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# ACROPOLIS

Aggregate and Cumulative Risk Of Pesticides: an On-Line  
Integrated Strategy  
SEVENTH FRAMEWORK PROGRAMME

**Deliverable 6.12 A report describing the user group 'regulators'  
activities and achievements.**

The dissemination level changed from Public to Confidential because informal letters or minutes are included in the deliverables, The letters or minutes prove that we have delivered what has been promised but were not announced as being openly available at the time we discussed these issues.

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## 1 Introduction

Within the EU project ACROPOLIS an IT tool has been developed to assess the cumulative dietary exposure to groups of pesticide residues. This tool can also be used to assess the dietary exposure to single compounds or to estimate the intake of beneficial compounds, like micro-nutrients. The IT tool can calculate both the acute and the chronic exposure. The IT tool is an update of the Monte Carlo Risk Assessment (MCRA) software tool and is released as MCRA 8.0 (de Boer and Kruisselbrink, 2013b). The tool is available via [mcra8.rivm.nl](http://mcra8.rivm.nl). During the ACROPOLIS project a training was organized for EU Regulators.

## 2 Training regulators

On May 31<sup>st</sup> 2013 a training on the ACROPOLIS tool was organized for the EU regulators in Brussels. Appendix 1 gives the list of participants.

In the first session of the training Jacob van Klaveren, coordinator of the ACROPOLIS project gave an overview of ACROPOLIS and in particular on the User groups formed during the ACROPOLIS project.

After this introduction Luc Mohimont (EFSA) presented the work regarding Cumulative Risk Assessment EFSA has achieved so far. In June 2013 EFSA will adopt an opinion on CAGs. At the end Luc Mohimont told more about the coherence between risk assessment and risk management and the consultation of Commission and Member States.

After the first two more theoretical presentations we continued with a demonstration of the MCRA 8.0 IT-tool. Jacob van Klaveren showed all the options in the programme and this part of the training ended with some exercises to be performed by the participants.

The practical session was followed by a presentation of Jacob van Klaveren where he explained more about the EFSA guidance on the use of probabilistic modelling. He explained the difference between the optimistic and pessimistic model run. In the EFSA guidance a table is included with a summary of recommended approaches for acute dietary assessment. E.g. how to deal with residues below LOR, unit variability and processing factors in an optimistic or pessimistic run. During the ACROPOLIS project it was noticed that an optimistic run might be too optimistic, and a pessimistic run too pessimistic. More guidance is needed to come to an optimal run.

For regulators it's important to be able to combine the commodity of interest with the background commodities. During this session some examples were shown of a consumer-only approach and the session was closed with some exercises for the participants.

It should be easy for a user to adjust certain variables, like variability factors, processing factors, or insert new supervised trial data for the focal commodity. After preparing or adjusting your data you can easily combine the database with already prepared data and do a risk assessment using MCRA 8.0. This session was also closed with some exercises for the participants.

After all the theoretical and practical work we finished with an open discussion. From the member states questions on how the Commission and EFSA will use the outcomes of MCRA 8.0.

### 3 Feedback regulators

**Paul Hamey ( HSE-UK)** reported on the experience collected by the regulators user group. The regulators were trained in May 2013 following an invitation of the European Commission. Paul Hamey started with a reviewed of the history, the current state of the art and future direction in probabilistic risk assessment and risk management needs from the perspective of European regulators.

Prior to the ACROPOLIS project experiences were already gained both in the UK and in the USA on probabilistic modeling. Probabilistic assessments were explored in several European funded projects such as the Monte Carlo project, SAFE Foods and the current ACROPOLIS project. In the early part of the century the EU regulatory framework changed significantly with the launch of EFSA , acceptance of MRL regulation 396/2005, and new PPP regulation 1107/2009 including articles describing the future regulatory obligation to address cumulative and aggregated exposure assessment. EFSA organized a colloquium on cumulative assessments, which was followed by publications of several EFSA opinions (criteria for cumulative assessment, triazole study, guidance on exposure assessments needed for cumulative dietary assessments, identification of CAG). EFSA is in the lead to set and to finalize the cumulative risk assessment methodology.

The ACROPOLIS project is well received by the regulatory process because it addresses complexities of factoring multiple sources of exposure from a wide range of related compounds. Despite all the complex issues, the ACROPOLIS IT tool is now user-friendly and it is possible to follow the EFSA guidance on the use of probabilistic modeling for dietary intake to pesticide residues using the ACROPOLIS IT tool. It enables implementation of cumulative dietary assessment, following the approaches recommended by EFSA into the risk management deliberations in Brussels. Furthermore, ACROPOLIS also provides an approach to consider non-dietary pathways in addition to the cumulative exposure assessment. Representatives of nearly all EU member states were trained and the general feeling is that ACROPOLIS is a useful tool for the assessment of cumulative exposures to multiple compounds via food in the coming year(s). However, still a

number of issues related to the acceptance and final use in risk assessment needs to be considered by the regulators and the Standing Committee on the Food Chain and Animal Health of DG SANCO. These issues are, among other things, related to uncertainty in the data and input variable and the required level of protection to be set in the European Union.

**Appendix 1**
**List of participants**
**Expert meeting on “Cumulative risk assessment and training on IT tool”**

**Date of the meeting: 31 May 2013**

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