports



Excel sheets with links to the methods by each EURL

Thank You for Your Attention



www.eurl-pesticides.eu