



**Enhancing Policy Uptake through Realism and Harmonization:
Stakeholder perspective on the Draft Guidance for Rice Pesticide Risk Assessment**

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On behalf of CropLife Europe

Outline

Rice in Europe

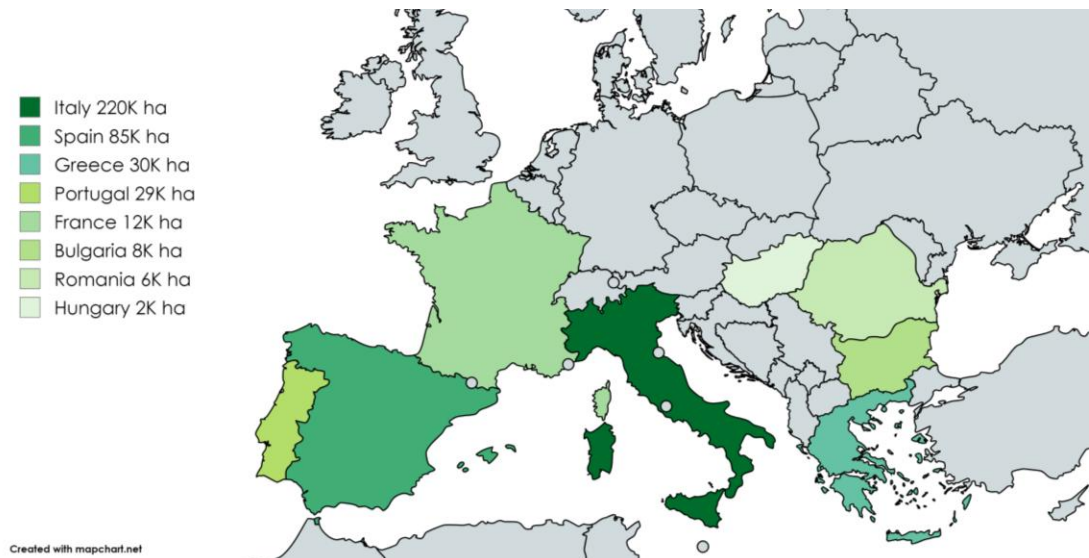
Review of Guidance documents

- SANCO MED-RICE
- New draft MED-RICE (ICPS Draft Guidance)

Conclusions

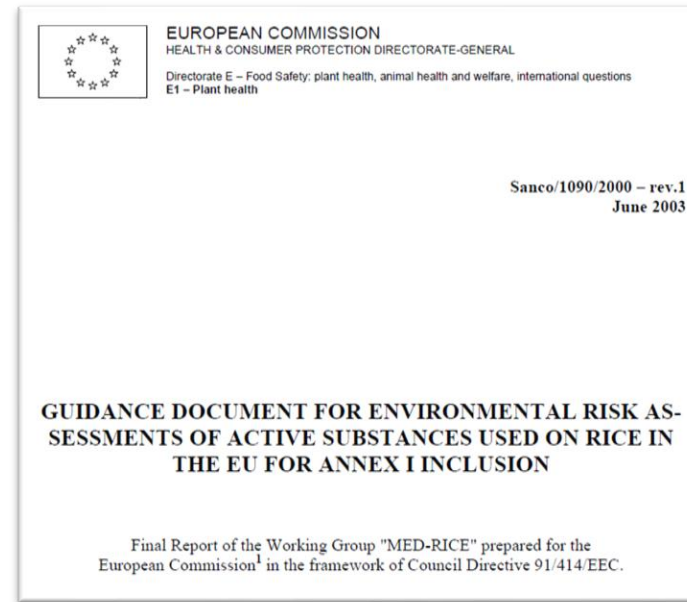
Rice in Europe

- Rice - regionally important crop, ~2.8 million tons annually; Italy and Spain ~80% of production
- Rice belongs to cereal family, but its cultivation differs substantially from conventional cereal crops
- Consequently, pesticide risk assessment for rice requires crop-specific considerations
- The current risk assessment framework for rice is SANCO MED-RICE Guidance (Sanco/1090/2000)



SANCO (2003) MED-RICE Guidance

- Two exposure scenarios
- Spreadsheet-based calculations
- Simplified exposure equations
- Cereal scenario used for birds and mammals
- Developed before many current EFSA guidance documents



SUBSTANCE:		
INPUT: Scenario data I		
	Scenario 1	Scenario 2
Soil texture	clayey	sandy
OC soil (%)	1.8	0.9
depth _{water} (m) (water level in field)	0.1	0.1
Water velocity:		
field (L/sec/ha)	3	3
outflow (L/sec/ha)	0.5	0.5
Leakage (mm/d) (infiltration rate)	1	10
Leakage rate constant (1/d)	0.01	0.1
t _{close} (d) (time of closure of field)	20	7
t _{flood} (d) (time of flooding)	90	90
depth _{canal} (m) (deepness of outflow)	1	1
INPUT: Scenario data II		
area (m ²) (area of rice field)	10000	10000
Volume of water in field (L)	1000000	1000000
depth _{soil} (m)	0.05	0.05
BD soil (kg/dm ³) (soil bulk density)	1.5	1.5
Outflow rate constant (1/d)	0.0432	0.0432
Dilution factor	10	10
depth _{sediment} (m) (active sediment	0.05	0.05
OC (%) of sediment	1.6	1.6

Several assumptions no longer represent current rice-production practices or current EFSA assessment frameworks

New draft MED-RICE guidance

- ICPS developed a proposal to update the MED-RICE Guidance
- Available since 2018/2020
- The update supports greater scientific and regulatory alignment in Europe

- CropLife Europe has compiled technical recommendations to strengthen its robustness and practical implementation

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**Update and harmonization
of rice pesticide risk
assessment and revision of
European guidelines**

A proposal

New draft MED-RICE guidance

Many positive elements:

-  Moves from expert judgement to a data-driven approach
-  Aims to improve consistency, transparency and harmonisation across the EU
-  Introduces a more structured assessment framework for rice pesticide risk assessment

	SANCO GD 2003	ICPS new draft MED-RICE
Scenario definition	Expert judgement	GIS + EU datasets
Tier 1 modelling	Simple equations	Improved equations
Closure period	Fixed 5 days	User-defined
Number of applications	Single application only	Multiple applications implemented
Metabolite calculations	Not available	Pseudo-parent calculation
Application type	Wet application only	Wet / dry application
Higher tier modelling	Recommended only	Country-specific RICEWQ/RIVWQ scenarios
Ecotoxicology	Mostly generic	Rice-specific framework

Protection Goals for Aquatic Organisms

- Points for which additional considerations are recommended
- New ***in-field*** protection goal for aquatic organisms and new risk assessment scheme
- “Aim of the paddy in-field risk assessment is to maintain the food sources for terrestrial vertebrates and not to protect the aquatic community per se”***
- Protection goal not reflecting modern agronomic practices for rice (next slide) and not aligned with EFSA frameworks (e.g. no protection of food sources for birds & mammals in other crops)
- Example of in-field risk assessment for some herbicides, which are part of rice growing practice

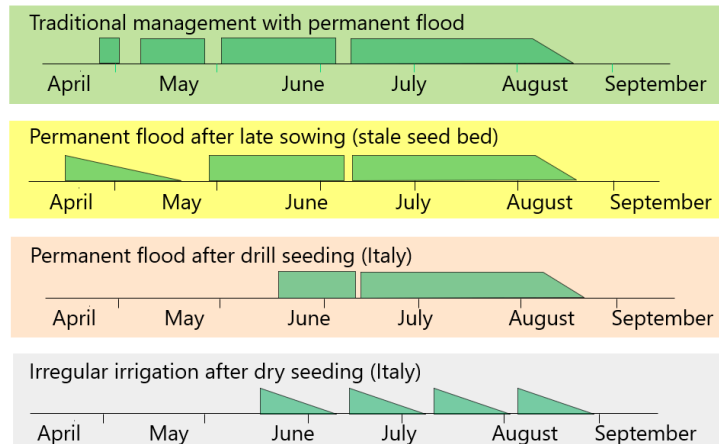
PEC paddy water, initial (µg/L)		In paddy Risk Assessment		
Draft Med-Rice		RAC AF 5	PEC/RAC	Meaning
Benzobicyclon	5.5	1.2	4.6	Fail
Cyhalofop-butyl	40.5	9.48	4.3	Fail
Penoxsulam	32	0.498	64	Fail
Florpyrauxifen-benzyl	0.22	0.024	9	Fail
Triclopyr	300	9.46	32	Fail
Halosulfuron-methyl	66	1.08	61	Fail

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; AF: Assessment factor

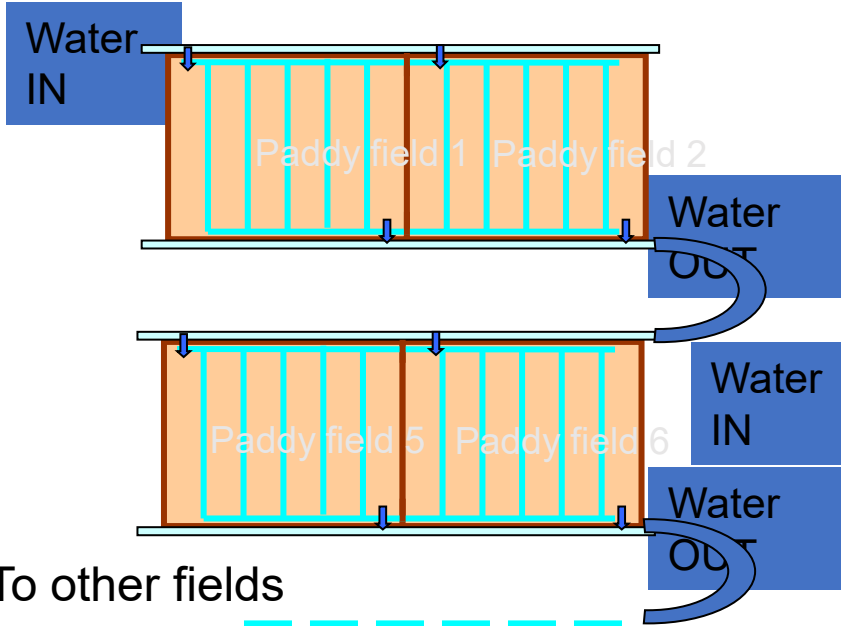
Protection Goals for Aquatic Organisms

Points for consideration

- Rice paddies are managed production systems, not permanent aquatic habitats
- Drainage and reflooding cycles create highly dynamic environmental conditions:
 - herbicides often applied to drained paddies
 - fungicides applied at later growth stages (no/little water in the paddy, high interception)
- Align protection goals with existing EFSA guidance focusing on relevant edge-of-field aquatic ecosystems



Rice Cultivation: Realistic Practice



Water management in rice paddy system is complex:

- Flooding-drainage regime
- Off-field canals = temporal irrigation supply



Birds and Mammals

- A high level of protection to birds and mammals is important
- Proposed risk assessment deviates from existing EFSA guidance, e.g. focal species derivation, exposure assumptions etc.
- Closer alignment with existing EFSA guidance would support regulatory coherence and transparency
- The ecological relevance of protecting Lemna / invertebrate biomass in paddy fields as a key food source for birds is uncertain



Feeding guild	Bird species	Mammal species
Granivorous	n.r.	Harvest mouse <i>Micromys minutus</i> (8 g ^a) FIR/bw=0.27
Herbivorous	Common moorhen <i>Gallinula chloropus</i> (271 g ^b) FIR/bw=0.66	European water vole <i>Arvicola amphibius</i> (150g ^c) FIR/bw=0.74
Insectivorous	Barn swallow <i>Hirundo rustica</i> (17g ^d) FIR/bw=0.47	Common pipistrelle <i>Pipistrellus pipistrellus</i> (5g ^e) FIR/bw=0.52
Benthophagous	Black-winged stilt <i>Himantopus himantopus</i> (161 g ^b) FIR/bw=0.38	n.r.
Piscivorous	Black-crowned Night-heron <i>Nycticorax nycticorax</i>	See EFSA GD

EFate and Non-Dietary Exposure

- 🌱 CropLife Europe welcomes several positive developments in the draft guidance regarding environmental fate and human exposure
- 🌱 For human exposure, further alignment with current EFSA methodologies and established regulatory practices would enhance consistency and harmonisation across EU frameworks

SUBSTANCE NAME:	Default substance
Paddy field condition during applications	Wet
f_{drift} (fraction drift to adjacent water body)	0.0277

K_{oc} (dm ³ /kg)	200
DT _{50 pw} (d) in water phase (flooded soil studies)	100
DT _{50 soil} (d) in solid phase (flooded soil studies)	100
DT _{50 pw} (d) in water phase (water/sediment studies)	1000
DT _{50 sed} (d) in solid phase (water/sediment studies)	1
DT _{50 soil} (d) in aerobic soil	1



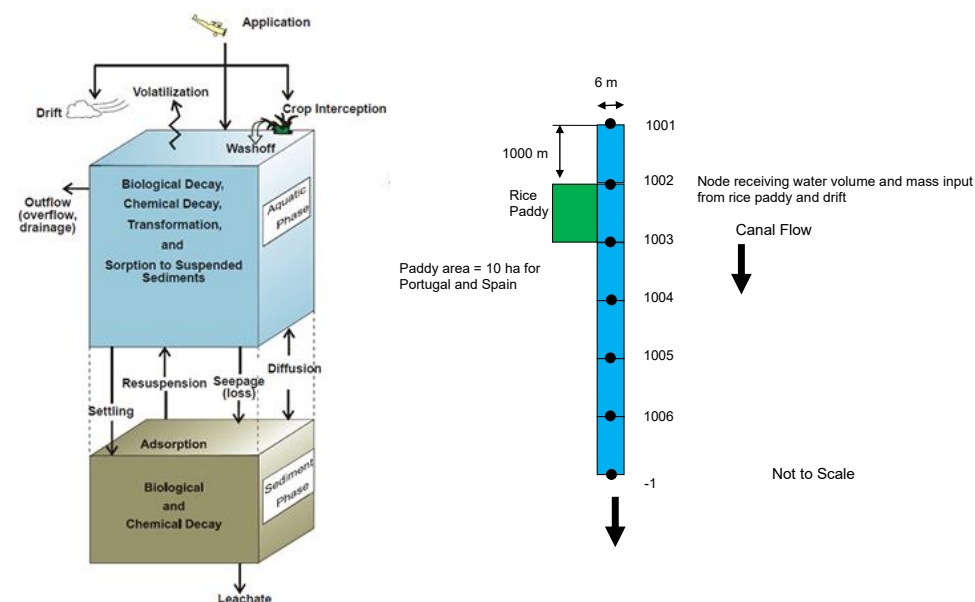
Application #	Dose (g/ha)	Days after previous appl	f_{dep} (deposition to paddy field)
Application 1	250	-	0.75
Application 2	250	14	0.75
Application 3			
Application 4			

Event type	Days after last application
Discharge (t_{close})	3

Metabolite calculation?		Yes	
Parent g/ha	MW met	MW p	Max occ%
3443.00	222.00	222.00	100.00

Metabolite g/ha	3443.00
This value must be entered manually in the 16-19 cells	

Default model-defined input data		
INPUT: Scenario data	Scenario 1	Scenario 2
Soil texture	clayey	sandy
OC soil (%)	0.9	0.9
depth _{water} (m) (water level in field)	0.1	0.1
Water velocity: field (L/sec/ha)	1.8	2.8
Water velocity: outflow (L/sec/ha)	0.5	0.5
Leakage (mm/d) (infiltration rate)	1	10
K_{leak} Leakage rate constant (1/d)	0.01	0.1
t_{flood} (d) (time of flooding)	120	120
depth _{canal} (m) (deepness of outflow)	1	1
area (m ²) (area of rice field)	10000	10000
Volume of water in field (L)	1000000	1000000
depth _{soil} (m)	0.05	0.05
BD soil (kg/dm ³) (soil bulk density)	1.4	1.5
Outflow rate constant (1/d)	0.0432	0.0432
Dilution factor	10	10
depth _{sediment} (m) (active sediment)	0.05	0.05
OC (%) of sediment	1.6	1.6
BD _{sediment} (kg/dm ³) (sediment bulk)	1.5	1.5
Kd (soil) (dm ³ /kg)	1.8	1.8
Kd (sediment) (dm ³ /kg)	3.2	3.2
F_{sorbed} (soil) (fraction partitioning to)	0.558	0.574
F_{sorbed} (sediment) (fraction)	0.194	0.194



Improved calculation tool in the draft guidance with some areas for further enhancement

Harmonised RICEWQ/RIVWQ scenarios, clearer guidance needed for MS-specific water management scenarios and result evaluation

Thank you!

Conclusions

- CropLife Europe welcomes the significant effort undertaken by ICPS to modernise rice pesticide risk assessment
- The proposed framework provides a valuable basis for greater scientific consistency, transparency and EU harmonisation
- However, some elements are not fit for purpose and do not reflect modern agronomic rice growing practices
- Aiming for a scientifically robust and protective guidance document, CropLife Europe would welcome the option for stakeholder feedback on the current draft
- CropLife Europe has collected detailed technical comments that could be shared with ICPS/MS/EFSA