Project number: 872.447.01
Project title: Cumulative Exposure Assessment

Project leader: J.D. van Klaveren

Report 2009.008 September 2009

Cumulative Exposure Assessment of Triazole Pesticides

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The research described in this report was funded by EFSA, European Food Safety Authority and the Dutch Food and Consumer Product Safety Authority.

The report is approved by EFSA European Food Safety Authority

Acknowledgements

For their contributions to this project we would like to thank Fanny Héraud and Amélie Crépet (French Food Safety Authority, AFFSA), Jiri Ruprich (National Institute of Public Health, NIPH), Angela Santilio (National Institute of Health, ISS), Kelevi Slivinen (Finnish Customs Laboratory, FCL), Kettil Svensson (National Food Administration, NFA), Aida Turrini (National Research Institute for Food and Nutrition, INRAN) and Waldo de Boer (Biometris, Wageningen UR).

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Summary

In the EFSA opinion on identification of new approaches to assess cumulative and synergistic risks from pesticides to human health a tiered approach for cumulative risk assessment has been proposed. The first tier is a deterministic approach using average and large portion consumption statistics. The higher tiers include probabilistic exposure assessment and Benchmark Dose (BMD) modeling.
The aim of this study is to demonstrate the feasibility and applicability of a higher tier assessment of cumulative exposure using probabilistic modeling in combination with the relative potency factor (RPF) approach. The RPFs are used to weigh the toxicity of each pesticide relative to the toxicity of a chosen index compound (pesticide). In this report we address both the short-term and long-term cumulative exposure to triazoles using different statistical models.

The input for the probabilistic software consisted of food consumption and residue concentration databases from several European countries, including Czech Republic, France, Italy, the Netherlands, Sweden, United Kingdom and Finland (only residue concentration data). The food consumption databases included the raw consumption data. Food as eaten was converted back to their corresponding raw agricultural commodities (RACs) in order to make food as eaten compatible with the agricultural commodities analyzed for triazoles.

The number of triazoles analyzed varied per country and per RAC. In many samples, not all triazoles were always analyzed. For example, in some samples three triazoles were analysed, while in some other samples four, five, six or more were analysed. A correct statistical model to cumulate the different triazoles that could also deal with unbalanced data sets was not available during this project. Instead an existing statistical model was used assuming that all triazoles were analysed in all samples. This statistical model has been used in cumulative exposure assessments up till now. An alternative model to assess the cumulative exposure using unbalanced data sets was developed in this project and used as well. A drawback of this alternative model was that existing correlations in residues found in RACs were not included. Pesticide use in agriculture will rule out certain combinations of triazoles and consequently correlation in residues found exists.

A probabilistic Monte Carlo model was used to estimate the short-term intake. For long-term intake assessments two statistical models (ISUF and BBN) were used. Results generated with both models were compared. Cumulative exposure assessments were performed for different countries, different age groups and for different scenarios. Half of the scenarios were aimed at calculating the actual exposure using only monitoring data. In the other half of the scenarios maximum residue limits (MRLs), supervised trials median residues (STMRs) or field trial data for one particular RAC were used as input for calculating the possible exposures as a consequence of MRL setting. In this type of calculations monitoring data for all other food (or RAC)-pesticide combinations were used to include a kind of background level of cumulative exposure.

The following conclusions were drawn:
1) Short-term and long-term cumulative dietary exposure to triazoles can be calculated with probabilistic models in combination with the RPF approach.

2) The method was applicable for calculating both the actual exposure using monitoring data as the possible exposure in the process of MRL setting.
3) Monte Carlo simulations can be used to calculate short-term cumulative exposure.
4) For long-term exposure assessments different models can be used. Not all models apply in all cases and a significant model uncertainty was observed in a few calculation scenarios.
5) When for a particular RAC-pesticide combination MRL, STMR or field trial data were used and monitoring data for other RAC-pesticide combinations a bimodal exposure distribution can be expected. In such cases the lower part of the exposure distribution (first mode) relates to the daily consumptions consisting of only food items for which monitoring results are used, and the other part (second mode) to daily consumptions of the particular RAC for which MRL, STMR or field trial data are used.
6) More research is needed on how to model bimodal distributions. However, first indications of simulation studies suggest that ISUF and BBN may overestimate the exposure level at the higher percentiles in the case of bimodality. If so, risk assessors may consider to calculate the distribution of individual mean exposure levels based on the observed individual mean consumption reported during the food consumption survey and average residue levels. This is regarded as a conservative starting point for modeling long-term exposure levels.
7) A statistical model assuming that the non-analyzed triazoles in samples are zero values (non-detects) might result in an underestimation of exposure. The alternative statistical model, which was pragmatically programmed, models each triazole separately and then combines the results. This alternative approach is assumed to be a more realistic, but also conservative, approach for unbalanced data sets.
8) Results of probabilistic modeling using RPFs derived from Benchmark Dose modeling are sometimes higher compared to results based on calculations using RPFs derived from NOAELs. Benchmark Dose modeling is proposed as a higher tier assessment and higher tier assessment should result in lower exposure levels because higher tier assessment includes less conservatism.
9) Uncertainty and sensitivity analyses demonstrated that different assumptions made and different models can result in higher or lower exposure levels.
10) We were able to perform all cumulative exposure calculations using food consumption data from several countries.

In conclusion the probabilistic model can be applied within the European context.

The most important recommendations are:
1) Development of statistical models to account for unbalanced data sets or to harmonize data collection resulting in datasets that contain the same pesticides in all samples.
2) Uncertainty and sensitivity analyses are needed to show where knowledge / data are lacking and what the effect of assumptions is on the exposure result. We therefore recommend further integration of exposure and BMD modeling aiming at a better quantification of the uncertainties in the calculations, including the uncertainty in the derivation of the RPF.
3) The models and data used in this project demonstrated that probabilistic modeling can be done as a higher tier assessment, but much effort is needed to make the models and data accessible and compatible in the European context.
4) Further elaboration on a tiered approach to assure that exposure levels resulting from lower tier assessments are higher (more conservative) than those calculated in higher tiers.

Contents

1 Introduction

Regulation (EC) No. 396/2005 on maximum residue levels (MRLs) of pesticides in or on food and feed of plant and animal origin emphasises the importance of the development of a methodology that accounts for additive and possible synergistic effects of pesticide residues on human health.

In the light of this Regulation EFSA organised a scientific colloquium to evaluate existing methodologies, and, if appropriate, identify new approaches (EFSA 2007). The outcome of this colloquium has provided a contribution to EFSA PPR Panel discussions. The colloquium reviewed the four major steps in risk assessment in relation to cumulative and synergistic effects of pesticides. These steps are:

- Cumulative hazard assessment;
- Non dose addition;
- Choice of data for combined exposure;
- Methodology for combined exposure.

Based on the outcome of this colloquium and further discussions within the PPR Panel, EFSA launched a call for tender on cumulative exposure assessment of triazole pesticides. In this report we describe the results that were generated in the EFSA project 'Cumulative exposure assessment of triazoles pesticides', which was performed as a result of this call. The results of this project will be considered in an EFSA opinion on the practical use of a tiered approach of cumulative modeling of actual exposure or theoretical possible exposure levels as a consequence of setting maximum residue limits (MRL). The opinion is planned to be an addition on the first opinion of the Scientific Panel on Plant Protection products and their Residues (PPR panel) to evaluate the suitability of existing methodologies and, if appropriate the identification of new approaches, to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of Regulation (EG) 396/2005 (EFSA 2008). In this opinion a tiered approach has been proposed from a simple first tier assessment using average and large portion size diets towards higher tiers using probabilistic modeling and a RPF (Relative Potency Factor) or similar approaches. The RPF approach enables the risk assessor to compare the relative toxicity of the different pesticides with each other and can be used as long as there is a common mechanism of action of the different pesticide to be addressed in the assessment. Exposure to different pesticides belonging to a common mechanism group can be calculated by using this approach in combinations with food consumption data as existing in a whole food consumption database (EFSA 2008).

The aim of this study is to demonstrate the feasibility and the applicability of probabilistic modeling in combination with the proposed RPF-method taking into account that diets in Europe can vary, and that the method should account for both short-term and long-term exposure to acute and chronic toxic pesticides. The methods should also be usable both in calculating actual exposure levels using existing monitoring results as well as in the process of MRL setting for pesticides evaluated for authorisation.

In this report the terms acute and short-term intake or exposure, and chronic and long-term intake or exposure are used alternatively meaning the exposure / intake during one single day and over a longer period of time, respectively.

Current international risk assessments require an international approach. Consumer diets vary from Northern to Southern Europe, and from Western to Eastern Europe, as well as the contamination of products with pesticide residues. Within the EU-project SAFE FOODS (www.safefoods.nl; QLRT number Food-CT-2004-506446) food consumption data of Denmark (DTU), Sweden (NFA), the Netherlands (RIKILT), Italy (ISS and INRAN), and Czech Republic (NIPH) were made compatible with each other. The food consumption data of the five countries was converted into consumption levels of raw agricultural commodities (RAC) in order to solve incompatibility between analytical results usually generated in RACs and food as eaten. Residue databases of those countries were also made compatible with each other in terms of coding. Residue and food consumption data of the different countries are connected via the Internet to the Monte Carlo Risk Assessment (MCRA) software (De Boer and Van der Voet 2007). In this way an Electronic Platform was created which can be used in performing exposure assessment in a standardised way addressing the exposure to pesticides in different European countries.

The Electronic Platform among other models and databases, was used in the EFSA Opinion of the Scientific Panel on Plant protection products and their Residues on a request from the Commission on acute dietary intake assessment of pesticide residues in fruit and vegetables. Different scenarios were calculated using probabilistic exposure calculations of single compounds covering approximately 200 different scenarios in order to clarify the Level of Protection related to different values for the variability factor (EFSA 2007).

Consumption and/or residue concentration data of Finland, United Kingdom and France have been added to this Electronic Platform of SAFE FOODS and data from Denmark have been removed because of a possible conflict of interest of participating in this study by the DTU . Table 1 gives an overview of the data used in this project. Details of data and models used in this study are given in Section 2.1 to 2.6.

EFSA provided the toxicological information needed for this study including RPFs based on dose-response modeling (benchmark doses, BMDs) and on no-observed adverse effect levels (NOAEL). Not all of the triazoles share a common mechanism of action. The RPFs of those triazoles sharing a common mechanism of action are described in Section 2.7. Further details regarding the quality of the toxicological data and the method for deriving critical effect sizes based on benchmark dose modeling are not provided in this report, because the scope of this project was exposure assessment.

In Sections 3.1, 3.2 and 3.3 the results of short-term and long-term actual exposure levels using the monitoring data in different countries are reported. This includes different scenarios using either monitoring data of a particular country or a database in which the monitoring data of the seven countries were pooled (all monitoring_data_together_database).

In Sections 3.4 and 3.5 the results are reported of exposure assessment using MRL, STMR or field trial data for nine different combinations of a certain crop or RAC and a certain pesticide in combination with monitoring data for all other RAC – pesticide combinations. This was done to illustrate the possible use of cumulative exposure calculations for MRL setting, again addressing short-term and long-term (acute or chronic) exposure levels.

Table 1. List of institutes which have provided data and models in this project.

Name of Institute	Short name	Role in the project
RIKILT - Institute of Food Safety, Wageningen UR (the Netherlands)	RIKILT	Dutch food consumption data Dutch pesticide residue concentration data MCRA software including statistical knowledge
Pesticide Safety Directorate (United Kingdom)	PSD	UK pesticide residue concentration data Organising, reporting and reviewing field trial data from DARs.
Food Standards Agency	FSA	UK food consumption data
National Food Administration (Sweden)	NFA	Swedish food consumption data Swedish pesticide residue concentration data
National Institute of Public Health (Czech Republic)	NIPH	Czech food consumption data Czech pesticide residue concentration data
National Institute of Health (Italy)	ISS	Italian pesticide residue concentration data
National Research Institute for Food and Nutrition (Italy)	INRAN	Italian food consumption data
French Food Safety Authority (France)	AFSSA	French food consumption data French pesticide residue concentration data Statistical input
Finnish Customs Laboratory (Finland)	FCL	Finnish pesticide residue concentration data

In Chapter 4 the results are discussed including the feasibility of probabilistic exposure assessment in combination with the RPF method at the international level. We also discuss the calculation method in the perspective of a tiered approach as proposed in the EFSA-opinion. A further elaboration is given regarding the quality of the statistical model used for calculating the cumulative exposure and uncertainties relevant for cumulative exposure assessment .
Finally conclusions and recommendations are drawn up in Chapter 5.

2 Materials and methods

2.1 Food consumption databases

This section gives an overview of the food consumption data used in this study. A short overview is provided in Table 2 and a more detailed description is given in the section below.

Czech Republic (CZ)
In CZ a food consumption survey (SISP04) was conducted between November 2003 and 2004 covering a 1-year period, including all four seasons (Ruprich et al. 2006). In this study 2,177 persons aged 10 - 90 years and 413 persons aged 4 to 9 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. The study included all days of the week. Amounts consumed were estimated using either photographs of portions for the most frequently consumed meals, as well as measuring guides, such as spoons and cups. Respondents were randomly selected from about 60 selected regions in the country.

Italy (IT)
For Italy food consumption data collected by the Italian National Institute of Nutrition during the period of 1994-1996 are included in the E-platform (INRAN; (Turrini et al. 2001)). Data were obtained from a multi-centre study (15 centres). The sampling unit of the study was at a household level and each individual of the household was asked to record their food consumption during 7 consecutive days using the 7-d dietary record method (foods weighed by precision scales at home, estimated food record for out of home consumption). Trained dieticians did the fieldwork. In total 2,734 individuals aged 0-94 years participated. These persons were representative of the total Italian population (whole country and four main geographical areas: North-West, North-East, Centre, South & Islands). An accurate revision of each recorded diary led to the removal of around 1/3 (27.7%) of the individuals as bad-reporters, resulting in the inclusion of the information of 1,978 individuals in the analyses. Post-calculation was performed to verify the compliance of the final distribution with the original sample structure.

All seasons and all days of the week were included, except for festive periods such as Christmas and Easter due to divergent food habits during those periods.

Sweden (SE)
Food consumption data from Sweden implemented in the E-platform is that of the 'Riksmaten' study (Becker 1999; Becker and Pearson 2002). This is a dietary study performed in 1997 and 1998 among 1,211 respondents (male and female) in the age of 18 to 75 years. Participants were asked to record their food consumption during 7 consecutive days using the 7-d dietary record method. As in Denmark, amounts consumed were estimated using photographs of portion sizes. The study was conducted from January 1997 up to March 1998. All seasons as well as all days of the week are represented.

The Netherlands (NL)
The food consumption data from the Netherlands included in the E-platform is that of the Dutch National Food Consumption Survey (DNFCS3) of 1997/1998 (Anonymous 1998; Kistemaker et al. 1998). In this survey 6,250 non-institutionalized persons aged 1 - 97 years from 2,564 households were selected from a stratified probability sample in the Netherlands. Respondents recorded their food intake

over two consecutive days using the 2-d dietary record method. Amounts eaten were weighed accurately. The survey was distributed equally over the 7 days of the week and over 1 year (holidays excluded).
Within the European Project Monte Carlo data was collected of 373 babies aged 8 -12 months. Caretakers of the babies were asked to weight the food given to the babies as accurate as possible using weighting scales. The survey was conducted from September 2000 until August 2001 (Boon et al. 2004).

France (FR)
For France, the food consumption data are coming from the Individual National Food Consumption Survey (INCA) conducted in 1998 and 1999 (Volatier 2000). The original sample of 1985 healthy adults (aged 15 and over) is representative of the French population through stratification (region of residence, agglomeration size) and use of the quota method (age, gender, household size, individual occupation and socio-professional status). An additional sample of 1018 children from 3–14 years-old is available. Subjects were asked to complete a seven-day food record diary (consecutive days) as well as other questionnaires on anthropometrical and socio-economical factors, throughout all four seasons of the year. Amounts consumed were estimated using a validated photographic booklet (Hercberg et al. 1994). Adult people identified as under-reporters by comparing their reported energy intake to their basal metabolic rate as estimated from the Schofield equations (Black 2000) were excluded from the study. Thus, the final sample contained 341 children aged 3-6 years and 2151 individuals aged 7 and over. This database is used by the French government for risk assessment purposes.

United Kingdom (UK)
Food consumption data from the UK are derived from published dietary surveys (Gregory et al. 2000). The field work for the dietary surveys was conducted over 12 months whereby a weighed diary record was taken for food consumed over 7 days. These data are provided to the Food Standard Agency.

2.2 Converting food as eaten to raw agricultural commodities

Residue monitoring is usually performed on agricultural crops or raw agricultural commodities (RACs), sometimes including inedible parts. Consequently there is a discrepancy between food as measured and food as eaten. In the cumulative exposure calculations not only the foods consumed as such (e.g. apple, endive) should be addressed but also those present in processed dishes (e.g. pizza, apple juice). To overcome the incompatibility between food as measured and food as eaten, food conversion tables or databases should be available.

In both the Netherlands (Van Dooren et al. 1995) and France such a conversion model is present. Food consumption data of the other countries included in this assessment are converted back to their raw agricultural products based on the experience of the Dutch food conversion method. Within the SAFE FOODS project food consumption data from Denmark, Sweden, the Czech Republic and Italy were linked as good as possible to similar foods coded in the Dutch food consumption survey. In this study we also converted the food coded in the British Food Consumption Survey to RACs in a similar way.

The French recipe database makes the link between the 895 food items coded in the French consumption survey and 153 RAC for which European MRLs are established according to Annex 1 of

Regulation 365/2005/EC. This database includes 402 recipes, which have been defined according to both industrial process and recipes, but also to home cooking habits. For a description of the Dutch food conversion model, see (Van Dooren et al. 1995).

2.3 Pesticide residue monitoring

This section overviews the monitoring data used in this study. It describes per country the number of samples and the analytical methods used to generate the results. In all national monitoring programmes samples were reported to contain no residue below a certain level (the so-called non- detects). This level is termed in this report the level of reporting (LOR) and is just the value below which results will be reported as 'less than'.

Czech Republic
For the Czech Republic data of 2004-2006 were available for six different triazoles. In Annex 1 the number of analyses per item/compound is given, as well as the range of LORs per compound. Depending on the food item the LOR may vary. For the analyses two different multi residual methods for food and baby food were used. Both methods were based on LC/MS/MS. Data were collected as part of the EU monitoring programme performed by the official control laboratory of the Czech Agriculture and Food Inspection Authority (CAFIA). Beside these data for the EU coordinated programme also data from the national control programme, produced by the CAFIA, were used.

Finland
For Finland, data of 2003-2006 were available for 15 different triazoles. The number of RACs sampled and relevant for the cumulative exposure assessment is listed in Annex 1. The analyses are performed by the Finnish Customs Laboratory (FCL). In Finland different multi residual methods are used. For each method and compound the LOR is given (see Annex 1).

The data used consist of the results of the national pesticide residues monitoring program. The program is planned annually in co-operation by the National Food Safety Authority and Customs Authority. It includes samples from farm gate, retail shops and wholesalers. Domestic (Finnish) products, products from other EU member states, and imported (third country) products are covered. Most samples are randomly collected but some are targeted to products with higher rate of pesticide occurrence. The data incorporates also the annual EU coordinated programs.

The samples were analyzed using the so called Luke method (AOAC 985.22) with some modifications. The method is based on acetone-water extraction of the samples. The analysis of the sample extracts is made using GCEC, GCNP or GCMS detection for GC amenable compounds. This method is called GC multimethod. An aliquot of the extract (of the above mentioned method) is taken and the solvent is changed for methanol and LCMSMS analysis is carried out. This method is called LC multimethod. In the data set used in this report both LC multimethod 1 and 2 were used. The only difference between these methods is that method 2 covers a wider scope of pesticides.

Italy
For Italy, residue concentration data of 2002-2004 were available for 16 different triazoles. In Annex 1 the number of analyses per item/compound is listed. Data were derived from the official monitoring

program according to EU regulation (EU coordinate program) and national law (Ministerial decree). The analyses were performed by laboratories of the Italian regions and all data were collected by the Ministry of Health. Although no specific information is supplied in the reports publishing the residue concentration data, it can be declared that all analyses were performed using routine multi-residue methods. No information on level of LOR was provided.

Sweden
For Sweden, data for the years 2003-2006 is available for 9 different triazoles. The data has been collected within the in EU monitoring programme according to EU regulation. The analytical methods are mainly developed by the NFA but for the validation of the methods and the results NFA cooperates with the laboratory Lantmännen Analycen AB (ALC). Most pesticide residues are measured and reported from the limit of determination (LOD).

The Netherlands
For the Netherlands, data of 2002-2007 were available for 23 different triazoles. Data were derived from the official monitoring program prescribed by the European Commission and performed by the Dutch Food and Consumer Product Safety Authority (VWA), including also data from other sources. In Annex 1 the number of samples for the relevant triazoles is listed.

The analyses were performed by different Dutch laboratories, including VWA, Laboratory Zeeuws Vlaanderen, Agro Control, and TNO-BLGG AgriQ BV. The VWA performs the analyses as part of directives 90/642/EEC (products of plant origin), 86/362/EEC (cereals) and recommendation 2002/663/EU (the harmonised specific programme 2003). The validity of the analytical results in all labs is governed by a quality assurance system complying with ISO17025. The LOR for the analyses varies depending on the pesticide-commodity combination and the year of analysis, and is between 0.01-0.05 mg/kg.

France
For France, data for the years 2004-2006 were available for 21 different triazoles. The analyses were performed by the Direction Générale de la Concurrence, de la Consommation et de la Repression de Fraude (DGCCRF) of the French Department on Consumers' Affairs. The provided data comprised results from both nationwide (including EU coordinated programme) and local programmes.
These various programmes may be unspecific (monitoring plans for pesticides residues in fruit and vegetables, in cereals, etc) or targeted on specific practices (e.g. organic farming) and processes (e.g. wine making).

Analyses were carried out by seven DGCCRF laboratories. The performed multiresidual methods were based on Gas Chromatography GC (Mestres method or NF EN 12393 or TSD method) or Liquid Chromatography LC (LC/MS) according to the laboratory, the year and the food-pesticide combination. The limit of quantification (LOQ) depends on the pesticide, the laboratory, the method and the year of analysis and is between 0.01 and 0.5 mg/kg. The number of analyses for each compound and the LOR are listed in Annex 1.

Table 2. Overview of food consumption data used in the cumulative exposure assessments

Country	Years of survey	Age range (y)	Sample size	Number of days	Consecutive days	Survey method	Weighed/estimated food weights	Comments	References
Czech Republic	2003-4	10-90	2177	2	No	24h recall	Estimated	All days and seasons	(Ruprich et al. 2006)
Czech Republic	2003-4	4-9	413	2	No	24h recall	Estimated	All days and seasons	(Ruprich et al. 2006)
France	1998-9	3-6	340	7	Yes	Dietary record	Estimated	All days and seasons	(Volatier 2000)
France	1998-9	7-92	2150	7	Yes	Dietary record	Estimated	All days and seasons	(Volatier 2000)
Italy	1994-6	1-17	283	7	Yes	Dietary record	Estimated	Excluded festive days	(Turrini et al. 2001)
Italy	1994-6	18-64	1482	7	Yes	Dietary record	Estimated	Excluded festive days	(Turrini et al. 2001)
Sweden	1997-8	17-79	1211	7	Yes	Dietary record	Estimated	All days and seasons	(Becker 1999; Becker and Pearson 2002)
Sweden	2003	3-13	2540	4	Yes	Dietary record	Estimated	All days, 2 seasons	Not published as far as known
The Netherlands	1997-8	1-97	6250	2	Yes	Dietary record	Weighed	All days and seasons	(Anonymous 1998)
The Netherlands	1997-8	1-6	530	2	Yes	Dietary record	Weighed	Subset of survey above	(Anonymous 1998)
The Netherlands	2002-3	8-12[a]	373	1	-	Dietary record	Weighed	All days and seasons[b]	(Boon et al. 2004)
UK	1997-8	4-18	1701	7	Yes	Dietary record	Weighed	All days and seasons	(Gregory et al. 2000)

[a] *Age range is in months*

[b] *Breast-fed children were not included*

United Kingdom
For the United Kingdom, data of 2003-2007 were available for 12 triazoles. The number of analyses for each compound is listed in Annex 1, as well as the number of positive finding. The data comprise the combined results of the UK's Pesticide Residue Committee (PRC) surveillance programme and the national School Fruit and Vegetable Scheme (A Department of Health initiative providing fruit and vegetables to primary school children) and include also the UK findings for the EU co-ordinated programme which are incorporated in the PRC data.

Analyses were performed by four contact laboratories that participate in the UK programme (Central Science Laboratory, LGC Ltd, Scottish Agricultural Science Agency and Direct Laboratories). Each laboratory has both an LC and a GC multi-residue method which are used to analyse for the 12 triazoles; whether a compound is analyzed by LC or GC will differ between laboratories. The LOR for the analyses varies depending on the pesticide-commodity combination and the year of analysis, but in general is between 0.01-0.05 mg/kg.

Extrapolation when monitoring data were not available
Not always all pesticides belonging to the common mechanism group were analyzed in all possible RACs (Annex 1). To make the exposure calculations as complete as possible, we therefore extrapolated residue levels analyzed in similar RACs to not analyzed RACs. For example, tebuconazole levels in pear were extrapolated to levels in apple if tebuconazole was not analyzed in apple. See Annex 2 for the extrapolation rules provided by EFSA. In Annex 3 the practical application of these rules to the different national residue concentration databases is listed.

2.4 Scenarios performed

The calculations were performed using the monitoring data of each country in combination with the consumption data of that particular country. Within the EFSA opinion on acute dietary intake it was recognized that uncertainties in the results were partly driven by the completeness of monitoring and the differences in monitoring practices between countries (EFSA 2007). We therefore merged monitoring data of the separate counties into one common residue concentration database, and combined this 'all monitoring data together' database with the consumption data of the individual countries listed in Table 3. In total we performed 24 different scenarios (Table 3). Samples with levels below LOR were assumed to contain no residue.

Table 3. Countries and age groups for which cumulative exposure assessments were performed, including linkage to pesticide residue concentration databases

Country		Population	Age (years)	Pesticide database
Czech Republic	CZ	Children	4-9	Monitoring data CZ All monitoring data together
		Over 10 years	10-90	Monitoring data CZ All monitoring data together
France	FR	3-6 years	3-6	Monitoring data FR All monitoring data together

Country		Population	Age (years)	Pesticide database
		Over 7 years	7-92	Monitoring data FR All monitoring data together
Italy	IT	Children	1-17	Monitoring data IT All monitoring data together
		Adults	18-64	Monitoring data IT All monitoring data together
Sweden	SE	Children	3-13	Monitoring data SE All monitoring data together
		Adults	17-79	Monitoring data SE All monitoring data together
The Netherlands	NL	Babies	0.6-1	Monitoring data NL All monitoring data together
		Children	1-6	Monitoring data NL All monitoring data together
		Total	1-97	Monitoring data NL All monitoring data together
United Kingdom	UK	Children	4-18	Monitoring data UK All monitoring data together

2.5 Probabilistic modeling of dietary exposure to single triazoles

When performing a risk assessment of compounds like triazoles a probabilistic approach provides the closest approximation of the real exposure to these compounds. A probabilistic approach is suitable because of the large variability in many components of the risk assessment database: some people eat more of a certain food than average, some batches of food contain higher concentrations of pesticide residues than average, and some unit portions contain lower concentrations of pesticide residues than average. Moreover, in a cumulative assessment it is unlikely that all individual compounds will be at a high value simultaneously, as would be assumed in typical deterministic approaches.

Probabilistic exposure assessments require the use of statistical programs. In acute assessments a common approach is to combine consumption and concentration distributions by Monte Carlo simulation. In chronic assessments a crucial step is to reconstruct the usual intake distribution from the observed data on multiple days per person. In this study the Monte Carlo Risk Assessment (MCRA) program was used, a program suitable for both acute and chronic exposure assessment (De Boer and Van der Voet 2007). The program is available on the internet for registered users[1], and is connected to an electronic platform of food consumption and chemical concentration databases. In this section we describe the existing MCRA system for single compounds, and in the next section adaptations for cumulative exposure assessment.

[1] MCRA Monte Carlo Risk Assessment (http://mcra.rikilt.wur.nl)

To estimate **acute exposure** to single chemicals, MCRA uses Monte Carlo (MC) simulation: individual food consumption records are resampled from food consumption databases and combined with concentration distributions (empirical or fitted distributions). Sampled food consumption amounts of different foods and food forms (e.g. apple peeled, apple juice, apple sauce) are portioned into standard-sized units (each of size "portion size") using a list of unit weights; residue concentrations are modified by processing and variability factors to incorporate processing and unit-to-unit variability, respectively. For example, the unit weight of apples is 112 grams (see Annex 6), and an individual who reported consuming 250 grams of apples would be recorded as having consuming 3 "portions" of apples, two of "portion size" 112 grams and one of "portion size" 26 grams[2]. The basic exposure calculation for this individual on this day is:

$$y_{ik} = \frac{\sum_{j}^{foods} \sum_{h}^{proctypes} \sum_{l}^{portions} portionsize_{jhil} \cdot pf_{jhk} \cdot svf_{ijhkl} \cdot residueconc_{ijhkl}}{BW_i} \qquad (1)$$

where y_{ik} is the exposure on personday i for compound k; $portion\ size_{jhil}$ is the amount in portion l of the randomly sampled consumption level of food j with processing type h on person day I; $residueconc_{ijkh}$ is the randomly sampled residue concentration of compound k in food j and processing type h on person day i ; pf_{jhk} is a fixed processing factor for compound k in food j of processing type h; svf_{ijhkl} is a stochastic variability factor sampled from a distribution for unit variability, for compound k in portion l of food j and processing type h on person day I; and BW_i is the body weight of person i. The processing factors used in this study are listed in Annex 4. Stochastic variability factors are values associated with concentrations in individual portions and reflect variability among individual items which comprise a given consumed amount. The variability between the portions in the consumed amount is taken equal to the variability between units in a composite sample. While the traditional variability factor is defined as the ratio between the concentration in the 97.5th percentile item in a composite and the mean of that composite (see annex 5 for the values used), the stochastic variability factors used in the MCRA model are sampled from a statistical distribution (in this work a lognormal distribution was used), and more appropriately reflect the natural variation that may be seen in concentrations in individual items that occur in a composite sample. The MCRA manual (De Boer and Van der Voet 2007) describes how a variability factor is transformed to the variance parameter of a lognormal distribution, from which a stochastic variability factor *svf* can be repeatedly generated and sampled in the simulations[3]. The resulting simulated exposure distribution reflects the variability of the underlying data. Inference about the population at risk can be derived from this distribution.

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[2] Note that each "portion size" would be associated with its own stochastic variability factor (drawn from a distribution of stochastic variability factors specific to the food commodity item) and its own residue concentration

[3] Briefly, a traditional variability factor is defined as the ratio between the 97.5 percentile concentration of the individual measurements making up a composite sample to the mean concentration of that composite sample. Given an assumed lognormal distribution for residues making up that composite, the ratio of the 97.5 percentile concentration (p97.5) to the (arithmetic) mean concentration can be estimated as follows:

$$v = \frac{p97.5}{mean} = \frac{\exp(\mu + 1.96\sigma)}{\exp(\mu + \frac{1}{2}\sigma^2)} = \exp(1.96\sigma - \frac{1}{2}\sigma^2)$$

where μ and σ are the corresponding (arithmetic) mean and standard deviation of the *log-transformed* concentrations. The above equation is solved for σ and the distribution of stochastic variability factors for use in

To estimate **chronic exposure** to chemicals, basically three methods are implemented in MCRA, all of which analyse the data set of daily exposures calculated as

$$y_{itk} = \frac{\sum_{j}^{foods} \sum_{h}^{proctypes} consumption_{itjh} \cdot pf_{jhk} \cdot residueconc_{jhk}}{BW_i} \qquad (2)$$

where y_{itk} is the exposure on day t of person i for compound k, $consumption_{itjh}$ is the consumed level of food j with processing h on day t of person i, and $residueconc_{jhk}$ is the average concentration of compound k in food j with processing h. It may be noted that for chronic risk concentration variability is not relevant and that division of the consumed amounts in separate portions is unnecessary. The exposures are calculated for multiple days per individual. The resulting exposure values are analyzed, usually after data transformation, to derive a chronic exposure distribution by variance component modeling to discern between-individual and within-individual (between-day) components.

The first method of analysis is a simple approach: all day exposures are averaged per individual, and the resulting distribution of observed invidual means (OIM) is interpreted as the chronic exposure distribution. However, the observed individual means are more variable than the true long-term exposures unless there are many measured days per individual (which is typically not the case). Consequently, high percentiles in the OIM distribution are expected to be conservative (too high). The second method of analysis is a parametric approach: exposure frequencies (frequencies of exposure >0) are modelled using a beta binomial model. Then, positive exposure amounts are transformed to approximate normality and the usual intake distribution is derived. Both exposure frequency and the amount distribution may be related to a covariable (e.g. age) and/or cofactor (e.g. sex) to obtain covariable- and/or cofactor-dependent estimates. This model is referred to as the Beta Binomial Normal (BBN) model (De Boer and van der Voet 2007) and is similar to the model proposed by Slob (Slob 2006). The third method of analysis is referred to as the ISUF model, and is a discrete/semi-parametric approach following the basic ideas of Nusser et al. (Nusser et al. 1996; Nusser et al. 1997) and Dodd (Dodd 1996). In this project the BBN and ISUF models were used for chronic exposure assessments, and the ISUF model was considered to be preferable for MRL assessments, because of lack of normality even after a simple transformation. This model provides a larger flexibility in modeling the distributional form of usual intakes. The long term exposure results presented in Section 3.3 and 3.4 are therefore all based on the ISUF model. However, recent research indicate that also the ISUF model may not always be optimal for estimating percentiles of a non-normal exposure distribution (De Boer et al, in prep.), although in many practical cases no problems are expected.

Equation (1) is defined as a lognormal distribution with an geometric mean of e^{μ} and a geometric standard deviation of e^{σ}. For example, assume that a composite sample of apples is measured and found to contain a concentration of 2 µg/kg for apples. The variability factor for apples is 3.6 (per Annex 5). Solving the above equation for σ, we find that σ = 0.83 (the smaller of the two roots, 3.09 and 0.83). Thus the stochastic variability factor for this composite sample is drawn from a lognormal distribution with a geometric mean 1.42 (calculated as $\exp(\ln(2) - 0.5*(0.83)^2$ as seen in the above equation) and a GSD of exp(0.83) = 2.3. The coefficient of variation associated with this lognormal distribution can be calculated as CV= $\sqrt{(\exp(\sigma^2) -1)}$ or 1.05. Note the lognormal option of MCRA *does not* truncate the distribution at the maximum possible value in the composite because it simulates values for any new apple in the population (not just the apples in the composite sample itself). On the other hand, the maximum possible value for a single apple in a composite of (for example) 15 apples with an average concentration of 2 ppb would be 30 ppb: this would occur if all residues were in one apple from that composite. For this case another distribution can be used in MCRA (the beta model), which was however not used in this study.

However, especially with strongly bimodal data, such as obtained in the field trial scenarios (see Section 2.10), risk assessors may want to use the simple though conservative IOM method as a starting point.

In addition, MCRA offers the possibility to assess the sampling uncertainty of estimates by bootstrap sampling of consumers and/or compound concentration data.

Through model options as unit variability, replacement of values below LOR and the use of processing factors different scenarios can be investigated and compared. Processing factors are used when concentrations in the consumed food differ from the concentrations in the food as measured. In this study processing values are considered as fixed factors and not as distributions.

MCRA delivers concise summaries of input data and resulting output. Percentiles of exposure and uncertainty limits are reported, or percentages based on predefined exposure limits. The contribution of foods to the exposure distribution is quantified, also allowing the user to zoom in on the upper tail of the exposure distribution.

The currently used version of the MCRA program (6.1) is written in C#. For a description of the program and theoretical backgrounds of the statistical methods, see De Boer and Van der Voet (De Boer and Van der Voet 2007).

2.6 Statistical models for cumulative exposure assessment

In this project there was no possibility to collect new data or develop new models. The chosen approach was therefore restricted by current practical possibilities. Two possible approaches (Approach 1 and 2) were addressed. The main difference between the approaches is how to deal with samples in which not all triazoles are analyzed. Approach 1 starts with summing up the concentrations of different triazoles in the same sample according to their corresponding RPF. This accounts for correlations in the use pattern of pesticides. Because in practice not all samples are analyzed for all triazoles it is difficult to assume the 'possible' value of the non analyzed triazoles. Approach 1 considers these triazoles as non-detects (or zero values if we assume that a non-detect is a zero). This might lead to an underestimation of the exposure because in reality those non analyzed triazoles might have been positive values if they had been analyzed. Therefore we pragmatically created an alternative approach which simulates all samples of each triazole separately and finally sums the results of the separate simulations according to the corresponding RPF in a later stage of the cumulative exposure calculations (Approach 2). In this approach the calculation was limited to the number of analyzed values for each triazoles and no assumptions were made for non analyzed triazoles. Because Approach 1 could underestimate the exposure, Approach 2 was used in all calculations, with the exception of the uncertainty analyses as described in Chapter 4. Below more statistical details are given.

Approach 1
A pragmatic approach for a short-term (acute) cumulative exposure assessment the basic Monte Carlo calculation for a large number of simulated individual-days is to calculate:

$$y_i = \frac{\sum_{j}^{foods} \sum_{h}^{proctypes} \left(\sum_{l}^{portions} portionsize_{ijhl} \cdot pf_{jh} \cdot svf_{jhl} \cdot \sum_{k}^{compounds} \left(RPF_k \cdot residueconc_{ijlhk} \right) \right)}{BW_i} \quad (3)$$

where on a given day an individual *i* consumes portions *l* of foods *j* of processing type *h*, which may contain residues from multiple compounds *k*. Individual portions $portionsize_{ijhl}$ are derived from resampled consumption patterns $consumption_{ijh}$ and a dataset of unit weights per food type. The individual has body weight BW_i. Concentrations $residueconc_{ijlhk}$ are resampled from the set of concentrations $residueconc_{ks}$ for compounds *k as* found in samples *s*. Correlations between compounds in the chemical concentrations can be retained by resampling concentration vectors (for all compounds simultaneously) from the set of samples. Residue concentrations are made comparable between compounds by weighing with relative potency factors (RPFs), and may be modified by applying processing factors *pf* and/or stochastic variability factors *svf*.

Approach 1 can be performed when a program for single-compound probabilistic exposure assessment is available. It is only necessary to calculate the RPF-weighted sums of concentrations in the chemical samples as input for a standard single-compound assessment. This approach has been used previously in several studies (Caldas et al. 2006, Boon et al. 2008).

It may be noted that Approach 1 is pragmatic by using the same processing factors *pf* and stochastic variability factors *svf* for all compounds *k*. An improved version of Approach 1 (not applied in this study) would use processing factors that may be different for the compounds and would draw independent stochastic variability factors for each compound by calculating:

$$y_i = \frac{\sum_{j}^{foods} \sum_{h}^{proctypes} \left(\sum_{l}^{portions} portionsize_{ijhl} \cdot \sum_{k}^{compounds} \left(RPF_k \cdot pf_{jhk} \cdot svf_{jhkl} \cdot residueconc_{ijlhk} \right) \right)}{BW_i} \quad (4)$$

Approach 2

This approach considers for each triazole only the samples where measurements for this compound have been made. In this way we avoid the assumption of zero concentrations in non-measured samples that had to be made in Approach 1. The approach can also be used when the residue concentration data are only available without sample identification.

For the acute calculation the residue concentrations are sampled without considering the chemical sample structure. Basically in this case separate exposure assessments will be done for the different triazoles, but the system will use the same sequence of simulated person days in each case, and afterwards it will calculate the RPF-weighted concentrations to be multiplied with each consumption vector.

$$y_i = \sum_{k}^{compounds} \left[RPF_k \cdot \frac{\sum_{j}^{foods} \sum_{h}^{proctypes} \sum_{l}^{portions} portionsize_{ijhl} \cdot pf_{jhk} \cdot svf_{ijhkl} \cdot residueconc_{ijhk}}{BW_i} \right] \quad (5)$$

Note that the residue concentrations are resampled now from different sets of samples *s* for each compound (sampels where compound *k* were not measured are ignored. The calculations in Approach

2 can be performed as a weighted summation over the exposures calculated for the separate compounds, provided the same set of simulated consumers is used.

It should be noted that this way of calculation ignores possible correlations between the intake distributions of the compounds.

Chosen approach for acute risk assessment
The advantage of Approach 1 over Approach 2 is its ability to incorporate correlations between compound concentrations. In principle this leads to lower exposure estimates when such correlations are negative (e.g. when compound A is never sprayed if compound B is being used) and to higher exposure estimates when such correlations are positive (e.g. when compounds A and B are often used as a mixture). A disadvantage of Approach 1 is that assumptions have to be made for non-measured compounds. The typical assumption will be ignore all compounds in the samples for which no measurement effort was made. This may lead to underestimation of the true exposure.

The advantage of Approach 2 over Approach 1 is that underestimation due to a wrong assumption of zero concentration for non-measured compounds is avoided. A second advantage is practical: concentration data may be used for each compound separately, and no identification of chemical samples is necessary. The disadvantage of Approach 2 is of course that correlations are not modelled.

Some preliminary experiments made clear that the differences between results from the two approaches may be large. There is uncertainty whether the assumption of zero concentrations for non-measured triazoles is always warranted. Therefore Approach 2 has been chosen for use in this project. A special program has been written to run MCRA assessments of the separate triazoles, and combine the results for the cumulative assessment.

Approach for chronic risk assessment
Chronic exposure assessment is a more indirect calculation than acute exposure assessment. First, a data set is constructed, then this data set is modelled by a statistical model (either IOM or BBN or ISUF or any other, see 2.5), and finally usual intake distributions are sampled from these statistical models.

For a long-term (chronic) exposure assessment the optimal basic calculation to create the data set of daily intakes for the actual individuals (i) and days (t) in the consumption database would be:

$$y_{it} = \frac{\sum_{j}^{foods} \sum_{h}^{proctypes} \left(consumption_{itjh} \cdot \sum_{k}^{compounds} RPF_k \cdot pf_{jhk} \cdot residueconc_{jk} \right)}{BW_i} \qquad (6)$$

As for acute assessment there is a choice how to use the residue concentration data. Average residue concentrations may be calculated from the total set of samples, assuming zero for both non-detects and non-measurements (as in Approach 1) or from separate sets per compound, assuming zero for non-detects, but ignoring samples where no measurements for this compound have been made (as in Approach 2). Similarly to the choice for acute assessments we have also chosen the latter approach for chronic assessments.

The calculation in equation 6 could not be performed with the existing software, Therefore a simpler calculation was made, by combining compound specific assessments:

$$y_{it} = \sum_{k}^{compounds} \left[RPF_k \cdot \frac{\sum_{j}^{foods} \sum_{h}^{proctypes} consumption_{itjh} \cdot pf_{jhk} \cdot residueconc_{jk}}{BW_i} \right] \quad (7)$$

Relative contributions to cumulative exposure
The total exposure to triazoles can be decomposed in two ways:
1) What are the relative contributions from the diverse compounds?
2) What are the relative contributions from the diverse foods?
These contributions will be estimated from a 2–way table specifying the exposure from each compound/food combination.

2.7 Relative Potency Factors

EFSA delivered the RPF factors, listed in Table 4, based on no-observed adverse effect levels (NOAELs) and dose-response modeling (benchmark dose; BMD). The index compound for acute toxic effects is flusilazole and the index compound for chronic effects is cyproconazole. Consequently the results of all intake assessments in this report are expressed as µg equivalents of the index compound.

For the triazoles addressed the common mechanism of actions was cranio-facial malformation for acute effects and hepatoxicity for chronic effects. At the period the calculation were performed EFSA could not indicated whether the acute or chronic effects were based on a common mechanism. Relevant information on the mechanism is lacking for some of the compounds. We therefore refer to a common assessment group instead of a common mechanism group.

When the toxic potency of each chemical within the group of pesticides - sharing a common mechanism of action - is determined, the relative potencies of all compounds of the group are established. To determine the relative potency for a chemical, one chemical from the common mechanism group (CMG) or common assessment group (CAG) is selected to serve as the index compound. The index compound is used as the point of reference for standardizing the toxic potency of the other chemical members of the CAG or CMG. Once the index compound is selected, relative potency factors (RPFs) are calculated (i.e., the ratio of the toxic potency of a given chemical relative to that of the index compound).

RPFs are used to convert exposures of all chemicals in the CAC or CMG into exposure equivalents of the index compound. Given that the RPF method portrays risk as exposure equivalents to one chemical (the index compound), it is preferred that the index compound: (1) has high-quality dose-response data; (2) has a toxicological/biological profile for the toxic effects that is representative of the toxic effect(s) the substances have in common; and (3) is well characterized for the common mechanism of toxicity (Callahan and Sexton 2007).

Table 4. Relative potency factors (RPF) based on benchmark doses (BMD) and no-observed adverse effect levels (NOAEL) for acute and chronic toxic effects. The RPFs refer to the relative toxicity compared to the index compound flusilazole for the toxic effect cranio-facial malformations for acute and cyproconazole for the chronic effect of hepatoxicity.

	RPFs		
	Acute		Chronic
Compound	BMD	NOAEL	NOAEL
Flusilazole[a]	1.0	1.0	4.0
Bitertanol	2.1	1.7	2.0
Cyproconazole[b]	2.2	4.2	1.0
Diniconazole	1.0	0.6	0.4
Epoxiconazole	1.5	0.8	2.5
Propiconazole	0.1	1.7	0.6
Triadimefon	1.2	1.0	0.1
Difenoconazole			2.0
Myclobutanil			0.05
Tebuconazole			0.1
Triadimenol			0.4

[a] *Flusilazole = index compound derivation acute RPFs*

[b] *Cyproconazole = index compound derivation chronic RPFs*

When the toxic potency of each chemical within the group of pesticides - sharing a common mechanism of action - is determined, the relative potencies of all compounds of the group are established. To determine the relative potency for a chemical, one chemical from the common mechanism group (CMG) or common assessment group (CAG) is selected to serve as the index compound. The index compound is used as the point of reference for standardizing the toxic potency.

2.8 Processing and variability factors

Where available the data were extracted from the relevant DARs and JMPR evaluations. The processing factors were either determined through specific 'nature and magnitude of residues' studies, or calculated from the results of supervised residue trials where the distribution of residues in the RAC had been studied, or additional processed commodities had been analyzed. No data were available for cyproconazole as the notified use was on wheat (giving residues below 0.1 mg/kg) and no JMPR report was available. Similarly diniconazole-M is used as seed treatment on cereals. Residues are not sufficiently high to require processing studies. The processing factors used in the assessment are listed in Annex 4.

A default variability factor of 3.6 was used for the calculations with the monitoring results (EFSA 2005). The UK consumer risk assessment models provided a number of specific variability factors, as well as a list of init weights. See Annex 5 for variability factors and unit weights used per RAC.

2.9 Uncertainties

In this report we address various sources of uncertainty according to the principles mentioned in the Opinion of the Scientific Committee related to uncertainties in dietary exposure assessment (EFSA 2006).

Model uncertainty
For two sets of food consumption and residue concentration data both approaches described in Section 2.6 will be applied to study differences in exposure. Also the differences between the two available models within MCRA to model long-term exposure (BBN vs. ISUF) will be addressed (described in Section 2.5), as well as two different approaches to model unit variability. Results of these simulations are described in Section 4.4.1.

Assigning residue levels to samples with a level below LOR (non-detects)
To show the effect of assigning levels to non-detects on the overall cumulative exposure, we performed calculations assigning either zero or ½ LOR to the non-detects of a selected RAC-pesticide combination. In the US levels are assigned based on the percentage of the crop that has been treated with the pesticide (EPA 2000). Due to absence of such statistics within the EU, we assumed that 10%, 50% or 100% of the selected RAC was treated with the pesticide. The calculations were performed for acute exposure using BMD-derived RPFs and are described in Section 4.4.2.

Monitoring and consumption data
In this report we address the uncertainty related to the completeness of monitoring and the representativeness of the data used. This was done by comparing the scenarios where consumption data were linked to both the 'all monitoring together' database and the national monitoring databases. Results are described in Section 4.3.

Another source of uncertainty is the limited size of the dataset for both residue concentration data and food consumption data. To quantify these uncertainties in the exposure, we examined the uncertainty in both data sources by using the bootstrap method (Efron 1979; Efron and Tibshirani 1993). With this method a bootstrap database is generated of the same size as the original database for both food consumption and residue levels by sampling with replacement from the original datasets. These bootstrap databases are considered as databases that could have been obtained from the original population if another sample was randomly drawn. These two bootstrap databases are then used for the exposure calculations and derivation of the relevant percentiles. Repeating this process many times results in a bootstrap distribution for each percentile that allows for the derivation of confidence intervals around it.

Table 5. Scheme of bootstrapping to demonstrate the effect of small / large residue and food consumption databases on the uncertainty in the resulting exposure percentiles.

Residue database	Bootstrap	Food consumption database	Bootstrap
Small database	Yes	Large database	No
Large database	Yes	Large database	No
Large database	No	Small database	Yes
Large database	No	Large database	Yes

In this report we either bootstrapped residue concentration or consumption data of either a small or large residue concentration, respectively food consumption database. In this way we could examine the effect of a small residue concentration database on the uncertainty in the resulting exposure percentiles compared to a large residue concentration database, keeping the consumption database constant. The same was done for the food consumption database keeping the residue concentration database constant. See Table 5 for the four scenarios.

In all four scenarios, we generated either 100 food consumption or 100 residue bootstrap databases and calculated the acute cumulative (with 100,000 iterations each) exposure. Of the resulting bootstrap distributions per percentile we calculated a 95% uncertainty interval by computing the 2.5% and 97.5% points of the empirical distribution. The uncertainty analysis using the bootstrap approach could only be applied to the approach where the residue levels were summed up per sample for the calculation of the cumulative exposure (Approach 1). With Approach 2 where the exposure distributions per compound are summed up, uncertainty analyses have not yet been implemented. See Section 4.4.3 for the results.

2.10 MRLs, STMR and field trial data used in the cumulative intake assessments

MRL, STMR or field trial data for different RAC-pesticide combination and monitoring data for all other combinations were used as input for the cumulative intake calculations. For acute exposure modeling this was the MRL, while for chronic exposure modeling the field trial data as such were used in the calculations. If these data were not available, the STMR was used in the chronic calculations, and if this level was not available the MRL. In practice, however, there were no situations in which the STMR was available while there were no field trial data. Therefore in the chronic calculations we used the field trial data, and in some cases the MRL. The field trial data were derived from JMPR reports and DARs, while the MRLs were derived from MRL regulation 396/2005. For a list of MRLs and field trial data used in the exposure calculations, see Annex 6. Field trial residue levels below LOR were assigned a level equal to LOR. For all the other RAC-pesticide combinations we used monitoring data, assigning zero to levels below LOR.

In acute exposure modeling for MRL setting especially those people consuming the RAC of interest should be protected, the so-called consumers-only approach. We included in the acute cumulative exposure calculations therefore only those consumption days at which consumption of the relevant

RAC was recorded. So in the case of the combination wheat – epoxiconazole only those consumption days were included in the analysis on which at least wheat was consumed. For the chronic assessment, however, we included all days in the analysis. This was done because on the long run it is reasonable to expect that everybody will be a consumer of all RACs considered.

The analyses were performed for different countries and subpopulations, combining national food consumption data with the 'all monitoring together' database. Based on a request of EFSA also the subpopulations adults (18-64 years) and women of child-bearing age (15-45 years) were addressed in the calculations. This last group was selected because of its relevance regarding the acute toxicological endpoint (cranio-facial effects) for the foetus on which the BMD-derived RPFs are based. For reasons of comparison this group was also addressed when using NOAEL-derived RPFs.

3 Results

The results of the 24 scenarios (Table 3) are listed in three different tables presenting a range of percentiles of estimated exposure. The 95th percentile (p95) of the estimated exposure means that on 1 out of 20 days an intake equal or above the listed value is expected. Similarly, the p99.9 of exposure means on 1 out of 1,000 days the estimated exposure is expected to be equal to or above the listed intake. Ultimately it is the task of risk managers to decide on the most appropriate percentile(s) to consider. For illustrative purposes only we stress the 99.9th percentile (p99.9) in this report.
The contribution of different RACs and triazoles to the (average) estimated cumulative exposure are presented in this chapter. This was done for acute exposure calculations based on monitoring residue concentration data, and both BMD- and NOAEL-derived RPFs. The percentiles for estimated chronic exposure are based on monitoring data and NOAEL-derived RPFs.

3.1 Short-term or acute intake calculations using monitoring results and BMD-derived RPFs

3.1.1 Estimated exposure distributions

Table 6 lists the most relevant percentiles of estimated exposure regarding acute exposure to triazoles using BMD-derived RPFs for different national (sub)populations. Residue concentration data used are either national data or all national residue concentration data pooled together.

Table 6 shows clear national differences in estimated exposure between the different countries. Although the monitoring in each country is prescribed by the European Commission, there are many known and unknown differences between the Member States in the number of samples taken annually, the way of sampling (at random, targeted) and analytical methods used when analysing the samples. The highest P99.9 level of estimated exposure was calculated for French children (8.8 µg equivalents of flusilazole/kg bw/d), while the lowest was calculated for the adult population in Sweden (0.9 µg equivalents of flusilazole/kg bw/d). Furthermore linking all residue concentration data to national food consumption data instead of the national data tended to result in either higher (CZ, IT, SE), lower (FR, UK) or comparable (NL) P99.9 levels of estimated cumulative exposure to triazoles. It is also evident that children tended to have the highest estimated exposure levels in each country. In the Netherlands babies aged 8 – 12 months had the highest level of estimated cumulative exposure (Table 6).

3.1.2 Contribution of RACs and individual triazoles

In Table 7 we list the top four RACs contributing most to the estimated exposure for all 24 scenarios linking national consumption databases to the ‘all monitoring together’ database. Banana, pineapple, tomato and wheat were the RACs contributing most to the average cumulative intake of triazoles in the different countries and populations.

Table 6. Percentiles and mean level of estimated acute cumulative exposure (µg equivalents of flusilazole/kg bw/d) to triazoles for different countries and different age groups using monitoring results and BMD-derived RPFs[a].

Country[b]	Population[b]	Age range (years)	Origin residue data[c]	Percentiles of estimated exposure (µg equivalents of flusilazole/kg bw/d)							
				50	90	95	97.5	99	**99.9**	99.99	Mean
CZ	Children	4-9	All	0	0.0	0.1	0.3	1.0	**4.5**	11.4	0.04
CZ	Children	4-9	CZ	0	0.0	0.0	0.0	0.2	**4.0**	9.7	0.02
CZ	Over 10 years	10-90	All	0	0.0	0.0	0.1	0.3	**1.7**	5.0	0.01
CZ	Over 10 years	10-90	CZ	0	0.0	0.0	0.0	0.0	**1.2**	3.8	0.00
FR	Children	3-6	All	0	0.0	0.0	0.1	0.7	**5.2**	17.0	0.03
FR	Children	3-6	FR	0	0.0	0.0	0.1	1.3	**8.8**	24.8	0.05
FR	Over 7 years	7-92	All	0	0.0	0.0	0.1	0.3	**2.1**	6.7	0.01
FR	Over 7 years	7-92	FR	0	0.0	0.0	0.1	0.3	**3.0**	9.2	0.02
IT	Children	1-17	All	0	0.0	0.1	0.1	0.5	**6.1**	25.9	0.04
IT	Children	1-17	IT	0	0.0	0.0	0.0	0.1	**4.0**	36.2	0.02
IT	Adults	18-64	All	0	0.0	0.0	0.1	0.2	**3.6**	16.0	0.02
IT	Adults	18-64	IT	0	0.0	0.0	0.0	0.0	**2.4**	19.2	0.01
NL	Babies	8-12[d]	All	0	0.1	0.4	0.8	1.9	**7.2**	19.2	0.09
NL	Babies	8-12	NL	0	0.1	0.2	0.5	1.2	**6.5**	17.9	0.06
NL	Children	1-6	All	0	0.0	0.1	0.3	0.8	**4.5**	13.8	0.04
NL	Children	1-6	NL	0	0.0	0.1	0.2	0.5	**4.0**	14.9	0.03
NL	Total	1-97	All	0	0.0	0.0	0.1	0.2	**1.6**	6.1	0.01
NL	Total	1-97	NL	0	0.0	0.0	0.1	0.2	**1.5**	6.4	0.01
SE	Children	3-13	All	0	0.0	0.1	0.3	0.7	**3.5**	12.0	0.03
SE	Children	3-13	SE	0	0.0	0.0	0.1	0.3	**1.8**	6.5	0.01
SE	Adults	17-79	All	0	0.0	0.1	0.2	0.5	**2.0**	5.0	0.02
SE	Adults	17-79	SE	0	0.0	0.0	0.0	0.1	**0.9**	2.4	0.01
UK	Children	4-18	All	0	0.0	0.0	0.1	0.4	**3.4**	11.9	0.02
UK	Children	4-18	UK	0	0.0	0.1	0.3	0.8	**5.0**	17.3	0.04

[a] *BMD = benchmark dose; RPF = relative potency factor*

[b] *For abbreviations of countries, see Table 3.*

[c] *All: all national monitoring residue concentration data are combined*

[d] *Age range in months*

Table 7. Contribution (%) of top four RACs[a] to the estimated cumulative acute exposure to triazoles for different countries and populations. Results are based on linking national food consumption databases to the 'all monitoring residue' database and BMD-derived RPFs[b].

Country[c]	Population[c]	RACs					
		Top 1	%	Top 2	%	Top 3	%
CZ	Children	Banana	18	Table grapes	18	Parsley	18
CZ	Over 10 years	Banana	41	Pineapple	23	Tomato	11
FR	Children	Banana	46	Pineapple	33	Tomato	8
FR	Over 7 years	Pineapple	39	Banana	32	Tomato	11
IT	Children	Tomato	57	Banana	19	Pineapple	11
IT	Adults	Tomato	66	Banana	11	Pineapple	5
NL	Babies	Banana	54	Pineapple	33	Apple	4
NL	Children	Pineapple	40	Banana	36	Apple	7
NL	Total	Pineapple	43	Banana	24	Tomato	12
SE	Children	Pineapple	52	Banana	21	Tomato	14
SE	Adults	Wheat	43	Pineapple	30	Banana	12
UK	Children	Pineapple	62	Banana	18	Tomato	10

[a] *RAC = raw agricultural commodity*

[b] *BMD = benchmark dose; RPF = relative potency factor*

[c] *For abbreviations of countries see Table 3 and ages of populations addressed, see Table 6.*

Table 8 lists the compounds that were responsible for the high contribution of the listed RACs (Table 7) to the overall estimated cumulative to triazoles. In the 75% of the calculations bitertanol was the residue most commonly found.

For banana and tomato bitertanol was the compound responsible for their high contribution to the overall estimated cumulative exposure. For pineapple the responsible compound was triadimefon and for carrots epoxiconazole. For table grapes there are more compounds explaining the high intake: dinicozole, flusilazole and cyproconazole. In all cases we have only listed those compounds contributing most. In case of the table grapes diniconazole was the largest contributor. We refer to Annex 7 for a more comprehensive overview of combinations of food items and pesticides contributing to the total intake. It is stressed that the total intake is considered. If focus is required on the upper end of the intake distribution, where most the higher intake occur, the contributions of food and pesticides will change.

Table 8. Contribution (%) of top four compounds to the estimated cumulative acute exposure to triazoles for different countries and populations. Results are based on linking national food consumption databases to the 'all monitoring residue' database and BMD-derived RPFs[a].

Country[b]	Population[b]	RACs					
		Top 1	%	Top 2	%	Top 3	%
CZ	Children	Bitertanol	70.0	Triadimefon	21.4	Cyproconazole	3.8
CZ	Over 10 years	Bitertanol	64.8	Triadimefon	23.1	Propiconazole	4.6
FR	Children	Bitertanol	59.3	Triadimefon	33.5	Propiconazole	3.5
FR	Over 7 years	Bitertanol	50.9	Triadimefon	39.1	Propiconazole	4.9
IT	Children	Bitertanol	83.0	Triadimefon	11.5	Propiconazole	2.7
IT	Adults	Bitertanol	87.4	Triadimefon	5.2	Propiconazole	2.9
NL	Babies	Bitertanol	62.9	Triadimefon	33.7	Epoxiconazole	0.9
NL	Children	Bitertanol	51.7	Triadimefon	40.7	Propiconazole	2.7
NL	Total	Bitertanol	45.3	Triadimefon	44.2	Propiconazole	3.7
SE	Children	Triadimefon	52.6	Bitertanol	42.6	Propiconazole	2.5
SE	Adults	Propiconazole	45.5	Triadimefon	31.4	Bitertanol	19.4
UK	Children	Triadimefon	62.1	Bitertanol	33.2	Propiconazole	2.3

[a] *BMD = benchmark dose; RPF = relative potency factor*

[b] *For abbreviations of countries see Table 3 and ages of populations addressed, see Table 6.*

In most of the scenario bitertanol is the risk driver and. In only the scenario addressing the Swedish adults, propiconazole was the risk driver. This can be explained by the relative large RPF factor for bitertanol (based on BMD) and the number of food items in which bitertanol was found (see Annex 1).

3.2 Short-term or acute intake calculations using monitoring results and NOAEL-derived RPFs

3.2.1 Estimated exposure distributions

In Table 9 we listed the acute estimated exposure to triazoles using NOAEL-derived RPFs. Using NOAEL-derived RPFs appears to result generally in slightly lower or comparable percentiles of exposure compared to BMD-derived RPFs.

The same conclusions can be drawn from Table 9 as were drawn from Table 6 as described in Section 3.1.1. Furthermore, on average the P99.9 level of exposure tended to be higher when using NOAEL-derived RPFs compared to BMD-derived RPFs, 3.7 vs 3.2 µg equivalents of flusilazole/kg bw/d. The difference between the levels of estimated exposure between the two approaches ranged from -0.1 µg equivalents of flusilazole/kg bw/d for Swedish children (3.6 vs 3.5 µg equivalents of flusilazole/kg

bw/d for BMD- and NOAEL-derived RPFs respectively) up to 1.3 µg equivalents of flusilazole/kg bw/d for French children (8.8 vs 7.5 µg equivalents of flusilazole/kg bw/d).

Table 9. Percentiles and mean level of estimated exposure of acute estimated cumulative exposure (µg equivalents of flusilazole/kg bw/d) to triazoles for different countries and different age groups using monitoring results and NOAEL-derived RPFs[a].

Country[b]	Population[b]	Age range (years)	Origin residue Data[c]	Percentiles of estimated exposure (µg equivalents of flusilazole/kg bw/d)							
				50	90	95	97.5	99	**99.9**	99.99	mean
CZ	Children	4-9	All	0	0.1	0.3	0.6	1.1	**3.8**	9.4	0.054
CZ	Children	4-9	CZ	0	0.0	0.0	0.0	0.2	**3.3**	8.0	0.014
CZ	Over 10 years	10-90	All	0	0.0	0.1	0.2	0.5	**1.5**	4.0	0.020
CZ	Over 10 years	10-90	CZ	0	0.0	0.0	0.0	0.0	**1.0**	2.9	0.004
FR	Children	3-6	All	0	0.0	0.1	0.5	1.2	**4.5**	13.6	0.046
FR	Children	3-6	FR	0	0.0	0.3	0.8	1.7	**7.5**	20.3	0.078
FR	Over 7 years	7-92	All	0	0.0	0.0	0.2	0.6	**2.1**	6.2	0.022
FR	Over 7 years	7-92	FR	0	0.0	0.1	0.4	0.8	**2.8**	8.5	0.033
IT	Children	1-17	All	0	0.0	0.1	0.4	0.9	**5.5**	24.6	0.047
IT	Children	1-17	IT	0	0.0	0.0	0.0	0.1	**2.9**	29.9	0.019
IT	Adults	18-64	All	0	0.0	0.1	0.2	0.5	**2.9**	11.6	0.025
IT	Adults	18-64	IT	0	0.0	0.0	0.0	0.0	**1.9**	16.6	0.010
NL	Babies	8-12[d]	All	0	0.1	0.4	0.8	1.6	**6.3**	17.4	0.084
NL	Babies	8-12[d]	NL	0	0.0	0.2	0.4	1.1	**5.7**	15.3	0.052
NL	Children	1-6	All	0	0.1	0.2	0.5	1.0	**3.8**	11.9	0.051
NL	Children	1-6	NL	0	0.0	0.1	0.2	0.4	**3.5**	11.7	0.029
NL	Total	1-97	All	0	0.0	0.1	0.2	0.4	**1.5**	5.1	0.019
NL	Total	1-97	NL	0	0.0	0.0	0.1	0.2	**1.3**	5.2	0.011
SE	Children	3-13	All	0	0.0	0.2	0.4	0.9	**3.6**	10.4	0.042
SE	Children	3-13	SE	0	0.0	0.0	0.1	0.2	**1.4**	5.3	0.012
SE	Adults	17-79	All	0	0.0	0.1	0.2	0.5	**1.6**	4.1	0.025
SE	Adults	17-79	SE	0	0.0	0.0	0.0	0.1	**0.7**	2.0	0.005
UK	Children	4-18	All	0	0.0	0.1	0.3	0.6	**2.8**	10.5	0.028
UK	Children	4-18	UK	0	0.0	0.1	0.3	0.6	**4.2**	16.3	0.035

[a] *NOAEL = no-observed adverse effect level; RPF = relative potency factor*

[b] *For abbreviations of countries, see Table 3.*

[c] *All: all national monitoring residue concentration data are lumped together*

3.2.2 Contribution of RACs and individual triazoles

Table 10 lists the top 3 RACs contributing most to the estimated exposure for all 12 scenarios linking national consumption databases to the 'all monitoring together' database using NOAEL-derived RPFs. Wheat was the RAC that contributed significantly to the average cumulative intake of triazoles in some scenarios, followed by banana, tomato or pineapple depending on country and population addressed.

Table 10. Contribution (%) of top 3 RACs[a] to the cumulative estimated acute cumulative exposure to triazoles for different countries and populations. Results are based on linking national food consumption databases to the 'all monitoring residue' database and NOAEL-derived RPFs[b].

Country[c]	Population[c]	Top 1	%	Top 2	%	Top 3	%
CZ	Children	Wheat	36	Banana	34	Pineapple	13
CZ	Over 10 years	Wheat	47	Banana	21	Pineapple	12
FR	Children	Wheat	43	Banana	26	Pineapple	20
FR	Over 7 years	Wheat	50	Pineapple	20	Banana	16
IT	Children	Tomato	38	Wheat	34	Banana	13
IT	Adults	Tomato	41	Wheat	47	Banana	7
NL	Babies	Banana	46	Pineapple	29	Wheat	13
NL	Children	Wheat	35	Pineapple	27	Banana	22
NL	Total	Wheat	42	Pineapple	25	Banana	13
SE	Children	Pineapple	34	Wheat	33	Banana	15
SE	Adults	Barley	30	Wheat	23	Sweet Pepper	19
UK	Children	Pineapple	43	Wheat	32	Banana	12

[a] *RAC = raw agricultural commodity*

[b] *NOAEL = no-observed adverse effect level; RPF = relative potency factor*

[c] *For abbreviations of countries and ages of populations addressed, see Table 3.*

Table 11. Contribution (%) of top three pesticides to the estimated acute cumulative exposure to triazoles for different countries and populations. Results are based on linking national food consumption databases to the 'all monitoring residue' database and NOAEL -derived RPFs[a].

Country[b]	Population[b]	Pesticides					
		Top 1	%	Top 2	%	Top 3	%
CZ	Children	Bitertanol	43.7	Propiconazole	36.8	Triadimefon	13.0
CZ	Over 10 years	Propiconazole	48.1	Bitertanol	33.1	Triadimefon	12.2
FR	Children	Propiconazole	43.2	Bitertanol	33.9	Triadimefon	19.7
FR	Over 7 years	Propiconazole	50.5	Bitertanol	25.7	Triadimefon	19.9
IT	Children	Bitertanol	55.4	Propiconazole	34.2	Triadimefon	7.4
IT	Adults	Bitertanol	54.1	Propiconazole	37.4	Cyproconazole	3.8
NL	Babies	Bitertanol	52.8	Triadimefon	29.1	Propiconazole	15.6
NL	Children	Propiconazole	36.0	Bitertanol	32.1	Triadimefon	27.3

Country[b]	Population[b]	Pesticides					
		Top 1	%	Top 2	%	Top 3	%
NL	Total	Propiconazole	43.7	Triadimefon	25.9	Bitertanol	25.0
SE	Children	Triadimefon	35.2	Propiconazole	34.1	Bitertanol	28.4
SE	Adults	Bitertanol	49.7	Propiconazole	34.2	Triadimefon	12.5
UK	Children	Triadimefon	43.0	Propiconazole	32.6	Bitertanol	21.9

[a] *BMD = benchmark dose; RPF = relative potency factor*

[b] *For abbreviations of countries see Table 3 and ages of populations addressed, see Table 6.*

In all countries the high contribution of wheat was due to the presence of propiconazole. Other relevant compounds were bitertanol (in banana and tomato) and triadimefon (in pineapple).

Propiconazole was more or less an equal important risk driver compared to bitertanol as we used the NOAEL derived RPFs. In Table 8 bitertanol was found to drive the risk. The difference is mainly explained by the difference between the RPF factor of propioconazole derived from BMD or NOAELs. When the RPF factors were derived from BMD-modeling propiconazole was ten times less toxic compared to the index compound and consequently it did not contribute largely to the overall intake. However when we compared the toxicity (RPF) based on comparison of NOAELs, propiconazole was nearly twice as toxic as the index compound (see Table 4). In France propiconazole was found in wheat, a food item that is consumed in large quantities by relative large part of the population.

3.3 Long-term or chronic intake calculations using monitoring results and NOAEL-derived RPFs

3.3.1 Estimated exposure distributions

In Table 12 we listed the percentiles of estimated chronic exposure to triazoles using NOAEL-derived RPFs. It is clear that the estimated exposure levels were lower compared to the estimated acute exposure percentiles as expected (Tables 6 and 9), and that also here children tended to have higher estimated exposure levels compared to the total population. Also, combining all residue concentration data instead of national residue concentration data to national food consumption data tended to result in higher, lower or comparable P99.9 levels of exposure. The main difference however was that for UK children the estimated exposure was comparable, while in the acute assessment the intake was higher using UK residue concentration data compared to all residue concentration data combined.

3.3.2 Contribution of RACs and individual compounds

Table 13 lists the top 3 RACs contributing most to the cumulative long-term estimated exposure to triazoles. As for the acute assessment using NOAEL-derived RPFs, also in the chronic analysis (which uses other NOAEL-derived RPFs, see Table 4) it was banana that contributed most to the estimated exposure, followed by tomato, pineapple and wheat depending on country and (sub)population addressed. For estimated long-term exposure, the presence of bitertanol resulted in the high

contribution of banana to the estimated cumulative exposure to triazoles. A list of most important pesticides contributing to the overall chronic exposure levels is presented in Table 14.

Table 12. Percentiles and mean level of estimated chronic cumulative exposure (µg equivalent of cyproconazole/kg bw/d) combining monitoring results and food consumption data from different countries, using NOAEL-derived RPFs[a].

Country[b]	Population[b]	Age range (years)	Origin residue data[c]	Estimated exposure (µg equivalent of cyproconazole /kg bw/d)							
				50	90	95	97.5	99	**99.9**	99.99	mean
CZ	Children	4-9	All	0.1	0.1	0.2	0.2	0.2	**0.3**	0.3	0.073
CZ	Children	4-9	CZ	0.0	0.1	0.1	0.1	0.1	**0.1**	0.1	0.029
CZ	Over 10 years	10-90	All	0.0	0.0	0.1	0.1	0.1	**0.1**	0.1	0.022
CZ	Over 10 years	10-90	CZ	0.0	0.0	0.0	0.0	0.0	**0.1**	0.1	0.007
FR	Children	3-6	All	0.0	0.1	0.1	0.1	0.1	**0.2**	0.2	0.037
FR	Children	3-6	FR	0.1	0.1	0.1	0.2	0.4	**0.5**	0.6	0.058
FR	Over 7 years	7-92	All	0.0	0.0	0.0	0.1	0.1	**0.1**	0.1	0.018
FR	Over 7 years	7-92	FR	0.0	0.1	0.1	0.2	0.2	**0.3**	0.4	0.029
IT	Children	1-17	All	0.0	0.1	0.1	0.1	0.1	**0.2**	0.2	0.045
IT	Children	1-17	IT	0.0	0.0	0.0	0.0	0.0	**0.1**	0.1	0.013
IT	Adults	18-64	All	0.0	0.0	0.1	0.1	0.1	**0.1**	0.1	0.026
IT	Adults	18-64	IT	0.0	0.0	0.0	0.0	0.0	**0.0**	0.0	0.008
NL	Children	1-6	All	0.0	0.1	0.1	0.2	0.2	**0.3**	0.3	0.056
NL	Children	1-6	NL	0.0	0.1	0.1	0.1	0.2	**0.3**	0.3	0.043
NL	Total	1-97	All	0.0	0.0	0.1	0.1	0.1	**0.1**	0.2	0.019
NL	Total	1-97	NL	0.0	0.0	0.0	0.1	0.1	**0.1**	0.1	0.017
SE	Children	3-13	All	0.0	0.1	0.1	0.1	0.1	**0.2**	0.2	0.037
SE	Children	3-13	SE	0.0	0.0	0.0	0.0	0.0	**0.1**	0.1	0.012
SE	Adults	17-79	All	0.0	0.1	0.1	0.1	0.1	**0.2**	0.2	0.031
SE	Adults	17-79	SE	0.0	0.0	0.0	0.0	0.0	**0.0**	0.0	0.005
UK	Children	4-18	All	0.0	0.0	0.1	0.1	0.1	**0.2**	0.2	0.022
UK	Children	4-18	UK	0.0	0.1	0.1	0.1	0.2	**0.3**	0.3	0.025

[a] *NOAEL = no-observed adverse effect level; RPF = relative potency factor*

[b] *For abbreviations of countries and ages of the populations addressed, see Table 3.*

[c] *All: all national monitoring residue concentration data are lumped together*

Table 13. Contribution (%) of top 3 RACs[a] to the estimated cumulative long-term exposure to triazoles for different countries and populations. Results are based on linking national food consumption databases to the 'all monitoring residue' database and NOAEL-derived RPFs[b].

Country[c]	Population[c]	RACs					
		Top 1	%	Top 2	%	Top 3	%
CZ	Children	Banana	51.2	Parsley	10.9	Wheat	8.6
CZ	Over 10 years	Banana	38.1	Wheat	13.4	Parsley	11.6
FR	Children	Banana	31.9	Wheat	16.1	Pineapple	12.3
FR	Over 7 years	Banana	20.1	Wheat	18.2	Pineapple	13.4
IT	Children	Tomato	33.2	Banana	27.1	Wheat	11.3
IT	Adults	Tomato	34.4	Banana	13.9	Wheat	11.4
NL	Children	Banana	40.4	Pineapple	12	Apple	10.7
NL	Total	Banana	25.1	Pineapple	14.5	Wheat	12.4
SE	Children	Banana	33.4	Pineapple	23.5	Tomato	11.1
SE	Adults	Banana	50.5	Tomato	12.6	Wheat	7.9
UK	Children	Banana	28.4	Pineapple	27.3	Wheat	11.5

[a] *RAC = raw agricultural commodity*

Table 14. Contribution (%) of top three pesticides to the estimated cumulative long-term exposure to triazoles for different countries and populations. Results are based on linking national food consumption databases to the 'all monitoring residue' database and NOAEL-derived RPFs

Country	Population	Pesticides					
		Top 1	%	Top 2	%	Top 3	%
CZ	Children	Bitertanol	58.4	Difenoconazole	19.1	Propiconazole	8.8
CZ	Over 10 years	Bitertanol	47.8	Difenoconazole	21.4	Propiconazole	13.6
FR	Children	Bitertanol	43.8	Propiconazole	16.3	Difenoconazole	15.3
FR	Over 7 years	Bitertanol	31.8	Difenoconazole	20.1	Propiconazole	18.3
IT	Children	Bitertanol	55.7	Difenoconazole	13.8	Triadimenol	13.5
IT	Adults	Bitertanol	44.3	Difenoconazole	22.2	Triadimenol	14.1
NL	Children	Bitertanol	52.9	Triadimenol	15.7	Difenoconazole	12.7
NL	Total	Bitertanol	37.5	Triadimenol	18.4	Difenoconazole	18.1
SE	Children	Bitertanol	47.4	Triadimenol	25.3	Propiconazole	11.4
SE	Adults	Bitertanol	65.0	Triadimenol	11.0	Difenoconazole	8.4
UK	Children	Bitertanol	39.6	Triadimenol	27.1	Difenoconazole	12.2

3.4 Short- and long-term intake calculations using MRLs, STMR or Field Trail data in combination with monitoring data for other RACs

New pesticides need to be evaluated before their use can be authorised. In such cases no monitoring data are available and the evaluator has to judge on the basis of analytical results of field trial studies. To study the use of estimated cumulative exposure modeling for MRL setting of pesticides belonging to a common mechanism group, we used the MRL or individual field trial data for selected RAC-pesticide combination. The RAC-pesticide combinations were selected based on their relevance for the estimated cumulative exposure to triazoles (Tables 7, 8, 10, 11, 13 and 14), as well as on wishes expressed by EFSA. For all other RAC-pesticide combinations monitoring data were used. Table 15 lists the selected combinations for the acute and chronic exposure modeling.

Table 15. Scenarios for replacing compound – RAC[a] combinations with MRL[b] or field trial data.

Scenario	Compound	RAC	Type of exposure estimates		Residue data	
			Acute	Chronic	Acute	Chronic
1	Bitertanol	Apple	+	+	MRL	FT[c]
2		Banana	+	+	MRL	FT
3		Tomato	+	+	MRL	FT
4	Cyproconazole	Table grape	+	+	MRL	FT
5		Lettuce	+	+	MRL	MRL
6		Peach	+	-	MRL	-
7	Diniconazole	Table grape	-	+	-	MRL
8	Epoxiconazole	Cabbage	+	-	MRL	-
9		Wheat	+	+	MRL	FT

[a] *RAC = raw agricultural commodity*

[b] *MRL = maximum residue limit*

[c] *FT = field trial data*

For the combinations listed in Table 15 the MRL, or field trial data for the mentioned RAC-pesticide combination and monitoring data for all other combinations were used as input for the calculations. For acute exposure modeling this was the MRL, while for chronic exposure modeling the field trial data as such were used in the calculations. If these data were not available, the MRL was used.

3.4.1 RAC-pesticide combinations using MRLs in acute exposure modeling

In Table 16 and 17 we listed the estimated acute cumulative exposure percentiles for different countries and populations in which the MRL of one RAC-pesticide combination was used in combination with monitoring data for all other RAC-pesticide combinations. Calculations are based on BMD- and NOAEL-derived RPFs, respectively.

Table 16. Percentiles and mean level of estimated acute cumulative exposure (in µg equivalents of flusilazole/kg bw/d) to triazoles in which MRL data for a selected RAC-pesticide was used in combination with monitoring data of other combinations. Calculations were performed using BMD-derived RPF, national food consumption data and residue concentration data of all countries combined.

Scenario	Country	Population	Age range (years)	Estimated exposure (µg equivalent of flusilazole/kg bw/d)						
				90	95	97.5	99	**99.9**	99.99	Mean
Bit/Apple/MRL	CZ	Children	4-9	47.2	64.3	83.5	112.4	204.6	333.6	21.3
Bit/Apple/MRL	FR	Children	3-6	37.9	58.5	81.4	114.5	218.7	364.3	13.4
Bit/Apple/MRL	IT	Children	1-17	33.3	49.8	70.1	102.3	210.7	348.2	12.2
Bit/Apple/MRL	NL	Children	1-6	31.1	47.7	66.6	95.3	196.3	345.1	10.6
Bit/Apple/MRL	SE	Children	3-13	45.3	64.1	84.8	115.2	206.2	315.3	16.7
Bit/Apple/MRL	UK	Children	4-18	22.5	33.6	46.6	67.0	137.8	240.9	8.1
Bit/Apple/MRL	FR	Adults	18-64	22.0	30.6	39.9	53.0	90.4	133.9	8.6
Bit/Apple/MRL	IT	Adults	18-64	22.4	30.2	38.7	51.5	90.6	136.6	9.4
Bit/Apple/MRL	NL	Adults	18-64	11.7	17.0	23.0	31.6	59.1	94.5	4.1
Bit/Apple/MRL	FR	Wmcba	15-45	21.1	29.0	37.5	49.6	85.9	136.1	8.0
Bit/Apple/MRL	IT	Wmcba	15-45	23.5	31.8	40.8	53.9	93.4	143.7	9.5
Bit/Apple/MRL	NL	Wmcba	15-45	11.1	16.6	22.7	31.8	60.3	98.2	3.8
Bit/Apple/MRL	NL	Total	1-97	14.1	21.7	31.3	47.3	112.6	211.9	5.2
Bit/Banana/MRL	NL	Total	1-97	9.8	15.9	24.3	39.1	93.8	176.2	3.7
Bit/Tomato/MRL	NL	Children	1-6	34.3	68.5	99.2	199.3	317.5	317.7	14.5
Bit/Tomato/MRL	NL	Wmcba	15-45	20.8	34.9	54.0	84.4	196.0	264.6	8.2
Bit/Tomato/MRL	NL	Total	1-97	19.5	32.3	50.7	83.1	202.9	317.5	7.6
Cyp/T-grape/MRL	NL	Children	1-6	1.3	2.4	3.9	6.5	18.4	45.6	0.5
Cyp/T-grape/MRL	NL	Wmcba	15-45	0.6	1.0	1.5	2.4	6.1	13.0	0.2
Cyp/Lettuce/MRL	NL	Children	1-6	0.6	0.9	1.2	1.7	3.9	9.1	0.3
Cyp/Lettuce/MRL	NL	Wmcba	15-45	0.2	0.3	0.5	0.8	2.0	5.3	0.1
Cyp/Peach/MRL	NL	Children	1-6	0.1	0.3	0.6	1.3	5.7	16.2	0.1
Cyp/Peach/MRL	NL	Wmcba	15-45	0.1	0.2	0.4	0.7	2.1	6.4	0.0
Epox/cabbage/MRL	NL	Children	1-6	1.9	3.1	4.5	6.8	15.4	29.7	0.8
Epox/cabbage/MRL	NL	Wmcba	15-45	0.8	1.2	1.8	2.7	6.7	14.6	0.3
Epox/wheat/MRL	NL	Total	1-97	1.1	1.4	1.7	2.1	3.4	7.5	0.6

Results show a large increase in estimated exposure levels compared to using only monitoring data. For example, the P99.9 of estimated exposure in Czech children increased from 4.5 (Table 6) to 204.5 µg equivalents of flusilazole/kg bw/d (Table 16) for the apple –bitertanol scenario, an increase with a factor 45. This increase was also due to the fact that we only included consumption days only in the

calculations. In such a calculation scenario everybody consumes the RAC for which an MRL is set. Consequently everybody has a positive intake. In Table 6 only about 5% of the population has a positive exposure. Many consumptions levels are multiplied with a zero concentration due to the presence of many zero values in the monitoring residue concentration database.

In the calculations, similar subpopulations covering the same age range (adults and women of child-bearing age) were examined. This shows that the estimated exposure percentiles, independent of the RPFs applied, were in the same order of magnitude in the different countries. For example, the P99.9 of estimated exposure for women of child-bearing age using BMD-derived RPFs was 85.9, 93.4 and 60.3 µg equivalents of flusilazole/kg bw/d in France, Italy and the Netherlands, respectively. For the subgroup adults the figures were 90.4, 90.6 and 59.1 µg equivalents of flusilazole/kg bw/d, respectively. The results obtained with NOAEL-derived RPFs tabulated in Table 17 show a similar picture. Estimated exposure levels calculated by using RPF derived from NOAEL are usually lower compared to the same calculations based on RPF derived from BMD for the scenarios in which an MRL was set for bitertanol. The RPF factor for bitertanol is 1.7 and 2.1 for the calculation based on NOAEL and BMD information respectively. A lower RPF factor for the major contributor bitertanol resulted in a lower estimated exposure level. The opposite is found in scenarios in which an MRL is set for cyproconazole. The P99.9 estimated exposure in Dutch children is estimated to be 7.4 and 5.7 µg equivalents of flusilazole/kg bw/d using RPFs derived from NOAEL and BMD respectively. Again this correlates with the magnitude of the RPFs which are 4.2 when derived from NOAEL and 2.2. when derived from BMDs.

We also calculated the contribution of the RACs and pesticides to the overall cumulative estimated exposure to triazoles for all combinations listed in Table 17 using both the NOAEL derived RPFs. In all scenarios the RAC - pesticide combination for which the MRL value was used as input for the exposure assessment contributed most to the total exposure. An extensive overview is given in Annex 7. In Table 18 we listed the contributions of the three major RAC-pesticide contributions for a few typical exposure scenarios. For the scenarios in which an MRL was set for bitertanol, the exposure levels were relatively high. For example, the P99.9 in children varied between 110.7 and 174.0 µg equivalents of flusilazole/kg bw/d. The MRL set at 2 mg/kg is approximately a factor 1000 to 2000 higher than the monitoring results for the other triazoles.

However in many cases the ratio between the MRL and the monitoring results is much smaller. The MRL proposed for cyproconazole in peaches is 0.1 mg/kg and a typical monitoring value is 0.03 mg/kg. In those cases the contribution of other RAC-pesticide combinations to the total estimated average exposure levels is larger.

Table 18 lists the estimated exposure levels at the overall average exposure levels. It would be interesting to know the contributions of different RAC-pesticide combinations at the upper tail of the distributions for each person individually (e.g. consumers exceeding toxicological reference values), but due to current limitation in the software this result cannot be provided yet, although information about all RACs eaten by a particular person around a certain percentile of exposure can be obtained. Estimated exposure levels are mainly caused by one RAC-pesticide combination. However in a few cases small or major contributions from more than one RAC - pesticide combination can be expected. How often this appears will depend on how often the pesticide is found and whether the RACs in which the pesticides are found are frequently eaten.

Table 17. Percentiles and mean level of estimated acute cumulative exposure (in µg equivalents of flusilazole/kg bw/d) to triazoles in which MRL[a] data for a selected RAC[b]-pesticide was used in combination with monitoring data of other combinations. Calculations were performed using NOAEL-derived RPFs[c], national food consumption data and residue concentration data of all countries combined.

Scenario	Country	Population	Age range (years)	Estimated exposure (µg equivalent of flusilazole/kg bw/d)						
				90	95	97.5	99	**99.9**	99.99	Mean
Bit/Apple/MRL	CZ	Children	4-9	38.2	52.1	67.8	91.5	167.4	272.1	17.2
Bit/Apple/MRL	FR	Children	3-6	30.8	47.5	66.0	92.6	174.0	288.6	10.8
Bit/Apple/MRL	IT	Children	1-17	26.9	40.3	56.5	82.6	170.0	282.4	9.9
Bit/Apple/MRL	NL	Children	1-6	25.2	38.5	53.9	77.3	158.3	280.9	8.6
Bit/Apple/MRL	SE	Children	3-13	36.7	52.0	68.6	93.5	167.7	266.6	11.8
Bit/Apple/MRL	UK	Children	4-18	18.2	27.3	37.8	54.1	110.7	190.2	13.6
Bit/Apple/MRL	FR	Adults	18-64	17.9	24.8	32.4	43.0	72.7	111.9	7.0
Bit/Apple/MRL	IT	Adults	18-64	18.1	24.5	31.4	41.8	74.4	114.0	7.6
Bit/Apple/MRL	NL	Adults	18-64	9.4	13.7	18.5	25.5	47.8	78.4	3.4
Bit/Apple/MRL	FR	Wmcba	15-45	17.1	23.5	30.5	40.4	69.6	109.8	6.5
Bit/Apple/MRL	IT	Wmcba	15-45	19.1	25.8	33.1	43.7	75.1	115.6	7.7
Bit/Apple/MRL	NL	Wmcba	15-45	9.0	13.5	18.4	25.8	49.0	82.9	3.1
Bit/Apple/MRL	NL	Total	1-97	11.4	17.6	25.2	38.1	88.0	171.1	4.2
Bit/Banana/MRL	NL	Total	1-97	7.9	13.0	19.8	31.8	75.8	144.4	3.0
Bit/Tomato/MRL	NL	Children	1-6	28.0	56.2	81.0	161.5	257.0	257.9	11.8
Bit/Tomato/MRL	NL	Wmcba	15-45	17.0	28.6	43.7	68.2	158.7	214.2	6.6
Bit/Tomato/MRL	NL	Total	1-97	15.8	26.2	41.0	67.3	164.6	257.0	6.2
Cyp/T-grape/MRL	NL	Children	1-6	2.4	4.5	7.2	12.1	35.7	89.2	0.9
Cyp/T-grape/MRL	NL	Wmcba	15-45	1.1	1.8	2.8	4.5	11.5	23.8	0.4
Cyp/Lettuce/MRL	NL	Children	1-6	1.1	1.6	2.1	2.9	5.7	9.9	0.5
Cyp/Lettuce/MRL	NL	Wmcba	15-45	0.4	0.6	0.9	1.3	2.9	5.8	0.2
Cyp/Peach/MRL	NL	Children	1-6	0.2	0.5	0.9	1.8	7.4	17.6	0.1
Cyp/Peach/MRL	NL	Wmcba	15-45	0.2	0.3	0.6	1.1	3.2	7.5	0.1
Epox/Cabbage/MRL	NL	Children	1-6	1.1	1.7	2.5	3.7	8.4	16.9	0.4
Epox/Cabbage/MRL	NL	Wmcba	15-45	0.4	0.7	1.0	1.5	3.6	8.1	0.2
Epox/Wheat/MRL	NL	Total	1-97	0.6	0.8	1.0	1.2	2.3	5.7	0.3

[a] *MRL = maximum residue limits. For the MRLs used in the calculations, see Annex 6.*

[b] *RAC = raw agricultural commodity*

[c] *NOAEL = no-observed adverse effect level; RPF = relative potency factor*

Table 18 Examples of RAC-pesticide combinations contributing to the total acute exposure in cases where the MRL or Field Trial data of one RAC was used as input in combination with monitoring results from all other food items.. Calculations were performed on a consumers only basis.

Scenario	Country	Population	Contribution of RAC-pesticide combination to total intake.		
			RAC[a]	Compound	%
NOAEL-derived RPFs					
Bitertanol MRL in apple	FR	children	Apple	Bitertanol	91.6
			Wheat	Propiconazole	0.2
			Banana	Bitertanol	0.2
Bitertanol MRLin apple	NL	Wmca	Apple	Bitertanol	99.4
			Wheat	Propiconazole	0.2
			Pineapple	Triadimefon	0.2
Bitertanol MRL in tomato	NL	Childeren	Tomato	Bitertanol	99.6
			Wheat	Propiconazole	0.2
			Pineapple	Triadimefon	0.2
Cyproconazole MRL in peach	NL	Children	Peach	Cyproconazole	59.0
			Pineapple	Triadimefon	13.2
			Wheat	Propiconazole	12.9
Epoxiconazole MRL in wheat	NL	Total	Wheat	Epoxiconazole	94.2
			Wheat	Propiconazole	2.5
			Pineapple	Triadimefon	1.5

[a] *RAC = raw agricultural commodity*

3.4.2 RAC-pesticide combinations using MRLs in the estimated chronic exposure

The calculations described in Section 3.4.1 were also performed for long-term intake. In these calculations field trial data were used for selected RAC-pesticide combinations in combination with monitoring data for all other RACs (Table 15). If field trial data were not available, the MRL was used. Calculations were performed using the ISUF model (Section 2.5). Results are listed in Table 19.

Using MRL or field trial data of a particular RAC-pesticide combination as input for the calculation resulted also in the long-term or chronic cumulative exposure calculations in an increase in estimated exposure levels compared to using only monitoring data, although less pronounced as for the acute calculations.

Table 19 Percentiles and mean level of estimated chronic cumulative exposure (in µg equivalent of cyproconazole/kg bw/d) to triazoles in which Field Trial or MRL[a] data of selected RAC[b]- pesticide combinations was used in combination with monitoring results for other combinations. Calculations were performed using NOAEL-derived RPFs[c], national food consumption data and residue concentration data of all countries combined.

Scenario	Country[e]	Population[e]	Age range (years)	Estimated exposure (µg equivalent of cyproconazole /kg bw/d)					
				90	95	99	**99.9**	99.99	Mean
Bit/Apple/FT	CZ	Children	4-9	1.4	1.6	2.0	**2.5**	2.5	0.8
Bit/Apple/FT	FR	Children	3-6	1.0	1.3	1.9	**2.7**	2.9	0.5
Bit/Apple/FT	IT	Children	1-17	0.8	1.1	1.7	**2.6**	2.7	0.3
Bit/Apple/FT	NL	Children	1-6	3.7	4.7	7.0	**8.5**	8.7	1.5
Bit/Apple/FT	SE	Children	3-13	1.9	2.4	3.5	**4.8**	5.1	0.8
Bit/Apple/FT	UK	Children	4-18	0.7	1.0	1.7	**2.7**	2.9	0.3
Bit/Apple/FT	FR	Adults	18-64	0.5	0.6	0.9	**1.4**	1.5	0.2
Bit/Apple/FT	IT	Adults	18-64	0.5	0.7	1.0	**1.4**	1.5	0.2
Bit/Apple/FT	NL	Adults	18-64	0.5	0.7	1.0	**1.3**	1.3	0.2
Bit/Apple/FT	NL	Total	1-97	0.9	1.2	2.1	**3.4**	3.7	0.3
Bit/Banana/FT	NL	Total	1-97	0.2	0.3	0.8	**1.3**	1.4	0.1
Bit/Tomato/FT	NL	Children	1-6	2.5	3.3	5.2	**6.5**	6.6	1.1
Bit/Tomato/FT	NL	Adult	15-45	1.4	1.9	2.9	**3.8**	3.8	0.7
Bit/Tomato/FT	NL	Total	1-97	1.5	1.9	3.1	**4.4**	4.7	0.7
Cyp/T-grape/FT	NL	Total	1-97	0.1	0.2	0.4	**0.6**	0.6	0.1
Cyp/Lettuce/MRL	NL	Children	1-6	0.1	0.1	0.2	**0.4**	0.7	0.0
Cyp/Lettuce/MRL	NL	Adults	18-64	0.0	0.0	0.1	**0.1**	0.1	0.0
Dini/T-grape/MRL	NL	Total	1-97	0.1	0.1	0.2	**0.4**	0.4	0.0
Epox/Wheat/FT	CZ	Children	4-9	0.8	0.9	1.1	**1.3**	1.3	0.6
Epox/Wheat/FT	FR	Children	3-6	0.8	0.9	1.2	**1.5**	1.5	0.5
Epox/Wheat/FT	IT	Children	1-17	0.7	0.8	1.0	**1.2**	1.2	0.5
Epox/Wheat/FT	NL	Children	1-6	0.7	0.8	1.1	**1.2**	1.3	0.5
Epox/Wheat/FT	SE	Children	3-13	0.6	0.7	0.8	**1.1**	1.1	0.4
Epox/Wheat/FT	UK	Children	4-18	0.4	0.5	0.6	**0.8**	0.8	0.2
Epox/Wheat/FT	NL	Total	1-97	0.4	0.4	0.6	**0.8**	0.8	0.2

[a] MRL = maximum residue limits.and Field Trial (FT) see also Annex 6 for the data used

[b] RAC = raw agricultural commodity [c] NOAEL = no-observed adverse effect level; RPF = Relative potency factor [d] For an explanation of the scenarios see Table 15.

[e] For abbreviations of countries and ages of the (sub)populations children and total, see Table 3. The age range of the subpopulation adults was 18-64 years.

For example, the P99.9 in again Czech children increased from 0.4 (Table 12) to 2.5 µg equivalents of cyproconazole/kg bw/d, an increase with a factor 6.2. Also here, when examining comparable subpopulations like adults, the estimated exposure between countries was comparable. For example, the P99.9 of estimated exposure in the apple – bitertanol scenario (scenario 1) for this subpopulation was 1.4, 1.4 and 1.3 µg equivalents of µg equivalents cyproconazole/kg bw/d for France, Italy and the Netherlands, respectively.

Table 20 Examples of RAC-pesticide combinations contributing to the total chronic exposure in cases where the MRL or Field Trial data of one RAC was used as input in combination with monitoring data for RACs. Calculations were based on RFP derived from NOAELs.

Scenario	Country	Population	Contribution of RAC-pesticide combination to total intake.		
			RAC	Compound	%
Bitertanol FTin apple	FR	Children	Apple	Bitertanol	87.7
			Banana	Bitertanol	4.2
			Wheat	Propiconazole	2.0
Bitertanol FTin apple	IT	Adults	Apple	Bitertanol	89.0
			Tomato	Bitertanol	4.4
			Wheat	Propiconazole	1.2
Bitertanol FT in tomato	NL	Childeren	Tomato	Bitertanol	97.4
			Wheat	Propiconazole	0.7
			Pineapple	Triadimefon	0.4
Cyproconazole MRL in lettuce	NL	Children	Banana	Bitertanol	22.2
			Pineapple	Triadimenol	10.7
			Wheat	Propiconazole	10.0
Epoxiconazole FT in wheat	NL	Children	Wheat	Epoxiconazole	90.9
			Banana	Bitertanol	1.3
			Wheat	Propiconazole	1.2

When examining the contribution of RACs and pesticides to the estimated long-term exposure for the different scenarios, countries and subpopulations, the largest contributions originated in the majority of cases from the RAC-pesticide combinations for which field trial data were used instead of monitoring data (Annex 8). Examples of typical RAC-pesticide combination are given in Table 20. The contributions ranged from 75.3 to 98.6% for the scenarios in which field trial data for bitertanol were used (see Annex 8). The field trial data for bitertanol is relatively high compared to the monitoring data for bitertanol. In other scenarios, e.g. when field trial data for cyproconazole in lettuce were used as input, other and more RAC-pesticide combinations contributed to the total exposure in equally percentages. Table 20 provides only an overview of contribution to the overall estimated exposure levels for one day, while in reality chronic exposure is related to life-long exposure and consequently a particular consumer will be exposed to many combinations of RAC-pesticide during a lifelong period. The contributions of RAC-pesticide combination to long-term exposure, however, can

not be overviewed because food consumption data are only available for a period of 2-7 days. Based on the variation between and within individuals exposure levels statistical extrapolations are made to long-term exposure levels and due to the nature of the modeling information of which RAC-pesticide combination is contributing to the long-term exposure is lost consequently.

4 Discussion

4.1 RPF approach

To calculate the cumulative exposure to triazoles, we used the relative potency factor (RPF) approach. There are other methods available to assess the cumulative exposure as summarised in the report of the EFSA Colloquium (EFSA 2007), as well as in a recent opinion of the EFSA PPR Panel (EFSA 2008).

The PPR Panel concluded that the most useful methods to assess the cumulative exposure to compounds belonging to a common mechanism group were in increasing levels of complexity and refinement, the HI, the RfPI, the RPF approach and physiologically-based toxicokinetic (PBTK) modeling (EFSA 2008). However, the last type of modeling is presently very resource intensive and demanding of specialised expertise. It is therefore unlikely to be routinely used in the near future (EFSA 2008). In this report we used the second best model, the RPF approach. In this approach the relative potency of each compound is expressed relative to an index compound. In this report the RPFs were supplied by EFSA. The derivation of these factors will therefore not be discussed in this report, including whether the condition of dose-additivity was met. This will be addressed in an EFSA opinion on the application of the suggested (tiered) cumulative exposure approach as described in (EFSA 2008).

When RPFs are available, we showed that these factors can be used to perform both acute and chronic cumulative exposure assessments, by combining the RPF approach with the probabilistic approach. We demonstrated that with this approach we could calculate the cumulative exposure for different countries and (sub)populations using either national and international (all national monitoring data combined) monitoring data addressing the whole diet and all compounds simultaneously. We also demonstrated the possible application of this approach in the regulatory field of pesticides by using MRLs (acute and chronic) or field trial data (chronic) for particular RAC-pesticide combinations. In these simulations, we used for all the other pesticide – RAC combinations monitoring data. Furthermore, in acute modeling we mimicked the consumers-only approach as used in deterministic estimations of exposure for MRL setting by only including those consumption days at which at least the consumption of the RAC of interest was recorded. In this way an estimated exposure distribution was generated containing only positive exposure levels.

It should be noted that in the present approach all RACs consumed on one day were combined, and the time-course of the exposure was not addressed. This includes for example whether the effect of a compound ingested during breakfast is still present when a compound of the same mechanism group is ingested during dinner. Also whether compounds ingested yesterday are still present the next day. Examination of this was outside the scope of this project, but can play a further role in refining exposure scenarios if information on toxicokinetics and / or -dynamics might become available. It was stated in the EFSA opinion that this was not expected to be a major refinement (EFSA 2008).

4.2 MRL-setting and a tiered approach

In the opinion of the EFSA PPR panel the use of a tiered approach, for both toxicological evaluation and exposure estimation, is advocated to perform a cumulative risk assessment (EFSA 2008). In this way the best and most efficient use of the available sources is made.

In a **tiered approach of exposure estimation** the first step is normally based on a very conservative estimate of exposure, which, if needed, can be refined in subsequent steps by using extra information (e.g. processing factors), more realistic data (e.g. instead of a conservative estimate of consumption a distribution of actual consumption levels) or more refined models (e.g. deterministic vs. probabilistic models). When going through the tiers, the resulting exposure estimates will become increasingly more realistic, ranging from one high level of estimated exposure to a probabilistic characterisation of estimated exposures for individual members of the relevant population.

EFSA proposes to use deterministic models based on fixed (conservative) consumption and residue levels as a first tier and using probabilistic modeling in combination with the RPF-method as a fourth tier. We did not test the relation between the deterministic and probabilistic models, although a further elaboration on this relationship is very important. An important issue is that in a tiered approach a first tier should be more conservative compared to the next tiers. Testing and comparing those tiers is recommended.

In this report we performed exposure modeling by combining national food consumption databases with different types of residue concentration data, including MRL, field trial data and monitoring data. These types of data can be used in different situations, e.g. to calculate the actual exposure or possible exposure levels when establishing new MRLs. In Figure 1 we plotted the estimated cumulative long-term exposure to triazoles for the total Dutch population using these three types of data. For reasons of comparison we also included here the estimated exposure when using the STMR. MRL, STMR and field trial data were included for epoxiconale in wheat. For the other RAC-pesticide combinations monitoring data were used derived from all national data available. It is clear that the estimated exposure decreased with an increasing level of refinement of the residue concentration data. Using the MRL resulted in very high percentiles of exposure compared to the other three types of input data, while monitoring data resulted in the lowest levels of estimated exposure. Wheat is a RAC that is consumed on more than 90% of the consumption days in the Dutch database, and monitoring levels of epoxiconazole were all below the limit of reporting (LOR). Replacing these levels with one high level like the MRL will result in a large increase in the estimated exposure. The increase in exposure when using STMR or field trial data instead of monitoring data was less pronounced but still large.

In the acute assessments, use of the MRL for a specific RAC–pesticide combination resulted also in a higher level of estimated exposure compared to monitoring data (Tables 16 and 17). Apart from a higher residue level, this was also due to the inclusion of only those consumption days in the assessment at which at least the RAC in question was consumed, as opposed to all consumption days when including solely monitoring data.

This is a nice example of how incorporating different residue levels affect the estimated exposure. It is clear that residue levels at MRL will result in conservative estimates of exposure, both in acute and chronic scenarios. How conservative will depend on the level of the MRL relative to the monitoring results, and a combination of the amount of and frequency in which the relevant RAC is consumed.

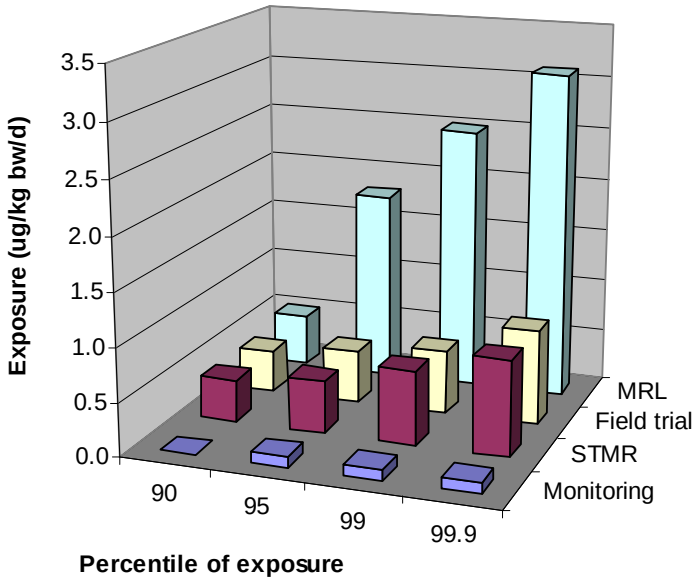

Figure 1. Percentiles of estimated chronic cumulative exposure to triazoles (in µg equivalents of cyproconazole/kg bw/d) in the total Dutch population using either MRL, field trial, STMR or monitoring data for epoxiconazole in wheat. For all the other RAC-pesticide combinations, monitoring data were used.

A possible tier regarding toxicological evaluation is the toxicological data used to derive RPFs. In this report we used for acute cumulative modeling of exposure RPFs that were based on either NOAELs or BMDs. The use of BMD data can be seen as a refinement (= higher tier) compared to NOAELs (EFSA 2008). NOAELs are more easily available from the toxicological literature compared to BMDs, while for the derivation of BMDs, in most cases, additional toxicological experiments and calculations involving dose response modeling need to be available or performed. Furthermore, BMD-derived RPFs represent better the relative toxicity of compounds belonging to a common mechanism group than NOAELs. BMDs represent a uniform level of response across chemicals, since they take into account the shape of the dose response curve and of the variation in the data ((Filipsson et al. 2003) in (EFSA 2008)). NOAELs on the other hand may not be an optimal choice to calculate RPFs because they do not necessarily reflect the relationship between dose and response for a given chemical, nor do they reflect a uniform response across different chemicals (EPA 2005). The 'real' NOAEL may be lower or higher than the observed level due to dosing levels used or insensitivity of the study (Slob and Pieters 1997; Moerbeek et al. 2004). Based on this the cumulative exposure levels calculated with BMD-derived RPFs are likely to be closer to reality.

In the context of a tiered approach estimated exposure levels calculated with NOAEL-derived RPFs should result in higher (= more conservative) estimates of exposure than those based on BMD-derived RPFs . This is however not always the case. In Figure 2 we plotted the estimated acute cumulative exposure to triazoles for the total population of different countries combined with all national residue concentration data using either NOAEL- or BMD-derived RPFs.

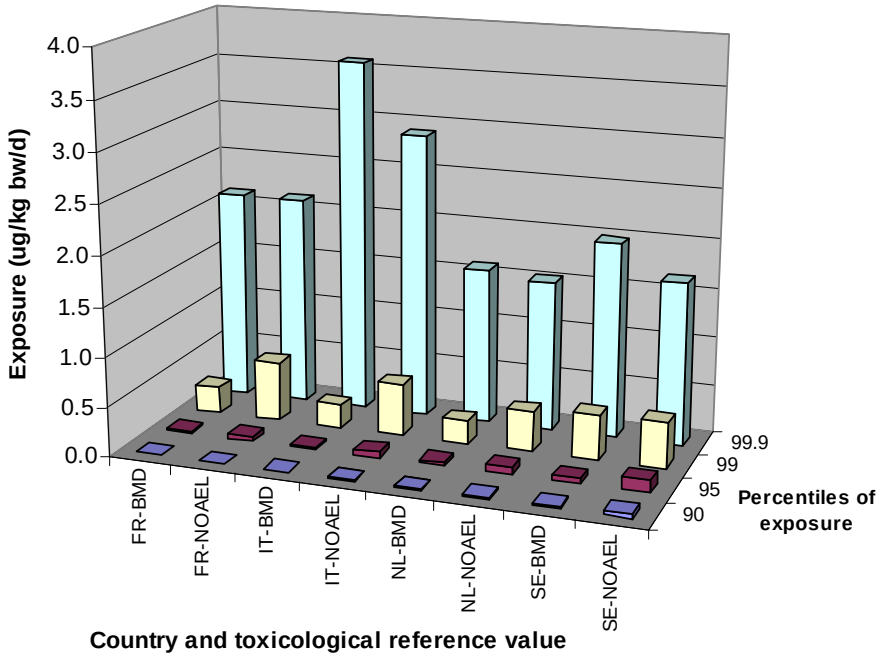

Figure 2. Percentiles of estimated acute cumulative exposure (in µg equivalents of flusilazole/kg bw/d) for different countries using either NOAEL- or BMD derived RPFs.

Calculations with BMD-derived RPFs resulted in either similar (France and the Netherlands) or somewhat higher levels of estimated exposure (Italy, Sweden) as those calculated with the NOAEL-derived RPFs. This shows that the BMD approach does not result always in less conservative levels, and that it should be recognized that using NOAEL-derived RPFs as part of a tiered approach will not necessarily result in a more conservative (= higher) estimate of exposure. It will result in another estimate of exposure that is very likely less close to the 'real' exposure than that derived with the BMD approach, given the characteristics of both approaches.

The differences in estimated exposure between the two approaches are due to differences in the derived RPFs, which can be very large (Table 4). For example, the RPF of propiconazole is either 0.1 or 1.7 depending on whether the RPF is derived from NOAELs or from BMDs. It is not known in advance whether RPFs derived from BMD modeling will result in higher or lower exposures compared to RPFs derived from NOAELs. It is assumed that RPFs derived from NOAEL are more uncertain for example because the risk assessors does not have any information on the range of doses given to the animals and differences in dose concentration given to the test animals (dose spacing).

Apart from resulting in different levels of estimated exposure, this difference also affects the contribution of RACs to the total estimated exposure. For example, based on NOAEL-derived RPFs wheat contributed by far most to the overall acute estimated exposure to triazoles in all countries and (sub)populations (>50%; Table 10). The reason for this was the presence of propiconazole in wheat with a relatively high RPF (1.7; Table 4). When applying BMD-derived RPFs wheat was replaced by banana and pineapple as contributing most to the exposure. Wheat was not important anymore due to the low RPF of propiconazole (0.1).

Examination of the toxicological differences between the NOAEL and BMD-derived RPFs as reported here is necessary, as well as a discussion on which of the approaches results in the most realistic level of estimated exposure of the groups of compounds relative to the toxic effect on which the BMD and NOAEL are based.

4.3 European dimension of the cumulative estimated exposure

In this report we used national food consumption and monitoring data from different European countries, including Czech Republic, France, Italy, the Netherlands, Sweden and the UK. For the estimated exposure calculations national food consumption data were either combined with national monitoring data or with a database in which all national residue concentration data were combined. In this database also monitoring residue concentration data of Finland were included. This database was generated to eliminate uncertainties in the estimated exposure results related to the completeness of the monitoring and differences in monitoring practices in countries, as recognized in the EFSA opinion on acute dietary intake (EFSA 2007).

This issue of differences in national monitoring databases is illustrated in Figure 3, where we plotted in the left panel the acute cumulative estimated exposure for the subpopulation 'children' for all countries combining national food consumption data with national monitoring residue concentration data using BMD-derived RPFs. In the right panel the national residue concentrationdata were replaced by all national monitoring data. In the left panel the estimated exposure levels differ largely per country with relatively high levels of estimated exposure in France and low levels in Sweden. Replacing the national monitoring data with all national monitoring data of all participating countries, the estimated exposure differences were very much reduced and more comparable.

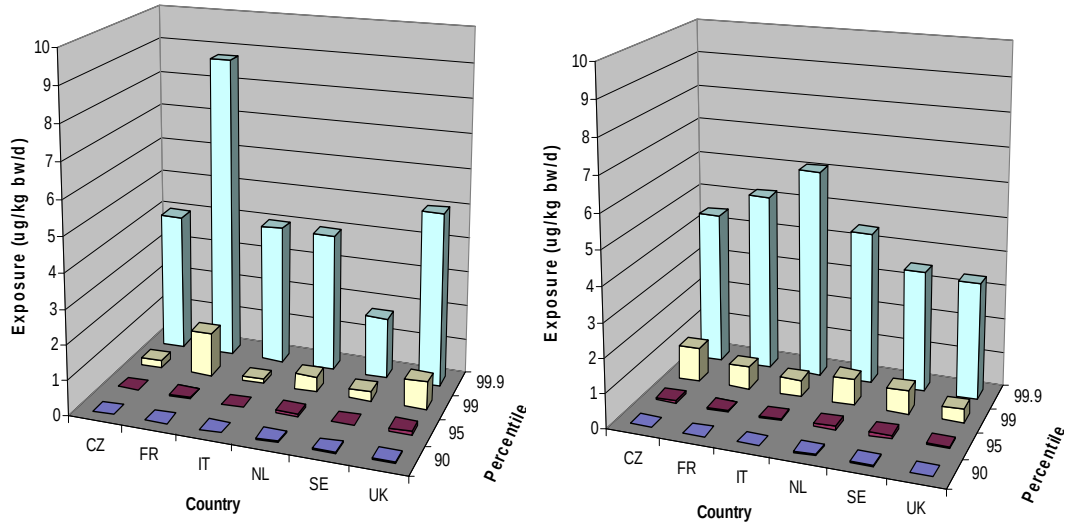

Figure 3. Percentiles of acute cumulative exposure (in µg equivalents of flusilazole/kg bw/d) to triazoles in different countries using either national monitoring residue data (A) or all monitoring data combined (B). The exposure was calculated using exposure BMD-derived

The reasons for these differences are the number of RAC analyzed in each country and the residue levels analysed. It is not known whether some countries might have more targeted monitoring practices compared to other countries. Apart from differences in monitoring practices and residue levels analyzed, there are also differences in dietary surveys that will explain (partly) the differences in estimated exposure. The differences include for example population involved (e.g. the age range of the French children was lower than that of the group children from Sweden (3-6 vs. 3-13 years), method of data collection, and the duration of the study. Also harmonisation at this level is needed to compare exposure assessments between countries.

To be able to link all the national residue concentration data to the different national food consumption databases the food coding of the national food consumption databases were harmonised at RAC level. This was achieved by converting foods coded in the different food consumption databases to their RAC ingredients by linking them to Dutch foods. These foods are in turn converted to RAC level using a food conversion model developed at RIKILT (Van Dooren et al. 1995). RACs are more or less similar in different countries, making harmonisation at that level feasible. However, due to lack of food conversion models in Europe we used the Dutch food conversion model, assuming therefore that similar foods in Europe consist of the same RAC ingredients in equal weight percentages. This is of course an approximation of the truth, but the best option available at this moment. Eventually, it is recommended that each country develops its own food conversion model, including all relevant foods. Apart from that, a food conversion model is also needed to perform exposure calculations for toxic compounds that are predominantly analyzed at RAC level to include also prepared foods in the calculations.

The approach taken in this report to model exposure for different European countries, including the harmonization of food coding and the link to probabilistic software, fits very well in the discussion of harmonizing risk assessment procedures within Europe (SSC 2000; SSC 2003) and the creation of an European data warehouse (EFSA 2005). By harmonizing the food coding in the different national food consumption surveys, as well as the coding of the resulting RACs in both the food consumption and residue concentration databases, the estimated exposure in the different countries was calculated in a harmonized way. This concept was already used in 2007 by EFSA in an opinion on acute intake (EFSA 2007), and extended in this report.

4.4 Uncertainties / sensitivity

4.4.1 Model uncertainties

4.4.1.1 Cumulative exposure: Approach 1 or 2

Two approaches are presently available to calculate the cumulative dietary exposure (Section 2.6). As explained in Section 2.6 each of these approaches has its advantages and disadvantages. In this report we chose Approach 2 because we expected an underestimation of the estimated exposure in some of the scenarios when applying Approach 1. This was mainly due to assumptions regarding the levels assigned to the non analyzed triazoles in this approach (see Section 2.6). Here we compare both approaches for two cases to study if the estimated exposure results are sensitive to the chosen model. The two cases selected were the Dutch and the French exposure assessments, using national residue

concentration data and BMD-derived RPFs. Table 20 gives the results for three selected percentiles of cumulative estimated exposure to triazoles.

Table 20 Selected percentiles of estimated exposure to triazoles for the two approaches of cumulative exposure modeling.

Percentiles of exposure	*The Netherlands*		*France*	
	Approach 1	Approach 2	Approach 1	Approach 2
P95	0.035	0.033	0.007	0.014
P99	0.21	0.19	0.09	0.32
P99.9	1.8	1	2.2	3.0

The results show that for the Dutch assessment there is little difference between the two approaches. For the French assessment however, the estimated exposure with Approach 1 is much lower compared to Approach 2. This result could be expected if many RAC samples are analyzed for only part of the triazoles. The French monitoring data listed in Annex 1 confirm that partial measurement of samples occurred quite often in the French monitoring programme, whereas most samples were analyzed for all triazoles in the Dutch monitoring data (Annex 1). The similarity of the results of Approach 1 and 2 in the Dutch situation seems to indicate that in this case correlation between compounds, which is not addressed in Approach 2, was not a major issue steering the tail of the cumulative distribution. Obviously, this conclusion cannot be generalised without further research, and it remains desirable to develop models allowing for correlation between compounds.

The bigger uncertainty issue related to modeling of (cumulative) exposure is however not so much related to the models used, but to the status of the data sets. It is recommended to develop procedures where the reasons for not analyzing pesticides in a RAC sample are clearly stated, and subsequently used to develop assumptions about the true concentrations for these non-analyzed concentrations. For example, if compounds A and B have, but compounds C, D and E have not, been analyzed in some samples because the latter could be assumed to be absent, then a zero concentration can be used. If the reason was to reduce analytical costs, then concentrations of C, D and E may be assumed to be similar to the rest of the sample population, conditional on the levels of A and B. Statistical techniques exist to incorporate such assumptions in the model (e.g. multiple imputation, see e.g.(Rubin 1996)).

Models to estimate long-term exposure: BBN vs ISUF

In this project two different models available in MCRA to model long-term exposure were compared, namely the Beta Binomial Normal (BBN) model based on Slob (2006), and the ISUF model ((Dodd 1996; Nusser et al. 1996; Nusser et al. 1997)}. See Section 2.5 for a description. The most important difference between the two models is their possibilities to transform the short-term intake distribution to normality. BBN uses for this a logaritmic or power transformation, while ISUF uses more extensive data transformation to achieve normality.

The advantages of the BBN model are that it is a simpler model (uses less calculation time), but most importantly that it can model the effects of a cofactor (e.g. gender) and / or covariable (e.g. age), in the assessment. For example, when estimated exposure levels are expected to be a function of age, BBN may be the preferred method of calculation. All exposure assessments performed in this report were

calculated using both models. However only those calculated with the ISUF approach were reported. The reasoning for this is explained below. In Figure 4 we plotted the long-term cumulative estimated exposure to triazoles for different countries using both models and linking national food consumption data either to all monitoring results (Figure 4A) or to all monitoring results except for the combination of apple – bitertanol. For this combination we replaced the monitoring results by field trial data (Figure 4B). The figures show clearly that the choice of model had little effect on the estimated exposure when solely monitoring data were used in the assessment (Figure 4A).

However, replacing one crop – pesticide combination with field trial data resulted in a much larger increase in estimated exposure using the BBN model compared to the ISUF model (Figure 4B). An explanation for this is the difference in transformation of the short-term intake distribution to normality between the two models. Field trial data (or MRL) are often much higher than the monitoring results and this results in a so called bimodal distribution (see Figure 5). The BBN model is then not applicable because it is based on the assumption of a normal distribution of exposure levels. Whereas the ISUF model applies an additional spline transformation to create an artificial normal distribution, it is currently not known very well if this model will always estimate the usual exposure distribution correctly in strongly bimodal cases. More modeling research is recommended on how to model bimodal distributions. Initial simulation studies preformed so far indicate that the calculated exposure levels calculated with ISUF or BBN are overestimating the real risks in the case of bimodality. If these first indications are confirmed the ISUF and BBN can still be considered as the best option for long-term exposure assessment modeling. In absence of a firm conclusion in this direction at the moment we also applied a more conservative approach which is based on estimating the long-term intake by multiplying the average consumption level of food reported during the food consumption survey with the average residue concentration for that food item for each individual (individual observed means method). This is a conservative approach for the upper percentiles in the distributions. The difference between modeling results obtained with the three models BBN, ISUF and IOM are visualized in Figure 6.

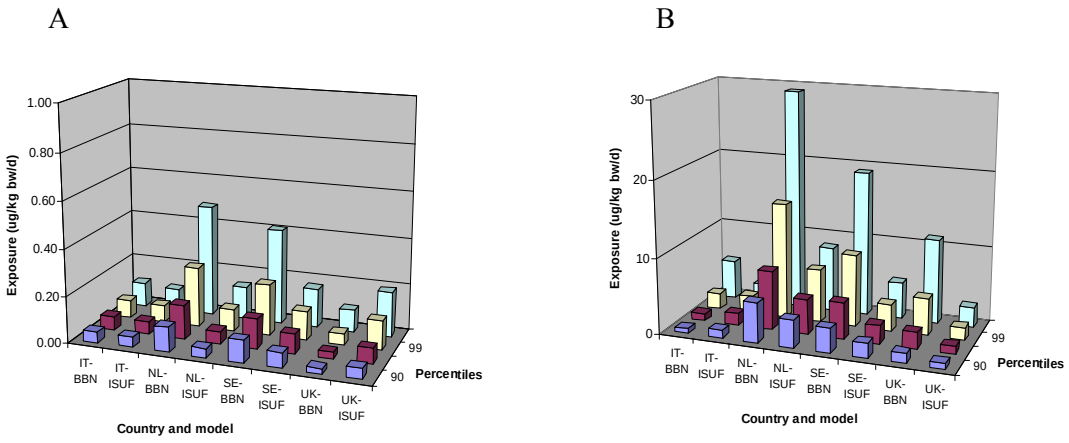

Figure 4. Comparison between the BBN and the ISUF model for calculating the chronic exposure. Percentiles of estimated chronic cumulative exposure (in µg equivalents of cyproconazole/kg bw/d) to triazoles in different countries using all monitoring data (A) or in which field trial data for a particular RAC-pesticide combination were used in combination with monitoring data for all other RAC-pesticide combinations (B).

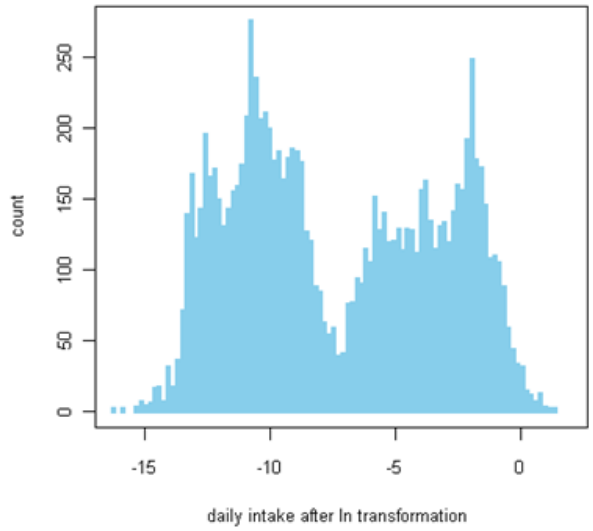

Figure 5. Example of a bimodal distribution. The right distribution is mainly associated with consumers of a particular RAC for which field trial or MRL data were used as input for the calculations in combination with monitoring data of all other RAC-pesticide combinations. The left distribution is mainly associated with the consumers not consuming the particular RAC. These consumers are consequently only exposed to monitoring results for all other RAC-pesticide combinations. These monitoring results are usually much lower compared to the field trial data.

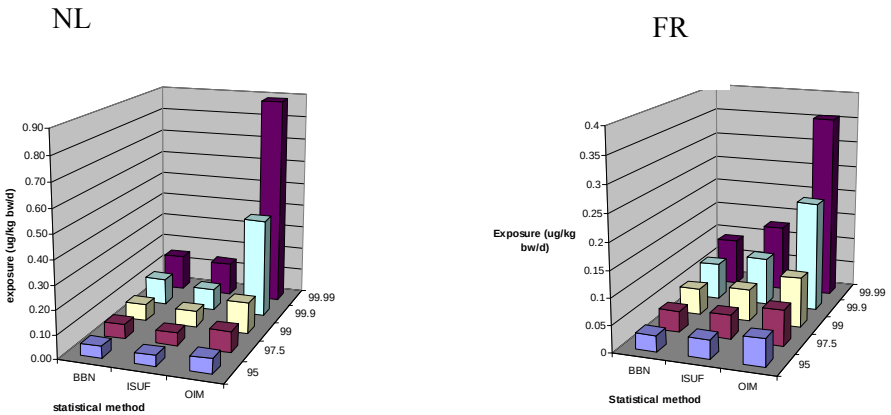

Figure 6. Comparison of chronic exposure levels at different percentiles calculated with three different models, BBN, ISUF and OIM. IOM (individual observed means) is a model without statistical transformation for usual intake. Data from The Netherland and France are used.

Modeling unit variability

When acute dietary exposure calculations are performed for single pesticides with monitoring residue levels derived from composite samples variability factors (also referred to as homogeneity factors) should be included in the assessment (EC 2001; EFSA 2005b; FAO 2002) . These factors account for the fact that the residue concentration analyzed in a mixed sample can originate from one individual unit of the commodity, and that consumers may be confronted with a residue concentration in a single

unit (e.g. an apple) rather than the averaged concentration as analyzed in composite samples (of e.g. 12 apples).

In the acute cumulative exposure calculations, we accounted for unit variability using a fixed variability factor of 3.6, derived from a study performed by the EFSA PPR Panel in 2005 (EFSA 2005). In this study an average variability factor of 3.6 was reported for samples collected from market places. There are no guidelines on how to include variability factors in a probabilistic exposure assessment. We therefore followed the same procedure as used in the EFSA opinion on acute dietary intake (EFSA 2007), and described in (De Boer and Van der Voet 2007). In this opinion the variability factor was transformed to a standard deviation of a lognormal distribution around a residue level of a composite sample. From this lognormal distribution stochastic variability factors (*svf*) are sampled to be used in the exposure assessment (see Section 2.5 and 2.6). Variability factors were not used for mixed food items or for small fruit and vegetables according to the different cases as defined by the WHO.

The lognormal distribution for unit variability is only one possibility for modeling unit variability. It is connected with the idea that unit concentrations are to be simulated for any possible unit in the population of units, e.g. all apples in a country/time period. An alternative strategy is to simulate concentrations only for the specific units underlying the actually measured composite samples. The most striking difference is that now the maximum possible simulated concentration is bounded: it cannot be higher than number of units in the composite sample times the concentration actually analysed in the composite sample. This highest concentration would correspond to the situation where all the pesticide resides are present in one unit, with all other units being absent of the pesticide.

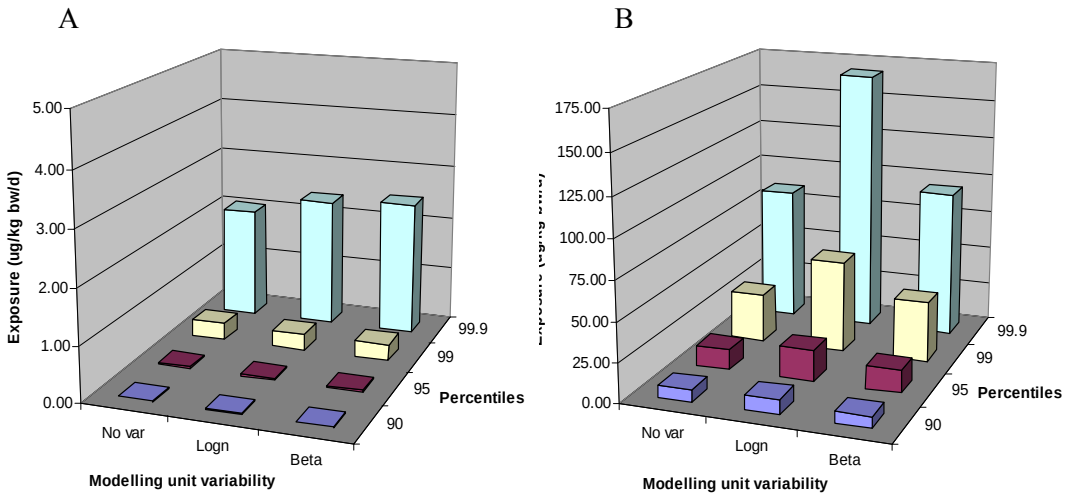

Figure 7. Percentiles of acute cumulative exposure (in µg equivalents of flusilazole/kg bw/d) to triazoles in the total Dutch population using either all national monitoring results (A) or in which monitoring residue data used in combination with the MRL for bitertanol on tomato (B). Unit variability was applied following three scenarios: no unit variability (No var), lognormal distribution (Logn) and beta distribution (Beta).

A statistical model that corresponds to this bounded situation can be based on a beta distribution. In MCRA both models for unit variability are implemented (see De Boer and van der Voet 2007 for full descriptions). The beta distribution model was used in cumulative exposure assessments of organophosphorus insecticides and carbamates (Van Klaveren et al. 2006; Boon et al. 2008).
To show the effect of choosing a different approach to model variability we performed one analysis in which we used no variability and two in which variability was modeled as a lognormal or beta distribution. See for the results Figure 7 in which we used Dutch food consumption data of the total population and linked that to all monitoring data (Figure 7A) or using MRL data for bitertanol in tomato in combination with other monitoring data (Figure 7B). We used in all three analyses BMD-derived RPFs.

In the analyses with only monitoring data the P99.9 of the estimated exposure was only very slightly increased by including variability in the assessment compared to no variability (Figure 7A). Including variability either as a beta or lognormal distribution did not result in significantly different levels of estimated exposure. However, in the scenario where one RAC-pesticide combination (in this case tomato – bitertanol) was replaced by the MRL, including variability as a lognormal distribution resulted in a high increase (97%) in estimated exposure compared to no variability. Including variability as a beta distribution resulted in a smaller (10%) increase in estimated exposure. This can be partially explained as follows. There are 12 individual tomatoes in a composite sample. Therefore one tomato corresponds to about 8% of a composite sample. If for simplicity we assume that the extreme upper tail of the estimated exposure distribution is related to single highly contaminated units, then any beta-distribution based estimate of percentiles higher than P92 cannot be based on the empirical data, but corresponds to extrapolation. In contrast, the lognormal-distribution model is not dependent on the number 12, it just assumes a smooth distribution, and for extreme percentiles like P99.9 it will also use values sampled in the right tail extending above 12 times the composite sample value.

Residue levels analyzed in monitoring programmes are mostly very low compared to MRL. Applying a low variability factor of 3.6 will therefore not have a large visible impact on the estimated exposure. Especially when you realize that variability in a stochastic model also means that lower levels than the averaged composite sample can be simulated. However, when including an MRL in the residue database with a relatively high level compared to the analyzed levels, a variability factor can result in the simulation of individual residue levels that are even higher than the MRL. This will result in extreme estimated exposure levels in the right tail of the distribution. This is especially true when using the lognormal distribution in which the upper limit of the residue level to be modeled is not bounded as in the beta distribution.

Which model to use depends on the wishes of the risk assessor and whether simulated residue levels in individual units should be representative of the total population of units, or just the units underlying the actually measured composite samples. In the simulations reported here we used the lognormal distribution, which resulted in comparable or higher levels of estimated exposure compared to the beta approach.

4.4.2 Assigning residue levels to samples with residue levels below LOR

When performing exposure assessments to pesticides, samples with residue levels below the limit of reporting (LOR) are commonly assumed to contain no residue. Because only a certain part of the commodities will be treated with the pesticide, a large part of these so-called non-detects will not contain the pesticide. In the US the Environmental Protection Agency (EPA) has developed a methodology to assign a level to these samples based on the percentage of the crop that has been treated with the pesticide (EPA 2000). Information on this statistic is however not available within Europe. Also in this study we assigned a zero level to non-detect samples analyzed in monitoring programmes. Non-detect samples from field trial data however were assigned LOR, because in these trials 100% of the crop is treated.

To demonstrate the effect on the estimated exposure of assigning levels to non-detect samples, including different scenarios for percentage crop treated, we performed acute exposure calculations using BMD-derived RPFs in which we replaced non-detect wheat samples for epoxiconazole with ½ LOR (= ½ x 0.05 mg/kg). This was done for three scenarios of percentage crop treated, namely 10%, 50% and 100% (which represents the worst case situation). In these calculations all other non-detect RAC –pesticide combinations were assumed to contain no residue. For reasons of comparison we also included the scenario in which all non-detects were assigned zero (including combination wheat – epoxiconazole). See Figure 8 for the results. Assigning ½ LOR to non-detect wheat samples analyzed for epoxiconazole resulted in a slight increase in estimated exposure over all percentiles of estimated exposure with increasing level of percentage crop treated. The relative increase was highest at the lower percentiles of estimated exposure (≤ P95).

As demonstrated by Boon et al (2003), the effect of replacing non-detects with LOR on the estimated exposure percentiles depends on the percentage of non-detects in the whole database, and the LOR level relative to the levels present in the monitoring database. It was found that generally intermediate percentiles (e.g. P95) were influenced most, whereas high percentiles (like P99.9) were not or less affected (Boon et al. 2003). Also percentage of crop treated will affect the results. The results plotted in Figure 8 comply with these results. Very likely the replacement of a part of the non-detects with low levels of one pesticide (epoxiconazole) does not influence the upper part of the estimated exposure distribution, because this part is dominated by samples with high cumulative levels. The influence of levels assigned to non-detects was however not tested for other RACs and might be more significant for RAC –pesticide combinations with a possible higher contribution to the estimated exposure levels.

4.4.3 Uncertainty in residue and / or consumption data: bootstrap method

Sometimes the number of samples is limited. This might cause uncertainty in the data. As long as all samples have the same or similar concentrations of the pesticide residue, it does not make any difference if the Monte Carlo simulations are performed with large or small databases. However if there is significant variation in residue levels, the sample size and the probability that high levels are sampled may affect the intake distributions. For example, high residue levels can occur in 10% (case A) of all samples or sometimes in only 1% of all samples (case B). If twenty samples are taken there is a reasonable probability that the high residue level sample is included in case A, but a low probability that it is also included in case B. The variation within samples and the sample size together have an effect on the results of exposure distributions.

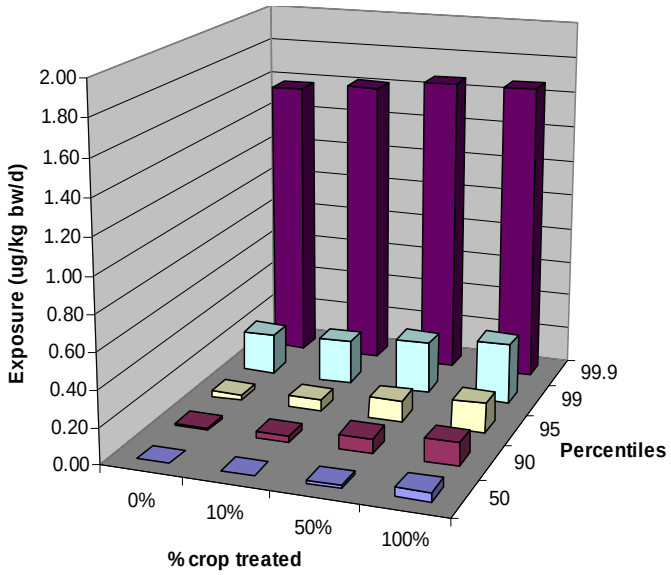

Figure 8. Percentiles of acute cumulative exposure (in µg equivalents of flusilazole/kg bw/d) to triazoles in the total Dutch population assuming non-detect wheat samples for epoxiconazole to contain this pesticide at ½ LOR at different levels of percentage crop treated.

The same applies for food consumption databases and the number of consumers which are included in the consumption survey. For example, a large consumption survey is needed to detect a reliable intake of rarely eaten fruit and vegetables (e.g. kiwi), while a smaller consumption survey might be suitable enough to reliably estimate the consumption amounts of a fruit or vegetables (e.g. apples) eaten by a large part of the populations.

This effect of sample sizes and sample reliability can be studied by using the bootstrap method (see also Chapter 2). This bootstrap technique was applied on a relatively small and a relatively large food consumption and residue concentration database. Briefly, the bootstrap permits the risk assessor to evaluate the degree of uncertainty of the estimated exposures at any given percentile that is due to the size and nature of the residue concentration and/or consumption databases in the assessment. The outcome of the bootstrap simulations performed as part of this illustrative exercise with the triazoles is listed in Table 21. For example, in the case where a small residue concentration database was used as input for the Monte Carlo simulations and no bootstrapping was applied ,repeated multiple analyses would be expected to produce differing estimates of the P99.9 exposure estimates due to the random nature of the Monte-Carlo process. As can be seen in the first row of Table 21, the average of these estimates (for the P99.9 of exposure) is expected to be 1.25 µg equivalents of flusilazole/kg bw/d with a 95%-confidence interval (CI) of 1.01-1.55. Bootstrapping involves performing multiple MC assessments except sampling occurs from a distribution of residue values that are sampled *with replacement*, in an attempt to evaluate the uncertainty associated with the size and nature of the input datasets. In short, the non-bootstrapped 95%-CI reflects the intrinsic uncertainty in the Monte Carlo simulation itself due to the random nature of the Monte-Carlo process, while the bootstrapped Monte-Carlo simulation 95%-CIs around the P99.9 reflects both the uncertainty in the Monte Carlo simulations and the uncertainty in the residue concentration dataset. Here (as seen in the second line of Table 21), the 95% CI from the bootstrap sample is 0.11 µg/kg bw/d (lower bound) to 3.20 µg/kg bw/d (95% upper bound). If the estimated exposure uncertainties (i.e., the confidence intervals) between the non-bootstrapped and bootstrapped samples are similar, this would suggest that the data anomalies,

outliers, or other peculiarities in the residue concentration data set are minimal and/or do not significantly impact the exposure outputs. To the extent that the confidence intervals around the P99.9 estimated exposure between the non-bootstrapped and bootstrapped samples diverge, this suggests the opposite: specifically, that outliers or other data anomalies may have a large impact on the exposure estimates, that there may be large uncertainties in the resulting estimated exposures, and that care should be taken in interpreting the estimated exposure results. Ideally in such a case, the input residue concentration data should be carefully examined and the collection of additional data might be considered if the differences were substantively meaningful (i.e, consequential) in a risk management context. In this specific (triazole) case with the small residue concentration dataset, there is a fair amount of divergence between the non-bootstrapped MC results (estimated exposure at the P99.9 of 1.25 µg/kg bw/d with a 95% CI between 1.01 and 1.55 µg/kg bw/d) and the bootstrapped version (95% CI of between 0.11- to 3.20- µg/kg bw/d). If such a difference is consequential to the risk manager (for example, the lower bound of the confidence interval and the upper bound of the confidence interval around the P99.9 of interest reflect small and large fractions of the Reference Dose or Allowable Daily Intake), then this might suggest -- as described above – that the results are uncertain due to the nature and size of the residue concentration database and should be interpreted with caution. Similar bootstraps were performed with a large residue concentration database and with a small and large consumption databases. All simulations resulted in an increase in the 95% CI, but these increases were not as significantly as those observed using the relative small residue concentration database (Table 21).

In summary, the uncertainty analyses performed here suggest that high-end exposure estimates are much less sensitive to small vs. large consumption databases than they are to large vs. small residue data sets, and that the risk manager should determine the extent to which the differences between the non-bootstrapped and bootstrapped results for the small residue concentration data set are substantially important in a risk management context.

Table 21. The effect of bootstrapping on the residue and consumption database on the 95% confidence intervals around the P99.9 of cumulative exposure (ug/kg bw/d) for different scenarios using residue concentration and consumption databases containing relatively small or large number of samples or respondents.

Scenario	Database	Bootstrapping	p99.9	95% confidence interval around P99.9			
				2.5	25	75	97.5
Scenario 1	Small residue	No	1.25	1.01	1.13	1.29	1.55
		Yes		0.11	0.33	2.03	3.20
Scenario 2	Large residue	No	2.09	1.76	1.96	2.14	2.31
		Yes		1.57	1.93	2.16	2.47
Scenario 3	Small consumption	No	3.45	3.01	3.32	3.55	3.96
		Yes		3.00	3.27	3.57	3.98
Scenario 4	Large consumption	No	2.09	1.85	1.97	2.17	2.30
		Yes		1.74	1.94	2.17	2.49

4.4.4 Other uncertainty

For all other possible uncertainties we refer to the EFSA-opinion of the PPR panel to evaluate the suitability of existing methodologies and, if appropriate the identification of new approaches to assess cumulative and synergistic risks from pesticides to human health with a view to set MRLs for those pesticides in the frame of Regulation (EC) 396/2005. In this opinion, a list of different uncertainties and their possible effect on the outcome of the estimated exposure assessment has been published in Table 5. Next to the uncertainties we have tried to quantify in the above mentioned sections, we assume that most of the other uncertainties are of a comparable magnitude as mentioned in this opinion (EFSA 2008).

5 Conclusions and recommendations

In the EFSA opinion on identification of new approaches to assess cumulative and synergistic risks from pesticides to human health a tiered approach for cumulative risk assessment is suggested by the PPR-panel. The first tier is a deterministic approach. Higher tiers exist of a probabilistic assessment in combination with relative potency factors (RPFs), to account for differences in toxicity of different compounds with a possible same mechanism of action, like the triazoles in this report.

The aim of this study was to demonstrate the feasibility and applicability of higher tier assessment of cumulative exposure calculations. The fourth tier using probabilistic modeling in combination with the RPF approach was tested both for short-term and long-term estimated exposure to triazoles, using both BMD- and NOAEL-derived RPFs. For the calculations food consumption and residue concentration databases were used from several European countries, including Czech Republic, France, Italy, the Netherlands, Sweden, UK and Finland (only residue concentration data).

The following conclusions were drawn:

1. Short-term and long-term cumulative dietary exposure to triazoles can be calculated with probabilistic models in combination with the RPF approach.
2. The method was applicable for calculating both the actual exposure using monitoring data as the possible exposure in the process of MRL setting.
3. Monte Carlo simulations can be used to calculate short-term cumulative exposure.
4. For long-term exposure assessments different models can be used. Not all models apply in all cases and a significant model uncertainty was observed in a few calculation scenarios.
5. When for a particular RAC-pesticide combination MRL, STMR or field trial data were used and monitoring data for other RAC-pesticide combinations a bimodal exposure distribution can be expected. In such cases the lower part of the exposure distribution (first mode) relates to the daily consumptions consisting of only food items for which monitoring results are used, and the other part (second mode) to daily consumptions of the particular RAC for which MRL, STMR or field trial data are used.
6. More research is needed on how to model bimodal distributions. However, first indications of simulation studies suggest that ISUF and BBN may overestimate the exposure level at the higher percentiles in the case of bimodality. If so, risk assessors may consider to calculate the distribution of individual mean exposure levels based on the observed individual mean consumption reported during the food consumption survey and average residue levels. This is regarded as a conservative starting point for modeling long-term exposure levels.
7. A statistical model assuming that the non-analyzed triazoles in samples are zero values (non-detects) might result in an underestimation of exposure. The alternative statistical model, which was pragmatically programmed, models each triazole separately and then combines the results. This alternative approach is assumed to be a more realistic, but also conservative, approach for unbalanced data sets.
8. Results of probabilistic modeling using RPFs derived from Benchmark Dose modeling are sometimes higher compared to results based on calculations using RPFs derived from NOAELs. Benchmark Dose modeling is proposed as a higher tier assessment and higher tier assessment should result in lower exposure levels because higher tier assessment includes less conservatism.

9. Uncertainty and sensitivity analyses demonstrated that different assumptions made and different models can result in higher or lower exposure levels.
10. We were able to perform all cumulative exposure calculations using food consumption data from several countries.

In conclusion the probabilistic model can be applied within the European context.

In this report we have touched upon different issues to improve the estimation of the cumulative dietary exposure to compounds belonging to a common mechanism group. The general conclusion is there are models available that are applicable for cumulative dietary exposure assessment, and that they can be used in the European context. Nevertheless it will take much effort to make those models accessible for all stakeholders in the process of pesticide risk assessment. Also effort is needed to make models and data compatible for cumulative exposure assessment. Bases on our experience we come to the following project specific recommendations:

- It is recommended to develop sampling procedures at an European level resulting in residue concentration data of all triazoles relevant for the assessment in equal numbers. If this is not possible, reasons for not analysing a pesticide in a RAC sample should be clearly stated (e.g. never used in practice, analytical or financial limitations). Different reasons will demand different solutions.
- Statistical models should be optimized to handle unbalanced data sets, and to address possible correlations in pesticide uses.
- Statistical models should pay more attention to RAC-pesticide specific processing and variability factors, and how to combine this information in cumulative pesticide exposure assessment. Experiments might even be needed to elucidate variability factors for different crops and pesticides in cumulative exposure assessment.
- Examination of the toxicological differences between the NOAEL and BMD-derived RPFs as reported here is necessary, as well as a discussion on which of the approaches results in the most realistic level of cumulative exposure relative to the toxic effect on which the BMD and NOAEL are based.
- A further integration of exposure and effect (BMD) modeling is recommended to clarify the uncertainty in different parameters of the risk assessment, including uncertainty analyses in RPFs derived from either NOAEL or BMD modeling. Uncertainty models should also include measurement uncertainty and uncertainty regarding LODs, LOQs and percentage crop treated.
- To optimize the European dimension of cumulative modeling of exposure to pesticides, it is recommended that countries develop their own food conversion models so that food coding of these databases can be harmonized at RAC level. Furthermore, these models are necessary to estimate the exposure to compounds analyzed mainly at RAC level. Apart from harmonization at RAC level, also the methodology used to assess food consumption habits should be harmonized.

<u>A few general recommendations:</u>

- More clarity and practice are needed about how to apply a tiered approach within cumulative exposure modeling as advocated by the EFSA PPR panel (EFSA 2008).
- Guidelines should be generated to harmonize pesticide monitoring practices in different countries within Europe so that each country analyses the same RACs in the same degree and uses similar analytical methods with comparable LORs.

- As stated in the opinion of the PPR panel, ideally risk assessments of chemicals, whether individually or in combination, should consider all pathways (e.g., food, drinking water, residential, occupational) and routes (ingestion, dermal, inhalation) of exposure that could contribute to a person's total estimated exposure. Models and data to assess this type of exposure should be generated for those compounds for which other pathways than food and drinking water sources and other routes than ingestion are important for the overall estimated exposure.
- The models described in this report are applicable, but do not warrant that they can be used by all stakeholders and member states. Much effort should be spent in making the models and data accessible to the international community.

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Annex I Description of the monitoring data per country

*Table 22 Triazole data **Czech Republic**, Overview of number of samples analyzed for different triazoles in the Czech Republic per raw agricultural commodity (RAC), between brackets the number of positive samples.*

RAC	Bitertanol	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.005-1	0.009-0.1	0.001-0.2	0.01-0.25	0.02-1	0.01-0.5
Apples	114 (1)	69	114 (1)	114	211	114 (1)
Apricots	33 (1)	24	33	33 (2)	66	33
Bananas	60 (2)	31	60	60	113	60
Beans	3	3	3	3	6	3
Beetroot	2	1	2	2	4	2
Bilberries	1		1	1	2	1
Biscuits	1	1	1	1	2	1
Bread					2	1
Broccoli	12	12	12	12	24	12
Buckwheat	4	3	4	4	8	4
Cabbage	43	26	43	43	86	43
Canned beans	2	2	2	2	4	2
Caraway seeds	1	1	1	1	2	1
Carrots	65	34	65	65	121	65
Cauliflower	49	34	49	49	91	49
Celeriac	36	24	36	36	67	36
Coarse wheat flour	11	9	11	11	21	11
Coca-cola	1	1	1	1	2	1
Common mushrooms	2	1	2	2	3	2
Corn flakes	1		1	1	2	1
Courgette	4	4	4	4	8	4
Cream cakes					2	1
Cucumbers	100	52	100	100	187	100

RAC	Bitertanol	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
Curry powder	1		1	1	1	1
Damsons	13	10	13	13 (6)	26	13
Dates	5	5	5	5	10	5
Egg plant	18	18	18	18	36	18
Fine semolina	8	4	8	8	15	8
Fine wheat flour	20	8	20	20 (1)	41	21
Frozen vegetables	12	9	12	12	24	12
Fruit in syrup	1		1	1	1	1
Fruit products	2	2	2	2	4	2
Fruit puree	1		1	1	1	1
Fruit tea	1	1	1	1	2	1
Garlic	6	4	6	6	10	6
Grapefruit	29	10	29	29	53	29
Grapes	68	36	68	68	127	68 (1)
Green beans	31	23	31	31	62	31
Green peas	24	14	24	24	48	24
Hard cheese Edam	1	1	1	1	2	1
Hazelnuts	1	1	1	1	6	3
Chinese leaves	48	19	48	48	93	48
Infant food - fruit puree	98	58	99	98	182	99
Infant formula "Sunar"	5	5	5	5	10	5
Instant infant porridge	34	17	34	34	55	34
Juice	36	19	36	36	67	36
Kiwi fruit	8	4	8	8	15	8
Kohlrabi	3	3	3	3	6	3
Leek	45	27	45	45 (1)	86	45
Lemonade	2	1	2	2	4	2
Lemons	4	4	4	4	8	4
Lettuce	63	46	63	63	116	63

RAC	Bitertanol	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
Mandarin oranges	56	19	54	54	107	56
Mangoes	3	3	3	3	7	3
Medium-coarse wheat flour	10	7	10	10	20	10
Millet	1	1	1	1	2	1
Muesli	2	1	2	2	4	2
Mushrooms	1		1	1	2	1
Nectarines	25 (1)	24	25	25	50	25
Oat flakes	15	12	15	15	30	15
Onions	37	17	37	37	70	37
Oranges	54	20	53	53	97	54
Sweet pepper	1		1	1 (1)	1	1
Parsley	36	21	36	36	68	36
Peaches	54	34	54	54 (1)	108	54
Peaches in syrup	2	1	2	2 (1)	4	2
Pears	43 (1)	26	43	43	85	43
Peas	6	5	6	6	12	6
Pepper	114	61	114	114 (2)	209	114
Pineapple	5	5	5	5	10	5
Plums	29	16	29	29 (6)	58	29
Poppy seeds	1	1	1	1	2	1
Potatoes	72	36	72	72	132	72
Pumpkin	1	1	1	1	2	1
Pumpkin seeds	2	2	2	2	4	2
Radish	8	7	8	8	15	8
Ready-to-eat cereals	1		1	1	2	1
Rice	51	27	51	51	90	51
Sesame seeds	1	1	1	1	2	1
Soya beans	1	1	1	1	2	1
Spinach	31	24	31	31	60	31

RAC	Bitertanol	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
Sponge biscuits	1		1	1	2	1
Stewed mixed vegetables	1		1	1	1	1
Strawberries	43	30	43	43	77	43
Sunflower seeds	1	1	1	1	2	1
Sweet buns					2	1
Syrup	6	3	6	6	11	6
Table water	5	5	5	5	10	5
Tea	6	6	6	6	12	6
Tomatoes	112	68	112	112 (1)	210	112
Vegetable salad	1	1	1	1	2	1
White radish	5	4	5	5	10	5
Wholemeal bread					2	1
Total	1977 (5)	1172 (0)	1975 (1)	1941 (22)	3741 (0)	1985 (2)
Percentage positive	0.25	0	0.05	1.13	0	0.1

*Table 23 Triazole data **Finland**, Overview of number of samples analyzed for different triazoles in Finland per raw agricultural commodity (RAC), between brackets the number of positive samples.*

RAC	Bitertanol	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol	Difenoconazole	Cyproconazole	Diniconazole	Epoxiconazole
LOR (mg/kg)	0.02	0.01	0.06	0.03	0.01	0.05	0.01	0.01	0.01	0.01
Apple	478 (9)	478	478	478	478	478	85	59	59	59
Apricot	14 (2)	14	14	14 (1)	14	14	4	3	3	3
Asparagus	53	53	53	53	53	53	4	4	4	4
Avocado	31	31	31	31	31	31	1	1	1	1
Banana	79	79	79	79	79	79	17	13	13	13
Basil, fresh	72	72	72	72	72	72	1			
Bean, fresh	41	41	41	41	41	41	7	5	5	5

RAC	Bitertanol	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol	Difenoconazole	Cyproconazole	Diniconazole	Epoxiconazole
LOR (mg/kg)	0.02	0.01	0.06	0.03	0.01	0.05	0.01	0.01	0.01	0.01
Black berry	9	9	9	9	9	9				
Bleach celery	29	29	29	29	29	29	2 (2)	2	2	2
Boysen berry	25	25	25	25	25	25				
Broccoli	51	51	51	51	51	51	3	2	2	2
Brussels sprouts	10	10	10	10	10	10	1			
Carambola	10	10	10	10	10	10 (1)				
Carrot	121	121	121	121	121	121	5	1	1	1
Cauliflower	102	102	102	102	102	102	13	11	11	11
Cherry	19	19	19	19 (3)	19	19	1	1	1	1
Chili pepper, fresh	108	108 (3)	108	108	108	108	26	16	16	16
Chinese Cabbage	83	83	83	83	83	83	4	1	1	1
Coriander, fresh	39	39	39	39	39	39				
Courgette	62	62	62	62	62	62	9	2	2	2
Cucumber	225	225 (1)	225	225	225	225	53	9	9	9
Currants (red, black, white	56	56	56	56	56	56	6 (1)	3	3	3
Dill, fresh	100	100	100	100	100	100 (1)				
Egg plant	69	69	69	69	69	69	17	11	11	11
Garlic	18	18	18	18	18	18				
Grapefruit	53	53	53	53	53	53	2	1	1	1
Iceberg lettuce	127	127	127	127 (1)	127	127	14	1	1	1
Kiwi	49	49	49	49	49	49	3	2	2	2
Leek	45	45	45	45	45	45	3	1	1	1
Lemon	63	63	63	63	63	63	4	1	1	1
Lettuce	52	52	52	52	52	52	9			
Lime	16	16	16	16	16	16	3			
Mandarin, clementine	293	293	293	293	293	293	54	9	9	9
Mango	51	51	51	51	51	51		5	5	5
Melon	21	21	21	21	21	21	9 (1)	3	3	3
Nectarine	55	55	55	55	55	55	17	10	10	10

RAC	Bitertanol	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol	Difenoconazole	Cyproconazole	Diniconazole	Epoxiconazole
LOR (mg/kg)	0.02	0.01	0.06	0.03	0.01	0.05	0.01	0.01	0.01	0.01
Onion	52	52	52	52	52	52	6	3	3	3
Orange	391	391	391	391	391	391	51	10	10	10
Papaya	30	30	30	30	30	30	7			
Parsley, fresh	53	53 (2)	53	53	53	53	8 (3)	1	1	1
Pea (fresh)	48	48	48	48 (1)	48	48	13	12	12	12
Peach	47	47	47	47	47	47	10	3	3	3
Pear	116	116	116	116 (1)	116	116	20	6	6	6
Persimon	19	19	19	19	19 (1)	19	7	4	4	4
Pineapple	25	25	25	25	25 (17)	25 (15)	9	4	4	4
Plum	96 (2)	96	96	96 (1)	96	96		4	4	4
Potatoes	159	159	159	159	159	159	9	8	8	8
Raspberry	136	136	136	136	136	136	21	7	7	7
Rucola	65	65	65	65	65	65	16	5	5	5
Savoy cabbage	77	77	77	77	77	77				
Spinach	67	67	67	67	67	67	8	2	2	2
Strawberry	207 (1)	207 (5)	207	207	207 (1)	207	53 (1)	16	16	16
Sweet pepper	251	251	251	251	251	251	43	23	23	23
Sweet potato	26	26	26	26	26	26	6	3	3	3
Table grape	217	217 (13)	217	217 (5)	217	217 (2	45 (1)	26 (1)	26	26
Tomato	246	246	246	246	246	246	29	18	18	18
Watermelon	26	26	26	26	26	26	7	2	2	2
Total	5083 (14)	5083 (24)	5083 (0)	5083 (14)	5083 (19)	5083 (19)	745 (9)	334 (1)	334 (0)	334 (0)
Percentage positive	0.28	0.45	0	0.28	0.37	0.37	1.21	0.30	0	0

*Table 24 Triazole data **France**, Overview of number of samples analyzed for different triazoles in France per raw agricultural commodity (RAC), between brackets the number of positive samples*

RAC	Bitertanol	Cyproconazole	Difenoconazole	Diniconazole	Epoxiconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.0001-0.2	0.0001-0.2	0.01-0.2	0.01-0.2	0.02	0.0001-0.02	0.0001-0.05	0.0001-0.2	0.0001-0.2	0.0001-0.5	0.0001-0.5
Almonds	11	11	7	5	1	10	12	12	12	8	11
Anise	1	1	1			1	1	1	1	1	1
Apples	434	427	280	140	37	488	784	861	559 (2)	755	709
Apricots	72	68	32	9	5	69	97	107	81 (1)	87	91
Asparagus	30	30	33	20	6	27	61	71	46	44	49
Egg plants	63	51	66	23	19	53	128	122	80	87	114
Avocados	51	41	40	16	13	44	79	85	60	54	66
Bananas	89 (15)	76	75	41	19	89	179	191	116	133	141
Barley	28	14	19	3	14	22	34	50	44	42	34
Basil	12	12	13	11		13	13	14	15	3	13
Bay leaves (laurel)	1	1				1	1	1	1	1	1
Beans	2	2				5	2	5	4	8	3
Beans (with pods)	69	61	48	20	12	71	150	149	85	128	133
Beans (without pods)	3	5	4	3		3	6	10	7	7	6
Beet leaves (chard)	20	20	18	5	3	22	30	32 (1)	28 (1)	24	27
Beetroot	24	18 (1)	29	11	12	24	45	52	41	40	40
Blackberries	3	3				3	3	3	3	3	3
Blueberries	4	4	3	3		4	10	11	5	8	8
Broccoli	36	33	42	17	7	30	63	71	63	50	52
Brussels sprouts	27	25 (3)	40	20	7	32	57	63	50 (4)	49	57
Buckwheat	15	3	13	2	12	3	15	15	15	3	15
Camomille flowers	1	1		1		1	1	1	1	1	1
Carrots	203	192 (9)	231	68	36	224	455 (2)	512	373 (1)	436	396
Cashew nuts	3	3	1	2		3	5	5	3	4	5
Cassava	2		2		2		7	7	2	5	7
Cauliflower	54	57	79	36	10	70	126	136	105	100	93
Celeriac	17	14	25	10	6	14	29	29	25	13	26
Celery	31	29 (1)	27	14	3	40	54	64	43 (1)	63	57
Celery leaves	44	43 (2)	12	7	3	48	64	79	59 (2)	74	66

RAC	Bitertanol	Cyproconazole	Difenoconazole	Diniconazole	Epoxiconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.0001-0.2	0.0001-0.2	0.01-0.2	0.01-0.2	0.02	0.0001-0.02	0.0001-0.05	0.0001-0.2	0.0001-0.2	0.0001-0.5	0.0001-0.5
Cherries	114	110	34	20	4	111	150 (1)	162	119 (6)	136	141
Chervil	5	5	3	1	1	4	6	6	6	4	5
Chestnuts	8	8	4	1		9	9	9	8	9	9
Chinese cabbage						10	1			11	1
Chives	7	5 (1)	8	2	2	9	11	13	12	10	11
Cinnamon							1	1		1	1
Cocoa (fermented beans)	4	3	1		1	3	5	5	4	4	5
Coconuts							1	1		1	1
Coffee beans	3	2	1		1	5	22	23	3	24	22
Courgettes	114	105	60	26	13	108	185	191	141	174	165
Cranberries							1	1		1	1
Cress	23	13	22	9	12	17	49	53	31	32	41
Cucumbers	145	99	105	41	50	101	245 (2)	257	167	182	225
Cultivated fungi	14	14	16	8	2	16	27	31	20	25	27
Currants (red,black,white)	13	8	12	6	5	12	22	26	16	19	21
Dates	6	7	2	2		6	8	8	7	6	6
Dill seed	2	2	2	1		2	2	3	3	2	2
Elderberries	2	2		2		2	2	2	2	2	2
Fennel	38	35	28	11	6	38	57	65	48	54	52
Fenugreek								2	2	2	
Figs	7	7	6	2	1	7	12	13	9	8	10
Garlic	34	36	18	5		35	40	44	38	41	41
Gherkins	4	3	1	2	1	5	4	6	6	7	4
Ginger	7	1	7	1	6	1	25	25	7	10	17
Ginseng root	7	7	5	7		7	7	7	7	7	7
Globe artichokes	25	24	49	6	4	42	61	71	66	64	58
Grapefruit	32	21	36	7	13	22	48	53	41	32	45
Hazelnuts	13	12	9	6	2	12	16	16	15	11	15
Head cabbage	46	50	39	27	1	63	97	107	72	91	67
Herbal infusions	71	71	10	69		72	73	73	71	66	72

RAC	Bitertanol	Cyproconazole	Difenoconazole	Diniconazole	Epoxiconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.0001-0.2	0.0001-0.2	0.01-0.2	0.01-0.2	0.02	0.0001-0.02	0.0001-0.05	0.0001-0.2	0.0001-0.2	0.0001-0.5	0.0001-0.5
Honey	5	5	1	1		5	9	18	5	13	14
Horseradish	1	1		1		1	1	1	1	1	1
Hybiscus flowers	1		1		1		1	1	1		1
Kale	2	2	2			2	2	2	2	2	2
Kiwi	49	46	18	6	3	48	83	102	50	97	100
Kohlrabi	1	1	1			1	1	1	1	1	1
Kumquatss	1	1				1	1	1	1	1	1
Lamb's lettuce	15	6	51	4	9	31	63	73	61	62	64
Leek	96	98	67	43	5	99	171	190	137 (7)	150	122
Lemons	175	158	126	53	28	179	286 (4)	302	219	239	250
Lentils	52	45	41	27	9	48	72	78	63	52	67
Lettuce	579	591	252	179	27	671	901	1023	747	970	833
Lime (linden)	2	2		2		2	3	3	2	3	3
Linseed	1	1	1	1		2	1	2	2	2	1
Lychee (Lychee)	11	9	4		2	11	17	19	12	18	17
Maize	64	61	9		3	61	68	84	80	80	67
Mandarins	137	134	73	32	9	141	202	195	159	184	183
Mangoes	13	12	6	1	1	12	22	20	13	18	19
Melons	76	53	55	8	27	55	137	158	93	118	138
Millet	1	1	1	1		1	2	2	1		1
Mustard seed	4	1	4	1	3	1	6	6	4	2	6
Oats	7	3	7	1	4	5	7	14	14	12	7
Okra, lady’s fingers	1	1				1	1	1	1	1	1
Olives for oil production	2	1	1		1	1	2	2	2	1	2
Onions	56	60	41	26		76	69	77	71 (2)	83	66
Oranges	162	141	104	37	31	173	359 (2)	368	194	333	325
Other cereal	4	3	4		1	3	4	4	4	3	4
Other cucurbits - edible peel	6		6		6		26	20	6	15	21
Other herbal infusions (dried leaves)	2	3	1	1		2	8	9	3	6	6

RAC	Bitertanol	Cyproconazole	Difenoconazole	Diniconazole	Epoxiconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.0001-0.2	0.0001-0.2	0.01-0.2	0.01-0.2	0.02	0.0001-0.02	0.0001-0.05	0.0001-0.2	0.0001-0.2	0.0001-0.5	0.0001-0.5
Other herbs	2	2	2	2		2	2	2	2		2
Other leafy brassica	2		2		2		4	2	2	2	4
Other lettuce and other salad plants	200	168	241	60	48	177	267	265	241	159	251
Other miscellaneous fruit	4	4	3	4		4	7	6	4	3	6
Other oilseeds	1		1		1		1	1	1		1
Other pome fruit	1	1	1	1		1	1	1	1	1	1
Other spinach and similar	3	2	4	2	1	3	4	4	4	1	4
Other tree nuts	1		1		1		1	1	1		1
Other tropical root and tuber vegetables	49		49		49		171	171	49	65	114
Papaya	3		3		3		4	4	3	1	4
Parsley	41	38 (1)	25 (1)	5	4	49	60 (1)	69	55	70	61
Passion fruit	1	1	1	1		1	1	1	1	1	1
Peaches	166	161	73	43	10	166 (1)	230	238	183 (6)	201	209
Peanuts	13	13	8	7	2	14	20	20	16	16	18
Pears	169	162	126	61	21	171	271	291	213	237	247
Peas	2	2				4	2	6	5	8	3 (1)
Peas (with pods)	12	11	13	4	1	12	15	16	14	11	15
Peas (without pods)	35	27	36	21	12	30	62	74	53	43	57 (1)
Peppers	189	181	107	42	15	186 (1)	242	259	221 (1)	228	241 (1)
Persimmon	2	1	2		1	1	2	3	2	2	3
Pine nuts	2	2	1			2	2	3	3	3	2
Pineapples	30	14	26	2	16	16	65	65	35	42 (6)	56 (5)
Pistachios	6	6	2	3		7	9	10	7	10	9
Plums	79 (6)	76	46	62	3	78	112 (1)	126	83 (9)	102	119
Pomegranate	1	1	1			1	1	1	1	1	1
Pomelo	43	43	8	11		48	62	66	44	63	53
Poppy seed			1				1	1	1	1	1

RAC	Bitertanol	Cyproconazole	Difenoconazole	Diniconazole	Epoxiconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.0001-0.2	0.0001-0.2	0.01-0.2	0.01-0.2	0.02	0.0001-0.02	0.0001-0.05	0.0001-0.2	0.0001-0.2	0.0001-0.5	0.0001-0.5
Potatoes	198	241	225	129	29	333	382	401	348	403	258
Pumpkin seeds	2	2	2	2		2	2	2	2		2
Pumpkins	8	1	8		7	1	18	18	8	10	17
Quinces							1	1		1	1
Radishes	36	33	35	15	8	39	56	67	56	56	48
Rape seed		1	1	1		1	1	4	4	4	
Raspberries	24	19	20	7	6	21	42	46	32	32	35
Rhubarb	3	3	1	3		4	7	7	3	7	6
Rice	132	129	44	1	3	133	145	140	133	148	146
Rose petals	1	1		1		1	1	1	1	1	1
Rosemary							1	1			
Rye	40	34	7		6	39	41	42	41	41	41
Saffron	1		1		1		6	6	1	3	4
Scarole (broad-leaf endive)	51	48	34	22	3	60	80	87	63	75	75
Sesame seed	5	2	5	1	3	2	7	7	5	3	7
Shallots	7	7	7	2		8	9	22	22	23	9
Soft drink	2	2	1	2		2	2	2	2	2	2
Soursop (guanabana)	1		1		1		1	1	1		1
Soya bean	13	8	14	2	5	8	17	22	20	16	15
Spices	16	15	4		1	18	32	34	17	33	30
Spinach	95	87	77	35	16	97	158	181	133	153	165
Spring onions	9		9		9		33	33	9	15	24
Squashes	2	2				4	3	3	2	5	3
Strawberries	256	240	139	52	25	276	422 (24)	462	313	415	408 (1)
Sugar beet (root)	1	1		1		1	1	1	1	1	1
Sugar cane	3	2	1		1	2	6	7	3	6	7
Sunflower seed	9	9	6	5	1	8	11	14	12	11	11
Swedes							1	1			
Sweet corn	4	2	4		2	2	4	4	4	2	4
Sweet potatoes	45	1	45		44	1	113	113	45	34	78

RAC	Bitertanol	Cyproconazole	Difenoconazole	Diniconazole	Epoxiconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.0001-0.2	0.0001-0.2	0.01-0.2	0.01-0.2	0.02	0.0001-0.02	0.0001-0.05	0.0001-0.2	0.0001-0.2	0.0001-0.5	0.0001-0.5
Table grapes	152	140	84	39	16	161	230 (15)	254	178 (4)	221 (1)	221 (10)
Table olives	25	25	22			28	25	25	25	28	25
Tarragon	5	6	3	3		6	6	6	6	4	5
Tea	29	17	32	10	14	21	65	68	40	47	62 (2)
Thyme	5	5	4	4		5	5	5	5	3	5
Tomatoes	337	297	243	110	59	343	579	600	429 (1)	494	509 (3)
Triticale							1	6	5	6	1
Turnips	51	49	77	29	14	49	111	200	184 (2)	165	95
Vine leaves	1	1	1			1	1	1	1	1	1
Walnuts	15	10	14	4	5	13	26	28	21	21	26
Water	1	1				1	4	5	2	5	4
Watermelons	5		5		5	1	8	8	5	2	6
Wheat	221	194	154	43	60	200	263	309 (9)	302	249	228
Wheat hard	20	21	15	5	3	19	24	26 (9)	26	21	20
Wild fungi	10	11	10	7	1	9	14	14	13	8	12
Wine grapes	36	40	26	14		37	73 (1)	73	40	65	69
Witloof	88	122	121	96	17	226	193	211	164	260	132
Yams	40		40		40		104	104	40	33	73
Total	6682 (21)	6080 (18)	4820 (1)	2150 (0)	1117 (0)	6922 (2)	11177 (53)	12188 (19)	8809 (50)	10138 (7)	9999 (4)
Percentage positive	0.31	0.30	0.02	0	0	0.03	0.47	0.16	0.57	0.07	0.24

Table 25 Triazole data ***Italy,*** *Overview of number of samples analyzed for different triazoles in Italy per raw agricultural commodity (RAC), between brackets the number of positive samples.*

RAC	Bitertanol	Cyproconazole	Difenoconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
Ananas	15	18	5	9	24	34	14	28 (8)	21 (8)
Apple	1009 (2)	941	157	783 (1)	1274 (4)	1492	1002 (7)	1320	974 (1)
Apricot	219 (1)	189	32	170 (1)	233 (1)	270	218 (8)	244	188
Artichok	70	68	27	28	62	151 (1)	96	102	74
Asparagus	32	27	2	23	44	53	31	40	25
Egg plant	110	111	49	50	84	194 (1)	118	97	114
Avocado	1	1		1	1	2	1	1	1
Banana	130 (2)	134	32	101	163 (1)	207 (1)	145	179	150
Barley	10	6			16	16	3	18	5
Basil	18	29	6	13	21	30	18	14	15
Beans with pod	73	63	30	36	138	224	78	89	72 (1)
Beat chard	77	73	27	53	59	97	81	90	82
Beat leaves	28	21	5	11	23	46	21	30	19
Brassica vegetables	44	42	9	27	57	114	61	59	45
Broad beans	13	9	3	5	23	42	16	19	10
Buck wheat	30	23		1	39	36	11	36	3
Cardoons	8	8		8	8	13	8	10	9
Carrots	533	524	264	236	353	702	567	555 (1)	637
Cauliflower	64	56	21	29	68	130	87	94	62
Celeriac	18	18	1	16	17	19	17	20	17
Celery	138	130	32	91	130	198	161	179	123
Cherries	116 (2)	112	13	99	125	160	125 (5)	142	108
Chestnut	8	8		8	14	14	9	9	9
Chicory	49	44	8	33	44	90	54	79	54
Chicory (radicchio)	93	86	22	71	93	119	87	116	89
Clementine	166	175	38	142	190 (1)	246 (1)	193 (1)	225	177
Courgettes	520 (1)	501	290	213	370 (2)	734 (1)	551	641	550

RAC	Bitertanol	Cyproconazole	Difenoconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
Cucumber	114	105	68	53	103	175	126	148 (1)	129
Currant	2	2							
Dates	9	9		9	14	11	9	9	9
Dewberries	8	8							
Endive	47	124	18	27	39	64	50	56	47
Fennel	129	116	49	58	105 (1)	211	1	1	1
French beans	123	110	29	91	128	170	141	160	127 (1)
Fungi cultivated	23	22	10	7	40	49	18	34	19
Garlic	33	29	4	25	29	34	32	24	33
Gooseberries		1		1	1	1	1	1	1
Grapefruit	108	108	13	103	111	130	110	120	114
Hazelnuts	5	5		5	6	6	5	5	5
Kiwi	357	384	65	341	390	480	405	446	410
Leek	21	21		21	22	23	21	23	23
Lemon	269	261	47	217	265 (1)	378 (1)	300	334	294
Lentils	14	14	8	4	52	73	28	33	17
Lettuce	287	265	94	152	294	513	321	435	387
Mais	10	5	3	2	13	22	17	28	10
Mandarines	106	99	30	68	103 (1)	159 (1)	115 (1)	132	107
Medlar	12	5	1	2	8	15	7	9	3
Melon	51	46	6	33	82 (1)	84	56	70	39
Oils	90	81		20	120	118	30	78	40
Olives	3	5	2	1	37	41	11	14	5
Onions	197	175	43	146	124	231	199	184	202
Oranges	441	421	93	314	450	697	504	575	445
Papaya	2	2	1	1	1	2	2	2	2
Parsley	20	20	5	16	17	26	20	24	21
Peaches	829 (3)	752 (3)	148	660	885 (3)	1042 (1)	829 (22)	965	756
Pear	698 (2)	676	138	536	708 (4)	957	720 (11)	862	704
Peas	50	50	6	48	63	94	63	71	51

RAC	Bitertanol	Cyproconazole	Difenoconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
Pepper	211	180	62	140	255	321	234 (1)		221 (1)
Persimmon	24	23	8	13	25	46	24	28	21
Plum	55	133 (1)	10	32	63 (1)	79	55 (3)	65	47
Plum (damson)	154	46 (1)	21	109	150 (1)	185	126 (3)	172	121
Potatoes	552	494	114	376	531	752	622	696	528
Quinces		1		1	2	2	1	1	1
Radishes	25	24	7	18	21	28	25	25	24
Rape	12	12	3	5	12	31	13	26	17
Raspberries	4	4		4	4	4	1	5	4
Rice	140	152		133	201	131	106	209	85
Rocket	22	22	3	19	21	25	20	25	22
Scarole	59	44	20	30	34	90	53	59	49
Shallot	3	3		3	1	3	3	3	5
Spinach	108	95	30	72	93	149	101	124	105
Squashes	12 (1)	11		7	17 (2)	20 (1)	10	15	8
Strawberries	347	116	48	275 (1)	413 (35)	479	338	414	303
Table grape	286	268 (1)	29	192 (1)	320 (17)	467	338 (3)	414 (2)	303 (12)
Tomatoes	619 (1)	651 (1)	211	395	774	1137	730 (1)	967	655 (2)
Walnuts	2	2	1	1	1	7	3	3	2
Watermelon	13	13	2	11	13	25	10	25	22
Wheat	45	6			94	142	60	106	55
Wine	343 (1)	325	12	191	460 (16)	536 (1)	259	572	196
Wine grape	117	87	3	69	101	129	82	115	69 (1)
Total	10803 (17)	10050 (7)	2538 (0)	7314 (4)	11489 (92)	16027 (11)	11128 (66)	13348 (12)	10497 (27)
Percentage positive	0.16	0.07	0	0.05	0.80	0.07	0.59	0.09	0.26

Table 26 Triazole data ***the Netherlands,*** *Overview of the number of samples analyzed for different triazoles in the Netherlands per raw agricultural commodity (RAC), between brackets the number of positive samples.*

RAC	Bitertanol	Cyproconazole	Difenoconazole	Dinicoazole	Epoxiconazole	Flusilazole	Myclorbutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg	0.02	0.01	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.05
Almond	1	1	1	1	1	1	1	1	1	1	1
Apple	830	794	858 (13)	843	843	843	843	843	843 (1)	830 (1)	830 (16)
Apricot	77 (2)	77	77 (1)	77	77	77 (1)	77	77	77 (9)	77	77 (1)
Artichokes	13	13	13	13	13	13	13	13	13	13	13 (1)
Asperagus	130	127	155 (2)	155	155	155	155	155	155	130	130 (1)
Avocado	128	131	131	131	131	131	131	131	131	128	128
Banana	228 (2)	228	228	228	228	228	228 (3)	228	228	228	228 (2)
Barley	26	26	26	26	26	26 (1)	26	26	26	26	26
Basil	87	87	87 (5)	87	87	87	87	87 (4)	87	87	87
Beans dry	51	51	51	51	51	51	51	51	51	51	51
Beans with pods	18	19	19 (1)	19 (6)	19	19	19 (3)	19 (1)	19 (6)	18 (1)	18 (9)
Beans without pods (fresh)	35	38	38 (2)	38	38	38	38	38	38	35	35 (1)
Beet leaves	7	7	7	7	7	7	7	7	7	7	7
Beetroot	111	111	111	111	111	111	111	111	111 (1)	111	111
Black pepper	11	11	11	11	11	11	11	11	11	11	11
Blackberries	73	77	77	77	77	77	77 (1)	77	77	73	73 (1)
Bleach celery	141	146	147 (55)	146	146	147	147	147	146 (7)	141	141 (1)
Blue Berry	89	101	102	101	101	101	101	101	101	89	89
Broccoli	266	255	276 (2)	272	272	272	272	272 (2)	272 (1)	266	266
Brussels sprouts	120	123	123 (3)	123	123 (2)	123	123	123	123 (37)	120	120
Buckwheat	1	1	1	1	1	1	1	1	1	1	1
Carambola	20	20	20	20	20	20	20	20	20	20	20 (6)
Carrot	419	435	436 (37)	435	435 (6)	435	435	435	435 (39)	419	419 (1)
Cassava	6	6	6	6	6	6	6	6	6	6	6
Cauliflower	345	338	357	356	356	356	356	356	356	345	345
Celeriac	65	53	72 (10)	72	72 (1)	72	72	72 (2)	72 (2)	65	65

RAC	Bitertanol	Cyproconazole	Difenoconazole	Dinicoazole	Epoxiconazole	Flusilazole	Myclorbutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg	0.02	0.01	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.05
Celery Leaves	104	104	104 (28)	104	104	104	104	104 (1)	104	104	104
Cherry	109 (4)	110	110	110	110	110	110 (2)	110	110 (21)	109	109
Chestnuts	1	1	1	1	1	1	1	1	1	1	1
Chinese cabbage	108	116	116	116	116	116	116	116	116	108	108
Chives	34	34 (1)	34 (1)	34	34	34	34	34	34 (2)	34 (1)	34 (1)
Cinnamon	1	1	1	1	1	1	1	1	1	1	1
Coconut	6	6	6	6	6	6	6	6	6	6	6
Common bean	231	197	242	238	238	238	238	238	238	231	231
Courgette	200 (1)	201	213	211	211	211	211	211	211	200	200 (9)
Cranberry	10	10	10	10	10	10	10	10	10	10	10
Cucumber	649 (3)	559	677 (1)	662	661	662	662 (2)	662 (1)	662 (3)	649	649 (17)
Curly kale	56	59	59 (2)	59	59	59	59	59	59 (3)	56	56
Currants (red, white, black)	100 (1)	102	111 (2)	102	102	102	102 (1)	102	102 (5)	100	100 (17)
Date	24	24	24	24	24	24	24 (1)	24	24	24 (4)	24 (3)
Dill	27	28	28	28	28	28 (2)	28	28	28	27	27 (1)
Egg plant	166	163	169	167	167	167	167	167	167 (1)	166	166 (1)
Endive	686	703	736 (1)	736	736	736	736	736	736 (1)	686	686
Fennel	43	48	51 (1)	48	48	48	48	48	48	43	43
Fennel fresh	13	14	14	14	14	14	14	14	14	13	13
Fig	54	54	54	54	54	54	54 (1)	54	54 (4)	54	54
Garlic	43	44	44	44	44	44	44	44	44	43	43
Gherkin	11	12	12	12	12	12	12	12	12	11	11
Ginger	35	35	35	35	35 (2)	35	35	35	35	35	35
Gooseberries	3	3	3	3	3	3	3	3	3	3	3 (2)
Grapefruit	140	140	140	140	140	140	140	140	140	140 (4)	140 (4)
Green bean	539	534	546	545	545	545	545	545	545	539	539
Guava	1	1	1	1	1	1	1	1	1	1	1
Hazelnuts	3	3	3	3	3	3	3	3	3	3	3

RAC	Bitertanol	Cyproconazole	Difenoconazole	Diniconazole	Epoxiconazole	Flusilazole	Myclorbutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg	0.02	0.01	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.05
Head lettuce	1380	1404	1510 (2)	1510	1510	1510	1510	1510	1510 (11)	1380	1380
Hops	1	1	1	1	1	1	1	1	1	1	1
Kiwi	175	178	178	178	178	178	178	178	178	175	175
Kohlrabi	18	20	20	20	20	20	20	20	20	18	18
Kumquats	7	7	7	7	7	7	7	7	7	7	7
Leek	415	412	445 (1)	438	438 (8)	445	444	445 (1)	438 (87)	415	415
Lemon	101	101	101	101	101	101	101 (4)	101 (1)	101	101	101
Lentils	10	10	10	10	10	10	10	10	10	10	10
Lime	69	69	69	69	69	69	69	69	69 (1)	69	69
Lychee	21	21	21	21	21	21	21	21	21	21	21
Maize	41	41	41	41	41	41	41	41	41	41	41
Mandarins	362	362	362 (2)	362	362	362	362 (2)	362 (2)	362 (8)	362	362
Mango	269	268	268	268	268	268	268	268	268 (1)	269	269
Medlar	1	1	1 (1)	1	1	1	1	1	1	1	1
Melon	314	314 (1)	314 (1)	314	314	314	314 (4)	314	314 (1)	314	314 (16)
Mineola	24	24	24	24	24	24	24	24	24	24	24
Mint	31	32	32	32	32	32 (2)	32	32	32	31	31
Mushroom	177	133	183	182	182	182	182	182	182	177	177
Nectarine	227 (8)	228	228	228 (2)	228	228 (3)	228 (3)	228	228 (21)	227	227
Nutmeg	1	1	1	1	1	1	1	1	1	1	1
Oats	2	2	2	2	2	2	2	2	2	2	2
Okra	118	118	118	118	118	118	118	118	118	118	118
Onion	356	364	364 (1)	364	364 (2)	364	364	364	364 (4)	356	356 (2)
Orange	680	680	680	680	680	680	680 (7)	680	680	680	680
Oregano	5	5	5	5	5	5	5	5	5	5	5
Oriental pear	1	1	1	1	1	1	1	1	1	1	1
Other herbs fresh	33	33	33	33	33	33	33	33	33 (1)	33	33
Pac choi	96	97	97	97	97	97	97	97	97	96 (1)	96 (1)

RAC	Bitertanol	Cyproconazole	Difenoconazole	Dinicoazole	Epoxiconazole	Flusilazole	Myclorbutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg	0.02	0.01	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.05
Papaya	68	68	68 (2)	68	68	68	68	68	68 (2)	68	68 (1)
Parsley	151 (1)	148 (5)	148 (19)	148	148 (1)	148	148	148 (1)	148 (1)	151	151 (1)
Parsnips	5	5	5	5	5	5	5	5	5	5	5
Passion fruit	94 (1)	94 (3)	94 (4)	94	94	94 (2)	94	94	94	94	94
Peach	185 (7)	185	185 (2)	185	185	185 (1)	185 (3)	185	185 (23)	185	185
Pear	617	550	628 (15)	621	621	621	621	621 (1)	621 (5)	616	617
Peas (fresh)	98	98	98	98	98	98	98	98	98	98	98 (1)
Peas with pods	288	289 (3)	289 (8)	289 (1)	289 (1)	289	289	289	289 (60)	288	288 (11)
Peppers	485	484 (4)	486 (4)	484 (1)	484	484 (5)	484 (8)	484 (21)	484 (4)	485	485 (11)
Persimmon	35	35	35	35	35	35	35	35	35	35	35
Pineapple	129	129	129	129	129	129	129	129	129	129 (89)	129 (89)
Plantain	5	5	5	5	5	5	5	5	5	5	5
Plum	191 (2)	190	191	191	191	191	191	191	191 (7)	191	191 (1)
Pointed head cabbage	117	121	121	121	121	121	121	121	121 (1)	117	117
Pomegranate	41	41	41 (1)	41	41	41	41	41 (1)	41	41	41
Pomelo	6	6	6	6	6	6	6	6	6	6	6
Potato	289	294	294	294	294	294	294	294	294	289	289
Pumpkin	23	23	23	23	23	23	23	23	23	23	23
Purslane	17	17	17	17	17	17	17	17	17	17	17
Quinces	5	5	5	5	5	5	5	5	5	5	5
Radicchio Rosso	223	225	225	225	225	225	225	225	225	223	223
Radish	103	98	115	114	114	114	114	114	114	103	103
Raisins	61	61	61	61	61	61	61 (2)	61	61	61	61 (2)
Rambutan	7	7	7	7	7	7	7	7	7	7	7
Raspberry	101	103	103	103	103	103	103 (2)	103	103	101	101 (2)
Red cabbage	133	136	136	136	136 (1)	136	136	136	136 (4)	133	133

RAC	Bitertanol	Cyproconazole	Difenoconazole	Dinicoazole	Epoxiconazole	Flusilazole	Myclorbutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg	0.02	0.01	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.05
Rettich	15	15	16	16	16	16	16	16	16	15	15
Rhubarb	46	52	52	52	52	52	52	52	52	46	46
Rice	69	69	69	69	69	69	69	69	69	69	69
Roodlof	3	2	2	2	2	2	2	2	2	3	3
Rosemary	27 (2)	27	27	27	27	27	27 (1)	27 (2)	27 (1)	27	27
Rucola	99	100	100	100	100	100	100	100	100	99	99 (4)
Rye	11	11	11	11	11	11	11	11	11	11	11
Sage	4	4	4	4	4	4	4 (1)	4	4	4	4
Salsify	5	8	8	8	8	8	8	8	8	5	5
Savoy cabbage	53	55	55 (6)	55	55	55	55	55	55 (1)	53	53
Sesame seed	30	30	30	30	30	30	30	30	30	30	30
Shallot	26	26	26	26	26	26	26	26	26	26	26
Spinach	446	438	458	458	458	458	458	458 (1)	458	446	446
Spring onion	8	8	8	8	8	8	8	8	8	8	8
Strawberry	1119 (1)	1062 (11)	1213 (1)	1146	1146	1145 (2)	1145 (69)	1146	1146	1118	1119 (68)
String bean	163 (7)	163	163 (6)	163	163	163	163 (1)	163 (1)	163 (1)	163	163 (5)
Swedes	18	18	18	18	18	18	18	18	18	18	18
Sweet corn	29	31	31	31	31	31	31	31	31	29	29
Sweet pepper	1065	1021 (20)	1115 (2)	1094 (5)	1094	1094 (4)	1094 (32)	1094	1094 (75)	1065	1065 (105)
Sweet potato	5	5	5	5	5	5	5	5	5	5	5
Table grape	1171	1172 (19)	1172 (10)	1172 (16)	1172	1172 (37)	1172 (200)	1172	1172 (101)	1172 (9)	1172 (236)
Tamarind	3	3	3	3	3	3	3	3	3	3	3
Tea	86	86	86 (1)	86	86	86 (1)	86	86	86 (1)	86	86 (4)
Thyme	28	28	28	28	28	28	28	28	28	28	28
Tomato	1026 (20)	945 (2)	1086 (1)	1063	1063	1063	1063 (2)	1063	1063 (43)	1026	1026 (68)
Walnuts	2	2	2	2	2	2	2	2	2	2	2
Water cress	13	14	14	14	14	14	14	14	14	13	13
Watermelon	25	25	25	25	25	25	25	25	25	25	25

RAC	Bitertanol	Cyproconazole	Difenoconazole	Dinicoazole	Epoxiconazole	Flusilazole	Myclorbutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg	0.02	0.01	0.02	0.01	0.01	0.01	0.01	0.01	0.01	0.02	0.05
Wheat	118	118	118	118	118	118	118	118	118	118	118
White cabbage	107	109	109	109	109	109	109	109	109 (1)	107	107
Wine, alcohol > 9%	247	247	247	247	247	247	247 (1)	247	247 (6)	247	247 (8)
Winter cress	1	1	1	1	1	1	1	1	1	1	1
Witloof, Chicory	181	166	197	186	186	186	186	186 (1)	186	181	181
Total	21356 (61)	20987 (69)	22104 (257)	21905 (36)	21904 (24)	21912 (61)	21907 (354)	21913 (44)	21796 (605)	21355 (109)	21357 (625)
Percentage positive	0.29	0.33	1.16	0.16	0.11	0.28	1.62	0.2	2.78	0.51	2.9

Table 27 Triazole data ***Sweden,*** *Overview of the number of samples analyzed for different triazoles in Sweden per raw agricultural commodity (RAC), between brackets the number of positive samples.*

RAC	Bitertanol	Cyproconazole	Epoxyconaole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.01	0.01	0.01	0.01-0.02	0.01-0.02	0.01-0.05	0.01	0.01-0.1	0.01-0.2
Apples	841 (15)	135	135	841	841 (2)	841	445	706	841 (1)
Apricots	7			7	7	7	2 (1)	7	7
Artichokes	83	18	18	83	83	83	46 (1)	65	83
Asparagus	19	3	3	19	19	19	9	16	19
Avocados	52	4	4	52	52	52	30	48	52
Bananas	348 (1)	51	51	348	348 (2)	348	186	297	348
Basil	15	7	7	15	15	15 (1)	15	8	15
Beans (with pods)	114	23	23	114	114	114	81	91	114
Beetroots	7			7	7	7	2	7	7
Black radishes	1	1	1	1	1	1	1		1
Broccoli	67	12	12	67	67	67	32	55	67
Brussels sprouts	3			3	3	3	1	3	3
Cabbages	120	18	18	120	120	120	61	102	120
Cabbages, pointed type	4			4	4	4	2	4	4

RAC	Bitertanol	Cyproconazole	Epoxyconaole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.01	0.01	0.01	0.01-0.02	0.01-0.02	0.01-0.05	0.01	0.01-0.1	0.01-0.2
Cabbages, red	120	18	18	120	120	120	61	102	120
Cabbages, savoy	1			1	1	1	1	1	1
Carambolas	3	1	1	3	3	3	2	2	3 (1)
Carrots	262	33	33	262	262	262	121 (1)	229	262
Cassavas	5			5	5	5		5	5
Cauliflower	61			61	61	61	25	61	61
Celeriac	15			15	15	15	5	15	15
Celery	21			21	21	21	10	21	21
Cherimoyas	1			1	1	1		1	1
Cherries	11	1	1	11	11	11	9	10	11
Chili peppers	5			5	5	5	5	5	5
Chinese broccoli	21	1	1	21	21 (1)	21	10	20	21
Chinese cabbages	27	1	1	27	27	27	13	26	27
Chinese chard	2	1	1	2	2	2	2	1	2
Coriander	12	4	4	12	12	12	12 (1)	8	12
Corn salad	1			1	1	1	1	1	1
Courgettes	62	11	11	62	62	62	26	51	62 (2)
Cucumbers	296	30	30	296	296 (1)	296	140	266	296 (3)
Cucumbers, other	296	30	30	296	296	296	140	266	296
Dates	1			1	1	1		1	1
Dill	12	2	2	12	12	12	2	10	12
Egg plants	83	18	18	83	83	83	46 (1)	65	83
Fennel	6	1	1	6	6	6	5	5	6
Figs	35			35	35	35	20	35	35
Garlic	14			14	14	14	6	14	14
Grapefruits	43	12	12	43	43	43	32	31	43
Ground cherries	11	1	1	11	11	11	4	10	11
Jerusalem artichokes	3	1	1	3	3	3	2	2	3
Kiwi fruits	99	21	21	99	99	99	61	78	99
Kohlrabies	4	1	1	4	4	4	3	3	4
Kumquatss	16			16	16	16	5	16	16

RAC	Bitertanol	Cyproconazole	Epoxyconaole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.01	0.01	0.01	0.01-0.02	0.01-0.02	0.01-0.05	0.01	0.01-0.1	0.01-0.2
Leeks	121	20	20 (1)	121	121	121	56	101	121
Lemons	50	1	1	50	50	50	28 (9)	49	50
Lettuce, head	260	28	28	260	260	260	110	232	260
Lettuce, iceberg	260	28	28	260	260	260	110 (1)	232	260
Lettuce, others	260	28	28	260	260	260	110	232	260
Limes	24	2	2	24	24	24	12	22	24
Lychees	32	1	1	32	32	32	21	31	32
Longan	1	1 (1)	1	1	1	1	1		1
Mandarins	315	59	59	315	315	315	181 (1)	256	315
Mangoes	77	17	17	77	77	77	47	60	77
Mangostan	1			1	1	1	1	1	1
Melons	145	15	15	145	145	145	68	130	145
Mushrooms	73	19	19	73	73	73	43	54	73
Mushrooms, cultivated	73	19	19	73	73	73	43	54	73
Nectarines	115 (1)	22	22	115	115	115 (2)	57 (9)	93	115
Okra	2			2	2	2	1	2	2
Onions	153	28	28	153	153	153	93	125	153
Oranges	321	67	67	321	321 (1)	321	190	254	321
Papayas	93	15	15	93	93	93	53 (4)	78	93
Parsley	42	1	1	42	42	42	11	41	42
Parsnips	15	10	10	15	15	15	10	5	15
Passion fruits	35	10	10	35	35	35	25 (1)	25	35
Peaches	101	20	20	101	101	101	45 (3)	81	101
Pears	527 (4)	61	61	527	527	527 (1)	270 (3)	466	527
Peas (with pods)	7	2	2	7	7	7	7	5	7
Peas (without pods)	44			44	44	44	20	44	44
Peppers	214	23	23	214 (1)	214 (1)	214 (1)	90 (4)	191	214 (4)
Persimmons	71	21	21	71	71	71	48	50	71
Pineapples	28	1	1	28	28	28	16	27 (12)	28 (10)
Plums	28	3	3	28	28	28	16 (1)	25	28
Pomegranates	18	15	15	18	18	18	18	3	18

RAC	Bitertanol	Cyproconazole	Epoxyconaole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.01	0.01	0.01	0.01-0.02	0.01-0.02	0.01-0.05	0.01	0.01-0.1	0.01-0.2
Potatoes	368	48	48	368	368	368	154	320	368
Potatoes (fresh)	368	48	48	368	368	368	154	320	368
Radishes	6	1	1	6	6	6	5	5	6
Raspberries	18	11	11	18	18	18	11	7	18
Rucola	15	14	14	15	15	15	15	1	15
Shallots	1	1	1	1	1	1	1		1
Spinach	63			63	63	63	30	63	63
Spring onions	17	9	9	17	17	17	13	8	17
Strawberries	228	30	30	228	228	228 (6)	110	198	228
Swedish turnips	12			12	12	12	5	12	12
Sweet corn (cobs)	2	1	1	2	2	2	2	1	2
Sweet potatoes	26	10	10	26	26	26	20	16	26
Swiss chard	2	1	1	2	2	2	2	1	2
Table grapes	497	79	79	497 (5)	497	497 (33)	279 (18)	418	497 (23)
Tomatoes	322 (3)	49	49	322 (2)	322	322	162 (1)	273	322 (3)
Water spinach	8	2	2	8	8	8	5	6	8
Watermelons	21			21	21	21		21	21
Wine grapes	1	1	1	1	1	1	1		1
Total	8711 (24)	1302 (1)	1302 (1)	8711 (8)	8711 (8)	8711 (44)	4452 (60)	7409 (12)	8711 (47)
Percentage positive	0.28	0.08	0.08	0.09	0.09	0.51	1.35	0.16	0.54

Table 28 Triazole data ***United Kingdom,*** *Overview of the number of samples analyzed for different triazoles in the United Kingdom per raw agricultural commodity (RAC), between brackets the number of positive samples.*

RAC	Bitertanol	Cyproconazole	Difenoconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.02-0.05	0.02	0.01-0.05	0.01-0.05	0.01-0.05	0.01-0.05	0.01-0.05	0.02-0.05	0.02-0.05
Apple	185	82	838	838	941 (6)	838	838	838	82
Asparagus					95		95	95	95
Banana	259 (48)	19	19	19	188	28	95	28	28

RAC	Bitertanol	Cyproconazole	Difenoconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.02-0.05	0.02	0.01-0.05	0.01-0.05	0.01-0.05	0.01-0.05	0.01-0.05	0.02-0.05	0.02-0.05
Bleach celery	47	47	47 (12)	47	47	47	47	47	47
Blue berry			49		49	49		49	49
Broccoli			96		96		96	96	96
Carrot	37	18	18	18	317	429	18 (2)	189	189
Cauliflower					96		96	96	96
Cherry	70		142	72	142 (12)	143 (1)	142 (16)	70	70
Courgette			95	95	95	95	95	47	48
Cucumber	3	3	3	110	110	110	110	110	110
Egg plant	35	35	35	35	131	35	131	131	131
French bean		94	94	94	94	94	94	94	94 (1)
Garlic					48		48	48	48
Grapefruit	72				72				
Kiwi	48	48	144	48	144	144	48	48	48
Leek	37	37	37	37	109	109	109	37	37
Lemon	72				72 (1)				
Lettuce	71	71	501 (6)	178	501	501	501 (9)	394	394 (1)
Lychee	26	10	26	10	26	26	10	26	26
Mandarine, clementine	296	62	62	62	296	62	62 (1)	62	62
Mango			96		96	96		96	96
Mushroom				48	48	48	48		
Nectarine	47 (1)	47	47	47	47	47 (1)	47 (2)	47	47
Onion					48		48	48	48
Orange	72				72			72	72
Papaya	32		32		32	32		32	32
Passion fruit	87	27	87 (5)	27	87	87	27 (1)	75	87
Pea (fresh)					120		120 (3)	120	120 (3)
Peach	30 (4)	30	30	30	30	30 (1)	30 (3)	30	30
Pear	123	46	46	46	679	46	854 (1)	458	458
Pepper	73	73 (1)	73	73	145	145	145 (1)	145	145 (2)
Pineapple			60		60		60	60 (32)	
Plum	72		72		72	72	72	72	72

RAC	Bitertanol	Cyproconazole	Difenoconazole	Flusilazole	Myclobutanil	Propiconazole	Tebuconazole	Triadimefon	Triadimenol
LOR (mg/kg)	0.02-0.05	0.02	0.01-0.05	0.01-0.05	0.01-0.05	0.01-0.05	0.01-0.05	0.02-0.05	0.02-0.05
Potato	66	66	66	66	209	66	66	209	209
Raspberry	25	25	55	55	55 (4)	55	55	25	25
Spinach				72	120	72	120	72	72
Strawberry	163	52 (1)	163	163	163 (15)	163	163	163	163 (5)
Sweet pepper				72	216	72	216	144	144
Table grape	235	235 (1)	307	307	795 (54)	307	498 (14)	532	532 (5)
Tomato	55 (1)	55	384 (2)	55	384	384	384 (2)	384	384 (17)
White cabbage			72		72		72	72	72
Total	2338 (54)	1182 (3)	3796 (25)	2724 (0)	7219 (92)	4432 (3)	5660 (45)	5361 (32)	4558 (34)
Percentage positive	2.31	0.25	0.66	0	1.27	0.07	0.80	0.60	0.75

Annex II Extrapolation rules of pesticide analyses

Compound	From	To
Tebuconazole	Pear	Apple
	Black currants	Red and white currants, blueberries, cranberries, gooseberries, rose hips, mulberries, azarole, Elderberries
	Carrots	Horse radish, parsnip, salsify, parsley root
	Tomatoes	Aubergines
	Green beans	Peas with pods (mange-tout)
Difenconazole	Apples and pears	Medlar, quinces, loquat
	Carrots	Horse radish, parsnip, salsify, parsley root
	Lettuce	Rocket (rucola)
	Savoy cabbage	All head cabbages
	Parsley, coriander, dill	All herbs
Triadimenol	Red currants	Black and white currants, blueberries, cranberries, gooseberries, rose hips, mulberries, azarole, Elderberries
Myclobutanil	Lemon and oranges	All other citrus
	Apples	Pears, quinces, medlar, loquat
	Peaches	Apricots, nectarines
	Raspberries	Blackberries
	Cucumbers	Gherkins, courgettes
	Melons	Pumpkins, watermelons
	Carrots	Horse radish, parsnip, salsify, parsley root
Bitertanol	Apples and pears	Quinces, medlar, loquat
	Courgettes and cucumbers	Gherkins
Diniconazole	Nectarines	Peaches and apricots

Annex III Extrapolation of pesticide residue levels as used in the exposure calculations

The following approach was followed:

- Positive findings in monitoring samples were identified.for each of the active substances present in the Common Assessment Groups. This was done acute or chronic effects.
- For each of the commodities, those for which MRLs above the LOQ are set by EU legislation, indicative of current registered uses, were selected.
- Commodities belonging to the same extrapolation group (using EU guidance document) and for which the same or very similar MRL is also in force were subsequently qualified for extrapolation of the available monitoring data, at the condition that no monitoring data were available for these extrapolated commodities.

Compound	Original RAC[a]	To RAC	CZ	FI	FR	IT	NL	SE	UK	All
Tebuconazole	Pear	Apple	<0	Yes	No, both pos	No, both pos	No, both pos	No, both pos	No, both pos	No, both pos
	Black currants	Red and white currants	No[b]	<0	<0	<0		No	No	
		Blueberries	No	<0	<0	<0	RAC is analyzed	No	No	
		Cranberries	No	<0	<0	<0	RAC is analyzed	No	No	
		Gooseberries	No	<0	<0	<0	RAC is analyzed	No	No	
		Rose hips	No	<0	<0	<0	Yes	No	No	Yes
		Mulberries	No	<0	<0	<0	Yes	No	No	Yes
		Elderberries	No	<0	<0	<0	Yes	No	No	Yes
	Carrots	Horse radish	<0[c]	<0	Yes	<0	Yes	Yes	Yes	Yes
		Parsnip	<0	<0	Yes	<0	RAC is analyzed	RAC is analyzed	Yes	Yes
		Salsify	<0	<0	Yes	<0	RAC is analyzed	Yes	Yes	Yes
		Parsley root	<0	<0	Yes	<0	Yes	Yes	Yes	Yes

Compound	Original RAC[a]	To RAC	CZ	FI	FR	IT	NL	SE	UK	All
	Tomatoes	Egg plant	Yes	<0	<0	Yes	No, both pos	Yes	Yes	
	Green beans	Peas with pods (mangetout)	<0	<0	<0	<0	No, both pos	<0	<0	
		Green beans	<0	<0	<0	<0	No, both pos	<0	<0	
Difenoconazole	Apples and pears	Medlar	No	<0	<0	<0	No, both pos	No	<0	
		Quinces	No	<0	<0	<0	No, both pos	No	<0	
		Loquat	No	<0	<0	<0	Yes	No	<0	Yes
	Carrots	Horse Radish	No	Yes	Yes	<0	Yes	No	<0	Yes
		Parsnip	No	Yes	Yes	<0	No, both pos	No	<0	
		Salsify	No	Yes	Yes	<0	No, both pos	No	<0	
		Parsley root	No	Yes	Yes	<0	Yes	No	<0	Yes
	Lettuce	Rocket (rucola)	No	<0	<0	<0	Yes	No	Yes	Yes
	Savoy cabbage	Cabbage, head	No	<0	No	<0	Yes	No	No	Yes
		Cabbage, red	No	<0	No	<0	No, both pos	No	No	
		Cabbage, ox head	No	<0	No	<0	No, both pos	No	No	
		Cabbage, white	No	<0	No	<0	No, both pos	No	No	
	Parsley, coriander, dill	All herbs	No	Yes	Yes[d]	<0	Yes[d]	No	No	No
Triadimenol	Red currants	Black and white currants	No	<0	<0	<0	No, both pos	No	No	

Compound	Original RAC[a]	To RAC	CZ	FI	FR	IT	NL	SE	UK	All
		Blueberries	No	<0	<0	<0	No, both pos	No	No	
		Cranberries	No	<0	<0	<0	No, both pos	No	No	
		Gooseberries	No	<0	<0	<0	No, both pos	No	No	
		Rose hips	No	<0	<0	<0	Yes	No	No	Yes
		Mulberries	No	<0	<0	<0	Yes	No	No	Yes
		Elderberries	No	<0	<0	<0	Yes	No	No	Yes
Myclobutanil	Lemon and oranges	All other citrus	<0	<0	Yes[e]	Yes[e]	Yes[e]	No	No	No
	Apples	Pears	<0	<0	<0	No, both pos	No, both pos	No, both pos	No, both pos	
		Medlar	<0	<0	<0	Yes	<0	Yes	Yes	Yes
		Quinces	<0	<0	<0	Yes	<0	Yes	Yes	Yes
		Loquat	<0	<0	<0	Yes	<0	Yes	Yes	Yes
	Peaches	Apricots	<0	<0	<0	No, both pos	No, both pos	No, both pos	<0	
		Nectarines	<0	<0	<0	Yes	No, both pos	No, both pos	<0	
	Raspberries	Blackberries	No	<0	<0	<0	No, both pos	<0	Yes	
	Cucumbers	Gherkins	<0	Yes	Yes	<0	No, both pos	Yes	<0	
		Courgette	<0	Yes	No	<0	No, both pos	No, both pos	<0	
	Melons	Pumpkins	<0	<0	<0	Yes	No, both pos	<0	No	
		Watermelons	<0	<0	<0	Yes	No, both pos	No, both pos	No	
	Carrots	Horse Radish	<0	<0	Yes	<0	<0	<0	<0	Yes

Compound	Original RAC[a]	To RAC	CZ	FI	FR	IT	NL	SE	UK	All
		Parsnip	<0	<0	Yes	<0	<0	<0	<0	Yes
		Salsify	<0	<0	Yes	<0	<0	<0	<0	Yes
		Parsley root	<0	<0	Yes	<0	<0	<0	<0	Yes
Bitertanol	Apples and pears	Medlar	Yes	Yes	<0	Yes	<0	Yes	<0	
		Quinces	Yes	Yes	<0	Yes	<0	Yes	<0	Yes
		Loquat	Yes	Yes	<0	Yes	<0	Yes	<0	Yes
	Courgettes and cucumber	Gherkins	<0	<0	<0	Yes	No, both pos	<0	No, both pos	
Diniconazole	Nectarines	Peaches	No	<0	No	No	No, both pos	No	No, both pos	
		Apricots	No	<0	No	No	No, both pos	No	No	

[a] *RAC = raw agricultural commodity*

[b] *No = the original RAC is not analyzed*

[c] *< 0 = All analytical results of original RAC are below limit of detection*

[d] *Some herbs had pos.*

[e] *Some citrus fruits were positive*

both positive should be explained as well

Annex IV Processing factors used in the exposure calculations

Compound	Raw agricultural commodity	Processing type	Processing factor
Bitertanol	Banana	Peeling	0.5
	Apple	Juicing	0.11
	Apple	Sauce/puree	0.1
	Plums (including prunes)	Sauce/puree	0.6
	Plums (including prunes)	Marmalade/jam	1
	Cherry, sweet	Washing/cleaning	0.8
	Cherry, sweet	Juicing	0.2
	Cherry, sweet	Canned/conserved	0.6
	Cherry, sweet	Marmalade/jam	0.5
	Tomato	Washing/cleaning	0.8
	Tomato	Sauce/puree	2.1
	Tomato	Canned/conserved	0.4
	Tomato	Juicing	0.1
Difenoconazool	Table-grapes	Juicing	0.5
	Table-grapes	Drying	1
	Wine-grapes	Wine making	0.35
	Apple	Sauce/puree	0.14
	Apple	Juicing	0.6
	Apple	Washing/cleaning	0.8
	Olives	Oil extraction	1.4
	Tomato	Canned/conserved	0.07
	Tomato	Juicing	0.22
	Tomato	Sauce/puree	0.72
	Carrot	Juicing	0.06
	Carrot	Canned/conserved	0.06
Epoxiconazool	Barley	Brewing	0.1
	Wheat	Milling	1
	Wheat	Baking of bread	1
Flusilazol	Table-grapes	Drying	1

Compound	Raw agricultural commodity	Processing type	Processing factor
	Table-grapes	Juicing	0.3
	Wine-grapes	Wine making	0.1
	Apple	Juicing	0.2
	Barley	Milling	0.4
	Wheat	Milling	0.96
	Wheat	Baking of bread	1
Myclobutanil	Currants, black, red, white	Juicing	0.3
	Currants, black, red, white	Canned/conserved	1
	Strawberry	Canned/conserved	0.85
	Strawberry	Marmalade/jam	0.5
	Table-grapes	Juicing	0.2
	Wine-grapes	Wine making	0.15
	Mandarins	Juicing	0.4
	Mandarins	Peeling	0
	Banana	Peeling	0.24
	Apple	Washing/cleaning	1
	Apple	Juicing	0.13
	Apple	Sauce/puree	0.25
	Tomato	Canned/conserved	0.75
	Tomato	Juicing	0.58
	Tomato	Washing/cleaning	1
	Tomato	Sauce/puree	1.6
Propiconazole	Tea, green, black	Cooking in water	0.02
	Table-grapes	Juicing	0.5
	Plums (including prunes)	Drying	1
	Barley	Brewing	1
	Maize	Milling	1
	Maize	Oil extraction	0.6
	Peanut	Oil extraction	0.6
Tebuconazole	Table-grapes	Juicing	0.05
	Wine-grapes	Wine making	0.2

Compound	Raw agricultural commodity	Processing type	Processing factor
	Banana	Peeling	0.6
	Plums (including prunes)	Washing/cleaning	0.7
	Plums (including prunes)	Marmalade/jam	1
	Plums (including prunes)	Canned/conserved	0.7
	Plums (including prunes)	Drying	1
	Barley	Brewing	0.03
	Peanut	Oil extraction	0.14
Triadimefon	Table-grapes	Drying	1
	Table-grapes	Juicing	0.45
	Wine-grapes	Wine making	0.42
	Pineapple	Peeling	0.1
	Apple	Washing/cleaning	0.92
	Apple	Sauce/puree	0.63
	Apple	Juicing	0.63
	Tomato	Washing/cleaning	0.97
	Tomato	Sauce/puree	2.4
	Tomato	Sauce/puree	5.2
	Tomato	Sauce/puree	0.78
	Tomato	Juicing	0.59
	Tomato	Canned/conserved	0.59
	Tomato	Peeling	0.33
Triadimenol	Table-grapes	Drying	1
	Table-grapes	Juicing	0.78
	Wine-grapes	Wine making	0.5
	Pineapple	Peeling	0.1
	Apple	Washing/cleaning	0.92
	Apple	Juicing	0.63
	Apple	Sauce/puree	0.63
	Tomato	Sauce/puree	0.78
	Tomato	Peeling	0.33
	Tomato	Juicing	0.59

Compound	Raw agricultural commodity	Processing type	Processing factor
	Tomato	Sauce/puree	2.4
	Tomato	Washing/cleaning	0.97
	Tomato	Canned/conserved	0.59

References

Bitertanol	Apple	Vol B7 DAR, March 2005
Bitertanol	Banana	JMPR, 1984
Bitertanol	Tomato	Vol B7 DAR, March 2005
Epoxiconazole	Wheat	Vol B7 DAR, April 2005

Processing Factors

Bitertanol	Apple	DAR 2005, JMPR 1999
	Banana	JMPR 1999
	Cherry	JMPR 1999
	Plum	JMPR 1999
	Tomato	DAR 2005, JMPR 1999
Difenoconazole	Apple	DAR 2006, JMPR 2007
	Carrot	JMPR 2007
	Grapes	JMPR 2007
	Olives	JMPR 2007
	Tomato	JMPR 2007
Epoxiconazole	Barley	DAR 2005
	Wheat	DAR 2005
Flusilazole	Apple	DAR addendum 2000, UK SC9830, JMPR 2007
	Barley	DAR 1996, JMPR 1993
	Grape	DAR addendum 2000, JMPR 2007
	Soya bean	JMPR 2007
	Wheat	DAR 1996, JMPR 1993, JMPR 2007

Myclobutanil	Apple	DAR 2005
	Banana	JMPR 1997
	Blackcurrant	JMPR 1997
	Grapes	DAR 2005, UK eval 2002
	Hops	JMPR 1998
	Mandarin	JMPR 1997
	Orange	JMPR 1997
	Strawberry	JMPR 1997
	Tomato	JMPR 1997
Propiconazole	Barley	DAR addendum 2002
	Grapes	DAR 1998, JMPR 2007
	Maize	DAR 1998
	Peanut	DAR 1998
	Plum	DAR 1998
	Sugar	DAR 1998
	Tea	DAR 1998, JMPR 2007
	Wheat	DAR 1998, DAR addendum 1996
Tebuconazole	Banana	JMPR 1997
	Barley	DAR 2006
	Grapes	DAR 2006, JMPR 1997
	Peanut	JMPR 1997
	Plum	JMPR 1997
Triadimefon	Apple	JMPR 2007
	Coffee	JMPR 2007
	Grapes	JMPR 2007
	Pineapple	JMPR 1995, JMPR 2007
	Tomato	JMPR 2007
Triadimenol	Apple	JMPR 2007
	Coffee	JMPR 2007
	Grapes	DAR year, JMPR 2007
	Pineapple	JMPR 1995, JMPR 2007
	Tomato	JMPR 2007

Annex V Variability factors used in the exposure calculations using monitoring data per raw agricultural commodity

The variability factor is defined as the ratio of the 97.5th percentile to the mean of the distribution of concentrations in individual units. In probabilistic modeling these (fixed) values are used to define distributions (lognormal or beta, see 4.4.1) from which *stochastic variability factors* are sampled for use in the simulations (see 2.5 and 2.6).

Raw agricultural commodity	Variability factor	Unit weight[a]
Almonds	1	Na
Apple	3.6	112
Apricot	3.6	65
Artichoke, globe	3.6	116
Asparagus	3.6	16
Avocado	3.6	na
Banana	3.6	100
Barley	1	Na
Beetroot	3.6	82
Blackberries	1	Na
Broccoli	3.6	608
Brussels sprouts	1	Na
Cabbage, red	3.6	908
Cabbage, savoy	3.6	908
Cabbage, white	3.6	908
Carrot	3.6	80
Cauliflower	3.6	1733
Celeriac	3.6	550
Celery	3.6	462
Chard	3.6	Na
Cherry, sweet	1	Na
Chestnuts	1	Na
Chicory (sprouts)	3.6	122
Coconut	1	Na
Common bean (pods and/or immature seeds)	1	Na

Raw agricultural commodity	Variability factor	Unit weight[a]
Corn salad	1	10
Cowberry, see bilberry, red	1	Na
Cress, garden	1	Na
Cucumber	3.6	490
Date	1	Na
Egg plant	3.6	271
Endive	3.6	122
Fennel, bulb	3.6	234
Fig	3.6	55
Garden pea (young pods)	1	Na
Garden pea, shelled (succulent seeds)	1	Na
Gherkin	1	15
Grapefruit	3.6	160
Hazelnuts	1	Na
Kale (including among others: collards, curly kale)	1	Na
Kiwifruit	3.6	76
Kohlrabi	3.6	135
Leek	3.6	140
Lemon	3.6	84
Lettuce, head	3.6	558
Lettuce, leaf	3.6	558
Lime	3.6	67
Linseed	1	Na
Lychee	1	Na
Maize	1	Na
Mandarin	3.6	100
Mango	3.6	207
Melons, except watermelon	3.6	552
Millet	1	Na
Mushrooms	1	Na
Nectarine	3.6	110

Raw agricultural commodity	Variability factor	Unit weight[a]
Oats	1	Na
Olives	1	Na
Onion, bulb	3.6	150
Orange, sweet	3.6	160
Papaya	3.6	268
Parsley	1	Na
Passion fruit	3.6	45
Peach	3.6	110
Peanut	1	Na
Pear	3.6	150
Peppers, sweet (including pimento or pimiento)	3.6	160
Persimmon, Japanese	3.6	150
Pineapple	3.6	1600
Plums (including prunes)	3.6	55
Pomegranate	3.6	154
Potato	3.6	216
Pumpkins	3.6	116
Quince	3.6	Na
Radish	1	Na
Raspberries, red, black	1	Na
Rhubarb	3.6	38
Rice	1	Na
Rye	1	Na
Sesame seed	1	Na
Soya bean (dry)	1	Na
Spinach	3.6	Na
Squash, summer	3.6	114
Strawberry	1	Na
Sunflower seed	1	Na
Swede	3.6	500
Sweet corn (corn-on-the-cob)	3.6	215

Raw agricultural commodity	Variability factor	Unit weight[a]
Sweet potato	3.6	130
Table-grapes	3.6	500
Tomato	3.6	85
Walnuts	1	Na
Watermelon	3.6	4518
Wheat	1	Na

[a] *na = not applicable. When the unit weight was not available, it was assumed in the calculations that each consumed amount consists of just one portion*

Annex VI MRLs and field trial data for selected pesticide – RAC combinations

Compound	RAC[a]	MRL[b] (mg/kg)	Field trial data (mg/kg)
Bitertanol	Apple	2	0.08; 0.09(2); 0.12(2); 0.15; 0.16; 0.18; 0.23; 0.24; 0.34
	Banana	3	0.06(2); 0.1; 0.24; 0.32; 0.36
	Tomato	3	0.39; 0.41; 0.48; 0.54; 0.56;0.96(2); 0.98; 2.1; 2.4
Cyproconazole	Table grape	0.2	-
	Lettuce	0.05	-
	Peach	0.1	-
Diniconazole	Table grape	0.2	-
Epoxiconazole	Cabbage	0.2	-
	Wheat	0.2	<0.01(2); 0.03; 0.04; <0.05(5); 0.1

[a] *RAC = raw agricultural commodity*

[b] *MRL = maximum residue limit*

Annex VII Contribution of RACs and compounds to acute cumulative estimated exposure after replacing monitoring data of selected RAC-pesticide combinations with MRLs or field trial data using NOAEL-derived RPFs

Scenario[a]	Country[b]	Population[b]	RACs and pesticides								
			Top 1			Top 2			Top 3		
			RAC[c]	Pesticide	%	RAC	Pesticide	%	RAC	Pesticide	%
MRL bitertanol in apple	CZ	Children	Apple	Bitertanol	99.7	Wheat	Propiconazole	0.1	Pineapple	Triadimefon	0.05
MRL bitertanol-apple	FR	Children	Apple	Bitertanol	99.5	Wheat	Propiconazole	0.2	Pineapple	Triadimefon	0.2
MRL bitertanol-apple	IT	Children	Apple	Bitertanol	99.4	Tomato	Bitertanol	0.2	Wheat	Propiconazole	0.2
MRL bitertanol-apple	NL	Children	Apple	Bitertanol	99.5	Wheat	Propiconazole	0.2	Pineapple	Triadimefon	0.2
MRL bitertanol-apple	SE	Children	Apple	Bitertanol	99.7	Pineapple	Triadimefon	0.2	Wheat	Propiconazole	0.1
MRL bitertanol-apple	UK	Children	Apple	Bitertanol	99.5	Pineapple	Triadimefon	0.2	Wheat	Propiconazole	0.1
MRL bitertanol-apple	FR	Adults	Apple	Bitertanol	99.8	Wheat	Propiconazole	0.1	Pineapple	Triadimefon	0.1
MRL bitertanol-apple	IT	Adults	Apple	Bitertanol	99.7	Wheat	Propiconazole	0.1	Tomato	Bitertanol	0.1
MRL bitertanol-apple	NL	Adults	Apple	Bitertanol	99.5	Wheat	Propiconazole	0.2	Pineapple	Triadimefon	0.2
MRL bitertanol-apple	NL	Total	Apple	Bitertanol	99.5	Wheat	Propiconazole	0.2	Pineapple	Triadimefon	0.2
MRL bitertanol-apple	FR	Wmcba	Apple	Bitertanol	99.7	Wheat	Propiconazole	0.1	Pineapple	Triadimefon	0.1
MRL bitertanol-apple	IT	Wmcba	Apple	Bitertanol	99.7	Wheat	Propiconazole	0.1	Tomato	Bitertanol	0.1
MRL bitertanol-apple	NL	Wmcba	Apple	Bitertanol	99.4	Wheat	Propiconazole	0.2	Pineapple	Triadimefon	0.2
MRL bitertanol in banana	NL	Total	Banana	Bitertanol	99.5	Wheat	Propiconazole	0.2	Pineapple	Triadimefon	0.2
MRL bitertanol in tomato	NL	Children	Tomato	Bitertanol	99.6	Wheat	Propiconazole	0.2	Pineapple	Triadimefon	0.1

Scenario[a]	Country[b]	Population[b]	RACs and pesticides								
			Top 1			Top 2			Top 3		
			RAC[c]	Pesticide	%	RAC	Pesticide	%	RAC	Pesticide	%
MRL bitertanol in tomato	NL	Wmcba	Tomato	Bitertanol	99.9	Wheat	Propiconazole	0.1	Pineapple	Triadimefon	0.1
MRL bitertanol in tomato	NL	Total	Tomato	Bitertanol	99.8	Wheat	Propiconazole	0.1	Pineapple	Triadimefon	0.1
MRL cyproconazole in table grape	NL	Children	Tablegrape	Cyproconazole	94.4	Wheat	Propiconazole	1.8	Pineapple	Triadimefon	1.7
MRL cyproconazole in table grape	NL	Wmcba	Tablegrape	Cyproconazole	95.2	Pineapple	Triadimefon	1.8	Wheat	Propiconazole	1.7
MRL cyproconazole in lettuce	NL	Children	Lettuce	Cyproconazole	89.8	Pineapple	Triadimefon	3.3	Wheat	Propiconazole	2.9
MRL cyproconazole in lettuce	NL	Wmcba	Lettuce	Cyproconazole	90.0	Wheat	Propiconazole	3.7	Pineapple	Triadimefon	2.4
MRL cyproconazole in peach	NL	Children	Peach	Cyproconazole	59.0	Pineapple	Triadimefon	13.2	Wheat	Propiconazole	12.9
MRL cyproconazole in peach	NL	Wmcba	Peach	Cyproconazole	70.3	Pineapple	Triadimefon	13.6	Wheat	Propiconazole	8.8
MRL epoxiconazole in cabbage	NL	Children	Cabbage, red	Epoxiconazole	49.3	Cabbage, white	Epoxiconazole	31.2	Cabbage, oxhead	Epoxiconazole	8.2
MRL epoxiconazole in cabbage	NL	Wmcba	Cabbage, white	Epoxiconazole	53.6	Cabbage, red	Epoxiconazole	26.6	Cabbage, oxhead	Epoxiconazole	10.2
MRL epoxiconazole in wheat	NL	Total	Wheat	Epoxiconazole	94.2	Wheat	Propiconazole	2.5	Pineapple	Triadimefon	1.5

[a] *For an explanation of the scenarios see Table 15.*

[b] *For abbreviations of countries and ages of the (sub)populations addressed, see Table 3. The age ranges of the subpopulations adults and women of child-bearing age (Wmbca) were 18-64 years and 15-45 years, respectively.*

[c] *RAC = raw agricultural commodity*

Annex VIII Contribution of RACs and compounds to chronic cumulative estimated exposure after replacing monitoring data of selected RAC-pesticide combinations with MRLs or field trial data using NOAEL-derived RPFs

Scenario[a]	Country[b]	Population[b]	RACs and pesticides								
			Top 1			Top 2			Top 3		
			RAC[c]	Pesticide	%	RAC	Pesticide	%	RAC	Pesticide	%
FT bitertanol-apple	CZ	Children	Apple	Bitertanol	93.4	Banana	Bitertanol	2.4	Parsley	Difenoconazole	0.9
FT bitertanol-apple	FR	Children	Apple	Bitertanol	87.7	Banana	Bitertanol	4.2	Wheat	Propiconazole	2.0
FT bitertanol-apple	IT	Children	Apple	Bitertanol	88.3	Tomato	Bitertanol	4.7	Banana	Bitertanol	1.6
FT bitertanol-apple	NL	Children	Apple	Bitertanol	93.6	Banana	Bitertanol	1.7	Pineapple	Triadimenol	0.9
FT bitertanol-apple	SE	Children	Apple	Bitertanol	94.8	Banana	Bitertanol	1.1	Tomato	Bitertanol	0.7
FT bitertanol-apple	UK	Children	Apple	Bitertanol	90.8	Pineapple	Triadimenol	2.3	Banana	Bitertanol	1.6
FT bitertanol-apple	FR	Adults	Apple	Bitertanol	91.7	Banana	Bitertanol	1.4	Pineapple	Triadimenol	0.8
FT bitertanol-apple	IT	Adults	Apple	Bitertanol	89.0	Tomato	Bitertanol	4.4	Wheat	Propiconazole	1.2
FT bitertanol-apple	NL	Adults	Apple	Bitertanol	91.6	Banana	Bitertanol	1.0	Tomato	Bitertanol	0.8
FT bitertanol-apple	NL	Total	Apple	Bitertanol	92.6	Banana	Bitertanol	1.0	Tomato	Bitertanol	0.6
FT bitertanol banana	NL	Total	Banana	Bitertanol	75.3	Pineapple	Triadimenol	3.4	Wheat	Propiconazole	3.9
FT bitertanol tomato	NL	Children	Tomato	Bitertanol	97.4	Banana	Bitertanol	0.7	Pineapple	Triadimenol	0.4
FT bitertanol tomato	NL	Adults	Tomato	Bitertanol	98.6	Wheat	Propiconazole	0.2	Banana	Bitertanol	0.2
FT bitertanol tomato	NL	Total	Tomato	Bitertanol	98.3	Banana	Bitertanol	0.3	Wheat	Propiconazole	0.2
MRL cyproconazole table grape	NL	Total	Tablegrapes	Cyproconazole	70.2	Banana	Bitertanol	4.2	Wheat	Propiconazole	4.1

Scenario[a]	Country[b]	Population[b]	RACs and pesticides								
			Top 1			Top 2			Top 3		
			RAC[c]	Pesticide	%	RAC	Pesticide	%	RAC	Pesticide	%
MRL cyproconazole lettuce	NL	Children	Banana	Bitertanol	22.2	Pineapple	Triadimenol	10.7	Wheat	Propiconazole	10.0
MRL cyproconazole Lettuce	NL	Adults	Wheat	Propiconazole	12.6	Lettuce, head	Cyproconazole	11.7	Banana	Bitertanol	9.5
MRL diniconazole tablegrapes	NL	Total	Tablegrapes	Diniconazole	48.1	Banana	Bitertanol	7.4	Wheat	Propiconazole	7.1
FT epoxiconazole wheat	CZ	Children	Wheat	Epoxiconazole	89.3	Banana	Bitertanol	3.7	Parsley	Difenoconazole	1.4
FT epoxiconazole wheat	FR	Children	Wheat	Epoxiconazole	92.2	Banana	Bitertanol	2.6	Wheat	Propiconazole	1.3
FT epoxiconazole wheat	IT	Children	Wheat	Epoxiconazole	89.3	Tomato	Bitertanol	4.3	Banana	Bitertanol	1.4
FT epoxiconazole wheat	NL	Children	Wheat	Epoxiconazole	89.4	Banana	Bitertanol	2.7	Pineapple	Triadimenol	1.3
FT epoxiconazole wheat	SE	Children	Wheat	Epoxiconazole	91.2	Pineapple	Triadimenol	1.8	Banana	Bitertanol	1.7
FT epoxiconazole wheat	UK	Children	Wheat	Epoxiconazole	90.5	Pineapple	Triadimefon	2.3	Banana	Bitertanol	1.5
FT epoxiconazole wheat	NL	Total	Wheat	Epoxiconazole	90.9	Banana	Bitertanol	1.3	Wheat	Propiconazole	1.2

[a] *For an explanation of the scenarios see Table 15.*

[b] *For abbreviations of countries and ages of the (sub)populations addressed, see Table 3. The age ranges of the subpopulations adults and women of child-bearing age (Wmbca) were 18-64 years and 15-45 years, respectively.*

[c] *RAC = raw agricultural commodity*