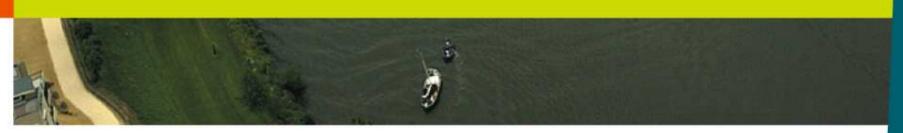


Hans Bergmans

Format for risk assessment summaries for submission to the BCH





CEE Regional Workshop, Chisinau; 26 – 28 November 2007

AHTEG in Rome

Information to support risk assessment:

Follow up

Governments should be encouraged to submit risk assessment summaries to the BCH in the standardized format, giving attention to, as appropriate,

- how risk assessment problems have been solved,
- in particular how existing information has been used to support risk assessments in these cases.

We have:

- Drafted an <u>example</u> of the format asking for this information
- Made an example of what a summary could look like



BCH information on Risk Assessments

What does the format look like now

What would we like to add

• <u>page 1</u>

-1- Reference to the methodology of risk

assesment

• <u>page 2</u>

-2- Information on recipient

-3- Characterization of the modification

• <u>page 3</u>

-4- Focus on 'further information' issues taken into consideration scenarios for adverse effects underpinning of conclusions of the RA

• <u>page 4</u>



Proposed additions to the format -1-

General information

Addition: reference to the methodology of Risk Assessment



Proposed additions to the format -2-

Information on the LMO

Addition: specify the information on the recipient



Proposed additions to the format -3-

Characteristics of modification

Addition:

List of 'points to consider':

- Method of transformation
- Molecular chracterization
- Functional characterization

Special attention to:

- sources of information
- validation of information
- basis for conclusions

Example



Proposed additions to the format -4-

Further risk assessment summary information

Addition (specification):

- issues for risk assessment
- potential risk scenarios based on these issues
- indicate at what point in the RA the conclusion is drawn that the scenario poses no risk

In short:

CRY 1F: familiar Bt toxin, resistance may develop in target population

PAT: familiar herbicide tolerance, no special issues

Example



Discussion

Problem identified in the Rome workshop:

Governments should be encouraged to submit risk assessment summaries to the BCH in the standardized format, giving attention to, as appropriate,

- how risk assessment problems have been solved,
- in particular how existing information has been used to support risk assessments in these cases.



Discussion

Problem identified in the Rome workshop:

Governments should be encouraged to submit risk assessment summaries to the BCH in the standardized format, giving attention to, as appropriate,

- how risk assessment problems have been solved,
- in particular how existing information has been used to support risk assessments in these cases.
- Do you recognize the problem
- Does the format help

Is it sufficiently clear:

- Characterisation
- Scenarios taken into consideration
- Data used in the RA
- Reasons for the conclusions
- What information should be added
- Is the form adequate



Discussion

Problem identified in the Rome workshop:

Governments should be encouraged to submit risk assessment summaries to the BCH in the standardized format, giving attention to, as appropriate,

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