



Cumulative risk assessment- expectations from the Commission

ACROPOLIS Stakeholder Conference

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Current risk management

- Consumer risks of plant protection products currently estimated substance by substance by EFSA
- Commission sets MRLs based on that risk assessment
- However, many pesticides have a similar mode of action and the adverse effects of one pesticide might add up to the effect of related pesticides or even unrelated pesticides might enhance each other's effects
- When Regulation (EC) No 396/2005 on MRLs was adopted, EP, Council and Commission agreed that as soon as the methodology is available, cumulative and synergistic effects should be taken into account when setting MRLs



Cumulative and synergistic effects

■ Mentioned 3 times in In Regulation 396:

- 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 established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety (Hereinafter the Authority)*



Cumulative and synergistic effects

■ In Regulation 396, Chapter II:

Article 14

Decisions on applications concerning MRLs

1. Upon receipt of the opinion of the Authority and taking into account that opinion, a Regulation on the setting, modification or deletion of an MRL or a Decision rejecting the application shall be prepared by the Commission without delay and at the latest within three months, and submitted for adoption in accordance with the procedure referred to in Article 45(2).
2. With regard to the acts referred to in paragraph 1, account shall be taken of:
 - (a) the scientific and technical 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;*



Cumulative and synergistic effects

- In Regulation 396, Chapter VII:

Article 36

Support measures relating to harmonised pesticide MRLs

- 1. Support measures relating to harmonised pesticide MRLs shall be established at Community level, including:
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 - (a) a consolidated database for Community legislation on MRLs of pesticide residues and for making such information publicly available;
 - (b) Community proficiency tests as referred to in Article 28(3);
 - (c) studies and other measures necessary for the preparation and development of legislation and of technical guidelines on pesticide residues, *aimed, in particular, at developing and using methods of assessing aggregate, cumulative and synergistic effects*;



Who is developing the method?

- EFSA is scientific advisor of Commission and Member States on Food Safety so it seems logical that EFSA develops the method and guidelines
- Commission has asked EFSA to do this in 2006.
- EFSA declared this as a "self task" meaning that EFSA will take the initiative and specify the timelines and procedure to do this

What do we expect?

3 issues

- (1) Risk assessment
- (2) Risk management
- (3) Risk communication: how do we inform the general public?

What do we expect?

■ (1) Risk assessment:

- How can additivity or synergy be demonstrated? Experimentally or theoretically? How to add up the effects of pesticides with similar mode of action? Toxic equivalents, common assessment groups.
- EFSA has already done a lot of work we hope guidance will be finalized soon so that it can be used for the review of the MRLs
- Also need tools to implement the method: Acropolis?



What do we expect?

- (2) Risk management: if pesticides with similar mode of action are additive, what are the consequences for manufacturers of single substances. Do we need additional data requirements e.g. info about the additivity re substances of competitors? When exposure not acceptable which uses to delete? The most toxic? How can we decide this? We need a method to identify the pesticidal use that must be deleted when the ADI/ARfD is exceeded.
- Risk Managers need IT tools. Acropolis?

What do we expect?

- (3) Risk communication: how do we inform the general public about the cumulative risks of pesticides in their food?
 - Public has a right to know about possible risks
 - Must be possible to verify risk management decisions
 - Acropolis IT tool publicly available?



Reg. (EC) 396/2005

Documents on the Internet

Regulation:

http://europa.eu.int/eur-lex/lex/RECH_naturel.do

MRL and Active substance database

http://ec.europa.eu/sanco_pesticides/public/index.cfm

Factsheet MRLs:

http://ec.europa.eu/food/plant/protection/pesticides/index_en.htm

Pesticides found in food in the EU:

http://ec.europa.eu/comm/food/fvo/specialreports/pesticides_index_en.htm

After 2006: <http://www.efsa.europa.eu/en/efsajournal/pub/2430.htm>