



# Guidance Document on Risk Assessment for Birds and Mammals The Revision Process

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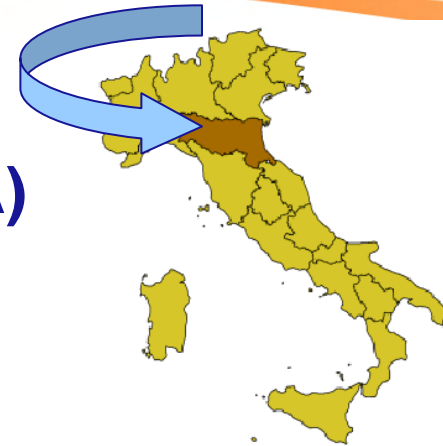
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# Overview of the GD revision process

## Content

- EFSA and its PPR Panel
- Current GD SANCO/4145/2000 – (final 25/09/2002)
- Request for revision of GD and process
- Public consultation
- Key areas for revision
- Role & membership of the core group & sub WG
- Involvement of Member States & all stakeholders
- Objectives of the workshop

# EFSA and its PPR Panel



## European Food Safety Authority (EFSA)

- Risk Assessment
- Risk Communication
- Independent scientific advice and opinions on food and feed safety

## Panel on Plant Protection Products & their Residues (PPR)

- 21 independent scientists
- Provide independent scientific opinions & guidance for the Community's legislation in the field of plant protection products on the basis of questions

# The „old“ GD



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate E - Food Safety: plant health, animal health and welfare,  
international questions  
**E1 - Plant health**

SANCO/4145/2000 - final

25 September 2002

**Working Document**

**Guidance Document  
on Risk Assessment for Birds and Mammals  
Under Council Directive 91/414/EEC**

# The GD on RA for Birds & Mammals

- GD conceived as a working document of the Commission's Services
- Elaborated in co-operation with the Member States
- Intends to provide guidance to notifiers and MS on how to conduct a RA for birds & mammals

# Authors of „old“ GD

## Participants

- Gerd Joermann (Germany)
- Mark Clook (United Kingdom)
- Elisabeth Dryselius (Sweden)
- Christian Wolf (Industry)
- Wolf Maier (Commission)
- Gaelle Baur (France)
- Victoria Pablos (Spain)
- Peter van Vliet (The Netherlands)
- Robert Luttik (The Netherlands)
- Wolfgang Pflüger (Industry)

# Why EFSA revises the GD

- GD should be updated to take on board advances in scientific understanding as the necessity arises.
- Responsibility to produce new or revise existing GD dealing with RA has been transferred EFSA.
- PPR Panel was requested to provide a revised version of this GD.
- PPR Plenary meeting accepted the request in June 2006

# The process

- Initial public consultation on EFSA website open to all interested parties
- Engagement of **all** key stakeholders (Member State Competent Authorities, industry, Commission, NGOs) to seek input
- Work of Core Group and several sub WG
- Final draft GD available on EFSA website for public consultation
- Final review and adoption by the PPR Panel
- Implementation of GD up to MS and Commission



# Timeline 2006

2006	Revision of the GD birds & mammals: activities
21 June 2006	Official Start during 19 <sup>th</sup> PPR Plenary meeting
22 June 2006	WG Ecotox Meeting
July 2006	Letter to MS & stakeholders (info)
17 July -22 Sept	Public Consultation
7 Sept 2006	WG Ecotox Meeting
2 Oct 2006	Letter to request MS nominations
19-20 Oct 2006	WG Ecotox Meeting
27 Oct 2006	Letter to MS, info about further planning
23-24 Nov 2006	WG Ecotox Meeting
6-7 Dec 2006	1 <sup>st</sup> Core WG meeting, Cologne/Germany
14-15 Dec 2006	WG Ecotox Meeting
21 Dec 2006	Announcement of Valencia Workshop

# Timeline 2007/2008

2007/2008	Revision of the GD birds & mammals: activities
17-19 Jan 2007	Sub WG "Modelling approaches + dermal exposure"; Parma/Italy
17-18 Jan 2007	Sub WG "Focal species + ecological parameters", Parma/Italy
22-23 Jan 2007	Sub WG "Residues in insects", Parma/Italy
28.2.-1.3. 2007	2 <sup>nd</sup> Core WG meeting Amsterdam/The Netherlands
2 March 2007	Invitation for Valencia Workshop
14-15 March 2007	Sub WG "Focal species + ecological parameters", Valencia/Spain
16-17 April 2007	Sub "Modelling approaches" + dermal exposure"; Parma/Italy
17-18 April 2007	3 <sup>rd</sup> Core WG meeting, Parma/Italy
18-19 April 2007	Sub WG "long term RA", Parma/Italy
8-11 May 2007	Workshop on focal species, Valencia/Spain
24-25 May 2007	Sub WG "Residues in insects", Porto/Portugal
18 June 2007	Sub WG "Focal species + ecological parameters", Amsterdam/NL
2-3 July 2007	4 <sup>th</sup> Core WG meeting, Parma/Italy
10-11 Sept 2007	5 <sup>th</sup> Core WG meeting, Parma/Italy
24-25 Oct 2007	Discussion of draft GD in PPR Plenary meeting
Nov-Dec 2007	Public web consultation
Jan-Feb 2008	Processing of comments and revising draft
<b>Spring 2008</b>	<b>Adoption of GD in PPR Plenary meeting</b>

**17 July until 22 September 2006**

Comments received from:

- 12 MS: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Hungary, Slovenia, Sweden, The Netherlands, United Kingdom
- European Crop Protection Association (ECPA)
- NOTOX, The Netherlands
- SCC - Scientific Consulting Company, Germany
- Springborn Smithers Laboratories, Switzerland

## PPR consultation

» You are here : [EFSA Web](#) > [Science](#) > [PPR Panel](#) > [PPR consultation](#)

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### Public consultation on a Guidance Document on Risk Assessment to be revised under the auspices of the Panel on plant protection products and their residues (PPR)

Last updated: 19 December 2006

Publication Date: 13 July 2006



The Consultation is closed.

The PPR Panel is requested to revise the Guidance Document on Risk Assessment for Birds and Mammals. This working document supports notifiers and Member States in the conduction of risk assessment for birds and mammals in the context of Council Directive 91/414/EEC.

#### Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EEC (SANCO Working Document)

The Panel on plant protection products and their residues deals with questions on the safety of plant protection products for the user/worker, the consumer of treated products, and the environment.

The Working Document: Guidance Document on Risk Assessment for Birds and Mammals under Council Directive 91/414/EE (SANCO/4145/2000 - final 25 September 2002) has been conceived as a working document of the Commission Services which we elaborated in co-operation with the Member States. This document intends to provide guidance to notifiers and Member States on how to conduct a risk assessment for birds and mammals in the context of the review of active substances for inclusion in Annex I of Directive 91/414/EEC. The document should be updated to take on board advances in scientific understanding as the necessity arises. Since the responsibility to produce new or revise existing Guidance Documents dealing with risk assessment has been transferred to the European Food Safety Authority (EFSA), the PPR Panel is requested to provide a revised version of this Guidance Document.

-  [Guidance Document on Risk Assessment for Birds and Mammals](#)
-  [Submitted comments to public consultation](#)

# Overview on key areas for revision

- **Principles of risk assessment**
- **First tier default values**
- **Other routes of exposure**
- **Refinement options**
- **Criteria for long-term RA**
- **Uncertainty factors**
- **Others**

# Principles of risk assessment

- **Level of protection/protection goal**
- **Individual or population level**
- **Field or landscape level**
- **Cumulative exposure of a.s. with same mode of action**
- **Value of avian short term dietary study**
- **Toxicity tests with formulations**
- **Probabilistic risk assessment**

# First tier default values

- **Relevant standard scenarios (crops, timing of application, geographical regions)**
- **Generic assumptions**
- **MAF (does it cover worst case?)**
- **RUD values and residue decline (update required in particular for insects)**
- **Palatability (exclusion of crops/seeds, pelleted seeds)**

# Other routes of exposure

- **Drinking water**
- **Dermal exposure**
- **Inhalation**
- **What is required and when?**
- **Metabolites via soil/earthworms**



# Refinement options (1)

- **Measured residues, type of studies and how should the endpoints be used**
- **Extrapolation of residue values/DT50 between crops**
- **Focal species, establishment of a list**
- **PD: acceptable diets and time scales, appropriate software**
- **PT: what data are required and how should they be used, applicable time-scales**

# Refinement options (2)

- **MS/zone specific scenarios**
- **Scenarios for “minor crops”**
- **Refined scenarios should cover “realistic worst case”**
- **Use of avian short term dietary study**

# Criteria for long-term RA

- **Ecologically relevant effect endpoints**
- **Long-term/delayed effects of short-term exposure**
- **TWA exposure**
- **Relevant time window**
- **Population modelling**

# Uncertainty factors

- **Are the current factors appropriate?**
- **When and how could uncertainty factors be lowered?**

# More guidance also needed on:

- **Avoidance (Appropriate test methods, incorporate equation from pirimicarb opinion,**
- **Dehusking (standard factors for focal species/crops)**
- **Bioaccumulation**
- **Granules and baits**
- **Assessment of possible endocrine effects**

# Additional comments

- **Appendices**
  - **Amendments**
  - **Clarifications**
- **Need for worked examples**

# The Working Groups

- **1 Core Working Group**
- **Several sub Working Groups**

# Membership of the Core WG

- Robert Luttik (PPR Panel)
- Mark Clook (PSD, UK)
- Pierre Mineau (Environment Canada)
- Andreas Höllrigl-Rosta (UBA, DE)
- Kees Romijn (BCS, representative industry)
- Andy Hart (PPR Panel)
- Herbert Köpp (PPR Panel)
- Gunilla Ericson (EFSA PRAPeR Unit)
- Christine Füll (EFSA PPR Panel Secretariat)





# Role of the Core WG

- Steering the process
- Discussion of all comments and identification of main areas of concern
- Discussion of scope and possible approach
- Development of a detailed work plan
- Identification of tasks and people with particular expertise to execute the chosen approach
- Creation of subgroups to work on specific topics

## **Sub WG Birds & mammals**

- “Focal species & ecological parameters”
- “Modelling approaches, dermal uptake, avoidance, metabolism”
- “Residues on insects & other food items”
- “Long term RA and appropriate endpoints”

# Sub WG: “Focal species...”

- Robert Luttik (RIVM, NL)
- German Canomanuel (Syngenta, ES)
- Mark Clook (PSD, UK)
- Joe Crocker (CSL, UK)
- Markus Ebeling (BCS, DE)
- Peter Edwards (Syngenta, UK)
- Andreas Höllrigl-Rosta (UBA, DE)
- Juan Pascual (BASF, DE)
- José Tarazona (INIA, ES)
- Christian Wolf (RIFCON, DE)



# Sub WG: “Focal species...”

## Tasks

- Methods to identify focal species
- Methods to assess PD
- Methods to assess PT
- Other issues being considered:
  - Dead insects as food
  - Dehusking of seeds
  - Unpalatability of plants and seeds
  - Inclusion of off-field vegetation, field boundaries?

# Sub WG: “Modelling approaches...”

- Andy Hart (CSL, UK)
- Mark Clook (PSD, UK)
- Peter Edwards (Syngenta, UK)
- David Fischer (BCS, US)
- Andreas Höllrigl-Rosta (UBA, DE)
- Annegaike Leopold (Wildlife International, NL)
- Leona Mattsoff (Finnish Environment Institute, FI)
- Pierre Mineau (Environment Canada)
- Angelo Moretto (ICPS, IT)
- Kees Romijn (BCS, DE)



## Tasks

- Discussion of bird & mammal field effects model
  - Empirical model on likelihood of avian mortality and small mammal population effects
  - Possible mechanisms
  - Influence of physical-chemical parameters
  - Relative dermal to oral toxicity
  - Use of model in risk assessment
- Body burden modelling
- Link to avoidance behaviour



## Sub WG: “Residues on food items...”

- Robert Luttik (RIVM, NL)
- Kevin Brown (Ecotox Limited, UK)
- Carsten Bruehl (University of Landau, DE)
- Andreas Höllrigl-Rosta (UBA, DE)
- Marc Kennedy (CSL, UK)
- Juan Pascual (BASF, DE)
- Helen Thompson (CSL, UK)
- Christian Wolf (RIFCON, DE)

## Tasks

- Collection of recent data on residues
- Residue dynamics and definition of criteria for assessing field and lab studies
- Guidance on how to carry out residue trials
- Crop grouping / categorisation
- Default RUD values for tier 1 for different types of insects and scenarios



# Sub WG: “Long term RA”

- Andreas Höllrigl-Rosta (UBA, DE)
- Richard Bennett (US EPA, US)
- Mark Clook (PSD, UK)
- Gunilla Ericson (EFSA PRAPeR Unit, IT)
- Leona Mattsoff (Finnish Environment Institute, FI)
- Pierre Mineau (Environment Canada)
- Angelo Moretto (ICPS, IT)
- Spencer Mortensen (BCS, US)
- Kees Romijn (BCS, DE)
- Richard Shore (Centre for Ecology & Hydrology, UK)

## Tasks

- Develop a proposal for 1<sup>st</sup> tier and refined assessment of long-term risk including endocrine effects
- Identify appropriate time scales for long term RA
- Identify endpoints (mammals and birds)
- Choice of endpoints
- Identification of relevant time periods
- Integration of exposure and effects

# Objectives of the workshop

Intention to focus on RA and associated scientific and procedural issues only. The objectives are:

- To update all stakeholders on the progress and the direction taken regarding the GD revision process
- Discuss possible 1<sup>st</sup> tier and refined RA
- Demonstrate methods for the collection of ecological parameter data
- Your thoughts and views are welcome!

# Objectives of the workshop

## Field visit

- Get familiar with field work associated with the collection of data on focal species, PT and PD



- Your thoughts and views will be helpful for the further development of the GD
- Public consultation on the draft GD in September 2007
- Consideration of comments
- The final adoption of the revised GD is expected by end 2007

# Revised GD end of 2007



Example from GMO



# Thank you for your attention!

