



Hans Bergmans

**Format for risk assessment summaries
for submission to the BCH**



rivm

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 example 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

- [page 1](#)
- [page 2](#)
- [page 3](#)
- [page 4](#)

What would we like to add

- 1- Reference to the methodology of risk assesment
- 2- Information on recipient
- 3- Characterization of the modification
- 4- Focus on 'further information' issues taken into consideration
scenarios for adverse effects
underpinning of conclusions of the RA

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 characterization
- 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

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- **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**

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