Executive Summary:
ACROPOLIS stands for Aggregate and Cumulative Risk Of Pesticides: an On-Line Integrated Strategy. The overall objective of the ACROPOLIS project is to improve risk assessment strategies in Europe regarding cumulative and aggregate dietary exposure. Current risk assessment of pesticides and the setting of Maximum Residue Limits (MRLs) does not sufficiently account for cumulative and aggregate exposure to pesticide residues (Regulation (EC) 396/2005). The European Food Safety Authority (EFSA) is responsible for setting the methodology to take these exposures into account, which was not available at the start of the ACROPOLIS project. EFSA published the guidance on the use of probabilistic methodology for modelling dietary exposure to pesticide residues in October 2012. The methodology is complex. Without ACROPOLIS, no practical tools to follow the methodology would have been available.
and consequently no practical implementation of Regulation 396/2005.

The ACROPOLIS project has delivered an IT tool including a tested, and fully described and documented cumulative exposure model. This tool also contains monitoring and consumption data of ten member states that can be used to perform cumulative exposure assessments. The cumulative model has been tested, and is scientifically sound and accessible for all actors involved in the European risk assessment and risk management. The aggregated exposure model developed within ACROPOLIS is best described as a ‘proof of principle’. Four case studies were set up and these studies demonstrated the applicability of the aggregated exposure model in various situations. The ACROPOLIS cumulative exposure model was validated by comparing the outcome of the model with a model in use by the Environmental Protection Agency (EPA) of the United States of America (USA). The aggregated exposure model was validated against measured intake using duplicate diets and biomarkers. Furthermore, toxicological test systems were developed and used to test for the relative potency of pesticides within a cumulative assessment group. The tests were also useful to determine whether the pesticide should be in- or excluded from a cumulative assessment group.

The beta-version of the ACROPOLIS IT tool was explained, discussed and tested for use by the industry, food regulators, EFSA and national food authorities: parties that are directly responsible for estimating cumulative risks. The European Commission has called, during midterm evaluation, for planning further acceptance and implementation of the ACROPOLIS models by the institutes responsible for future cumulative risk assessment. The testing results of the aggregated exposure model, the toxicological testing and the validation studies were discussed among scientists within the project and the results are described in several draft scientific papers ready for publication.

Qualitative and quantitative analyses of stakeholders’ attitudes, as well as their understanding and willingness to accept new advanced models for cumulative and aggregate exposure were performed. The result of this analysis was that the relevance and expected outcomes of ACROPOLIS were perceived favourably. Industry, national food authorities, regulators and NGOs were invited for training. Two stakeholder meetings were organised to discuss the usefulness of the ACROPOLIS IT tool. Nearly all stakeholders experienced the ACROPOLIS IT tool as easy-to-use and relevant for future cumulative exposure assessment in Europe. The proceedings of the second stakeholder conference are posted on the ACROPOLIS web site (acropolis.eu.com).

DG SANCO, EFSA and a number of member states have discussed the usefulness of the ACROPOLIS IT tool in future risk assessment and management practices. EFSA and DG SANCO have decided to use the ACROPOLIS IT tool because the models are fully in line with the EFSA methodology. A working group of DG SANCO, exploring the risk management issues, will start using the ACROPOLIS IT tool. Consumers and trade organisations may regain trust in future MRLs that take cumulative effects into account after DG SANCO has implemented the methodology in future risk management decision on MRL settings.

Project Context and Objectives:
ACROPOLIS stands for Aggregate and Cumulative Risk Of Pesticides: an On-Line Integrated Strategy. The overall objective of the ACROPOLIS project is to improve risk assessment strategies in Europe. In this project a framework for cumulative and aggregate risk assessment of pesticides was developed that is scientifically sound and accessible for all actors involved in the European risk assessment and management.
The specific objectives of the project were:
1. Improving cumulative exposure assessment methodology;
2. Devising new models for aggregate exposure assessment addressing different routes of exposure;
3. Testing the feasibility of using in vitro methods to refine cumulative assessment groups and to assess the outcome of combined exposures. In particular to confirm or discount the dose-additivity hypothesis for compounds having a similar mode of action;
4. Integrating single-compound, cumulative and aggregate risk models in a web-based tool, including accessible data for all stakeholders;
5. Improving the understanding of cumulative and aggregated e-risk assessment methodology by different stakeholders.

Cumulative dietary exposure model
Within the ACROPOLIS project a model was developed to assess the dietary cumulative exposure to compounds belonging to a cumulative assessment group (CAG). In 2012 the European Food Safety Authority (EFSA) published a guidance document on the use of probabilistic methodology for modelling dietary exposure to both single and multiple residues in food. In this document, an optimistic and pessimistic model run are proposed aiming, respectively, to estimate the possible lower and upper range of exposures in a population. For assessing cumulative dietary exposures, both the EFSA Guidance model runs as well as other more refined models were implemented in the web-based Monte Carlo Risk Assessment (MCRA) system (ACROPOLIS IT tool). To test the implementation of the EFSA Guidance model runs in MCRA, as well as their practicality, cumulative dietary exposure assessments were performed to two CAGs of triazole pesticides. For this, national food consumption and monitoring data of several European countries was used. The food consumption data were obtained from the EFSA Comprehensive database. Processing factors were obtained from the database compiled by the German Federal Institute for risk assessment (BfR) and supplemented with additional information from Draft Assessment Reports. The observed gaps in concentration data were filled as required by the EFSA Guidance. It was concluded that the two model runs can be performed with the model developed within ACROPOLIS in a user-friendly way. Especially, the application of the optimistic model run was feasible, resulting however in underestimates of the real exposure. The pessimistic model run may severely overestimate the exposure. Especially the inclusion of maximum residue limits (MRLs) of unmeasured animal commodities seemed to result in unrealistic conclusions regarding the contribution of animal commodities to the dietary exposure. A conclusion may be that some kind of intermediate model run, more realistic than either the optimistic or the pessimistic model run, is needed. Such a ‘realistic’ model run would combine the available optimistic and pessimistic options and possibly include some of the new options developed in ACROPOLIS to provide exposures that in case of missing information still can be argued to be conservative (precautionary principle) but not over-conservative, as seems the case with the pessimistic model run.

Apart from practicalities to get external data connected to the model and open issues regarding risk management of cumulative exposure assessments, the cumulative ACROPOLIS model was well-received throughout Europe, and several European countries and stakeholders such as pesticide industry and food authorities are presently making use of the model. Cumulative dietary exposure assessments, including uncertainty analyses, can be performed on-line, which is an innovation. Extensive detailed information about food consumption, concentration data and other relevant input variables is available at a percentile of exposure predefined by the user. With this information the user has the possibility to check the realism of the exposure estimates.
of the calculations in relation to the modelling assumptions applied. The system works well with the currently available datasets, but may need further testing when addressing the cumulative exposure to larger CAGs or when exposure to CAGs are to be performed with merged concentration data from many European countries (as done by EFSA when performing exposure assessments to (environmental) contaminants).

Aggregate exposure
Aggregate exposure combines dietary and non-dietary sources of external exposure, as may be relevant for pesticide residues. Examples of non-dietary exposure to these chemicals are exposure through occupational farming activities, the use of consumer products, or incidental exposures experienced by residents of farms or bystanders. All these individuals are also exposed to pesticide residues via food. A conceptual framework of aggregated exposure was implemented in the MCRA system and tested addressing four different aggregated exposure scenarios in the form of case studies. This model should be seen as a ‘proof of principle’ ready for future use.

Both the cumulative and the aggregate models were validated, and are transparent and fully documented. Validation was performed against simulated data where the true outcome is known, and against the factor standard program used by the US-Environmental Protection Agency (EPA), namely DEEM-FCID which stands for Dietary Exposure Evaluation Model - Food Commodity Intake Database.

Testing of in vitro models
The ACROPOLIS project has also delivered two useful in vitro test systems and two Physiologically Based-PharmacoKinetic (PB-PK) models to extrapolate intake information obtained via MCRA to internal dose effects based on the toxico-kinetics and toxico-dynamics of the compounds belonging to a mixture. In vitro tests were used to express the relationship between the dose and the combined effect for different compounds and mixtures of compounds belonging to the same CAG. To extrapolate these in vitro results to a potential adverse health effect, PB-PK modelling was used and found to be very useful. PB-PK modelling techniques are also helpful to extrapolate in vitro testing from animals to realistic exposure levels in humans. In the context of cumulative risk assessment, in vitro studies as performed in the ACROPOLIS project have proven to be valuable for both refinement of grouping and confirmation of the dose-additively assumption.

Stakeholders attitudes
A qualitative and quantitative analysis of stakeholders’ attitudes, including their understanding and willingness to accept new advanced models for cumulative and aggregate exposure, was tested. This analysis showed that the relevance and expected outcomes of ACROPOLIS were perceived favourably. Stakeholders generally asked for targeted information, dissemination and training programmes in relation to the proposed cumulative and aggregate pesticide exposure assessment models and tools. The research defined barriers and challenges, which were transferred into practice by providing training. Furthermore, a worldwide dissemination and interaction with relevant authorities in and outside Europe was achieved within the project.

Project Results:
Cumulative model as part of the ACROPOLIS IT tool
The consortium members DLO and RIVM have developed a cumulative exposure model, as part of the ACROPOLIS IT tool. This cumulative model addresses both acute and chronic exposure assessments to individual chemicals belonging to a single CAG (Category) and/or mixtures of such chemicals (Category Mix).
single (existing background) and multiple compounds belonging to CAGs (foreground). The software system, which is part of the ACROPOLIS IT tool, is also referred to as Monte Carlo Risk Assessment (MCRA) version 8. This version is now available for stakeholders in pesticide risk assessment. The cumulative model, as recommended in the 2012 EFSA Guidance on the use of probabilistic modelling for dietary exposure to pesticide residues, were implemented in the MCRA version 8. The EFSA guidance prescribes the need for optimistic and a pessimistic model runs, which are both implemented in the MCRA 8. In the optimistic model runs, major uncertainties are addressed in such a way that the resulting exposure outcome results in an under-estimation, while the pessimistic model sets major uncertainties in such a way that an over-estimation will occur.

The guidance document describes how these two model runs should be performed. The optimistic and pessimistic model approaches consists of many parameters that can be set on an optimistic and pessimistic values or assumption. For example, there are two approaches to use concentration data in an exposure assessment. Concentration data can be included based on observations (empirically) or on a distribution (after the observations have been transferred to lognormal distribution). Furthermore, there are two options to handle the optimistic and pessimistic values for samples that were measured, but without detecting a pesticide residue. Non-detects might be assumed as being zero-values or as values as high as the limit of detection or anything in between. In addition, it was observed that not all samples are measured for all pesticides in the cumulative assessment group. If these unmeasured pesticides are not addressed the risk may be underestimated.

For a correct modelling it is important to overview all the potential non-detects and the uncertainties related to unmeasured pesticides in the same sample. Therefore, two approaches were implemented in MCRA, sample-based and compound-based. In approach 1 (the sample-based approach), residue concentrations per sample are recalculated in terms of an index compound, and then summed. In approach 2 (the compound-based approach), exposures are calculated independently for each compound, and then the cumulative exposure is calculated as a weighted sum. The EFSA guidance prescribes a sample-based approach to avoid underestimation. However it is also experienced that in practice this approach can result in a gross overestimation of the real risk.

Furthermore, pesticides can have acute and chronic toxic effects. MCRA can perform acute and chronic (cumulative) exposure assessments according to the EFSA guidance. An acute exposure assessment is based on single day (24-h) consumption patterns combined to residue concentration data of single units (e.g. a single apple, a single pear, etc.). The consumption and concentration distributions are integrated by Monte Carlo (MC) sampling. The number of MC iterations can be chosen freely. A number of 100,000 is typically found to be sufficient. This assessment results in a distribution of exposures that may occur on an arbitrary day and which can differ substantially from one day to another for a certain individual. Estimates of the chronic exposure distribution are obtained from statistical modelling of the 24-h consumption patterns multiplied by the average residue concentration. These models are based on the concept of removing the within-individual variation from the exposure distribution. Furthermore, frequency and amount of intake are modelled separately, followed by an integration step.

MCRA gives the user also the possibility to perform uncertainty analyses. These analyses can provide confidence limits around exposure estimates, such as percentiles of exposure. Uncertainty analyses can be performed using the bootstrap approach (e.g. resampling of food consumption and concentration data) or using parametric approaches as described in the EFSA guidance. Both options are implemented in MCRA.
The cumulative model and its implementation in software was validated, using both simulated data and comparisons against the standard software DEEM-FCID used by the Environmental Protection Agency in the USA (EPA-US).

Aggregated model as part of the ACROPOLIS IT tool

The aggregated model was developed by the ACROPOLIS consortium members Fera, DLO and RIVM. It was designed to be as flexible as possible, to accommodate existing models of non-dietary and dietary exposure in all their forms, and to facilitate future extensions. An aggregated exposure assessment involves:

1. Definition of an exposure question, including selection of an appropriate population, health effect and relevant compound(s);
2. Estimation of non-dietary exposures from one or more activities resulting in exposure;
3. Matching non-dietary exposures with dietary exposures at the individual level;
4. Aggregation of those exposures and conversion to an appropriate common unit.

If a chronic assessment is required, exposures are calculated per individual, typically representing average daily exposure. In the case of an acute assessment, exposure values per individual-day are calculated. To simplify the generic descriptions below the term 'individual' is used to represent both options.

The aggregated exposure module contains dietary and non-dietary databases, and models of exposure for relevant routes. The population can be a national population, but will more often be a specific subgroup. It is not necessary for model and data sources to relate to the entire population in both the dietary and non-dietary components, as long as they are compatible in such a way that the aggregated estimates relate to a meaningful subset of the population.

Aggregate risk assessments can take various forms, depending on the needs of the risk manager and the availability of quality data. Risk assessment typically uses a tiered approach. The lower (or first) tier models are the simplest to apply and use generic and conservative assumptions, therefore making them well suited for screening assessments. Higher tier models offer refinements in terms of realism at the cost of more detailed data and/or model assumptions, perhaps specific to a particular sub-population. These models often require additional expertise and specialist tools, and are therefore only used when triggered by an inconclusive screening assessment. The aggregate exposure model developed in the ACROPOLIS project encompasses a wide range of options to allow for simple or complex analyses as required. The following choices are available for non-dietary exposures:

- A single deterministic value applied to all individuals (in the chronic case) or individual-days (acute case). This could represent a point estimate or a conservative upper percentile. The level of conservatism of the model is dependent on the value selected in this case.
- A vector of deterministic values, with one value for each individual or individual day in a group. This corresponds to variable exposures, with a known variability distribution.
- A vector corresponding to realisations from an uncertainty distribution of a fixed but unknown non-dietary exposure to apply to all individuals
- Multiple vectors, each of which represents a simulated realisation of the population of individual
exposures. Together these realisations quantify uncertainty about the true variability in the population. Such a representation commonly arises as part of a two-dimensional Monte Carlo (2DMC) analysis. A person-orientated approach is adopted. For every individual of the modelled population a non-dietary exposure value is assigned. Various probabilistic methods are available to simulate exposures for a representative sample of individuals within the population, taking account of individual characteristics and activities, and variations in contaminant levels. The probability of any given individual, or the proportion of the population, exceeding certain exposure thresholds can then be estimated. The final option in the list above (the multiple vector choice) quantifies uncertainty, indicating the strength of evidence associated with the exposure estimates given the data and other information used. The treatment of variability and uncertainty more generally within the ACROPOLIS model were described in detail.

The cumulative dietary data and modelling results are linked to a table containing non-dietary information. Each non-dietary table can correspond to a single activity or a relevant combination of activities. The latter is important to allow assessments to reflect the combinations of exposure that may occur in reality (e.g. a person who is exposed through their diet and also exposed via different activities such as worker with pesticides in the field or being exposed to pesticides as a resident. The aggregated model also allows for including correlations between these activities.

Regulatory purposes and the current EFSA documents does not require that level of complexity yet, and therefore the models can be used for each activity in isolation (e.g. diet only, worker only, resident only), if this is required for regulatory purposes or to analyse the contribution of different components to overall exposure.

The aggregated model has been tested using case studies covering the UK, Italy and the Netherlands, and address different scenarios (occupational, resident/bystander and consumer exposure) generated with the aggregated model.

The aggregated exposure model was validated by comparing calculated intakes with measured concentrations of the same pesticides in duplicate diets and measured concentration in the urine of volunteers applying pesticides in agriculture.

Databases as part of the models developed within ACROPOLIS
The monitoring and consumption data owned by European countries are essential for performing cumulative and aggregated exposure assessments and can be used with the cumulative and aggregated models described above. At the start of the ACROPOLIS project, data was defined as background necessary for the model development in the ACROPOLIS project. At the end of the ACROPOLIS project, data has been integrated and consequently it became foreground. Data owners have defined use rights and access rights in the consortium agreement and use agreements. Stakeholders using the ACROOLIS IT tool signed the use agreements.

National food consumption data
All national food consumption databases included in ACROPOLIS refer to the data that are part of the Comprehensive database of EFSA. The food consumption data included are summarized below.

In Cyprus, a national study evaluating the frequency of eating disorder cases (Cyprus Study on eating disorders, Child Health Cyprus Study on eating disorders).
disorders among High School students, "Child Health") was conducted in 2003. Food consumption data were collected of 303 children, aged 11 to 15 years using a 3-day estimated dietary record. Most, but not all, dietary records were collected during consecutive days. Amounts consumed were estimated using food package sizes and household measures (e.g. cups and spoons).

In the Czech Republic a food consumption survey (SISP04) was conducted between November 2003 and 2004 covering a 1-year period. In this national study 2177 persons aged 10-90 years were asked about their eating habits via two 24-h recalls. The repeated recall was within a period of 1-6 months after the first recall and addressed another day of the week. Amounts consumed were estimated using either photographs of portions for the most frequently consumed meals, or measuring guides, such as spoons and cups.

For Denmark food consumption levels derived from the National Food Consumption Survey conducted in 2000-2002 were used. In this survey 4120 persons aged 4-75 years were asked to record their food consumption during seven consecutive days using the 7-day dietary record method. Amounts consumed were estimated using photographs of portion sizes or household measures (e.g. cups and spoons).

The French food consumption data were derived from the second French Individual National Food Consumption Survey (INCA 2) conducted between December 2005 and May 2007. Two independent population groups were included in the study: 2,624 adults aged 18-79 and 1,455 children aged 3-17. Subjects were asked to complete a seven-day food record diary (consecutive days). Participants estimated portion sizes using photographs or expressed by weight or household measures (spoons, cups, etc.).

For Italy food consumption data collected by the Italian Agricultural Research Council - Research center for food and nutrition (CRA-NUT), formerly known as National Research Institute on Food and Nutrition (INRAN), during the period of 2005-2006 were used. In this survey, named INRAN-SCAI 2005-06, information on food consumption was collected from 1,329 randomly selected households. The individual food consumption levels were quantified using a consecutive 3-day dietary record. Amounts consumed were estimated using a photographic booklet. Food consumption data were collected from 3,323 individuals aged 0-97 years.

The food consumption data from the Netherlands were those of the Dutch National Food Consumption Survey of 2003. In this survey 750 persons aged 19-30 years were asked about their eating habits via two independent computerized 24-hour dietary recalls administered by telephone. The repeated recall was within a period of 7-14 days after the first recall and on another day of the week. Amounts consumed were estimated using photographs of portion sizes or household measures.

Food consumption data from Sweden were those of the 'Riksmaten' study. This dietary study was performed in 1997-1998 among 1211 respondents aged 18-74 years. Participants were asked to record their food consumption during seven consecutive days using the 7-day dietary record method. Amounts consumed were estimated using pre-printed quantity indications in household measures and photographs.
Food consumption data from the United Kingdom were derived from the National Diet and Nutrition Survey (NDNS) of 2000-2001 among 1,724 adults aged 19 to 64 years living in private households in Great Britain. Participants completed a weighed dietary record for seven consecutive days.

All the national food consumption databases covered all seasons of the year and days of the week, excluding holidays and festive periods due to divergent food habits during those periods. All surveys obtained non-food characteristics, including sex, age and body weight.

Data from Slovenia, Latvia, Austria and Belgium were also included in the ACROPOLIS tool but these data still have to be organised because these partners became associated partners at a late stage of the project.

National pesticide residue data

As part of the ACROPOLIS project, also pesticide residue data were collected and organised. EU countries perform annually analyses of pesticides mainly on raw agricultural commodities (RACs) intended for human consumption to monitor the occurrence of pesticide residues and to check compliance with the maximum residue limits (MRLs) as set in Regulation (EC) No 396/2005. These analyses are performed as part of national monitoring programmes undertaken by the Member States’ authorities and as part of an EU-wide programme co-ordinated by the European Commission. In this project national monitoring results of the acute and chronic CAG group of triazole pesticides sampled in the period 2007-2010 were used. All countries in our study had monitoring results for these pesticides.

The monitoring data obtained as part of the EU coordinated monitoring are untargeted. National monitoring programmes, however, may contain samples that are targeted to particular RACs, regions, etc. suspected to contain higher residue levels. Inclusion of these samples may result in an overestimation of exposure, but may also cause underestimation because certain pesticides and/or RACs that are not expected to contain pesticides at levels above the MRL may be neglected. In the databases used in this project, targeted samples were removed from the assessment if clearly identified, but it cannot be excluded that the databases still contained samples obtained via targeted sampling. The effect of this is considered as part of the evaluation of unquantified uncertainties.

Concentration data from Slovenia, Latvia, Austria, Greece and Belgium were also included in the ACROPOLIS tool but these data still have to be organised because these partners became associated partners in a late stage.

Potential Impact:
Socio-economic impact and consumers’ confidence and public health

Pesticides residues on foods are one of the principal worries of EU consumers. So far cumulative risk assessment has not been part of the risk management and in the MRL setting. The ACROPOLIS project contributed to the development of a methodology to ensure that these missing aspects in the risk assessment of pesticides can be included in the future. This will increase trust of the consumer in the safety regulation of pesticides.
Greenpeace, being a consumer group, was a member of the Scientific Advisory Board of ACROPOLIS. Just after the start of the project, the representative left and PAN Europe was asked to represent consumers’ interest in relation to cumulative exposure assessment modelling. PAN Europe, however, did not attend meetings or trainings, with the exception of the first stakeholder meeting. During that meeting, they made a statement of not being interested in probabilistic exposure assessment.

After the ACROPOLIS project ended, and DG SANCO and EFSA had accepted the ACROPOLIS IT tool, PAN Europe launched a negative campaign and published their worries in a report called ‘A poisonous injection’. This report was criticized by many organizations. Politicians have reacted in favour of the ACROPOLIS project.

The link between the ACROPOLIS IT tool, its use in practice and consumers’ confidence cannot be directly monitored. According to the expectation of politicians, trade and farmer organizations, which are very sensitive for consumer concerns and food safety worries, the ACROPOLIS project has positively contributed to regain consumer trust in the MRL setting process of the government.

Socio-economic impact on trade and industry
An increased understanding of the complexity and concrete effects of multiple pesticide residues could help to convince major food retailers to refrain from introducing unscientific criteria to deal with the issue of multiple residues. Commonly these restrictions do not allow fruit and vegetables on the market with more than 3-5 pesticides on an analysed sample irrespective of whether those pesticides share a common mechanism of action.

Pesticide industry has a need for good, predictive models and reliable, detailed databases on EU food consumption and residue concentrations in commodities marketed in the EU in order to make clear investment strategies. Development of a new active substance costs in excess of 150 million Euros with an average 10-year development time. Without the ability to accurately predict that a pesticide may be registered already early in the development phase, research will be inhibited, limiting the introduction of new potentially safer products on the market and reduce the tools available for effective resistance management. The ACROPOLIS IT outcome has an impact on this pending uncertainty.

The industry participated in the scientific advisory board and in the user group. All major pesticide industry companies in the USA and Europe attended the training and were involved in the discussion on how the models can be tailored for their practical use. The major companies have helped to improve the models by intensive testing.

Pesticide industry companies were able to enter their own company-specific compound information and compared results generated with deterministic and probabilistic approaches. During the evaluation, the calculation procedures of MCRA8 and DEEM were directly compared by using US consumption data. The industry user group was very pleased to see how the model could work with the data from two different continents. This may help the harmonisation of pesticide risk assessment procedures. The industry user group studied the impact that the different input parameters such as processing and variability factors had on the results of probabilistic modelling.

Pesticide industry companies felt that probabilistic modelling is necessary for cumulative risk assessment and that the ACROPOLIS project has brought the relevant IT tool and data accessible to industry. DG SANCO should take the lead in in the discussions on realistic assumptions related to the input variables. Furthermore, the European Commission should strive for a set of basic criteria for risk managers to decide on the required level of protection.
During the second stakeholder conference Axel Moehrke (Dole Fresh Fruit /Freshfel Europe) presented the views of the fresh fruit and vegetables sector on how the result of the ACROPOLIS project impact trade. The need of trust in legislations of trade companies, and the role of cumulative exposure assessment to cover for multiple pesticides, is evident. The consumption of fresh produce witnessed an on-going decline over the last decade. This trend is the result of several factors, including consumers concerns about pesticide residues. The ACROPOLIS project was judged as an important milestone to provide greater confidence in the EU regulatory process.

The ACROPOLIS project was presented at the GLOBAL G.A.P. Technical Committee composed of ca. 20 supplier and retailer representatives with an interest in the fresh produce sector. A number of retailers are setting secondary standard, which means residue limits that are lower than the DG SANCO limits, because of retail and consumer concerns.

After awareness was raised of the impact of the ACRROLIS IT tool some retailers were convinced that future MRL setting might address their concern.

Impact on the regulatory process

The European Parliament itself has – at the time of the adoption of the Regulation (EC) No. 396/2005 on MRLs - insisted that a methodology to address cumulative effects should be developed and applied as soon as possible to estimate the safety of MRLs.

Representatives of nearly all member states were trained in using the IT tool, and experienced the tool as user-friendly. Regulators were able to follow the EFSA guidance on the use of probabilistic modelling for dietary intake to pesticide residues. However, a number of issues related to the acceptance and final use in risk assessment still need to be considered by the regulators and the Standing Committee on the Food Chain and Animal Health of DG SANCO.

Regulation also requires aggregated exposure, but the methodology for this is still in its infancy. Therefore, representatives of the European regulators recommended to gain more experience and to include robust pesticide usage data and behaviour patterns of operator, worker, bystander and resident into the aggregated exposure models. In a follow-up of the ACROPOLIS project, the stakeholders and DG SANCO should secure the achievements of the project for better risk assessment and risk management of real risks in Europe.

DG SANCO director Eric Poudelet called the project ‘the best practice in cooperation linking innovation in research to the practical needs of the European Commission and it stakeholders (including societal concern about pesticide regulation). DG SANCO called for follow-up cooperation between EFSA and ACROPOLIS to implement cumulative risk assessment of pesticides in the procedures of the European Commission.

DG SANCO and EFSA have now accepted the ACROPOLIS IT tool and will use it in a working group to discuss the required level of protection and how to optimize input parameters. This working group will study the optimistic and pessimistic approaches set in the EFSA guidance and will aim to make the calculations as practical as possible. Furthermore, DG SANCO will try to find consensus on the use of the probabilistic methodology, as developed in ACROPOLIS, with representatives of international organisation to avoid trading disputes.
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Last update: 18 November 2014
Record number: 149282