BASELINE

SELECTION AND IMPROVING OF FIT-FOR-PURPOSE SAMPLING PROCEDURES FOR SPECIFIC FOODS AND RISKS

PROJECT DELIVERABLE

Collaborative project	Large-scale integrating project
Project acronym	BASELINE
Project title	Selection and improving of fit-for-purpose sampling procedures for specific foods and risks
Grant Agreement number	222738
Date of latest version of Annex I	22/01/2013

Del. No.	Deliverable name	WP no.	Lead participant	Nature	Dissemination level	Due delivery date
D6.10	Early warning sampling plans formulated	6	DKFZ	R	PU	50

Delivery Date: 30/11/2013

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Project funded under the Food, Agriculture and Fisheries, and Biotechnology theme (KBBE)

SEVENTH FRAMEWORK PROGRAMME

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Project funded under the Food, Agriculture and Fisheries, and Biotechnology theme (KBBE)

SEVENTH FRAMEWORK PROGRAMME

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1. EXECUTIVE SUMMARY

The safe production of food satisfying the food safety objectives and complying with the legal limits or buyers' requirements can only be assured by identifying the critical control points for the whole production chain and verifying that the performance criteria established are met along the production chain.

In order to assist the business operators and competent authorities, the use of uncertainty of measured parameters for interpretation of the premarketing and post-marketing control results are described.

The application of the action limits as part of the process control is illustrated with the examples of pesticide residues in apples and aflatoxin M1 in milk.

The principles of the control of the whole production or part of the production chain are described in worked examples.

A glossary of terms in the appendix provides precise definitions and corresponding references.

2. INTRODUCTION

Production of food is usually a multi-phase procedure and may involve several independent business operators taking part in the various steps of the production chain. Each of them should fulfil its own responsibilities, and establish the appropriate performance objectives and corresponding performance criteria to assure that the product would comply with the relevant legal provisions or satisfy the buyers' requirements. The following examples illustrate the complexity of the process.

Persistent organochlorine compounds (pesticides, polychlorinated hydrocarbons) heavy metals, etc. have been sparingly used in the past and contaminated the soil. Certain plants may take up these chemical substances and accumulate them in their tissues. Furthermore, the plants can be infected with various diseases and insects which should be controlled with pesticides. The chemical residues may remain in foods of plant origin, or when such plants or part of them are fed to animals the chemical residues may be transferred to the edible animal tissues, milk and eggs, and further carried over to the processed final food product. Grazing cattle on pasture land contaminated with persistent chemicals led to DDT concentration well above the corresponding MRLs in meat and milk and resulted in interruption of international trade and significant loss of the farmers. Similar problems caused by heavy fungi infection of cereals, peanut, maize and other plants leading to high mycotoxin contamination in flour, bread, and or milk. In some cases the situation may vary from year to year, in other cases the undesirable conditions may prevail for longer periods.

In such cases, the control of the end-product is not the best solution as the contaminated products might have to be destroyed resulting in substantial financial and credibility loss of producers. Therefore, the critical phases of the production shall be identified and appropriate preventive measures shall be taken, starting with testing of the contamination level of soil and select appropriate sites for growing 'critical' plants ready to uptake the contaminants, following 'good agricultural practice' in the use of pesticides and fertilizers, monitor the pest and disease gradation and infection level of plants, and implement appropriate sampling (inspection) programmes, which indicate the change in production conditions in time to enable making the most effective preventive measures.

The applicable early warning sampling and inspection plans vary depending on the actual situation, production and economic conditions. The sampling methods and principles of deciding on the acceptability of the products are the same in case of early warning systems and premarketing tests of the end-products. The notable difference is in the timing and frequency of the tests for which occasionally less stringent methods can be applied in case of the early warning programmes

The present document provides the theoretical background for the proper control of the chemical contamination level along the production chain to verify that the produce would satisfy the performance objectives. It can be equally applied for the raw, semi-processed and final products. The practical applications of the principles are illustrated with two case studies. Furthermore the sampling schemes elaborated for performing risk-based monitoring programmes described in D6.9 can be applied for the early warning sampling plans as well.

3. NATURE OF THE AMONG FIELDS VARIATION OF PESTICIDE RESIDUES

The nature of the distribution of pesticide residues and mycotoxins in food commodities is summarised in the deliverables 6.9 and 7.2. Furthermore, they are described in details in scientific papers[1,2,3,4] prepared from the results of the research carried out within the frame of BASELINE project.

4. INTERPRETATION OF MAXIMUM LEGAL LIMITS

For assuring safety of marketed food, the regulatory agencies establish maximum residue limits (MRL) for pesticides[5] and veterinary drug residues, maximum limits (ML) for chemical[6,7] and microbial contaminations[8].

The MRLs and MLs are defined as the maximum legally permissible average concentration of chemical contaminants in a sample. The relevant EU Directives [9, 10, 11,12] specify the minimum size of the sample in terms number of primary samples (single sample increments)

[1] Zsuzsanna Horváth , Árpád Ambrus , László Mészáros and Simone Braun: Characterization of distribution of pesticide residues in crop units, Journal of Environmental Science and Health, Part B: Pesticides, Food Contaminants, and Agricultural Wastes, 48:8, 615-625 2013

[2] Zsuzsa Farkas, Zsuzsanna Horváth, K Kerekes, Á. Ambrus, A. Hámos and M. Szeitzné Szabó, Estimation of sampling uncertainty for pesticide residues in root vegetable crops
J. Environ. Sci and Health MS.#B1811 DOI:10.1080/03601234.2013.836851

[3] Zsuzsanna. Horváth, Judit . Sali, Anna. Zentai, Enikő . Dorogházi, Zsuzsa. Farkas, Kata. Kerekes, Mária Szeitzné-Szabó and Árpád Ambrus, Limitations in the determination of maximum residue limits and highest residues of pesticides, J. Environ. Sci and Health DOI:10.1080/03601234.2014.857960

[4] Árpád Ambrus, Zsuzsanna Horváth, Zsuzsa Farkas, István J. Szabó, Enikő Dorogházi and Mária Szeitzné-Szabó, Nature of the field-to-field distribution of pesticide residues,
Accepted for publication in J. Environ. Sci and Health MS.# B-1841

[5] REGULATION (EC) No 299/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 March 2008 amending Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, as regards the implementing powers conferred on the Commission, Official Journal of the European Union L97 67-71.

[6] COMMISSION REGULATION (EU) No 420/2011 of 29 April 2011 amending Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs Official Journal of the European Union L 111, 3-6.

[7] COMMISSION REGULATION (EC) No 199/2006 of 3 February 2006 amending Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs as regards dioxins and dioxin-like PCBs Official Journal of the European Union L32, 34-38.

[8] DIRECTIVE 2003/99/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC OJ. L. No. 325. p. 31-40

[9] Codex Secretariat, (2002) Recommended method of sampling for the determination of pesticide residues for compliance with MRLs, www.codexalimentarius.org/input/download/standards/361/CXG_033e.pdf

[10] COMMISSION REGULATION (EU) No 178/2010 of 2 March 2010 amending Regulation (EC) No 401/2006 as regards groundnuts (peanuts), other oilseeds, tree nuts, apricot kernels, liquorice and vegetable oil, Official Journal of the European Union L52, 32-43

[11] COMMISSION REGULATION (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs L70, 12-34

[12] COMMISSION REGULATION (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs L88 29-38

and or mass, as well as the portion of commodity to which the maximum limits apply and which should be analysed[13].

4.1 Inclusion of uncertainty of measured concentrations in decision making process

The combined relative standard uncertainty of measurement result (CV_R) can be expressed as

$$CV_R = \sqrt{CV_S^2 + CV_{SS}^2 + CV_{Sp}^2 + CV_A^2} \qquad \text{Equ. 1}$$

It incorporates the uncertainties of sampling (CV_S), sub-sampling (CV_{SS}), sample processing (chopping, mincing and homogenisation of analytical sample) (S_{Sp}) and analysis (CV_A).

Where the contribution of uncertainty of sub-sampling, sample processing is included in the estimated uncertainty of the laboratory phase of measurement (CV_L), then the two phases of the process can be distinguished as:

$$\mathrm{CV_R} = \sqrt{\mathrm{CV_S^2} + \mathrm{CV_L^2}} \qquad \text{Equ.2}$$

$$\mathrm{CV_L} = \sqrt{\mathrm{CV_{SS}^2} + \mathrm{CV_{Sp}^2} + \mathrm{CV_A^2}} \qquad \text{Equ.3.}$$

The CV_L is calculated as

$$\mathrm{CV_L} = \sqrt{\frac{\sum \Delta^2}{2n}} \qquad \text{Equ. 4}$$

Where $\Delta^2 = \left(\frac{R_1 - R_2}{\bar{R}}\right)^2$ and R_1 and R_2 are the results of analyses of retained test portions taken from the homogenised laboratory sample.

The measurement uncertainty shall be taken into account in assessing the compliance of inspected lot. The possible options are illustrated in Figure 1.

[13] Codex Alimentarius Codex Classification of Foods and Animal Feeds, Codex Alimentarius Volume 2, Pesticides Residues in Food 2nd ed, Rome 1993. www.codexalimentarius.org/input/download/.../41/CXA_004_1993e.pdf

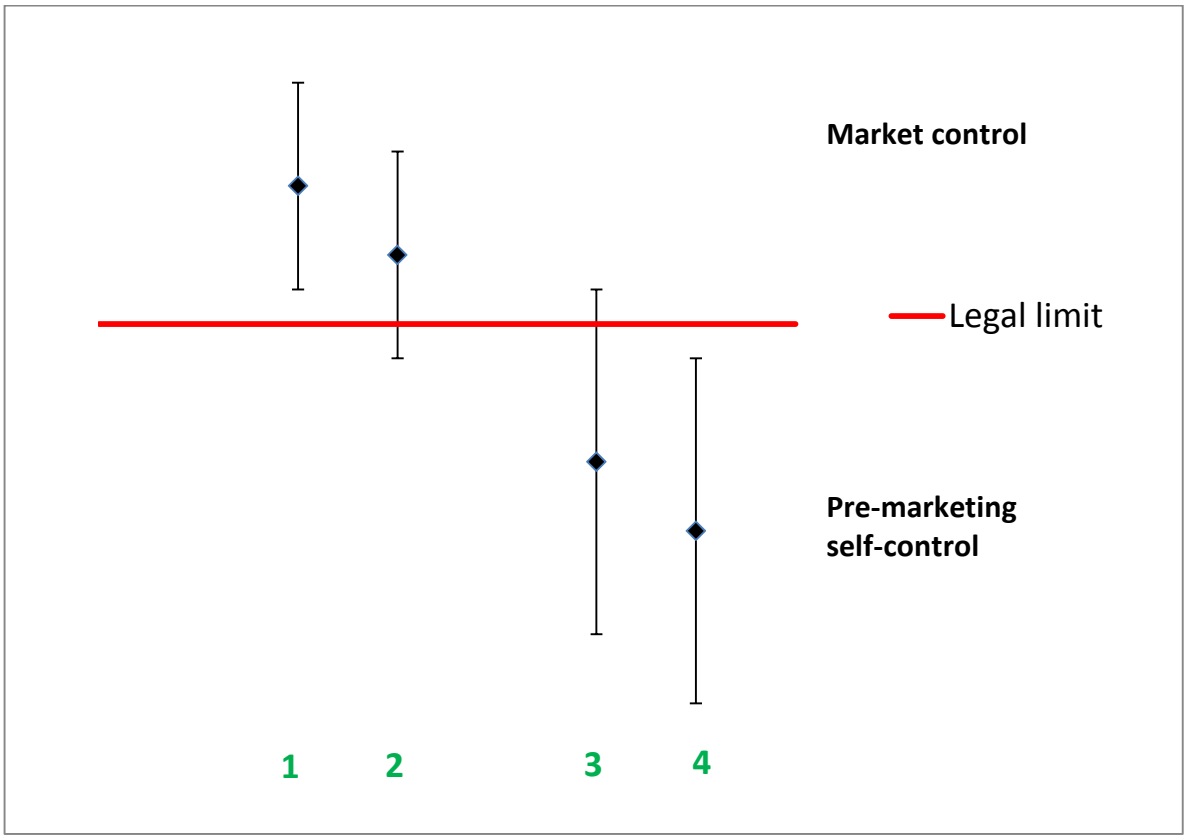

Figure 1: Illustration of taking into consideration of combined uncertainty of the measurement result

1. The lower 95% boundary of the measured concentration of the analyte is above the legal limit. The sampled lot does not comply with the legal limit.
2. The measured concentration is above the legal limit but the legal limit is within the uncertainty range. The product cannot be considered non-compliant.
3. The measured concentration is below the legal limit but the limit is within the uncertainty range of the measured value. Certain proportion of the product would contain the analyte above the legal limit. If that proportion is larger than the targeted violation rate (e.g. 1-βp=1-0.98=0.02) then the product cannot be considered to meet the specification.
4. The upper bound of the uncertainty range is below the legal limit. The product sampled complies with the specification.

4.2 Control of commodities for compliance with MRLs or MLs

There are two distinctly different situations which need different sampling plans.

(a) Control of commodities on the market (enforcement or monitoring programme)

As the permissible maximum concentrations of residues and chemical contaminants apply to the average concentration of the substances in the bulk/laboratory sample, the combined uncertainty of the measured concentration (CV_L) shall be taken into account in deciding on the compliance or non-compliance of the sampled product.

In order to make regulatory action in accordance with the relevant ISO [14]and Codex guidelines[15],[16] the European Commission regulations are clearly indicate that a lot is considered non-compliant if the measured analyte concentration corrected for recovery, where specified, minus the expanded uncertainty of the results are above the legal limit (Figure 1). For pesticide residues the default combined relative uncertainty reflecting the CV_L value (equ.4) is defined as 25%[17]. The relationship of the decision limit (DL) and the MRL is illustrated in Figure 3.

(b) Premarketing self-control carried out

When the product is tested before placing it on the market it has to be certified that at least a specified proportion of the product in terms of the minimum size and mass of bulk/laboratory sample complies with the legal limit. The BASELINE project recommended 98% compliance as performance objective. Naturally the interested parties may agree in a different PO.

In this case the combined uncertainty including sampling uncertainty (CVR) shall be taken into account, and the measured value should not be directly compared to the MRL as it may allow placing a product on the market with substantial proportion containing the contaminant above the permitted limit. Let's assume, that the MRL is 1 mg/kg, and the average concentration of a pesticide residue is also 1 mg/kg in the sampled lot. If the measured residue in the sample taken from the given lot is < 1 mg/kg and it would be compared to the MRL the sampled lot would be declared to be compliant. However the decision would only be correct in about 30% of the cases and would be wrong in 70% of the cases as indicated by the cumulative frequency distribution curve in Figure 2.

Therefore a lower concentration shall be selected as **Action Li**mit (AL) which can be calculated taking into account the relevant CVR value and the targeted level of compliance.

If the relative uncertainty of the measured value is CVR (equation 2), the relationship of AL and ML can be described with the following equations:

$$\mathrm{AL} + \mathrm{k} \times \mathrm{CV_R} \times \mathrm{AL} = \mathrm{ML} \qquad \text{Equ. 5}$$

$$\mathrm{AL} = \frac{\mathrm{ML}}{1+\mathrm{kCV_R}} \qquad \text{Equ. 6.}$$

The value of k depends on the selected percentile of the measurand which should be below the legal limit and the nature of the frequency distribution of the measurand in the samples.

[14] Joint Committee for Guides in Metrology (JCGM/WG 1), Evaluation of measurement data — Guide to the expression of uncertainty in measurement, http://www.bipm.org/utils/common/documents/jcgm/JCGM_100_2008_E.pdf

[15] Codex Alimentarius Commission, Guidelines on Measurement Uncertainty, CAC/GL 54-2004, http://www.codexalimentarius.org/search-results/?cx=018170620143701104933%3Ai-zresgmxec&cof=FORID%3A11&q=CAC%2FGL+54-2004&siteurl=http%3A%2F%2Fwww.codexalimentarius.org%2F&sa.x=16&sa.y=5

[16] Guidelines for Settling Disputes on Analytical (Test) Results, CAC/GL 70-2009 http://www.codexalimentarius.org/search-results/?cx=018170620143701104933%3Ai-zresgmxec&cof=FORID%3A11&q=Guidelines+for+Settling+Disputes+on+Analytical+%28Test%29+Results%2C++CAC%2FGL+70-2009&siteurl=http%3A%2F%2Fwww.codexalimentarius.org%2F&sa.x=16&sa.y=8

[17] Method Validation and Quality Control Procedures for Pesticide Residues Analysis in Food and Feed, Document N° SANCO/12495/2011, http://ec.europa.eu/food/plant/plant_protection_products/guidance_documents/docs/qualcontrol_en.pdf

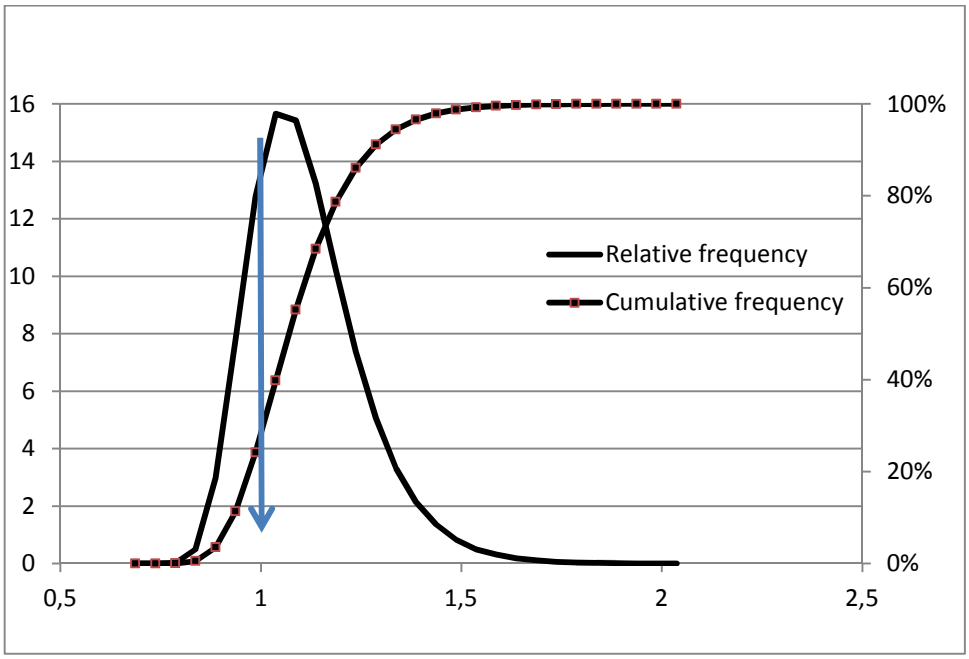

Figure 2: Distribution of residues in apple composite samples. MRL is 1 mg/kg;

The relationship of the uncertainties involved in the pre- and post-marketing testing programmes is illustrated on Figure 3 assuming that the CV_R is 43% (e.g. when apple fruits are tested) and the MRL is 1 mg/kg.

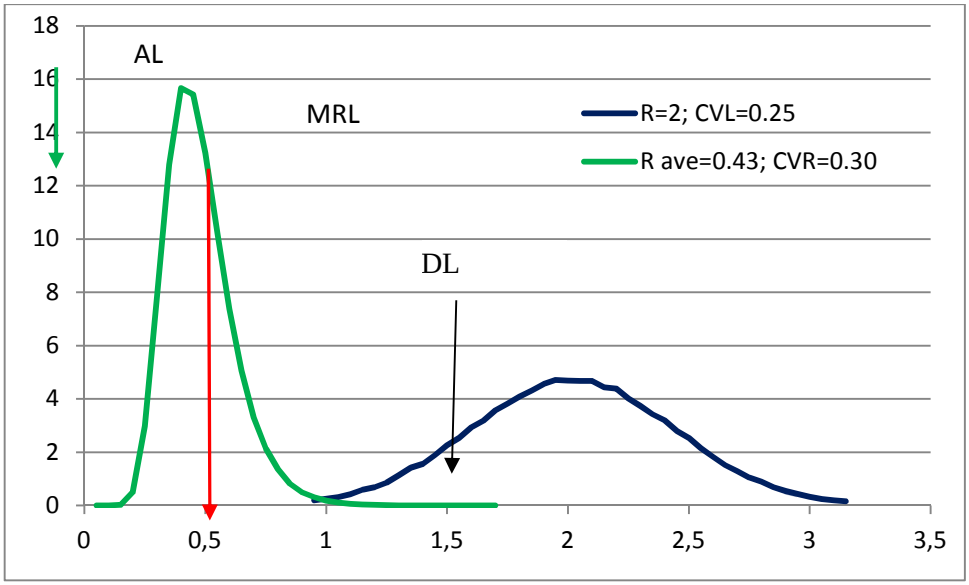

Figure 3: Relationship of the Action limit (AL) for testing and the decision limit (DL) for verifying compliance with an MRL of 1 mg/kg of an apple lot.

Where the product to be tested can be considered homogeneous such as bulk milk, the sampling uncertainty is practically zero. In this case only the uncertainty of the analytical measurement (CV_L) should be taken into account in equation 6. Figure 4 illustrates the situation with the example of aflatoxin M1 (AFM1) in milk.

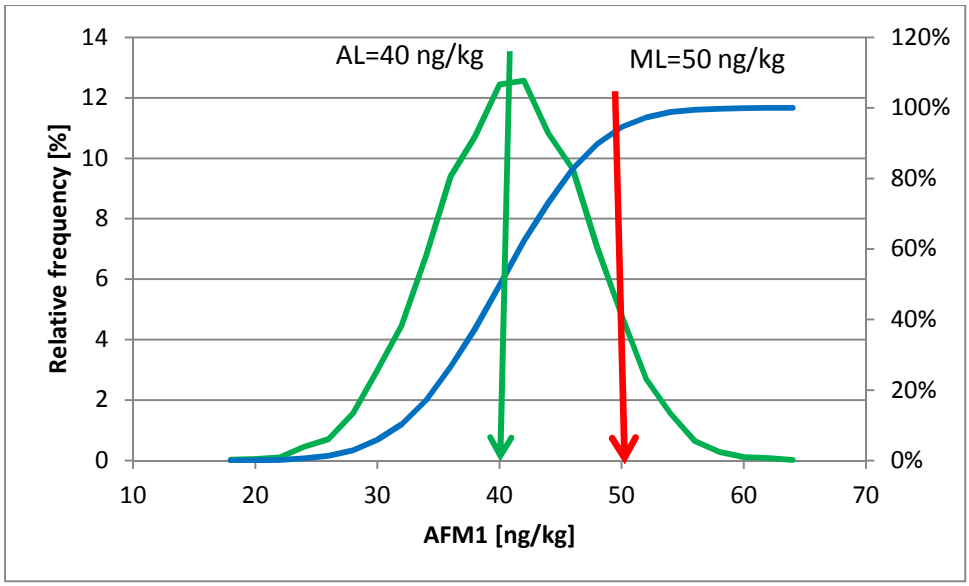

Figure 4: Relationship of AL and ML in case of determination of AFM1 in milk.

Taking the relative uncertainty of the values measured with quick ELISA-based method (15%) and aiming to verify the compliance at 95% level, then the value of k is 1.645 and the calculated AL is 40.1 0 ng/kg. The k can be taken from any normal probability table as it is generally accepted that the results of repeated analytical measurements can practically be described with normal distribution. If different compliance level should be verified then other factors should be used for the calculation.

If the contaminants are not homogeneously distributed in the product to be tested then the sampling uncertainty must be taken into account in the calculation of the combined uncertainty of the measured values (equation 2).

The distribution of pesticide residues can practically be described with lognormal distribution, while the distribution of mycotoxins depends on the toxin and sampled material. Some cases can be described with lognormal distribution while in other cases negative binomial distribution provides the suitable basis for calculation of sampling uncertainty [18],[19],[20].

[18] Food and Agriculture Organisation Sampling plans for aflatoxin analysis in peanuts and corn. FAO Food and Nutrition Paper #55, Rome, Italy, pp 75

[19] Johansson, A. S., T. B. Whitaker, W. M. Hagler, Jr., F. G. Giesbrecht, J. H. Young, and D. T. Bowman. 2000. Testing shelled corn for aflatoxin, Part III: Evaluating the performance of aflatoxin sampling plans. Assoc. Off. Anal. Chem., Int., pp 1279-1284.

[20] Brera C., T. B. Whitaker, B. D. Santis, E. Pantera, F. Debegnach, E. Pannunzi, F. Fasano, C. Berdini, A. B. Slate, M. Miraglia. 2010. Effect of Sample Size in the Evaluation of “In-Field” Sampling Plans for Aflatoxin B1 Determination in Corn. J. Agric. Food Chem., 58:8481–8489.

5. CASE STUDIES

The concept of the action limit can be applied for the verification of the compliance of a particular lot, or can be used within an early warning control programme. The programme is based on the precise definition of the sampling frame, weighting the potential risk associated with the production of a given product and the random sampling of the products all over the production cycle.

The binomial distribution theory can be used to calculate the number of random samples required for claiming the compliance of a specified percentage of the production with desired probability even in case of strongly skewed and scattered distribution of chemical substances in various kinds of food chemical combinations such as pesticide residues in products of plant origin or mycotoxin contamination in cereals, oil seeds and milk. The results of the validation of the applicability of the binomial theory under such circumstances are presented in D7.2.

The number of *random samples* (n) required for finding at least one value above a selected percentile (β_p) of the elements of the sampling frame, called parent population (e.g. difenoconazole residues in orange, cypermethrin residues in green beans etc.), with a specified probability level (β_t) can be calculated applying the binomial distribution with the following equation:

$$\beta_t = 1 - \beta_p^n \quad \text{or} \quad n = \frac{\lg(1-\beta_t)}{\lg\beta_p} \qquad \text{Equ.7}$$

The probability to find at least 2 samples above the selected percentile is:

$$\beta_t = 1 - \binom{n}{0} p^0 (1-p)^n - \binom{n}{1} p^1 (1-p)^{n-1} \qquad \text{Equ. 8}$$

The number of samples required is rapidly increasing depending on the selected percentile (βp) and detection probability (βt). For instance, to verify compliance of 98% of the production with 90%, 95% and 99% probability, 80, 149, and 228 samples shall be analysed. The advantage of the application of binomial distribution for deciding on the required number of sample is that the sample size is independent from the number of farms or consignments (N) to be sampled if N >> n. For small number of sampling units a modified equation should be used leading to smaller number of samples.

It should be emphasised that the sampling programme based on the above sample size calculations is suitable only to verify that the production is under proper control, but without that sampling and analysis regardless the sample size (unless each lot is sampled separately) cannot assure meeting the performance criteria.

5.1 Early warning sampling programme for control of the production of fresh vegetables

5.1.1 Setting the scene

Some legume vegetables are among the major export item of a country amounting to annual revenue of several million US$. The crops are grown in about 65000 small and medium size farms of 0.5- 10 ha. The crop is fast growing and can be harvested eight to ten times a year. The product is transported to the collection centres of the exporters where the beans are pre-sorted and cleaned from foreign materials. The pre-cleaned crop is transported to the packing houses within 12 hours where it is stored in cold rooms until final sorting, washing

and packing in labelled boxes are carried out. The packed product is ready to airfreight during the night to the importing county and distributed in the market next morning.

Several shipments had been rejected due to high and unauthorised pesticide residue content leading to the risk of losing the export market. The Government requested the assistance to prepare a control plan.

The main objectives were:

- elaboration of a production control system suitable for growing good quality vegetables complying with maximum residue limits;
- development of sampling plan enabling the early detection of deviations and making the necessary corrective actions.

5.1.2 Action plan

(a) Basic principles:

- Compliance with legal provisions can only be assured by strict control of the production, collection, sorting and handling of the commodities;
- Sampling programme shall be implemented to verify that appropriate growing and processing practice is effectively in place.

(b) All parties (exporters, producers, brokers, government officials) shall understand their joint and individual responsibilities related to the safe export of agricultural produce which provides major income for a substantial proportion of the citizens and revenue of the Government.

(c) Each party shall perform its activities with full commitment for realization of the common goal.

(d) Parties acting irresponsibly shall be excluded from the export of agricultural commodities, and shall bear the responsibility of placing noncompliant products on the domestic market.

Two examples for specified responsibilities are described hereunder.

5.1.2.1 Responsibilities of exporters

The exporters were identified as the key players in the production chain as they had the revenue from the export therefore they could set their quality standards and pay premium price for suitable quality products.

Therefore the exporters should:

(a) Establish contractual agreement with sufficient number of growers with detailed specifications of responsibilities and consequences of non-compliance;

(b) Provide the growers with appropriate agronomical and plant protection guidance for safe and profitable production of the commodities;

(c) Employing agronomists to give practical instructions for the growers on the spot, and supervise the production;

(d) Consider the option of providing:

- pesticides of high quality from reputable suppliers for the protection of the crops. (Pesticides being in the high risk category should be avoided or strictly limited to the early growing stage of the plants);
- calibrated spraying equipment with nozzles suitable for the specific application;

(e) Contract and train spray operators who will efficiently apply the pesticide on the fields strictly following the use recommendations and keeping accurate records on the use of pesticide;

(f) Separate the lots from commodities deriving from one field as far as possible.

(g) Minimising the mixing of the products of different growers; where such an option is inevitable making special arrangement for strict control of the production, and raising awareness of joint responsibility of the grouped growers. „One for all, all for one"

(h) Get the spray records attached to each lot.

(i) Establish full traceability of the production which enables identification of the grower and preferably the particular filed based on the lot number.

(j) Cover the cost of sampling and analysis involving the products all registered growers proportionally to the average value of their export in the previous two years.

5.1.2.2 Responsibilities of growers

(a) Seeking and following the advice of the agronomists;

(b) Starting harvesting the crops only after the pre-harvest intervals (PHI) expire; 1 and 2 -day PHI should be interpreted as 24 and 48 hours, respectively.

(c) Refraining from the application of pesticides which are not on the list provided by the supervising agronomist.

(d) *Reporting any deviation from the prescribed agronomic practice to the supervising agronomist.*

5.1.3 Random sampling programme

The exporters are obliged to provide to the responsible Government institute the list of contracted growers, the location of collection points and packing houses and their average annual output of the previous two years. The annual regular sampling plan is prepared based on this information.

The trained government inspectors are taking the samples according to the predefined random sampling plan and carry out the plant health inspections at the same time.

The sampling plan will be prepared separately for each commodity applying stratified random sampling.

(i) *Number of samples to be tested annually*

Performance objective: 99% of the products comply with the MRLs of importing country in 95% of the cases

(a) Commodity A: 300 samples in each of the 10 cycles (3000 sample/year)

(b) Commodity B: 300 samples in each of 8 cycles (2400 samples /year)

(ii) Targeted sampling

(a) Products grown by small farms (consisting of 5-30 farmers) which are grouped together shall be sampled separately by each group at two times during the harvesting period in each growing cycle to verify the application of the plant protection technology recommended by the contractor (exporter). This targeted sampling serves to reduce the risk resulted from mixing of the produce (sometimes 5-15 kg) of individual farmers. Under other circumstances other weighting options may be used to take into account the risk associated with certain type of products.

(b) Further products of exporters which have contained noncompliant residues shall be sampled weekly.

5.1.4 Evaluation of the results

The residues measured in the samples shall be compared to the action limits determined for each pesticide taking into account the estimated sampling uncertainty estimated and validated within the BASELINE project[21]. It should be pointed out that the within laboratory reproducibility (CV_L) of the analytical laboratories which would carry out the analyses were not available at the time of calculation of action limits given as an examples in Table 1. Therefore all action limits provided for the control plan should be revised according the actual performance of the laboratories. The calculated CV_R should take into account all components of the combined uncertainty indicated in equation 1.

	MRL	AL
acephate	0.02*	LD≤0.008
azaconazole	NR	nd
azoxystrobin	3	1.2
chlorpyrifos	0.05*	LD≤0.02
cyfluthrin	0.1	0.04
difenoconazole	1	0.4
indoxacarb	0.3	0.12
teradifon	0.01*	LD≤0.004

Table 1: Examples of estimated action limits for selected pesticide residue

The AL concentrations listed in the table varies at a large extent depending on the MRL and dictates the expectable minimum laboratory performance. The stringent performance requirements, especially where the MRL is 0.01*, are not easy to meet. In this case the testing laboratories should have suitable instrumentation to enable detection residues as low as technically possible.

There may be some cases where such a low level as 0.004 cannot be achieved, therefore higher action levels should be considered in combination of taking more than one samples from a lot.

The results of analyses can be interpreted as follow:

[21] D.7.2 Validation of Targeted Sampling with the new data and development of quantitative indices on reliability and precision, accounting for on food risk factor information

Provided that truly random 300 representative samples are taken and correctly analysed, then:

(a) If none of the samples contain residue above the corresponding AL, one can claim that over 99% of the product complies with the MRL in 95% of the cases.

(b) If one sample contains residue above the corresponding AL one can state that at least 99% of the product complies with the MRL in 95% of the cases.

(c) If during a year no sample contained residue above the AL than it would indicate that about 99.9% of the exported product complied with the MRL in 95% of the cases.

If a sample contains residue above the corresponding AL, the origin of the sampled lot shall be traced back, the field records checked and the new sample shall be taken from the freshly grown beans. If the result of the analysis confirms the high residues or the use of not-authorised pesticide, the crop harvested during the growing cycle should be excluded from the export programme.

Further on, the principle of evaluation of the results of the monitoring programmes[22] described in tier 2 in D6.9 should be applied inserting the corresponding AL value in equation 9.

$$f_p = 100 \frac{\sum(R_i AL_i^{-1})}{N} \qquad \text{Equ. 9}$$

Where R_i–s are the measured residues in samples derived from the control programmes, N is the number of samples analysed and AL is the calculated action limit for the particular pesticide. If R_i< LOQ (limit of quantification) then R_i is counted with the reported LOQ. *Where there is no MRL insert AI value of 0.004 mg/kg in the calculation of f_p.*

The production can be considered well controlled if N ≥ 75, the fp is below 80%, and there is no result exceeding the AL level.

If the fp is increasing over 80%, it is another early warning sign indicating potential problem. Therefore the source of high residues should be traced back and the growing conditions as well as the plant protection practice should be reviewed.

6. MONITORING THE OCCURRENCE OF AFLATOXIN M1 (AFLAM1) IN MILK (MOVING WINDOW CONCEPT)

The risk based control plan elaborated for controlling AFLAM1 in milk[22] can also be considered as an early warning system, as it enables the identification of dairy farms producing non-compliant milk within 24 hours under normal circumstances.

The production of milks complying with the legal limit can be further enhanced with the operation of effective pest and diseases forecast system and regular publication of its predictions. When the forecast indicates fungi infection above a threshold level, the harvested corn grains and by-products used as animal feed should be sorted, handled and stored with special attention. Furthermore, the aflatoxin contamination of feeds used by dairy farms should be regularly checked and their compliance with the 5 μg/kg maximum limit should be verified by comparing the aflatoxin B1 concentration to the 2 μg/kg action limit.

[22] D.6.9 Recommended sampling schemes to test for chemical contaminants and micro-organisms

7. GLOSSARY OF TERMS

Acceptable daily intake (ADI)	The estimate of the amount of a chemical in food or drinking-water, expressed on a body weight basis that can be ingested daily over a lifetime without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of the evaluation. The ADI is expressed in milligrams of the chemical per kilogram of body weight (a standard adult person weighs 60 kg). It is applied to food additives, residues of pesticides and residues of veterinary drugs in food.
Acceptable risk	A risk management term. The acceptability of the risk depends on scientific data, social, economic and political factors, and the perceived benefits arising from exposure to an agent.
Accuracy	Degree of agreement between average predictions of a model or the average of measurements and the true value of the quantity being predicted or measured.
Acute exposure	A short-term exposure to a chemical, usually consisting of a single exposure or dose administered for a period of 24 h or less.
Acute reference dose (ARfD)	The estimate of the amount of a substance in food or drinking-water, expressed on a body weight basis, that can be ingested in a period of 24 h or less without appreciable health risk to the consumer. It is derived on the basis of all the known facts at the time of evaluation. The ARfD is expressed in milligrams of the chemical per kilogram of body weight.
Analyte	Component demonstrated or measured directly or indirectly by the method of analysis. In the case of microbiological methods, it may be a target microorganism (bacteria, viruses, yeasts, moulds, algae, parasitic protozoa, microscopic parasitic helminths), its components or associated by-products (e.g. enzymes, metabolites or toxins).
Analytical sample (Commission Directive 2002/63/EC)	The material prepared for analysis from the laboratory sample, by separation of the portion of the product to be analysed and then by mixing, grinding, fine chopping, etc., for the removal of analytical portions with minimal sampling error.

Chronic exposure	A continuous or intermittent long-term contact between an agent and a target.
Codex Alimentarius Commission (CAC)[1]	CAC was formed in 1962 to implement the Joint FAO/WHO Food Standards Programme. It is an intergovernmental body made up of currently[1] 186 member nations and 1 Member Organization, the delegates of which represent their own countries. CAC's work of harmonizing food standards is carried out through various committees, such as the Codex Committee on Food Additives (CCFA), the Codex Committee on Contaminants in Food (CCCF), the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF) and the Codex Committee on Pesticide Residues (CCPR). The Joint FAO/WHO Expert Committee on Food Additives serves as the advisory body to CAC on all scientific matters concerning food additives, food contaminants, naturally occurring toxicants and residues of veterinary drugs in food. The Joint FAO/WHO Meeting on Pesticide Residues serves as the advisory body to CAC on all scientific matters concerning pesticide residues.
Competent Authority (Regulation (EC) No 882/2004)	Means the central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country.
Composite sample	Often prepared as a representative mixture of several different (usually bulk) samples, from which the laboratory sample is taken.
Confidence interval	An estimated two-sided interval from the lower to upper confidence limit of a statistical parameter. This interval is expected to enclose the true value of the parameter with a specified confidence. For example, 95% confidence intervals are expected to enclose the true values of estimated parameters with a frequency of 95%.
Conservative estimate	An estimate that tends to err on the side of caution. A conservative estimate of dietary exposure, for example, assigns the "worst case" food chemical concentrations and/or food consumption levels to maximize (or minimize, in the case of nutrients, when assessing nutrient deficiency) the estimated food chemical exposure.
Contaminant	Any substance not intentionally added to food that is present in such food as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packaging, transport or holding of such food or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.

Convenient sampling	Strategy based on the selection of a sample for which units are selected only on the basis of feasibility or ease of data collection. It's a not random sampling. The data reported refer themselves to units selected according to this strategy.
Count (ISO 17994:2004, ISO 7218:2006)	Observed number of objects, e.g. colonies or cells of microorganisms, plaques of viruses or bacteriophages.
Definition of residues (for compliance with MRLs)[1]	The definition of a residue (for compliance with MRLs) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the MRL applies. (JMPR Report 1995, 2.8.1.) Explanatory not: The residue definition for compliance with MRLs depends on the results of metabolism and toxicology studies, supervised residue trials, analytical methods and its general suitability for monitoring compliance with GAP.
Definition of residues (for estimation of dietary intake)[1]	The definition of a residue (for estimation of dietary intake) is that combination of the pesticide and its metabolites, impurities and degradation products to which the STMR applies. Explanatory note: The residue definition for estimation of dietary intake depends on the results of metabolism and toxicology studies and its general suitability for estimating dietary intake of the residue for comparison with the ADI.
Deterministic (point) estimate	In exposure assessment, an estimate that is based on a single value for each model input and a corresponding individual value for a model output, without quantification of the cumulative probability or, in some cases, plausibility of the estimate with respect to the real-world system being modelled. This term is also used to refer to a model for which the output is uniquely specified based on selected single values for each of its inputs.

Error (gross, random, systematic)	Any discrepancy between a computed, observed or measured quantity and the true, specified or theoretically correct value of that quantity. *Gross errors* refer to unintentional or unpredictable errors while generating the analytical result. Errors of this type invalidate the measurement. It is not possible or desirable to statistically evaluate and include the gross errors in the estimation of uncertainty. *Random errors* are present in all measurements and cause replicate results to fall on either side of the mean value. The random error of a measurement cannot be compensated for, but increasing the number of observations and training of the analyst may reduce the effects. *Systematic errors* are those resulting from some bias in the measurement process and are not due to chance. Systematic errors occur in most experiments, but their effects are quite different. The sum of all the systematic errors in an experiment is referred to as the bias.
Food	In the Codex Alimentarius Commission context, any substance, whether processed, semi-processed or raw, that is intended for human consumption. It includes drink, chewing gum and any substance that has been used in the manufacture, preparation or treatment of food, but it does not include cosmetics or tobacco or substances used only as drugs.
Food consumption	For assessing dietary chemical hazards, an estimate of the quantity of a food or group of foods (including beverages and drinking-water) consumed by a specified population or individual. Food consumption is expressed in grams of food per person per day.
Food safety objective (FSO)	The maximum frequency and/or concentration of a hazard in a food at the point of consumption that provides, or contributes to, achievement of the Appropriate Level of Protection (ALOP).

Good Agricultural Practice (GAP)	For pesticide use, includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner that leaves a residue that is the smallest amount practicable. Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations. Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed.
Good Laboratory Practice (GLP)	The formalized process and conditions under which laboratory studies are planned, performed, monitored, recorded, reported and audited. Studies performed under GLP are based on the national regulations of a country and are designed to assure the reliability and integrity of the studies and associated data.
Hazard	Inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub)population is exposed to that agent.
Hazard assessment	A process designed to determine the possible adverse effects of an agent or situation to which an organism, system or (sub)population could be exposed. The process includes hazard identification and hazard characterization. The process focuses on the hazard, in contrast to risk assessment, where exposure assessment is a distinct additional step.
Hazard characterization	The qualitative and, wherever possible, quantitative description of the inherent properties of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties. Hazard characterization is the second stage in the process of hazard assessment and the second step in risk assessment.
Hazard identification	The identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system or (sub)-population. Hazard identification is the first stage in hazard assessment and the first step in the process of risk assessment.

Highest residue (HR)	The highest residue level (expressed as milligrams per kilogram) in a composite sample of the edible portion of a food commodity when a pesticide has been used according to maximum Good Agricultural Practice (GAP) conditions. The HR is estimated as the highest of the residue values (one from each trial) from supervised trials conducted according to maximum GAP conditions and includes residue components defined by the Joint FAO/WHO Meeting on Pesticide Residues for estimation of dietary intake.
Homogeneity (ISO Guide 30:1992)	The condition of being of uniform structure or composition with respect to one or more specified properties. A reference material is said to be homogeneous with respect to a specified property if the property value, as determined by tests on samples of specified size, is found to lie within the specified uncertainty limits, the samples being taken either from different supply units (bottles, packages, etc.) or from a single supply unit.
Incurred residue	Residue present in food or feed as a result of treatment with pesticides or veterinary drugs, for example, in the field (as opposed to residue resulting from spiking samples in the laboratory).
Intake	For the purposes of food and feed risk assessment, the amount of a substance (including nutrients) ingested by a person or an animal as part of its diet (via food, beverages, drinking-water and food supplements). This term does not refer to whole foods. The “intake” of whole foods is termed “food consumption”.
International estimated daily intake (IEDI)	A prediction of the long-term daily intake of a pesticide residue on the basis of the assumptions of average daily food consumption per person and median residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components defined by the competent national, bodies, (EFSA in EU) and at international level the Joint FAO/WHO Meeting on Pesticide Residues for estimation of dietary intake. Changes in residue levels resulting from preparation, cooking or commercial processing are included. When information is available, dietary intake of residues resulting from other sources should be included. The IEDI is expressed in milligrams of residue per person.

International estimated short-term intake (IESTI)	A prediction of the short-term intake of a pesticide residue on the basis of the assumptions of high daily food consumption per person and highest residues from supervised trials, allowing for residues in the edible portion of a commodity and including residue components defined by the Joint FAO/WHO Meeting on Pesticide Residues for estimation of dietary intake. The IESTI is expressed in milligrams of residue per kilogram of body weight.
Joint FAO/WHO Meeting on Pesticide Residues (JMPR)	The abbreviated title for the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group on Pesticide Residues, which has been meeting since 1963. The meetings are normally convened annually. The FAO Panel of Experts is responsible for reviewing residue and analytical aspects of the pesticides considered, including data on their metabolism, fate in the environment and use patterns, and for estimating the maximum residue levels and supervised trials median residue levels that might occur as a result of the use of the pesticide according to Good Agricultural Practice. The WHO Core Assessment Group on Pesticide Residues is responsible for reviewing toxicological and related data on the pesticides and, when possible, for estimating acceptable daily intakes and long-term dietary intakes of residues. As necessary, acute reference doses for pesticides are estimated along with appropriate estimates of short-term dietary intake. JMPR is a technical committee of specialists acting in their individual capacities. Each is a separately constituted committee. When the term “JMPR” or “the Meeting” is used without reference to a specific meeting, it is meant to imply the common policy or combined output of the separate meetings over the years.
Laboratory sample (Commission Directive 33/2007/EC, 401/2006/EC)	A sample intended to the laboratory. The sample sent to, or received by, the laboratory. A representative quantity of material removed from the bulk sample. Notes: a) The laboratory sample may be the whole or a part of the bulk sample. b) Units should not be cut or broken to produce the laboratory sample(s), except where subdivision of units is specified c) Replicate laboratory samples may be prepared.
Large portion size	A food consumption amount that represents the 97.5th-percentile consumption (eaters only) of a food that is derived from individual consumer days in a food consumption survey. This is useful in calculating acute dietary exposures.

Limit of detection (LOD)	The minimum concentration of a component in a dietary sample that can be qualitatively detected, but cannot be quantitatively determined, under a pre-established set of analytical conditions.
Limit of quantification (LOQ)	The minimum concentration of a component that can be determined quantitatively with acceptable accuracy and consistency. It often approximates to a value of 3 times the limit of detection.
Maximum level (ML)	For contaminants, naturally occurring toxicants and nutrients, the maximum concentration of a substance recommended by the Codex Alimentarius Commission to be legally permitted in a given commodity. For food additives, the level of permission of use given in food standards for the additive in that food or food category.
Maximum residue limit (MRL)	The maximum concentration of a pesticide residue (expressed as milligrams per kilogram) to be legally permitted in or on food commodities and animal feed. MRLs for meat and poultry apply to a bulk sample derived from a single primary sample, whereas MRLs for plant products, eggs and dairy products apply to a the specified portion of the composite bulk sample derived from 1-10 primary samples[1],[1].
Measurand (VIM, International Vocabulary of Metrology)	Quantity intended to be measured. In chemistry, 'analyte' or the name of a substance or compound are terms sometime used for measurand.
Monitoring (Reg. (EC) N. 882/2004)	Conducting a planned sequence of observations or measurements with a view to obtaining an overview of the state of compliance with feed or food law, animal health and animal welfare rules.
Non-compliance (Reg. (EC) N. 882/2004)	Non-compliance with feed or food law, and with the rules for the protection of animal health and welfare.
Performance criterion (PC)	The frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a performance objective.
Performance objective (PO):	The maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain that provides, or contributes to, achievement of the FSO or ALOP.

Pesticide	Any substance or mixture of substances intended for preventing, destroying or controlling any pest, including vectors of human or animal disease, unwanted species of plants or animals causing harm during or otherwise interfering with the production, processing, storage, transport or marketing of food, agricultural commodities, wood and wood products or animal feedstuffs, or substances that may be administered to animals for the control of insects, arachnids or other pests in or on their bodies. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant or agent for thinning fruit or preventing the premature fall of fruit, and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage or transport.
Precision	A measure of the reproducibility of the predictions of a model or repeated measurements, usually in terms of the standard deviation or other measures of variation among such predictions or measurements.
Processing factor	For a specified pesticide residue, commodity and food process, the residue level in the processed product divided by the residue level in the starting commodity, usually a raw agricultural commodity.
Provisional maximum tolerable daily intake (PMTDI)	The reference value, established by the Joint FAO/WHO Expert Committee on Food Additives, used to indicate the safe level of intake of a contaminant with no cumulative properties. Its value represents permissible human exposure as a result of the natural occurrence of the substance in food and drinking-water... The tolerable intake is generally referred to as “provisional” as there is often a paucity of data on the consequences of human exposure at low levels, and new data may result in a change to the tolerable level. *Related term*: Tolerable daily intake.
Provisional tolerable weekly intake (PTWI)	The end-point used by the Joint FAO/WHO Expert Committee on Food Additives for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods.
Quality assurance	A set of activities whose purpose is to demonstrate that an entity meets all quality requirements. These activities are carried out in order to inspire the confidence of both customers and managers that all quality requirements are being met.
Quality control	A set of activities or techniques whose purpose is to ensure that all quality requirements are being met. In order to achieve this purpose, processes are monitored and performance problems are solved.
Random sampling	A sample selected from a statistical population such that each individual has an equal probability of being selected.

Recovery	Proportion of the amount of analyte, present in, added to or present in and added to the analytical portion of the test material, which is resented for measurement.
Residues of pesticides	Any specified substances in or on food, agricultural commodities or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products and impurities considered to be of toxicological significance. The term “pesticide residue” includes residues from unknown or unavoidable sources (e.g. environmental) as well as known uses of the chemical. The definition of a residue for compliance with maximum residue limits (MRLs) is that combination of the pesticide and its metabolites, derivatives and related compounds to which the MRL applies.
Residues of veterinary drugs	The parent compounds and/or their metabolites in any edible portion of the animal product. They include residues of associated impurities of the veterinary drug concerned.
Risk	The probability of an adverse effect in an organism, system or (sub)-population caused under specified circumstances by exposure to an agent.
Sample (Commission Directive 2002/63/EC)	One or more units selected from a population of units, or a portion of material selected from a larger quantity of material. For the purposes of these recommendations, a representative sample is intended to be representative of the lot, the bulk sample, the animal, etc., in respect of its pesticide residue content and not necessarily in respect of other attributes.
Sample preparation	Includes actions taken to prepare the analytical sample from the laboratory (bulk) sample, such as reducing the size of a large bulk sample by subsampling or removing foreign materials and parts of the sample material that are not analysed (e.g. stones, withered leaves, stones of fruits, bones of meat). Sample preparation may include, for instance, washing, peeling, cooking, etc. so that foods are prepared as for normal consumption (i.e. table ready). Sample preparation may also involve compositing of food samples taken from different regions, brands and even food types before homogenization and analysis.
Sample processing	Includes physical operations performed to prepare a well-mixed or homogeneous matrix to form the analytical sample, from which the test portions for the analysis are taken.
Sampled size	It indicates the number of natural units and the weight expressed in grams or kg of all units collected as one sample

Sampling plan	Planned procedure which enables one to choose, or draw separate samples from a lot, in order to get the information needed, such as a decision on compliance status of the lot. More precisely, a sampling plan is a scheme defining the number of items to collect and the number of non confirming items required in a sample to evaluate the compliance status of a lot.
Sampling procedure (protocol)	Operational requirements and/or instructions relating to the use of a particular sample plan (i.e. the instructions for the implementation of the plan).
Selective field survey (SFS)	Samples are collected from fields of known pesticide treatment history taking into account the pesticide application record book.
Selective sampling (EUROSTAT)	Strategy based on the selection of a random sample from a subpopulation (or more frequently from subpopulations) of a population on which the data are reported. The subpopulations are determined on a risk basis or not. The sampling from each subpopulation is not proportional: the sample size is proportionally bigger for instance in subpopulations considered at high risk. This sampling includes also the case when the data reported refer themselves to censuses on subpopulations.
Stratified sampling	A method that selects values at regular intervals throughout each distribution. Calculating the result using the average or median value for each distribution may be thought of as the simplest example of a stratified sampling process, where each distribution has a single stratum.
Supervised trials	Scientific studies in which pesticides are applied to crops or animals according to specified conditions intended to reflect commercial practice, after which harvested crops or tissues of slaughtered animals are analysed for pesticide residues. Specified conditions are usually those that approximate existing or proposed Good Agricultural Practice.
Suspect sampling (EUROSTAT)	Selection of an individual product or establishment in order to confirm or reject a suspicion of non-conformity. It's a not random sampling. The data reported refer themselves to suspect units of the population.
Tolerable daily intake (TDI)	Analogous to acceptable daily intake. The term tolerable is used for agents that are not deliberately added, such as contaminants in food. Note that the Joint FAO/WHO Expert Committee on Food Additives uses the term provisional maximum tolerable daily intake. Related terms: Acceptable daily intake, Health-based guidance value, Provisional maximum tolerable daily intake.

Uncertainty	In risk assessment, imperfect knowledge concerning the present or future state of an organism, system or (sub)population under consideration. In exposure assessment, lack of knowledge regarding the “true” value of a quantity, lack of knowledge regarding which of several alternative model representations best describes a system of interest or lack of knowledge regarding which probability distribution function and its specification should represent a quantity of interest. In chemical analysis.[1] A parameter associated with the result of a measurement, that characterises the dispersion of the values that could reasonably be attributed to the measurand.
Use pattern	The combination of all factors involved in the use of a pesticide, including the concentration of active ingredient in the preparation being applied, rate of application, time of treatment, number of treatments, use of adjuvants and methods and sites of application, which determine the quantity applied, timing of treatment and interval before harvest.
Validation (ISO8402:1994,ISO/TR 13843:2001)	Establishment of the performance characteristics of a method and provision of objective evidence that the particular requirements for a specified intended use are fulfilled. Note: Providing evidence that the requirements for an intended use are fulfilled is a fitness for purpose exercise and is ultimately the responsibility of the users of the method. For guidance and as part of the calculations in the frame of validation of microbiological methods acceptability limits/acceptance criteria of the method to be validated are defined in (the revised) ISO 16140.
Variability	Heterogeneity of values over time, space or different members of a population. Variability implies real differences among members of that population...