

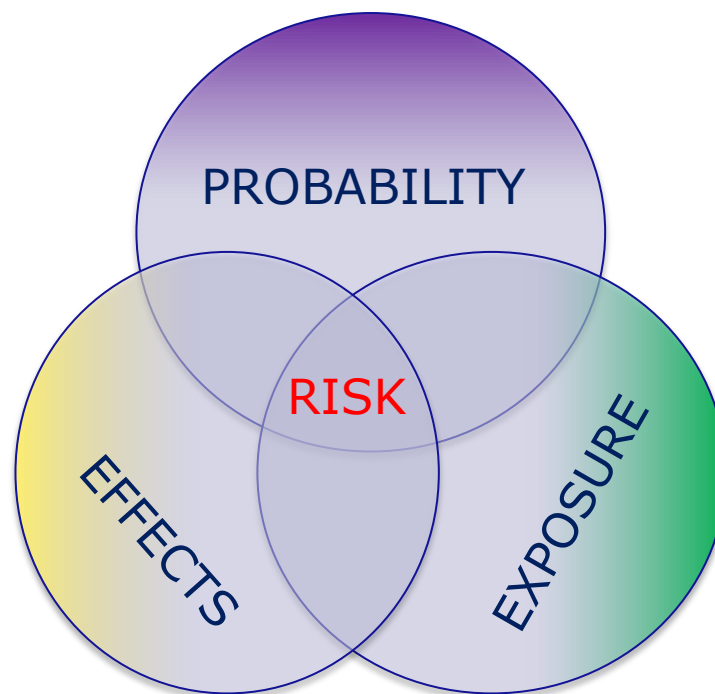


Regulatory environmental risk assessment of pesticides

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ERA: ENVIRONMENTAL RISK ASSESSMENT

A process that evaluates the likelihood that adverse environmental effects may occur or are occurring as a result of exposure to one or more stressors



REGULATORY ERA OF PESTICIDES

Scientific advancements in the regulatory environmental risk assessment of pesticides (environmental fate and ecotoxicology)



1993



2016

the origin.....

...the picture now



REGULATORY SCIENCE

- Regulatory science relates the regulatory and legal requirements to the scientific research needed to ensure the **safety and efficacy of products**
- Regulatory science is characterized by an **inter-linkage** between science, regulatory policy and industrial practice
- Regulatory science provides **reliable scientific information** for decision makers needed to meet regulatory requirements
- Whereas in academic science uncertainty is expected, in regulatory science **predictive certainty** is required by the legal requirements
- The EFSA's role is clear: provide for independent scientific conclusion within the **legal framework** set out by the legislator; the EFSA cannot ignore the legislation, under pretext of the independence of its conclusions

REGULATORY ERA: E-FATE (GROUND WATER)



Creation of FOCUS (FORum for the Co-ordination of pesticide fate models and their Use) Group

Sanco/321/2000 rev.2

FOCUS groundwater scenarios in the EU review of active substances

The report of the work of the Groundwater Scenarios Workgroup of FOCUS (FORum for the Co-ordination of pesticide fate models and their Use), Version 1 of November 2000.

“Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU” *FOCUS GW II* (SANCO/13144/2010)

2013: EFSA opinion

Version 3
10 October 2014

FOCUS DG SANTE

NO agreed methodology

- ✓ EU and US EPA GW models
- ✓ Lysimeter studies

FOCUS “Leaching models and EU registration” (EU DOC. 4952/VI/95)

Generic guidance for FOCUS groundwater scenarios

2006: FOCUS Degradation Kinetics (SANCO/10058/2005)

2014: GD for evaluating lab and field studies to obtain DegT50 values (SANCO/12117/2014)

Generic Guidance for Tier 1 FOCUS Ground Water Assessments

1993

1995

2000

2002

2009

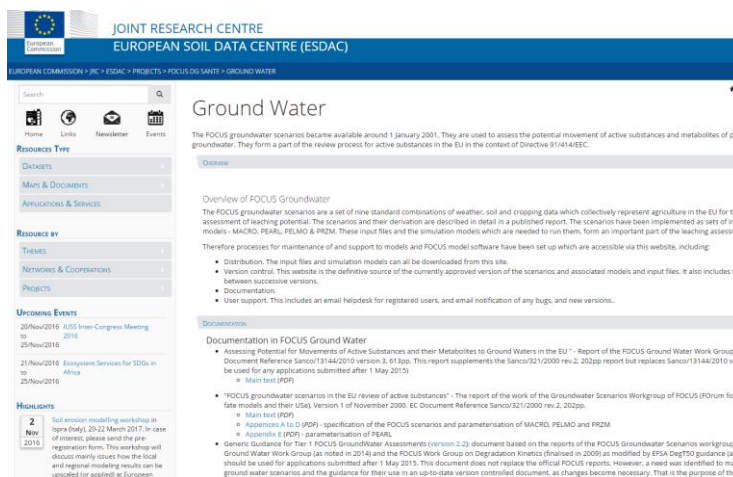
2014

2015



REGULATORY ERA: E-FATE (GROUND WATER)

<http://esdac.jrc.ec.europa.eu/projects/focus-dg-sante>

The screenshot shows the ESDAC website interface. The main heading is 'Ground Water'. Below it, there is a brief description: 'The FOCUS groundwater scenarios became available around 1 January 2001. They are used to assess the potential movement of active substances and metabolites of pesticides in groundwater. They form a part of the review process for active substances in the EU in the context of Directive 91/414/EEC.' There is also a section for 'Overview of FOCUS Groundwater' and a list of 'Documentation in FOCUS Ground Water'.

Version: 2.2
Date: May 2014

Generic Guidance for Tier 1 FOCUS Ground Water Assessments

New in Version 2.2

The content was updated to include documents prepared by the FOCUS Work Group made to achieve the objectives of SANCO/4802/2003 agreed between Member States concerning safety of pesticides. The content of the meetings has been added.

The title of this document was changed to indicate that this guidance applied only to Tier 1 scenarios.

New in Version 2.1

Wording on selecting pesticide input parameters has been updated to reflect the exponent for moisture response that has to be used with FOCUS_MACROv5.5.3 and above. For transparency changes from Version 2.0 are highlighted in yellow.

New in Version 2.2

Wording on selecting pesticide input parameters has been updated to reflect the EFSA guidance (2014) and implementable recommendations of the EFSA PPR scientific opinion (2013a) on FOCUS, 2009, assessment of lower tiers. For transparency changes from Version 2.0 are highlighted in yellow.

REGULATORY ERA: E-FATE (SURFACE WATER)


Ganzelmeier, 1995

Estimation of water body exposure based on drift values

Compartment:- WATER		Assumed rate:- 1st order	
APP RATE (g/ha)	96	No. APPLS/YEAR	3
% SPRAY DRIFT	2.77	INTERVAL (days)	14
	100	DT50 (days)	814
		ASSUMED RATE	
		1st order	
		1.5 order	
		2nd order	
		root 1st order	
		root 1.5 order	
		root 2nd order	
		COMPARTMENT	
		soil	

Days after last appl's	PECsw (µg/l)	Aw. PECsw (µg/l)
0	1.652	1.652
1	1.651	1.651
2	1.649	1.651
4	1.647	1.649
7	1.642	1.647
14	1.633	1.642
28	1.633	1.633

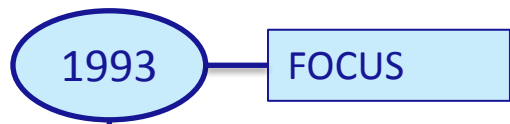
SANCO/4802/2001-rev.2 final (May 2003)


EUROPEAN COMMISSION
 HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
 Directorate E - Food Safety, plant health, animal health and welfare, international questions
 E1 - Plant health

FOCUS SURFACE WATER SCENARIOS

IN THE EU EVALUATION PROCESS UNDER 91/414/EEC.

Report prepared by the FOCUS Working Group on Surface Water Scenarios



FOCUS



FOCUS Surface Water Models and EU Registration of Plant Protection Products (EU Doc. 6476/VI/96)



2006: FOCUS Degradation Kinetics (SANCO/10058/2005)

2007: FOCUS Landscape and mitigation factor (incl. EFSA opinion)



2014: GD for evaluating lab and field studies to obtain DegT50 values (SANCO/12117/2014)



Generic Guidance for FOCUS surface water Scenarios (version 1.0)

version 1.4 (May 2015)

FOCUS DG SANTE

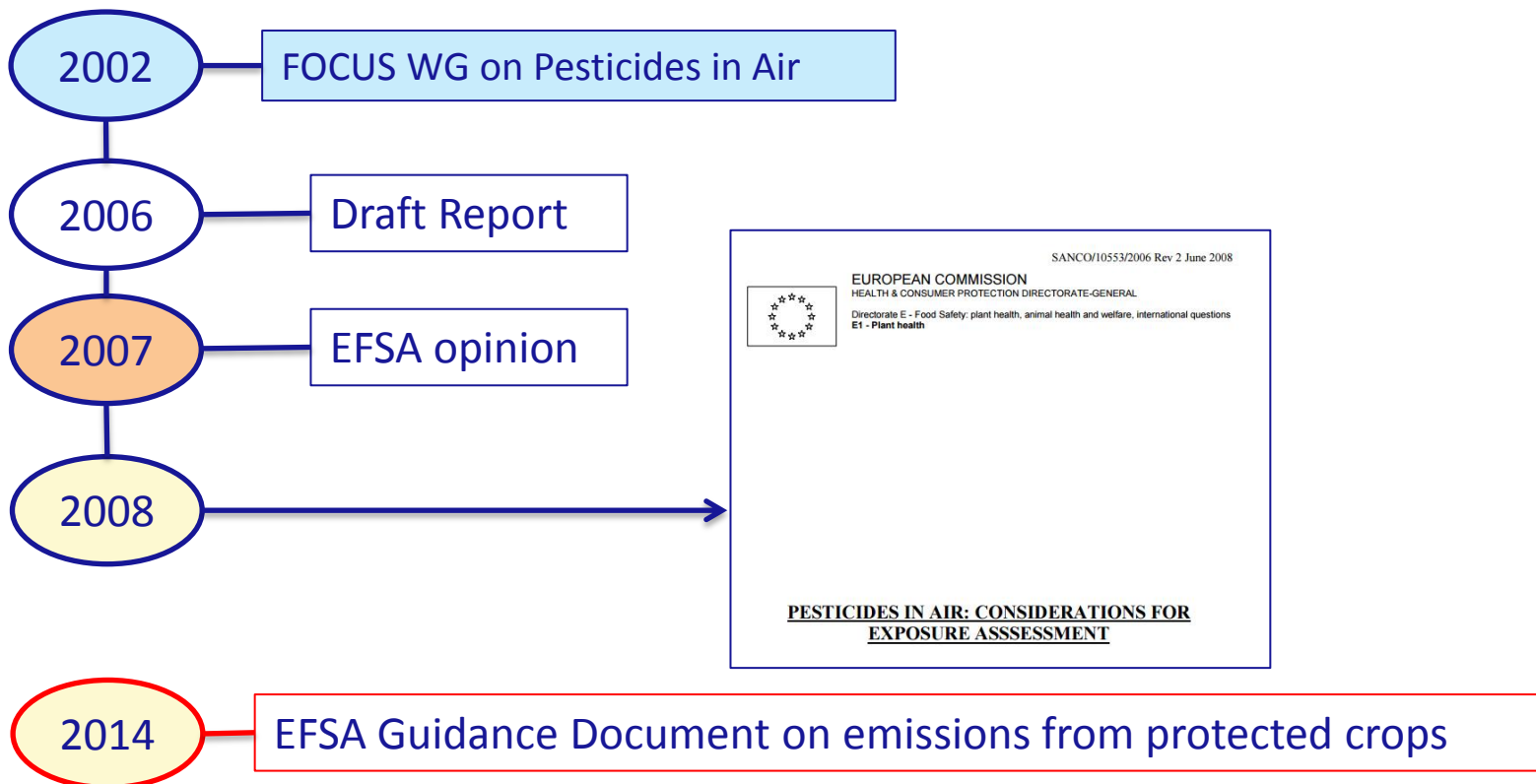


REGULATORY ERA: E-FATE

SOIL

(ad hoc presentation in the afternoon)

AIR



BIRDS AND MAMMALS



Hoerger&kenaga , 1972

It considered small and large birds and mammals with single diet (100% contaminated grass, or seed, or insects, or leaves or fruit)

1991

SANCO/4145/2000

- ✓ It considered crop specific scenarios and diets.
- ✓ It included few options for refinements

2002

EFSA opinion, 2008

2008

EFSA guidance, 2009

- ✓ It considered crop/growth stage specific scenarios and diets.
- ✓ It included several options for refinements and methodologies

2009

2017-2018
EFSA GD revision

AQUATIC ORGANISMS



Ganzelmeier, 1995
 Estimation of water body exposure based on drift values

SANCO/3268/2001
 ✓ Tier approach developed based on FOCUS
 ✓ It included several option for refinements

1991


2002

2010


EFSA opinion on SPGs

2015

2013


 European Food Safety Authority
EFSA Journal 2015;13(7):4176

SCIENTIFIC OPINION
Scientific Opinion on the effect assessment for pesticides on sediment organisms in edge-of-field surface water¹
EFSA Panel on Plant Protection Products and their Residues^{2,3}
 European Food Safety Authority (EFSA), Parma, Italy

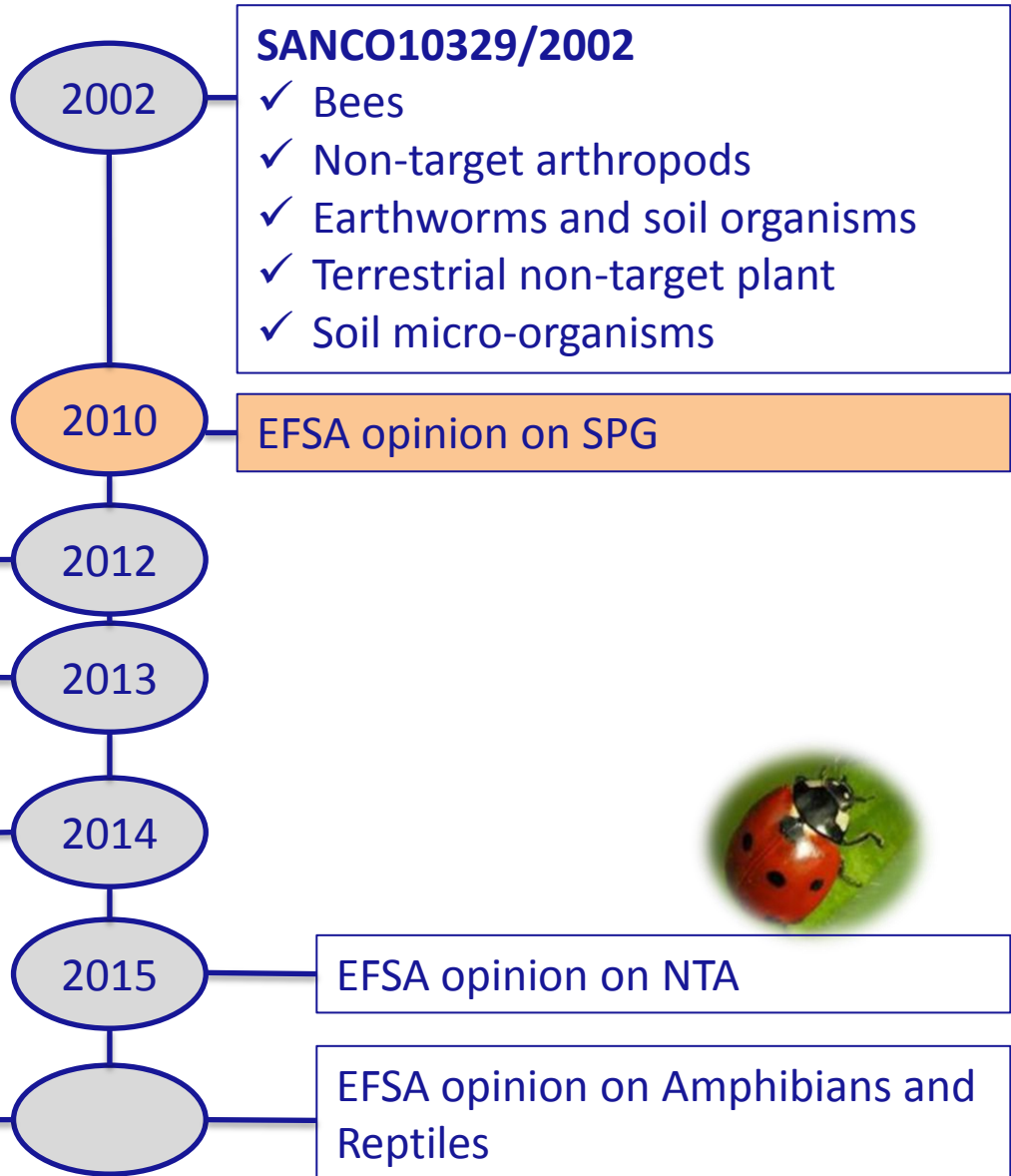

 European Food Safety Authority
EFSA Journal 2013;11(7):3290

SCIENTIFIC OPINION
Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters¹
EFSA Panel on Plant Protection Products and their Residues (PPR)^{2,3}
 European Food Safety Authority (EFSA), Parma, Italy


2016-2017
Corrigendum

EFSA opinion on TK/TD aquatic

OTHER TERRESTRIAL ORGANISMS



CONCLUSIONS

- 
- Defined level of protection
 - Constructive interaction and communication between fate and effects experts
 - More realistic assessment
 - Increasing of complexity
 - Demanding highly specialised level of expertise