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ACROPOLIS

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

SEVENTH FRAMEWORK PROGRAMME

Deliverable 2.1 Paper on the availability and quality of input data, current monitoring practice in Europe and how data can be selected for cumulative modelling.

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Summary

This paper gives an overview of the availability and quality of the pesticide residue monitoring data available in Europe and in more specific for the countries contractually involved in the EU project ACROPOLIS, including Czech Republic, Italy, The Netherlands, Sweden and the UK. Cyprus, Denmark and France are also included as the countries that have voluntarily joined the project in a later phase as associated partners. This data can be used for exposure modeling to pesticides. Apart from pesticide monitoring data also processing information and data on the variability of residues within a composite sample are needed to make the assessment as realistic as possible. These two types of input data are also discussed, as well as the Standard Sample Description (SSD) format used by EFSA to collect pesticide residue monitoring data from the different Member States. Finally, the data needs in relation to cumulative exposure modeling to pesticide residues were discussed. The data needs for cumulative exposure assessments are covered with the data gathered using the SSD format of EFSA. Important is the collection of information at sample level, including all analysed values, as well as those below a certain reporting or analytical level. This also includes the information on relevant compounds that have not been analysed at a level above a certain reporting or analytical level in the whole monitoring program. Furthermore, to be able to model the compounds belonging to a Cumulative Assessment Group that have not been analysed usage data on pesticides may be helpful.

Abbreviations

ADI	Acceptable daily intake
ARfD	Acute reference dose
CAG	Cumulative Assessment Group
EEA	European Economic Area
EFSA	European Food Safety Authority
EU	European Union
GAP	Good Agricultural Practice
LOD	Limit of detection
LOQ	Limit of quantification
LOR	Limit of reporting
MOR	Magnitude of the residues
MRL	Maximum Residue Limit
NOR	Nature of the residues
PC	Processed commodity
RAC	Raw agricultural commodity
RASFF	Rapid Alert System for Food and Feed
RPF	Relative Potency Factors
SSD	Standard Sample Description
TMDI	Theoretical maximum daily intake

1 Legislation around pesticide concentration data

Member States of the European Union (EU) regularly perform analyses of pesticides on commodities destined for human consumption to monitor the occurrence of pesticide residues and to check compliance with the maximum residue limits (MRLs) for pesticide residues. These control activities are performed as part of national monitoring programs undertaken by the EU Member States' authorities (including EEA (European Economic Area) members Iceland and Norway).

Until 1 September 2008, the Directives 76/895/EEC and 90/642/EEC (fruit and vegetables and other plant products), 86/362/EEC (cereals), and 86/363/EEC (animal products) required Member States to establish national control programs and to carry out regular official controls on pesticide residues in food commodities to check compliance with the MRLs for pesticide residues. Since 1 September 2008, these directives were replaced by Chapter V of Regulation (EC) No. 396/2005 on MRLs in or on food and feed of plant and animal origin (EC, 2005b). According to Article 31 of the regulation, Member States have to submit the results of official controls and other relevant information to the European Commission (EC), the European Food Safety Authority (EFSA) and to other Member States. Under Article 32 the responsibility for preparing the Annual Report on pesticide residues was transferred from the EC to EFSA. This regulation also contains general provisions regarding the content of the Annual Report. To date EFSA has released three reports covering monitoring activities performed in 2007 (EFSA, 2009a), 2008 (EFSA, 2010a) and 2009 (EFSA, 2011).

In addition to the general provisions on national monitoring programs, the EC has recommended that EU Member States and EEA countries also participate in a specific EU coordinated monitoring program, which aims to provide statistically representative data regarding pesticide residues in food available to European consumers (EC, 2005b). Details of the coordinated monitoring program for e.g. 2008 have been laid down in Commission Recommendation 2008/103/EC (EC, 2008).

The aim of this report is to provide a description of the current availability and quality of data present in Europe for the assessment of pesticide exposure via the diet. This data includes monitoring data, processing data and data on the variability of residues within composite samples. The description of the monitoring data (Chapters 2 and 3) focuses on the countries contractually involved in the ACROPOLIS project (Czech Republic, Italy, The Netherlands, Sweden and the UK) and the three countries that voluntarily joined the project in a later phase, the so-called associated partners (Cyprus, Denmark and France).

2 Monitoring practices in Europe

All EU and EEA (Iceland and Norway) Member States conduct national monitoring programs on pesticide residues. Commission Regulation (EC) No. 645/2000 (EC, 2000) provides detailed implementing rules for the monitoring provisions of Directives 86/362/EEC and 90/642/EEC concerning pesticide MRLs in and on cereals and products of plant origin, including fruit and vegetables respectively. This regulation also recommends multi-annual planning with the possibility of annual adjustments as the most effective approach to establish EC coordinated monitoring programs.

Commission Regulation EC 645/2000 (EC, 2000) also states that every Member State should give a summary overview of the monitoring systems, in order to improve the monitoring of pesticide residues in the Community and to assist in its proper functioning.

2.1 Sampling strategy and methodology

The definition of sampling strategy given below is obtained from the 2008 Annual report on Pesticide Residues of EFSA (2010).

The sampling strategy is the approach used to select the units of the target population subject to control. Implementation of an efficient, targeted sampling strategy would result in a higher percentage of positive findings and non-compliant results. Thus, it is important to stress that, for a correct interpretation of the results obtained in control programs, information about the sampling strategy applied is indispensable. There are two types of sampling strategies:

Surveillance sampling: samples are collected without any particular suspicion towards a particular producer, consignment, etc. Surveillance samples could be targeted for specific food products and countries, but the selection of samples is randomised. The samples taken in the framework of the EC coordinated program are considered to be surveillance samples.

Enforcement sampling: samples are taken if there is suspicion about the safety of a product and/or as a follow-up of violations found previously. The selection of the samples is not randomised and therefore cannot be considered representative of the food available on the European market. Follow-up or enforcement sampling is directed to a specific grower/producer or to a specific consignment.

The key difference between surveillance and enforcement sampling is not so much targeting but randomisation of the selected samples.

To ensure that a sample taken is representative for a given food lot/consignment, the sampling has to be performed according to the sampling methodology for the official control of pesticide residues, as established by Commission Directive 2002/63/EC (EC, 2002). For most plant products the minimum size of a laboratory sample is between one or two kilograms of the food item.

2.2 Organization of monitoring programs and sampling per country

In this section we will describe the organisation of the monitoring programs for the countries included in the ACROPOLIS project, including the three associate partners. These descriptions were taken from the 2008 Annual report by EFSA (2010), and adjusted / refined by the partners if necessary.

Cyprus
In Cyprus the Ministry of Health is the competent authority for the enforcement of the Pesticide Residues Legislation and the execution of the national monitoring and surveillance programs. The enforcement of Legislation and sampling is allocated to the Department of Medical and Public Health Services (MPHS).

The sampling regime is based on a combination of "at random" sampling and target oriented sampling focusing towards problematic pesticides/food combinations. This combination is in a way biased towards problematic products and might thus end up with higher violation rates. In this way, it can provide a higher degree of consumer protection and cost-effectiveness. Furthermore, sampling is focused at the key points of the food chain: producers, market, import, processing, primary storage etc.

Main criteria used in the sampling design are: violations from previous years, pattern of actual pesticide usage, information from Rapid Alert System for Food and Feed (RASFF[1,2]), toxicological data, consumption data especially by children and the needs of exports control.

Czech Republic
In the Czech Republic, the Czech Agriculture and Food Inspection Authority (CAFIA) is responsible for controls of pesticide residues in foodstuffs. They provide data for the national and EU coordinated monitoring programs in cooperation with the Ministry of Agriculture.

Until 2009, the sampling plan for the national and the EU coordinated monitoring, drawn up for one calendar year, was drawn up by the headquarters of CAFIA and distributed to the CAFIA regional inspectorates which were responsible for its implementation. The plan was based on the Commission Recommendations (such as 2007/225/EC for year 2008 and 2008/103/EC for year 2009) defining the EU coordinated monitoring program. These recommendations set the minimum number of samples for the Czech Republic. Prescribed number of samples was usually increased according to the current situation. When choosing commodities and their proportional representation, the data about consumption of foodstuffs in the Czech Republic provided by the National Institute of Public Health (NIPH) were taken into consideration as well as further information, for example findings revealed in previous years (in the Czech Republic and other Member States) or RASFF reports. Sampling was performed in accordance with sampling procedures referred to in Commission Directive No. 2002/63/EC (EC, 2002).

[1] If in control activities pesticides are found at a concentration level of concern for consumer health, the RASFF circulates the information among competent authorities and measures are taken to protect the consumer. Thus, RASFF is to ensure that urgent notifications are sent, received and responded to in the shortest time possible by all members of the RASFF (EU Member States, Commission, EFSA and Norway, Liechtenstein and Iceland).
[2] RASFF is described in ec.europa.eu/food/food/rapidalert/index_en.htm, and the data occurrences can be found at ec.europa.eu/food/food/rapidalert/rasff_portal_database_en.htm.

Since 2010, the sampling plan is drawn up by the Ministry of Health, Section of Chief Officer for Public Health Protection and Vice minister for Promotion and Protection of Public Health, Department of Public Health Protection. The plan is also discussed and approved by the Inter-ministerial Working Group for Pesticide Residues.

The multi-annual sampling plan for pesticide residue monitoring (now approved for years 2010-2012) is considered both for the national and the EU coordinated monitoring program, taking into account requirements given by the European Parliament and Council Regulation (EC) No. 396/2005. The following criteria or factors are used for the selection of commodities being listed in the national program on pesticide residues control:

- The overall food consumption in the Czech Republic and the consumption described as a typical food basket
- The results of official controls and monitoring of pesticide residues in previous years
- The foodstuffs intended for risky groups of population (namely infant formula and foods for young children)
- The products having specific stricter rules on the use of pesticides (organic products);
- The reports in RASFF system;
- The annual reports of the European Commission
- Commission Regulation (EC) No 901/2009 of 28 September 2009 concerning the coordinated multi-annual Community control program for 2010, 2011 and 2012 to ensure compliance with maximum levels of and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin;
- The final reports on results of monitoring at the Community level

The number of samples is set to determine characteristic profiles of pesticide residues content in selected commodities and to map trends in the presence of pesticide residues and their levels in analysed commodities with respect to statistical evaluation. The multi-annual EU coordinated program laid down in the Regulation (EC) No 901/2009 forms a part of this control program. The number of samples is set as a minimum. It is possible to change and update the number of samples according to the current situation. Sampling is performed in accordance with sampling procedures referred to in Commission Directive No. 2002/63/EC (EC, 2002).

Denmark

The Danish Veterinary and Food Administration (DVFA) under the Ministry of Food, Agriculture and Fisheries has the responsibility for the control of pesticide residues in foodstuffs in Denmark (www.fvst.dk).

The National Food Institute, Technical University of Denmark, designs the monitoring programs in cooperation with the DVFA. Since 2006 the sampling plan has been based on dietary consumption patterns with regard to pesticide intake from a 2005 report (Poulsen *et al.*, 2005), which analysed monitoring data from 1998-2003. This report showed that 25 commodities were responsible for more than 98 % of the intake of pesticide residues (Top25 commodities). These commodities are included in the sampling plan along with commodities suggested by the Commission for the EU-coordinated monitoring. The focus on the Top25 commodities provides a better basis for comparison between years,

so that trends in pesticide residues found may be analysed. In addition to these samples, a broad range of commodities common on the Danish market are analysed, including processed foods, foods for infants and organically grown products. Most sampling projects are designed to cover surveillance as well as control. The sampling strategy for these samples is listed as objective or selective sampling, respectively.

Directive 2002/63/EC (EC, 2002) on sampling procedures for control of pesticide residues is implemented in Danish legislation.

France
The monitoring program for pesticide residues in France is carried out by the Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes (DGCCRF - General Directorate for Competition Policy, Consumer Affairs and Fraud Control) for fruits and vegetables and by the Direction Générale de l'Alimentation (DGAl- Food General Directorate) for animal products. The aims of this multi-year Community program are to:

1. Monitor compliance with MRLs, and therefore compliance with reported good agricultural practices,
2. Collect data to assess actual dietary exposure of consumers to pesticide residues.

The program is developed with the technical and scientific support of the French Agency for Food, Environmental and Occupational Health Safety (ANSES). It takes into account the results of previous monitoring programs, the requirements of the EU coordinated program, the dietary proportion of plant products and the specific and sometimes targeted inspections of certain animal products, fruits and vegetables (specific exercise). In 2008 for example, the French targeted program focused on egg plants, lemons, cucumbers, plums, table grapes and lettuces.

Each department receives a crop sampling plan. Inspections are made at every marketing level. The inspection of cereal grains generally takes place at the storage stage, at silos, or at the processing stage. Cereal products, fruits and vegetables are sampled at retailers or wholesalers. Sampling at the level of the growers is less frequent. For all products entering the French territory, specific action is deployed at points of arrival.

Directive 2002/63/EC (EC, 2002) on sampling procedures for control of pesticide residues is implemented in French legislation.

Italy
In Italy the Ministry of Health[3] – General Directorate for Food Safety and Nutrition[4] – coordinates and defines the Italian official control programs on foodstuffs, including the annual plans regarding pesticide residues. The national reference laboratories connected to the European network[5] are part of this program[6].

[3] www.salute.gov.it
[4] www.salute.gov.it/pianoNazionaleIntegrato/homePianoNazionaleIntegrato.jsp
[5] www.iss.it/vtec/index.php
[6] www.salute.gov.it/pianoNazionaleIntegrato/paginaInternaMenuPianoNazionaleIntegrato.jsp?id=2012&lingua=italiano&menu=capitolo2http://www.iss.it/vtec/index.php

The annual official control plans on pesticide residues are defined by Ministerial Decree 23 December 1992, transposing Directive 90/642/EEC (EEC, 1990), integrated by the Ministerial Decree 30 July 1993 regarding the programming of official controls for importation from Third Countries.

The National Program Pesticide Residues (P.N.R.A.) foresees a detailed program implementing the checks to be carried out by all the Regions and Autonomous Provinces of Trento and Bolzano, with indication of the minimum number and the typology of samples to be analysed. The division of the number of samples to be taken for each region/province is calculated according to the data on consumption and production of a given foodstuff in the region or autonomous province concerned. The Decree contains some tables reporting the number of samples to be taken per region/province for the following foodstuffs: vegetables, fruits, cereals, wine, oils, meat, milks and derivatives, eggs. The plan foresees also priority of a research of pesticide residues both in animal and vegetable origin foodstuffs. As regards products of plant origin imported from Third Countries, the sampling is performed by Uffici di Sanità Marittima, Aerea e di Frontiera (USMAF)[7] of the Ministry of Health, in at least 3 % of a lot present at importation with a priority given to fruit and vegetable origin products.

The sampling spots indicated in P.N.R.A concerning products of plant origin are the collection centres and cooperatives for products coming from within the region or Autonomous province, specialised and non-specialised wholesale markets, wholesale stores, hypermarkets and supermarkets for products coming from outside the region or Autonomous province.

The sampling methods are those established by the Decree of the Ministry of Health of 23 July 2003, transposing Directive 2002/63/EC regarding the methods of Sampling for the Official control for pesticide residues in plant and animal origin products (EC, 2002).

The Ministry of Agricultural, Food and Forestry Policy publishes two databases for authorized users[8]:

- Declarations of sales of pesticides by phytoiatric action at sub-regional level (provinces)[9]
- Phytochemical database for products and usage[10]

Italy signals regularly the market (both alert and information) notifications and border rejections like news on to the RASFF system referring to the Department of European Policies[11].

The Netherlands

In the Netherlands the Dutch Food and Consumer Product Safety Authority (nVWA) performs the official monitoring. The samples are taken without prior information about the presence of pesticides in the individual sample. Therefore, they represent the situation on the market for the product at that time. However, sampling is directed relatively more to products that need attention because of violation rates in previous years. Therefore, high violation rates can

[7] Sea, Air, and Border Health Bureaus
[8] At www.sian.it/portale-sian/home.jsp
[9] www.sian.it/farmaven
[10] www.sian.it/fitovis
[11] www.politichecomunitarie.it/newsletter/16786/euroacronimi-rasff

indicate both an efficient sampling strategy and problems in the agricultural practice.

The Dutch Food and Commodity Law regulates the sampling procedure, i.e. the number of samples taken from a lot. This regulation is the implementation of the Directive 2002/63/EC (EC, 2002). Inspectors of the five regional inspectorates take the samples. The main sampling points are the distribution centres of retail chains, importers, warehouses for both domestic and non-domestic products, the premises of the auction system for Dutch products and at ports of EU-entry. At those inspection points it is clear who is responsible for the product, so that appropriate legal action can be taken in case of non-compliance.

Sweden
In Sweden the National Food Administration (NFA) is the responsible authority for the monitoring of pesticide residues in foods.

The number of samples to be collected of each food is risk related and partly linked to the food consumption rates and takes into account both the amount of domestic production and the amount of imports from EU-countries and third countries. However, the number is also based on the importance of the foodstuff in the diets of infants and young children as well as residues found in prior samples. The number of samples from the organic sector is roughly dependent on its share of the market and availability on the market.

Samples collected in accordance with the monitoring program are defined as surveillance samples, i.e. there were no suspicions about excessive amounts of pesticide residues in the lots prior to sampling. The sampling is done according to Commission Directive 2002/63/EEC (EC, 2002). Fresh fruit and vegetables are sampled at wholesalers' warehouses in the first trade channel. The imported cereal grains are sampled at the port where the shipment is discharged. Samples of domestic produced cereal grains are collected at the milling plants. Most of the samples of processed or frozen fruit and vegetables, juices, fruit drinks, rice, cereal products and vegetable oils are collected in retail shops or department stores.

United Kingdom
The UK monitoring program is overseen by the Defra Expert Committee on Pesticide Residues in Food (PRiF). The Chemicals Regulation Directorate (CRD) of the Health and Safety Directorate is responsible for managing the UK’s monitoring program for pesticide residues on behalf of the Department of Environment, Food and Rural Affairs (for England), Welsh Assembly, Scottish Government and Government for Northern Ireland . The Food Safety Agency (FSA) is responsible for risk management and is the UK’s contact point for the RASFF.

The majority of the samples taken in the program are purchased by shoppers employed by a leading market research company at retail outlets in locations throughout the twelve regions of the UK (18 towns/cities in England, and 2 each in Scotland, Wales and Northern Ireland). The locations selected are changed each year. Samples are taken, prepared and analysed according to Commission Directive 2002/63/EC (EC, 2002).

The UK’s program is a monitoring (surveillance) program. Brand name details are published for all samples.

2.3 Conclusion

All countries sample their commodities to be analysed according to Directive 2002/63/EC (EC, 2002). For most countries, the sampling is designed to cover both the needs for generating data to monitor food safety in relation to pesticides present in foods available on the national markets as well as for control. Whereas sampling to address the first need is relatively at random, the samples taken for the second purpose are targeted at those commodities suspected to contain residue levels with a higher probability to exceed the MRL. Data collected for control is not suitable for exposure assessments aimed to assess the exposure to pesticide residues within a population.

Furthermore, from the description of the individual countries it is clear that there are differences in how Directive 2002/63/EC is implemented in the different countries. It is important to keep these differences in mind when comparing exposure assessments between countries, as well as when combining pesticide residue data in one EU database.

3 Quality of the monitoring concentration data

To confirm that the reported results can be used with confidence, laboratories undertaking analyses of pesticide residues must operate with high levels of quality assurance. For this, in accordance with Article 12 of Regulation 882/2004 (EC, 2004), laboratories must be accredited to ISO/IEC 17025 (ISO, 2005), or make use of the derogation in Art. 18 of Regulation 2076/2005 (EC, 2005a). Non-accredited laboratories must, as a minimum, have a quality system as described in document SANCO/10684/2009 (EC, 2009). Furthermore, laboratories should participate in regular proficiency tests and implement common quality control procedures in order to fulfil the accreditation requirements of Article 3 of Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs (EC, 1993).

3.1 Quality control monitoring concentration data per country

From the 2008 Annual report by EFSA (2010), a summary of the quality of the data as reported to EFSA by the ACROPOLIS partners, including the three associate partners, is given in the section below. The description has been adjusted / refined by the partners, if necessary.

Cyprus
In Cyprus the Pesticide Residue Lab of the State General Laboratory (PR-SGL) is the official laboratory to analyse pesticide residues in samples obtained in the national and EU coordinated monitoring programs conducted in this country.

The PR-SGL is accredited by the Greek Accreditation body ESYD since 2002 according to EN 45001, from June 2003 according to ISO/IEC 17025 and from July 2006 according to ISO/IEC 17025/2005. The following validated methods are mainly used in relation to the analysis of pesticide residues:

1) "Multi residue method for fruits, vegetables and milk
2) GC/FPD-S determination of dithiocarbamates as CS2.

The validation of Liquid Chromatography (LC-)tandem Mass Spectrometry (MS/MS) analytical system has been extended, resulting in the analysis of 150 pesticides in 2008. The PR-Lab applies Quality Control procedures, which are in line with the provisions of "EU Quality control procedures" concerning the determination, confirmation and method quality. The laboratory participated in the European Commission's Proficiency Test on Pesticide Residues EUPT-FV-10[12], EUPTSRM3, EUPTC2 and EUPT-AO-03.

Czech Republic
Most of analyses (> 95 %) are conducted in the laboratory of Czech Agriculture and Food Inspection Authority (CAFIA), and only a minority of samples are analysed in the laboratory of Institute of Chemical Technology (ICT). Both laboratories are accredited by Czech Accreditation Institute (CAI) according to the ISO/IEC 17025 standard for all methods used for monitoring and/or enforcement analysis. Involved laboratories took part in the EU proficiency tests.

[12] www.crl-pesticides.eu/library/docs/fv/EUPT10fin.pdf

Multi residual method based on QUECHERS with Gas Chromatography (GC) – Time Of Flight (TOF)-Mass Spectrometry (MS) and LC-MS/MS detection has been implemented in CAFIA laboratory. This multi-residual method is designed for 304 analytes (incl. metabolites), covering 240 pesticides. Beside the QUECHERS method also single methods are used, such as GC- mass selective detection (MSD) for dithiocarbamates, GC-Electron Capture Detection (ECD) for inorganic bromine, LC-MS/MS for chlormequat, mepiquate and glyphosate. The requirements from the EU quality control guidelines (EC, 2009) have been implemented in laboratories.

Denmark
The analytical methods used to analyse pesticide residues have been developed and validated by the National Food Institute, Technical University of Denmark. All samples are analysed at the laboratory of the Regional Veterinary and Food Control in Ringsted. Both laboratories are accredited to analyse pesticide residues in compliance with EN45001/ISO17025 by the Danish Accreditation body, DANAK. Furthermore, the laboratories participated in the relevant FAPAS proficiency test scheme and in the EU-proficiency tests.

All samples of fruit and vegetables are analysed for about 220 pesticides including isomers and metabolites. In addition, part of the samples are analysed for dithiocarbamates. All cereal samples are analysed for 124 pesticides, including isomers and metabolites. The EU quality control guidelines (EC, 2009) are applied for all methods. Mass selective confirmation is performed for part of the GC multi methods and for the LC/MS-MS methods for fruit and vegetables.

France
Five of the seven laboratories who take part in the monitoring program and targeted surveillance program are COFRAC accredited, and for the remaining two, the step for accreditation is on hand. All laboratories apply the "guidance concerning quality control procedures for pesticide residue analysis" and participate in proficiency tests organised by the European Union (EUPT) and by independent suppliers (BIPEA, FAPAS, and CHEK).

Laboratories use multi-residue methods on the majority of samples, and sometimes single residue methods, depending on the probability of finding active substances covered in the monitoring programs. Techniques for multi-residue analysis include a phase of solvent extraction and, if necessary, a purification step and the identification and quantification are carried out by chromatography coupled with mass spectrometry (GC/MS and/or LC/MS).

Italy
In 2008, 37 official control public laboratories participated in the national program on pesticide residues in vegetables. Of these 37 laboratories 25 are accredited in accordance with norm EN 17025.

Analytical methods that are used to analyse pesticide residues include mainly GC multi-residue methods, associated with selective detectors (ECG, Nitrogen-Phosphorus Detection (NPD), and MS) and High Performance Liquid Chromatography (HPLC)-Ultraviolet (UV).

During 2007, 16 Italian Laboratories attended the Community Reference Laboratories (CRL) European Proficiency FV10 test and some laboratories attended FAPAS proficiency test and national ring tests.

The Netherlands
One regional laboratory (nVWA-Northwest, in Amsterdam) performs the analyses of the samples. The general strategy is to detect as many pesticide residues as possible in one analysis by using multi-residue methods. The main detection methods are GC - Ion-Trap Mass Spectrometric Detection (ITD) and (LC-MS/MS). Only for some analytes that are not detectable sensitively enough by ITD, additionally GC with Electron Capture Detection (ECD) is used.

For some pesticides not amenable to the multi-residue methods, single residue methods based on LCMS/MS detection are used. In the 2008 program for example, this was used for chlormequat, and propamocarb. Dithiocarbamates are analysed as CS2 using GC- Flame Photometric Detection (FPD) and GC- Ion Trap Detector (ITD) after decomposing with acidic tin-chloride solution and extraction into iso-octane.

Together the scope of the methods is about 400 analytes. The validity of the analytical results is governed by a quality assurance system under ISO17025 accreditation. The multi-residue methods are within the scope of the accreditation of the laboratory. The centralised laboratory has implemented the EU quality control guidelines (EC, 2009). It takes also part in FAPAS and EU proficiency tests.

Sweden
In Sweden two laboratories are involved in the EU coordinated program and the National control program: the National Food Administration (NFA) and Eurofins Food & Agro AB (official laboratory). They are accredited by the Swedish accreditation authority SWEDAC for all analytical methods used for the NFA's official control of pesticide residues in food of plant origin.

All samples of fruit and vegetables are analysed by multi-residue methods. The uncleaned extracts were determined by LC-MS/MS and GC-MS/MS. In all, by using both multi-residue methods and single residue methods, 320 pesticides corresponding to 421 analytes could be analysed in 2010. All laboratories involved in pesticide analyses take part in proficiency testing exercises, including European Union Proficiency Testing (EUPT) and also the FAPAS scheme.

The EC quality control guidelines (EC, 2009) have been fully implemented in Sweden.

United Kingdom
Five laboratories are commissioned to carry out the analysis for the EU coordinated and national monitoring programs. All of the laboratories meet the requirements of a recognised accreditation scheme, such as the UK Accreditation Service (UKAS) or the requirements of Good Laboratory Practice (GLP). Analytical methods used are validated in accordance with ISO 17025 (ISO, 2005) or IUPAC harmonised guidelines (Thompson *et al.*, 2002). All of the official laboratories involved in the UK's pesticide residue monitoring follow the same European quality control guidelines (EC, 2009).

It is a condition of undertaking the work that laboratories take part in relevant rounds of national proficiency tests organised by FAPAS[13]. Their performance in these tests is reviewed throughout the year at regular meetings between CRD

[13] www.fapas.com/fapas.cfm

and the laboratories. It is also a legal obligation as part of Regulation 396/2005 that laboratories take part in proficiency tests organised by the community reference laboratories as a minimum requirement.

3.2 Conclusion

The quality of the generated data is guaranteed by the fact that the samples are analysed by accredited laboratories. The laboratories also participate in proficiency tests organised by the community reference laboratories and sometime also organised within the countries itself.

Pesticides are predominantly analysed by the use of multi-residue methods. The number of analytes that are covered by the different national laboratories varies.

4 Pesticide residue concentration data reported to EFSA

Until 2007 pesticide monitoring data was submitted to the EC using Excel file in which the residue data was reported in histogram format. This means that per analysed product and residue Member States indicated the number of samples with concentration level below 0.01 mg/kg, the number between 0.01 and 0.02 mg/kg, etc. In 2008 EFSA became responsible for the pesticide monitoring data collection within the EU, as well as for the preparation of the Annual Report. In that year, EFSA initiated a pilot project in which six Member States agreed to submit the 2008 monitoring data via the Data Collection Framework (DCF) according to a draft version of the Standard Description Data (SSD) model for analytical measurements in food and feed (EFSA, 2010c). Based on the recommendations for improving the draft Standard Description, the system has been improved and was used in the collection of the monitoring data of all Member States in 2009 (EFSA, 2009a), 2010 (EFSA, 2010a), and 2011 (EFSA, 2011).

The SSD model is targeted to support the data collection and the data transmission of samples and the results of analytical measurement to support exposure assessments for food and feed safety. It also facilitates the harmonised collection of analytical measurement data for the presence of harmful or beneficial chemical substances in food, feed and water within the EU (EFSA, 2010c). The legislation taken into consideration for the design and specification of the SSD model were those for the chemical contaminants (e.g. chemicals included in Regulation (EC) No. 1881/2006 and its amendments) and the pesticide residues (Regulation (EC) No. 396/2005). The model is primarily designed for control and monitoring programs run by the Member States or by other private organisations. While some provision of specific variables were made for ad-hoc studies (i.e. product packaging, product ingredients, etc.), additional model validations and considerations should be performed before applying the data model outside the scope it was designed. Furthermore, data providers and receivers can use different file formats – e.g. Microsoft Excel, Comma Separated Values (CSV), Extensible Markup Language (XML), etc… – to submit transmissions depending on their technological constraints (EFSA, 2010b).

In 2010, the Technical Working Group on Data Collection developed a guideline on the standard description of samples and analytical results. The guidance describes additional data elements which connect the Standard Description with local systems of data providers and receivers (e.g. sending organisation, receiving organisation, the data collection title and the risk assessment area to which the data collection belongs to).

The SSD is intended to support the following analyses:
1) Assessment of acute and/or chronic consumer exposure,
2) The number of samples for specific product / parameter combinations below and above detection limits,
3) The number of samples for specific product / parameter combinations above legal limits (legal compliance).

For a full list of all the elements that are included in the SSD model see Appendix A.

5 Processing information

A high proportion of our food items are consumed in a processed form. During industrial and domestic processing procedures, pesticide residues in or on a commodity may change in nature and/or magnitude. Having information on these changes allows a more refined estimate of consumer exposure to be made and indicates whether there is the potential for the formation of novel degradation products of greater toxicological concern.

In accordance with Directive 91/414/EEC (REF) processing information is not required if the commodity is typically consumed raw (unless considered to have inedible peel), if residues arising from the intended use are below 0.1 mg/kg (as demonstrated by supervised residues trials conducted according to Good Agricultural Practice (GAP)), or where the total theoretical maximum daily intake (TMDI) is less than 10 % of the Acceptable Daily Intake (ADI).

Studies on the nature of the residues (NOR) following processing typically cover three different hydrolysis scenarios, simulating the conditions of pasteurisation (20 minutes at 90 °C and pH 4), baking/brewing/boiling (1 hour at 100 °C and pH 5) and sterilisation (20 minutes at 120 °C and pH 6). The major components of the terminal residue are then considered with respect to the need for their inclusion in residue definitions for both risk assessment and enforcement purposes.

Following the identification of the key residues, magnitude of residues (MOR) studies are carried out to determine the quantitative distribution of each analyte in the Raw Agricultural Commodity (RAC) and its associated processed fractions. Currently, one balance study is used to determine the distribution of residues in all intermediate and end-products. Three further follow-up studies are also required but are limited to only those processed fractions used as food and therefore relevant to the overall consumer exposure. It is noted that processing studies conducted on a single commodity may be considered to be representative of the associated crop group reducing the need for repeated studies.

Full details on the key processing procedures for each commodity or crop group are given in Annex 3 of Appendix E to document 7035/VI/95 rev.5[14].

5.1 Distribution of residues, e.g. peel-pulp distribution

Where a commodity is typically eaten raw but has inedible portions such as the peel of bananas, other fruits and some cucurbits, data on the distribution of the residue in the peel and pulp may be required in order to derive peeling factors. The data used to derive peeling factors should be taken from GAP-compliant residues trials and include information on the residue levels in both the whole RAC and the pulp portion according to the appropriate residue definition. Using this data the peeling factor is calculated according to the following equation:

$$\text{peeling factor} = \frac{\text{pulp residue (mg/kg)}}{\text{whole commodity residue (mg/kg)}}$$

[14] ec.europa.eu/food/plant/protection/resources/app-e.pdf

Only data from trials where residues were analysed for (and detected in) both pulp and the whole commodity samples should be used in the calculation of the peeling factor as the appropriate value may be the highest, mean or median of the individual factors.

5.2 Definition of terms and calculation methods

5.2.1 Processing factors

Processing factor is a generic term designating a ratio between the residue level in a processed commodity (PC) and the residue level in the RAC. There are two types of processing factors: transfer factors and yield factors, depending on how the processing influences the nature of the residues (NOR). These are described here below.

Case A. Transfer factors

These are by far the most frequent ones in practice. Transfer factors apply to processing situations where no new-formed product of toxicological relevance is produced. In these situations the residue definition for the processed product is the same as for the RAC. Transfer factors are calculated accordingly to the following equation:

$$\text{Transfer factor RAC/PC} = \frac{\text{Residue PC}_{\text{initial compound}}}{\text{Residue RAC}_{\text{initial compound}}}$$

Case B. Yield factors

Sometimes during processing, the nature of the residue in the RAC is chemically modified, e.g. into a degradation product. This new-formed compound can be of toxicological relevance in the processed commodity. Yield factors should therefore be calculated in those cases where processing of commodities leads to a change of the nature of residues and where the new-formed product is to be considered as toxicologically relevant.

In addition to this, it may be that the critical toxicological end points applicable to the new-formed compound are different from that of the initial compound, making it necessary to carry out a separate risk assessment for the processed commodity with a different ADI and/or acute reference dose (ARfD). For this reason, two different calculation methods are proposed for yield factors.

B1. This formula applies when the toxicological end points for the initial compound in the RAC and for the new-formed compound are the same.

$$\text{Yield factor RAC/PC} = \frac{\text{Residue PC}_{\text{new - formed compound}}}{\text{Residue RAC}_{\text{initial compound}}} \times \frac{\text{MW}_{\text{initial compound}}}{\text{MW}_{\text{new - formed compound}}}$$

The yield factor is calculated with correction for the molecular weight ratio to allow easier intake calculations in practice as the toxicological burden of the new-formed compound should be added to the toxicological burden of the initial compound in the RAC (identical toxicological end points). For consistency the definition of the residue should be expressed in the same way in the raw and processed commodities.

B2. This formula applies when the toxicological end points for the initial compound in the RAC and for the new-formed compound are different:

$$\text{Yield factor RAC/PC} = \frac{\text{Residue PC}_{\text{new - formed compound}}}{\text{Residue RAC}_{\text{initial compound}}}$$

The yield factor is then calculated without correction for the molecular weight ratio. Indeed the yield factor should here be used for calculating the potential residue level of the new-formed product as such from the residue level of the initial compound in the RAC, in order to carry out a specific risk assessment for the processed commodity. In this case the residue definition in the processed commodity should address the new-formed compound, expressed as such.

5.2.2 Percentage of transference (amount transferred (%)).

The percentage transference (amount transferred (%)) is derived from balance studies and represents the % of the total amount of residues present in the RAC which is transferred to the processed commodities. When the nature of the residue is changed during processing, it is needed to take into account the respective molecular weights of the initial compound and new compound, independent of whether the new-formed product has or doesn't have the same toxicological end points.

$$\text{Amount transferred (\%)} = \frac{\text{Residue PC}_{\text{initial compound}}}{\text{Residue RAC}_{\text{initial compound}}} \times \frac{\text{weight PC}}{\text{weight RAC}} \times 100$$

or

Amount transferred (%) =

$$\frac{\text{Residue PC}_{\text{new - formed compound}}}{\text{Residue RAC}_{\text{initial compound}}} \times \frac{\text{MW}_{\text{initial compound}}}{\text{MW}_{\text{new - formed compound}}} \times \frac{\text{weight PC}}{\text{weight RAC}} \times 100$$

Note: the calculation of percentage of transference (amount transferred (%)) is optional as this parameter is not necessary for intake assessments.

5.2.3 Examples.

<u>Example 1 (case A):</u>

Assumption:

- 15 kg wine grapes will result in 10 L of must
- Residues in wine grapes: 2 mg/kg
- There is no change in the nature of residues during must production
- Residues in must: 1 mg/L (equivalent to 1 mg/kg)

Results:

- Transfer factor $_{\text{grapes/must}} = \frac{1 \text{ mg/kg}}{2 \text{ mg/kg}} = 0.5$
- Amount transferred (%) (taking into account the mass of grapes and must)

$$= \frac{1\,\text{mg/L x}\,10\text{L}}{2\,\text{mg/kg x}\,15\text{kg}} \text{ x } 100 = 33\ \%$$

Example 2 (case B1):

Assumption:

- 10 kg apples will result in 8 L apple juice
- Residues in apple fruit (e.g. parent): 2.2 mg/kg
- Residues in apple juice (new compound): 1.3 mg/L (equivalent to 1.3 mg/kg)
- The nature of residue is changed during juice production and the toxicological end points for the initial compound and the new-formed compound are the same
- Molecular weight (MW) initial compound: 300 g/mol
- Molecular weight (MW) new compound: 150 g/mol

Results:

- Yield factor $_{\text{fruit/juice}} = \frac{1.3\,\text{mg/kg}}{2.2\,\text{mg/kg}} \text{ x } \frac{300\,\text{g/mol}}{150\,\text{g/mol}} = 1.2$
- Amount transferred (%) (taking into account the mass of apples and juice):

$$= \frac{1.3\,\text{mg/kg}}{2.2\,\text{mg/kg}} \text{ x } \frac{300\,\text{g/mol}}{150\,\text{g/mol}} \text{ x } \frac{8\text{L}}{10\text{kg}} \text{ x } 100 = 96\ \%$$

Example 3 (case B2):

Assumption:

- 10 kg apples will result in 8 l of apple juice
- Residues in apple fruit (e.g. parent): 2.2 mg/kg
- Residues in apple juice (new compound): 1.3 mg/L (equivalent to 1.3 mg/kg)
- The nature of residue is changed during juice production and the toxicological end points for the initial compound and the new-formed compound are different
- Molecular weight (MW) initial compound: 300 g/mol
- Molecular weight (MW) new compound: 150 g/mol

Results:

- Yield factor fruit/juice = $\frac{1.3\,\text{mg/kg}}{2.2\,\text{mg/kg}} = 0.59$
- Amount transferred (%) (taking into account the mass of apples and juice):

$$= \frac{1.3\,\text{mg/L}}{2.2\,\text{mg/kg}} \text{ x } \frac{300\,\text{g/mol}}{150\,\text{g/mol}} \text{ x } \frac{8\text{L}}{10\text{kg}} \text{ x } 100 = 96\ \%$$

6 Variability factor

Analyses of pesticide residues, in support of registration or for monitoring purposes, are typically made for composite samples rather than on an individual unit basis in order to obtain a representative picture of the overall residue situation. As composite samples contain multiple units, variability in the concentration of residues between the individual units of any commodity will exist as a consequence of a number of factors. This variability is in part due to the difficulties in achieving a uniform distribution of residues during application procedures and may be further increased by changes in size, metabolism, microbial action and climatic differences experienced by the growing crop. Therefore the residues of a pesticide remaining in/on single food items at the time of consumption can vary, but the distribution of residue levels will not be reflected by the analytical result.

It is important to take account of this variation when assessing the risk to consumers as the consumer may select an individual unit containing the highest residue rather than a unit reflecting the average residues of the composite sample. As certain commodities are bulked or blended prior to consumption (e.g. cereals, milk) the residue, or range of residues, found in a single portion will be adequately reflected by the composite sample data and therefore variability need not be considered. However when considering the consumption of medium (25-250 g, e.g. apple, tomato) or large (> 250 g, e.g. melon, pineapples) commodities on an acute basis, the portion may comprise only a single or low number of units. Therefore acute dietary exposure estimates for these food items employ a variability factor to account for the possibility that the consumer may be exposed to the highest residue of any individual unit within a composite sample.

International assessment procedures of acute exposure are based on the 97.5th percentile of the distribution of residues; i.e. the level that is exceeded by 2.5% of residues in food items (i.e. 1 in 40). This residue level is not measured directly, but estimated by measuring the concentration in a small batch of items and multiplying it by a "variability factor" to estimate the 97.5th percentile residue. The JMPR estimated that unit to unit variability of pesticides residues could be up to a factor of seven depending on the commodity involved, and from 1997 the JMPR used default values of 5 and 7 depending on the unit weight of the commodity (with the possibility of using 10 in the case of granular pesticide use) to estimate acute exposure (FAO/WHO, 1999; WHO, 1997); these values were subsequently adopted by the European Commission. Later, in 2003, the JMPR adopted a more general default value of 3 for all commodities with unit weights over 25 g, on the recommendations of the IUPAC Advisory Committee on Crop Protection Chemistry, in the absence of more accurate information (FAO/WHO, 2004).

The default variability factors currently included in the EFSA Pesticide Residue Intake Model (PRIMo) are 5 (unit weight >250 g) and 7 (unit weight 25-250 g) (EFSA, 2007b) and these are used in the EU for both risk assessment (EFSA, 2009a; EFSA, 2010a; EFSA, 2011) and MRL setting purposes. An exception to this is for head cabbage and lettuce where default values of 3 may be used, based on an EU Commission position paper for the 35th session of the CCPR in 2003 (EC, 2003). Subsequently the PPR Panel used a factor of 3 in considering

the impact of a possible change of variability factors on the overall level of consumer protection (EFSA, 2005).

The average variability factor is defined as the ratio of the 97.5th percentile residue to the mean, taken from the analysis of individual units (typically of greater than 100 individual units). Hamilton et al. (Hamilton *et al.*, 2004) concluded that 119 individual unit samples are required to achieve a 95 % certainty that at least one unit exceeds the 97.5th percentile of the sampled population. In 2005 the PPR Panel considered the appropriate use of variability factors in the acute exposure assessment of pesticide residues (EFSA, 2005). The Panel reviewed variability factors from existing studies where residues were measured separately in individual food items, excluding studies where the variability factor could not be estimated reliably, i.e. studies with less than 50 items or with pesticide residues below the limit of quantification.

The PPR Panel found that on average, variability factors estimated from samples collected in the marketplace (3.6) were higher than those from samples obtained in experimental studies (supervised trials; 2.8) and recommended that consideration be given to using different variability factors when doing exposure assessments with data from these two types of study (EFSA, 2005). In addition, further variability was identified between individual trials and surveys. When considering the use of default values it was estimated that variability factors from supervised trials would exceed a default value of 3 in 34% of cases, whereas the current default value of 7 for medium sized food items would be exceeded in only 0.2 % of cases. Similarly, the variability factors for market surveys exceed 3 in about 65 % of cases and 7 in about 1% of cases. Since the data analysed related mostly to medium-sized commodities it was concluded that there was insufficient evidence to support a real difference between variability factors for medium and large sized commodities. Therefore variability factors for large commodities would need re-examination when further data on large-sized commodities is available.

The results are affected by a number of uncertainties. The PPR Panel calculated confidence intervals to indicate the degree of uncertainty due to limitations in the amounts of data available for the analysis (EFSA, 2005). Other uncertainties, e.g. in extrapolating variability factors between pesticides and between crops, were considered qualitatively. Finally, the PPR Panel noted that the assessment of acute risks from dietary exposure uses conservative assumptions for portion size and the mean residue concentration as well as the variability factor. The combined effect of these conservative assumptions on the overall level of consumer protection may warrant further consideration.

There is presently no guidance for the design and conduction of unit-to-unit variability studies.

7 Data needs for cumulative exposure modelling

To assess whether pesticide residue levels analysed as part of the national and EU coordinated programs may pose a risk for human health exposure assessments are preformed. At European level these assessments are performed by EFSA as part of the annual reporting on pesticide residues within Europe.

The assessments performed by EFSA, and also many Member States, include both long-term and short-term exposure assessments. To assess whether there is a potential health risk, the estimated long-term and short-term dietary exposure, calculated per kg body weight, is compared with the relevant toxicological reference values, i.e. ADI and ARfD, respectively. A consumer health risk is identified if the estimated dietary exposure to a pesticide exceeds the ADI and/or the ARfD. The assessments performed with the residue data from 2007 and 2008 showed that long-term exposure to pesticide residues are of no health concern. However, for acute exposure the analyses showed that for about 52 and 35 pesticide /commodity combinations in 2007 and 2008 respectively a potential consumer risk could not be excluded.

These assessment are however only suitable for the assessment of the exposure to single compounds. In Regulation 396/2005 (EC, 2005b) it is stated that as soon as a methodology to do so is available also the exposure to compounds with a cumulative or synergistic effect should be addressed. Since the release of this Regulation EFSA has performed different activities with the goal to develop an approach to include cumulative and synergistic effects of pesticide residues in the evaluation of pesticide residues. These activities include the organisation of a workshop (EFSA, 2007a), the release of two opinions on available methods (EFSA, 2008; EFSA, 2009b) and a case study (EFSA, 2009b), and the establishment of two EFSA work groups that look at how to use probabilistic modelling for single compounds (as a first step to the use of this approach in cumulative exposure modelling) and to set up criteria for establishing groups of compounds that should be addressed simultaneously in a risk assessment, the so-called Cumulative Assessment Group (CAG).

Internationally however cumulative exposure assessment have already been performed for quite a number of years using probabilistic techniques and the relative potency factor (RPF) approach to cumulate residue level per individual compound belonging to a CAG. In the RPF approach the toxicity of each compound is expressed relative to that of an index compound. These factors are subsequently used to sum of the concentrations per compound to a summed concentration, or to cumulate the individual exposure per compound to an overall cumulative exposure. These assessments have all been performed as part of safety assessments of residue levels analysed as part of monitoring programs. Cumulative assessments have not yet been incorporated in the authorisation process of pesticides within the EU.

To perform cumulative exposure assessments to pesticide residues using monitoring data as done up till now, concentrations of individual active substances are mostly added per analysed sample using RPFs. Since it is expected that this approach will also be the basis for a new model for cumulative exposure modelling to be developed within ACROPOLIS, information on the levels of individual active substances analysed per sample, including the

results analysed at levels below a certain reporting (LOR = limit of reporting) or analytical level (LOQ or LOD = limit of quantification or detection, respectively), are necessary. The information collected as part of the SSD model minimally relevant for this are (for the full description per label see Appendix A)

- ParamCode
- ParamText
- LabSampleCode
- OrigCountry
- EFSAProdCode
- ProdText
- SampY
- SampMethod
- AnMethRefCode
- AnMethText
- ResUnit
- ResLOD
- ResLOQ
- ResVal

For cumulative exposure calculations, additional information is needed on the substance analysed (code and text). It is very important to realise that, opposed to exposure assessments to single compounds, information needs to be collected at sample level. For single compounds it is mostly enough to know the number of samples with a level equal to e.g. 0.1, 0.2, 0.3 mg/kg or <LOR. See Table 1 for an example.

Table 1. *Reporting of concentration values*

Single Compounds		
CompoundID	Number of samples	Concentration (mg/kg)
A1	2	0.5
A1	3	0.6
A1	4	0.3
A1	200	< LOR
Cumulative group A1 and A2		
CompoundID	SampleID	Concentration (mg/kg)
A1	B1	0.5
A2	B1	0.3
A1	B2	0.5
A1	B2	< LOR
A1	B3	0.1
A2	B3	0.5
A1	B4	< LOR
A2	B4	0.1

In practice, not all active substances will be analysed in all samples collected in a monitoring program. The reasons for this may be that no residues are expected because the substance is not authorised for use on the analysed commodity. Other reasons may be financial constraints or that it is known from past monitoring programs that the substance rarely occurs in samples of certain commodities. A big challenge in cumulative exposure modelling will be how to deal with these 'missing' analyses. Up till now, the approach has been to assume that non-analysed compounds were not present and therefore assigned a concentration equal to 0 mg/kg, since it is difficult to assume the 'possible' value to be assigned to non analyzed substances. However, this approach is very likely not valid in all cases and may result in an underestimation of the overall exposure because in reality those non analyzed substances might have been

positive values if they had been analyzed. In a study examining the exposure to triazole pesticides (van Klaveren *et al.*, 2009), also another approach was used to assess the exposure to circumvent this problem by calculating the exposure per substance and adding the individual exposure distributions according to the corresponding RPFs in a later stage of the cumulative exposure assessment. In this approach the calculation is limited to the number of analyzed values for each substance and no assumptions have to be made for non analyzed substances. The disadvantage of this approach is however that correlations between substances are not taken into account. In principle this leads to lower exposure estimates when such correlations are negative (e.g. when compound A is never used in combination with compound B) and to higher exposure estimates when such correlations are positive (e.g. when compounds A and B are often used as a mixture) (van Klaveren *et al.*, 2009). Based on the results of this study it was concluded to it remains desirable to develop models allowing for correlation between substances.

Data that may be useful to obtain information on the likelihood that a compound that has not been analysed but may be present in the commodity, is data on the actual usage of pesticides within countries. An example of this is the data collected within the UK as collected within Pesticide Usage Surveys (PUS). Based on this data it can be deduced whether it is likely that a compound that was not analysed could have resulted in a positive concentration value if analysed. The level to be assigned to such a not-analysed but likely to be present compound will be very likely based on the levels of this compound on similar commodities that have been analysed. This is subject for research and will be developed within the ACROPOLIS project.

Apart from data on monitoring data and PUS data, it is for the further refinement of cumulative exposure assessments important to have data on variability and processing factors, as for analyses of single compounds.

To summarize, the data needs for cumulative exposure assessments are covered with the data gathered using the SSD format of EFSA. Important is the collection of information at sample level, including all analysed values, including those below a certain reporting or analytical level. This also includes the information on relevant compounds that have not been analysed at a level above a certain reporting or analytical level in the whole monitoring program. Furthermore, to be able to model the compounds belonging to a CAG that have not been analysed PUS data may be helpful.

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Appendix A. Data element Standard Sample Description

Element Code	Element Label	Element name	Description	Mandatory
S.01	labSampCode	Laboratory sample code	Alphanumeric code of the analysed sample.	Yes
S.02	labSubSampCode	Laboratory sub-sample code	Numeric sequence number reflecting a subgroup of the analysed sample. The default value is 1.	No
S.03	lang	Language	Language used to fill in the free text fields (ISO-639-1).	Yes
S.04	sampCountry	Country of sampling	Country where the sample was collected. (ISO 3166-1-alpha-2).	Yes
S.05	sampArea	Area of sampling	Area where the sample was collected (Nomenclature of territorial units for statistics – NUTS – coding system valid only for EEA and Switzerland).	No
S.06	origCountry	Country of origin of the product	Country of origin of the product (ISO 3166-1-alpha-2 country code).	Yes
S.07	origArea	Area of origin of the product	Area of origin of the product (Nomenclature of territorial units for statistics – NUTS – coding system valid only for EEA and Switzerland).	No
S.08	origFishAreaCode	Area of origin for fisheries or aquaculture activities code	Fisheries or aquaculture area specifying the origin of the sample (FAO Fisheries areas).	No
S.09	origFishAreaText	Area of origin for fisheries or aquaculture activities text	Fisheries or aquaculture area specified in free text.	No
S.10	procCountry	Country of processing	Country where the food was process (ISO 3166-1-alpha-2).	No
S.11	procArea	Area of processing	Area of product processing (Nomenclature of territorial units for statistics – NUTS – coding system valid only for EEA and Switzerland).	No
S.12	EFSAProdCode	EFSA Product Code	Product under analysis described according to the EFSA Food Classification and Description System, currently under development.	No
S.13	prodCode	Product code	Product under analysis described according to the MATRIX catalogue, currently available.	Yes
S.14	prodText	Product full text description	Free text to describe in detail the product sampled. The text should provide additional information in respect to S.13. This element becomes mandatory if "product code" is 'XXXXXXA' (Not in list).	No
S.15	prodProdMeth	Method of production	Code providing additional information on the type of production for the food under analysis.	No

S.16	prodPack	Packaging	Describe container or wrapper that holds the product. Common type of packaging: paper or plastic bags, boxes, tinplate or aluminium cans, plastic trays, plastic bottles, glass bottles or jars.	No
S.17	prodTreat	Product treatment	Used to characterise a food product based on the treatment or processes applied to the product or any indexed ingredient.	Yes
S.18	prodBrandName	Brand name	Brand name of the product under analysis.	No
S.19	prodManuf	Manufacturer	Company manufacturer of the product.	No
S.20	prodIngred	Ingredients	List of ingredients, separated by "$", for the product under analysis. Use to provide further information on composite product.	No
S.21	prodCom	Product comment	Additional information on the product, particularly home preparation details if available.	No
S.22	prodY	Year of production	Year of production	No
S.23	prodM	Month of production	Month of production	No
S.24	prodD	Day of production	Day of production	No
S.25	expiryY	Year of expiry	Best before year or use by year or other indication of the expiry year.	No
S.26	expiryM	Month of expiry	Best before month or use by month or other indication of expiry month.	No
S.27	expiryD	Day of expiry	Best before day or use by day or other indication of the expiry day.	No
S.28	sampY	Year of sampling	Year of sampling. If the measure is the result of a sampling over a period of time, this field should contain the year when the first sample was collected.	Yes
S.29	sampM	Month of sampling	Month of sampling. If the measure is the result of a sampling over a period of time, this field should contain the month when the first sample was collected.	No
S.30	sampD	Day of sampling	Day of sampling. If the measure is the result of a sampling over a period of time, this field should contain the day when the first sample was collected.	No
S.31	progCode	Sampling program code	Sender's unique identification code of the program or project for which the sample analysed was taken.	No
S.32	progLegalRef	Program legal reference	Reference to the legislation for the program defined by program number.	No
S.33	progSampStrategy	Sampling strategy	Sampling strategy (ref. EUROSTAT - Typology of sampling strategy, version of July 2009) performed in the program or project identified by program code.	Yes
S.34	progType	Type of sampling program	Indicate the type program for which the samples have been collected.	Yes
S.35	sampMethod	Sampling method	Code describing the sampling method	Yes

S.36	sampleNum	Number of samples	Number of food samples analysed, only if composite samples were used.	No
S.37	lotSize	Lot size	Size of the lot the sample belong to	No
S.38	lotSizeUnit	Lot size unit	Unit in which the lot size is expressed.	No
S.39	sampPoint	Sampling point	Point in the food chain where the sample was taken. (Doc. ESTAT/F5/ES/155 "Data dictionary of activities of the establishments").	Yes
L.1	labCode	Laboratory	Laboratory code (National laboratory code if available). This code should be unique and consistent through the transmissions.	No
L.2	labAccred	Laboratory accreditation	The laboratory accreditation to ISO/IEC 17025.	Yes
L.3	labCountry	Laboratory country	Country where the laboratory is placed. (ISO 3166-1-alpha-2).	No
O.1	localOrg	Local organisation	Local or regional organisation (Competent authority or company affiliate) who requested initially the analysis.	No
O.2	localOrgCountry	Local organisation country	Country where the local organisation is placed. (ISO 3166-1-alpha-2).	No
R.01	resultCode	Result code	Unique identification number of an analytical result (a row of the data table) in the transmitted file. The result code must be maintained at organisation level and it will be used in further updated/deletion operation from the senders.	Yes
R.02	analysisY	Year of analysis	Year when the analysis was completed.	Yes
R.03	analysisM	Month of analysis	Month when the analysis was completed.	No
R.04	analysisD	Day of analysis	Day when the analysis was completed.	No
R.05	EFSAParamCode	EFSA Parameter Code	Parameter/analyte of the analysis described according to the EFSA Parameters System, currently under development.	No
R.06	paramCode	Parameter code	Parameter/analyte of the analysis described according to the Substance Code of the PARAM catalogue	Yes
R.07	paramText	Parameter text	Parameter subject of the analysis described according to the PARAM catalogue	No
R.08	paramType	Type of parameter	Define if the parameter reported is an individual residue/analyte, a summed residue definition or part of a sum a summed residue definition.	Yes
R.09	anMethRefCode	Analytical method reference code	Identifier for the method used. When validated methods are used, the official reference code should be provided.	No
R.10	anMethCode	Analytical method code	Code describing the instrument used in the method.	No
R.11	anMethText	Analytical method text	Free text describing the analytical instrument used, particularly if "other" was reported for "Analytical method code".	No

R.12	accredProc	Accreditation procedure for the analytical method	Accreditation procedure for the analytical method used	No
R.13	resUnit	Result unit	Unit of measurement for the values reported in "Result LOD", "result LOQ, "CC Alpha", "CC Beta", "Result value", "Result value uncertainty standard deviation, "Result value uncertainty" and "Result legal limit".	Yes/No
R.14	resLOD	Result LOD	Limit of detection reported in the unit specified by the variable "Result unit".	No
R.15	resLOQ	Result LOQ	Limit of quantification reported in the unit specified by the variable "Result unit"	No
R.16	CCalpha	CC alpha	CC alpha value (decision limit) reported in the unit specified by the variable "Result unit"	No
R.17	CCbeta	CC beta	CC beta value (detection capability) reported in the unit specified by the variable "Result unit"	No
R.18	resVal	Result value	The result of the analytical measure reported in the unit specified by the variable "Result unit",	No
R.19	resValRec	Result value recovery	Recovery value associated with the concentration measurement expressed as a percentage (%). i.e. report 100 for 100%.	No
R.20	resValRecCorr	Result value corrected for recovery	Define if the result value has been corrected by calculation for recovery.	No
R.21	resValUncertSD	Result value uncertainty Standard deviation	Standard deviation for the uncertainty measure	No
R.22	resValUncert	Result value uncertainty	Indicate the expanded uncertainty (usually 95% confidence interval) value associated with the measurement expressed in the unit reported in the field "Result unit".	No
R.23	moistPerc	Percentage of moisture in the original sample	Percentage of moisture in the original sample	No
R.24	fatPerc	Percentage of fat in the original sample	Percentage of fat in the original sample	No
R.25	exprRes	Expression of result	Code to describe the how the result has been expressed: Whole weight, fat weight, dry weight, etc…	No
R.26	resQualValue	Result qualitative value	This field should be completed only if the result value is qualitative e.g. Positive / Negative. In this case the element "Result value" should be left blank	No
R.27	resType	Type of result	Indicate the type of result, whether it could be quantified/determined or	Yes

			not.	
R.28	resLegalLimit	Legal Limit for the result	Report the legal limit for the analyte in the product sampled.	No
R.29	resLegalLimitType	Type of legal limit	Type of legal limit applied for the evaluation of the result. ML, MRPL, MRL, action limit.	No
R.30	resEvaluation	Evaluation of the result	Indicate if the result exceeds a legal limit.	Yes/No
R.31	actTakenCode	Action Taken	Describe any follow-up actions taken as a result of the exceeding a legal limit.	No
R.32	resComm	Comment of the result	Additional comments for this analytical result	No