



Technical Meeting with stakeholders on Cumulative Risk Assessment

Cumulative risk assessment – legal framework and perspective of DG SANCO

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Overview

- Cumulative risk assessment in current EU legislation
- DG SANCO view on EFSA activities on CRA
- Implementation of CRA – short, medium and long term
- Main challenges for risk managers
- Questions from the audience

Cumulative risk assessment in current legislation

-Regulation (EC) No 1107/2009 on the placing on the market of plant protection products

-Regulation (EC) No 396/2005 on maximum residue levels of pesticides in food and feed

CRA in Reg. (EC) No. 1107/2009

Art. 4 (Approval criteria for active substances):

*The residues of plant protection products shall not have any harmful effects on human health, including that of vulnerable groups, ..., **taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available, ...***

CRA in Reg. (EC) No. 396/2005

*Rationale for Art. 14 in **Recital (6)**:*

*"It is also important to carry out further work **to develop a methodology to take into account cumulative and synergistic effects**. In view of human exposure to combinations of active substances and their cumulative and possible aggregate and synergistic effects on human health, MRLs should be set after consultation of the European Food Safety Authority..."*

CRA in Reg. (EC) No. 396/2005

Art. 14 (Decision on applications concerning MRLs)

"...account shall be taken of:

(a) the scientific knowledge available

*(b) the possible presence of pesticide residues arising from other sources than current plant protection uses of active substances, **and their known cumulative and synergistic effects, when the methods to assess such effects are available...**"*

CRA in Reg. (EC) No. 396/2005

Art. 36 on support measures relating to harmonised pesticides MRLs – studies aimed at developing methods for cumulative risk assessment

SANCO view on EFSA activities (1)

- Cumulative risk assessment (CRA) is of major importance for DG SANCO and one of the biggest challenges for the future.
- Developments in EFSA are very valuable to DG SANCO.
- CRA will enable COM to respond to strong concerns from citizens and stakeholders that effects of pesticides may add up.
- EFSA work establishing cumulative assessment groups is now progressing well, despite delays at the beginning.

SANCO view on EFSA activities (2)

- SANCO acknowledges that the task is very complex. The initial aim to use CRA for the review of all existing MRLs under Art. 12 of Reg. 396/2005 can however not be met
- Good collaboration between SANCO and EFSA is established and needs to be continued to find solutions to the challenges in implementation of the methodology

Implementation of CRA in risk management – short and medium term

- Discussions with Member States on implementation are only starting now, many open questions still need to be addressed.
- CRA test-cases were already described in the EFSA annual monitoring report. They give some indications of possible impact of using certain approaches/methodologies, however refinement will be necessary to get to more realistic estimations.
- DG SANCO set up an electronic Working group with Member States' experts in December 2013.
- Main focus: address open questions for risk managers that need to be solved before using the methodology.

Implementation of CRA in risk management – short and medium term

First steps:

- An inventory of open questions is being established
- Questions should be prioritised and addressed in order of priority
- Evaluation of the possible impact of all the options under discussion
- Report back to the Standing Committee on Food and Feed on any progress regularly and get agreement for proposed approaches step by step
- Collaboration with EFSA essential in this phase

Implementation of CRA in risk management –long term

- Long term means for SANCO: once all the Cumulative risk assessment groups have been established by EFSA
- Impact assessment of using cumulative risk assessment in MRL setting and authorization procedures, including impact on international trade
- Decision how and when implementation in routine practice should take place
- Define the detailed procedures
- Define a communication strategy

Examples of main challenges for risk managers (1)

- Define the level of protection (percentile of the population that will have an exposure below the toxicological threshold values)
- Different strategies for chronic and acute risks?
- Risk communication aspects related to the discussion on the level of protection

Examples of main challenges for risk managers (2)

- Define the input parameters for deterministic and/ or probabilistic exposure calculations: define realistic scenarios (pessimistic and optimistic scenarios suggested by EFSA)
- How to carry out an assessment of the impacts on trade?
- Alignment of the methodology with other international systems to avoid conflicts with trading partners

Some Conclusions

Work is now well underway on both risk assessment and risk management side.

There are still many open questions that need to be resolved before cumulative risk assessment can be implemented in practice.

Collaboration of risk assessors and risk managers as well as input from stakeholders is essential to progress in this area.

Discussions needed at international level to avoid trade disruptions.

Questions?

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