



European Food Safety Authority

“Other things” Valencia, 11th May 2007

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Risk assessment for particles

- Second EPPO scheme
- SCP opinion on fosthiazate
- Route for granules eaten by birds and mammals because they consider it as food (little seeds).
- Route for granules taken up by birds as grit.
- Route for granules not intentional taken up as part of soil intake during foraging by birds and mammals.
- Will try to change the EPPO scheme to a scheme more appropriate for use in the EU
- Will include guidance in choosing right type of soil

Bioaccumulation

- No real changes in approaches
- Will provide more help when it is allowed to use the QSAR approach for earthworms

In case more than the standard number of toxicity data are available for risk assessment we propose to use the approach of the safety opinion of the EFSA (options 1 or 2):

Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from EFSA related to the assessment of the acute and chronic risk to aquatic organisms with regard to the possibility of lowering the uncertainty factor if additional species were tested. *The EFSA Journal* (2005) 301, 1-45

- **Methods to achieve at least the current level of protection**
 - Where current procedure is based on single measurement (**method 1**)
 - Where current procedure is minimum of two measurements (**method 2**)
- **(Methods requiring specification of a desired level of protection)**

Where current procedure is based on 1 measurement

Goal here is to define procedures which are at least as protective of current practice and which do not require the level of protection to be specified. In addition they do not excessively penalise the use of multiple measurements.

Where current procedure is based on single measurement

Procedure: Take **geometric mean** of measurements and divide by **current extrapolation factor**.

Where current procedure is minimum of two measurements

Procedure:

- Order the data.
- Depending on the sample size, choose from the ordered data the i^{th} value based on the table below.
- Divide the obtained value by the current extrapolation factor.

Sample size	Endpoint to use
2-4	Lowest
5-7	2 nd lowest
8-10	3 rd lowest
11-12	4 th lowest

Additional toxicity data (general)

Where current procedure is minimum of two measurements

Procedure:

- Order the data.
- Depending on the sample size, choose from the ordered data the i^{th} value based on the table below.
- Divide the obtained value by the current extrapolation factor.

Example:

9.5
4
3.5
2.9
1.8
1.1
0.22
0.21
0.15
0.12
0.033

Sample size	Endpoint to use
2-4	Lowest
5-7	2 nd lowest
8-10	3 rd lowest
11-12	4 th lowest

Additional toxicity data (general)

Where current procedure is minimum of two measurements

Procedure:

- Order the data.
- Depending on the sample size, choose from the ordered data the i^{th} value based on the table below.
- Divide the obtained value by the current extrapolation factor.

Sample size	Endpoint to use
2-4	Lowest
5-7	2 nd lowest
8-10	3 rd lowest
11-12	4 th lowest

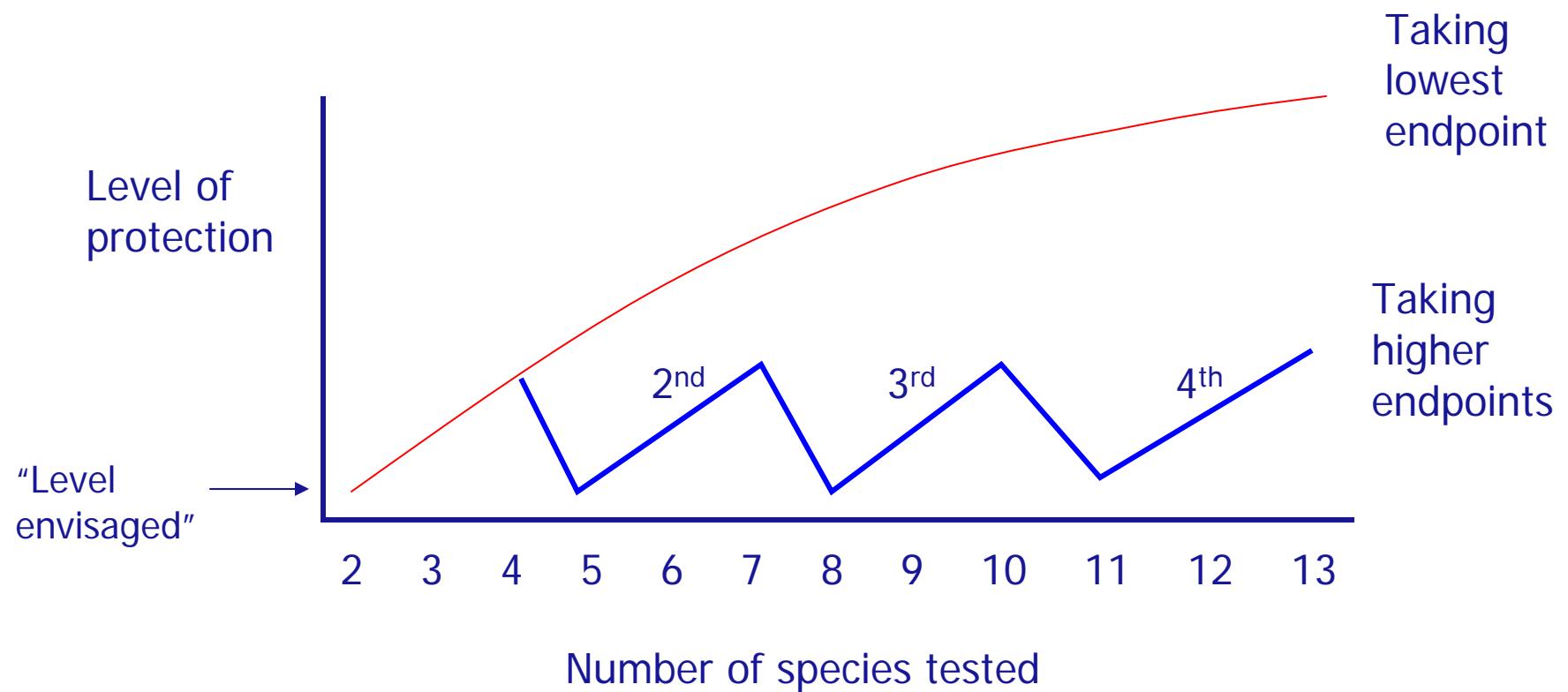
Example:

11 species

Take 4th lowest

9.5
4
3.5
2.9
1.8
1.1
0.22
0.21
0.15
0.12
0.033

Additional toxicity data (general)



Additional toxicity data (Fish)

Where current procedure is minimum of two measurements

Procedure:

- Order the data.
- Depending on the sample size, choose from the ordered data the i^{th} value based on the table below.
- Divide the obtained value by the current extrapolation factor.

Sample size	Endpoint to use
3-5	Lowest
6-8	2 nd lowest
9-11	3 rd lowest
12-13	4 th lowest

Example:

11 species

Take 3rd lowest

9.5
4
3.5
2.9
1.8
1.1
0.22
0.21
0.15
0.12
0.033