

EFSA – Ctgb
IUCLID
collaboration

PSN IUCLID sub-group meeting 5
december 2022

ctgb

Tasks

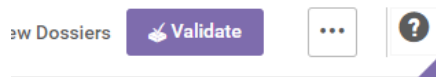
- Further development/adaptation of NoS checklist

Publication of the notified information of the studies (NoS) in accordance with Article 32b(7) of Regulation (EC) No 178/2002, as amended by the Reg (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019, and Article 6(1)(f) of EFSA's Practical Arrangements. Pursuant to Article 24 of the EFSA Practical Arrangements on pre-submission phase and public consultation the assessment of the compliance with the obligations of study notifications laid down in Article 32b(2) and (3) of Regulation (EU) 2019/1381 was carried out exclusively by the RMS/EMS. The NoS information was extracted from the NoS database during the admissibility check of the dossier.

EFSA Study Identification	Study Title	Study Title (English Name)	Study Objective	Business Operator	Laboratory Name	Test Item	Notification Date	Study Starting Date	Study Planned Completion Date	Study Type	International Standard Certification	Intended study area
EFSA-2021-0000000X	Template	Template	Template	Template	Template	Template	Template	Template	Template	Template	Template	Template

Tasks

- IUCLID validation assistant feature



Validation assistant report

! Submission checks 0 ? Quality checks 0

✓ Business rules 0 ✓ Completeness check rules 0

Rules	Description	Flexible summary
QLT_PPP_116	FLEXIBLE_SUMMARY.ResiduesInLivestock must be provided in case KS, WoE is present in the section Feeding studies (ENDPOINT_STUDY_RECORD.ResiduesInLivestock)	FLEXIBLE_SUMMARY.ResiduesInLivestock
QLT_PPP_124	Flexible Summary Endocrine disrupting properties must be provided	FLEXIBLE_SUMMARY.EndocrineDisruptingPropert
QLT_PPP_125	Flexible Summary MRL Proposal must be provided	FLEXIBLE_SUMMARY.MRLProposal
QLT_PPP_126	Flexible Summary Expected Exposure must be provided	FLEXIBLE_SUMMARY.ExpectedExposure
QLT_PPP_127	Flexible Summary Residue Definition Fate must be provided	FLEXIBLE_SUMMARY.DefinitionResidueFate
QLT_PPP_131	Flexible Summary Ecotoxicology Risk Assessment must be provided	FLEXIBLE_SUMMARY.EcotoxRiskAssessmentPes
QLT_PPP_128	Flexible Summary Effects on aquatic organisms must be provided	FLEXIBLE_SUMMARY.AquaticToxicityRacReporting
QLT_PPP_129	Flexible Summary Relevance of metabolites in ground water must be provided	FLEXIBLE_SUMMARY.RelevantMetabolitesGround
QLT_PPP_057	Flexible Summary Toxicological reference values must be provided	FLEXIBLE_SUMMARY.ToxRefValues
QLT_PPP_132	Flexible Summary Data on exposure must be provided	FLEXIBLE_SUMMARY.NonDietaryExpo
QLT_PPP_133	Flexible Summary Information on metabolites must be provided	FLEXIBLE_SUMMARY.Metabolites
QLT_PPP_134	Flexible Summary Estimation of concentrations in soil must be provided	FLEXIBLE_SUMMARY.EstConcSoil
QLT_PPP_135	Flexible Summary Estimation of concentrations in groundwater must be provided	FLEXIBLE_SUMMARY.EstConcGroundwater
QLT_PPP_136	Flexible Summary Estimation of concentrations in surface water and sediment must be provided	FLEXIBLE_SUMMARY.EstConcWaterSed



Tasks

- IUCLID report generator feature

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment			PHI (days) (m)	Remarks
					Type (g-f)	Conc. a.s. (g)	method kind (f-h)	range of growth stages & season (i)	number min-max (k)	Interval between application (min)	g a.s. /L min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
Grapevine VITVI	All member states	BIFOS	F	Grey mould (<i>Borytis cinerea</i> f. <i>biliana</i>) BOTRCI	SL	25%	Foliar spray using backpack sprayers, tractor mounted sprayers and conventional application equipment.	From end of flowering to harvest BBCH 51 - 89 Spring - autumn	1-5	3 days - 5 days	1.7 - 1.8 g/L	450-750 L/ha	0.8 - 0.8 kg/ha	0	
Rice ORYSA	South zone member states	BIFOS	F	Rice blast (<i>Magnaporthe oryzae</i>) PYRIOR	SL	25%	Foliar spray using backpack sprayers, tractor mounted sprayers and conventional application equipment.	BBCH 20 - 89 Early summer - autumn	1-19	3 days - 18 days	0.6 - 0.6 g/L	300 L/ha	0.2 - 0.2 kg/ha	0	
Potato SOLTU	All member states	BIFOS	F	Late blight (<i>Phytophthora infestans</i>) PHYTTN	SL	25%	Foliar spray using backpack sprayers, tractor mounted sprayers and conventional application equipment.	BBCH 20 - 89 Early summer - autumn	1-19	3 days - 15 days	1.31 - 1.31 g/L	300 L/ha	0.4 - 0.4 kg/ha	0	
Sugar beet BEAVP	All member states	BIFOS	F	<i>Cercospora leaf spot (Cercospora a. beticola)</i> CERCBE	SL	25%	Foliar spray using backpack sprayers, tractor mounted sprayers and conventional application equipment.	BBCH 20 - 89 Early summer - autumn	1-19	5 days - 15 days	1.00 - 1.20 g/L	200 L/ha	0.2 - 0.2 kg/ha	0	

(a) For crops, the EU and Codex classifications (both) should be taken into account, where relevant, the use situation should be described (e.g. fumigation of a structure)
 (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
 (c) e.g. biting and sucking insects, soil born insects, foliar fungi, weeds
 (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
 (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticides
 (f) All abbreviations used must be explained
 (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
 (i) g/kg or g/L. Normally the rate should be given for the active ingredient in order to compare the rate for same active ingredient. In certain cases, where only one variant give the rate for the variant (e.g. benthiavalkarb-isopro) Blackwell, ISBN 3-8263-3152-4), including where relevant application
 (k) Indicate the minimum and maximum number of applicat use
 (l) The values should be given in g or kg whatever gives the instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/l
 (m) PHI - minimum pre-harvest interval

Crop / situation	MS / country	F, G or I	Pests controlled	Application			Application rate per treatment			PHI	Remarks	
				Method / kind	Growth stage and season	No	Interval	a.s.	Water			Conc. dilution
<i>Solanum lycopersicum</i> (Tomato) (LYPES)	EU	F	<i>Agriotes</i> sp. (AGRISP)	drenching (3DRENM) on Pre-transplant plant module application	BBCH 12 - 20 (autumn; spring; summer; winter)	1	Not applicable	235 g/ha	200 - 1000 L/ha	0.2 - 1 L/hL	Not applicable	Crop destination: grown for human consumption (3HCND); grown for industrial use or biomass production (3INDUD). major use. User: professional. App. rate product: 2 L/ha. Max. annual a.s.: 216 g/ha. 5.00E+13 CFU/ha Planting density: 40.000 plants/ha.
<i>Solanum tuberosum</i> (Potato) (SOLTU)	EU	F	<i>Agriotes</i> sp. (AGRISP)	spraying (3SPRYM) on seed/seed pieces	BBCH 00 - 03 (autumn; spring; summer)	1	Not applicable	235 g/ha	100 - 400 L/ha	0.5 - 2 L/hL	Not applicable	Crop destination: grown for human consumption (3HCND); grown for industrial use or biomass production (3INDUD). major use. User: professional. App. rate product: 2 L/ha. Max. annual a.s.: 216 g/ha. 5.00E+13 CFU/ha
<i>Solanum tuberosum</i> (Potato) (SOLTU)	EU	F	<i>Agriotes</i> sp. (AGRISP)	dripping (3DRIPM) on soil (surface)	BBCH 20 - 98 (autumn; spring; summer)	1 - 4	14d	235 g/ha	2000 - 30000 L/ha	0.007 - 0.1 L/hL	Not applicable	Crop destination: grown for human consumption (3HCND); grown for industrial use or biomass production (3INDUD). major use. User: professional. App. rate product: 2 L/ha. Max. annual a.s.: 864 g/ha. 5.00E+13 CFU/ha
<i>Zea mays</i> (Corn) (ZEAMX)	EU (interzonal?)	F	<i>Agriotes</i> sp. (AGRISP)	coating (3COATM) on seed/seed pieces	BBCH 00 - 03 (spring)	1	Not applicable	0.65 g/ha	75 - 375 ml/seed unit	-	Not applicable	Crop destination: grown for human consumption (3HCND); grown for industrial use or biomass production (3INDUD). major use. User: professional. App. rate product: 0.006 L/ha. Max. annual a.s.: 0.65 g/ha. 1.50E+11 CFU/ha Max. seeding rate: 150000 number of seeds/ha.

