[redacted]

Von: [redacted]
Gesendet: Montag, 30. September 2024 18:09
An: [redacted]
Betreff: WG: methods of sampling and analysis for the control of pesticide residues (PLAN 2023/636 Rev.6)
Anlagen: 2024-08-20_THIE-comments on pesticide sampling and analysis.pdf; 2024-08-16 THIE-position on autocontrols.pdf

Von: [redacted]
Gesendet: Mittwoch, 28. August 2024 09:20
An: [redacted]
Cc: [redacted]
Betreff: tee: methods of sampling and analysis for the control of pesticide residues (PLAN 2023/636 Rev.6)

Sehr geehrt[redacted]

über den Lebensmittelverband Deutschland haben wir den Entwurf Regulation on methods of sampling and analysis for the control of pesticide residues (PLAN 2023/636 Rev.6) erhalten. Bitte finden Sie anliegend die Kommentare unseres europäischen Verbands THIE hierzu.

Wir möchten Ihnen bei dieser Gelegenheit auch das *THIE position paper on autocontrols – Sampling methods as well as pesticide residue and contaminants analysis and interpretation of results* übersenden, welches die Basis der Kommentare bildet und gleichzeitig einen vertieftere Ausführungen zu der Thematik in Hinblick auf die Spezifika der Produktgruppe Tee sowie Kräuter- und Früchtetee enthält.

Für Rückfragen stehen wir gern zur Verfügung.

Mit freundlichen Grüßen

Deutscher Tee & Kräutertee Verband

[redacted]

tee • Deutscher Tee & Kräutertee Verband e.V.
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2020 haben sich der Deutsche Teeverband e.V. und die Wirtschaftsvereinigung Kräuter- und Früchtetee e.V. zum Deutschen Tee & Kräutertee Verband e.V. zusammengeschlossen. Was uns verbindet ist die Faszination einer unvergleichlichen Genusskultur, was uns antreibt ist die Leidenschaft für ein einzigartiges Naturprodukt.

TEA & HERBAL INFUSIONS EUROPE

Formerly: European Tea Committee (ETC) and European Herbal Infusions Association (EHIA)

Hamburg, 20 August, 2024

Comments by the Tea and Herbal Infusion Industry on the revision of the Commission's regulation on methods of sampling and analysis for the control of pesticide residues in and on products of plant and animal origin and repealing Directive 2002/63/EC

THIE as the representative of the European tea and herbal infusions industry has carefully reviewed PLAN 2023/636 Rev.6 and its Annex. THIE would like to take the opportunity to comment on some aspects of the Drafts.

THIE welcomes, that:

- a framework of equal rules applies to samples collected by FBOs and enforcement authorities.
- within this framework a flexibility is granted to FBOs to apply equivalent sampling measures to those foreseen for the enforcement authorities.
- the clarification, that the interpretation of analytical results and the consideration of the expanded measurement uncertainty apply equally to samples taken by FBOs and by the enforcement authorities.

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Specific remarks on PLAN 2023/636 Rev.6

→ Recital 7

"As those elements form the basis of risk management decisions, they should be integrated in an Implementing Regulation to ensure harmonised enforcement action by Member States."

Comment

In general, THIE welcomes an approach to harmonize requirements for sampling and methods of analysis as this promotes the functioning of the single market and increases a common approach to food safety. However, such a regulation should allow sufficient flexibility in order to meet the different circumstances alongside the value chain.

THIE welcomes the approach to apply the same framework for sampling, sample preparation & methods of analysis and measurement uncertainty for Food Business Operators (FBOs) and enforcement authorities. However, the selection of the methods used should be part of the primary responsibility of the FBOs according to Art. 19 of Reg. (EC) 178/2002. Currently, the different interpretation by national enforcement authorities leads to considerable disturbances of free trade in the single market.

→ Recital 9 & Article 1

Recital 9: "Furthermore, it is appropriate to ensure that food business operators applying the controls performed within the framework of Article 4 of Regulation (EC) No 852/2004 of the European Parliament and of the Council apply sampling procedures equivalent to the sampling procedures provided for by this Regulation in order to ensure that samples taken for those controls are representative."

Article 1: "The rules apply equally to samples collected in the framework of official controls and to samples taken by food business operators. Food business operators may use other sampling rules if they can demonstrate to the competent authority that these rules provide at least equivalent guarantees."

Comment

We fully support the clarification that the rules including especially the interpretation of analytical results and the expanded measurement uncertainty as described in chapter C in the Annex apply equally to samples taken by FBOs and by the enforcement authorities. This is also inline with the provisions foreseen for certain contaminants in Regulation (EU) 2023/2782 and Regulation (EU) 2024/1045. This clarification will considerably contribute to a common practice in the single market as currently different interpretations are done by Member States, which creates severe barriers to trade.

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Rules for sampling as well as methods of analysis are technical rules. Both shall contribute to deliver a meaningful analytical result representative for the load present in the batch/product analysed. The practical and technical challenges are independent of whether the assessment is done by the FBOs or officials.

In particular, the measurement uncertainty only depends on the analytical method. Therefore, the consideration of the measurement uncertainty is related to the fulfilment of the requirements of analytical performance criteria. As long as these performance criteria are met the measurement uncertainty is a fact given and is independent of who has done the analysis – a FBO or an enforcement authority.

The representativity of a sample for the sampled batch is key to achieve meaningful analytical results for the load present in the batch/product analysed. However, taking sufficient incremental samples and sufficient large samples does not guarantee representativeness. The published sampling methods are valuable tools. However, to achieve the most representative samples the specifics of the individual batch should be taken into consideration. Such specifics can be the type of product, the type of pesticide residue or contaminant, the processing status of the product, the origin of the goods, (long-term) trading relationships, batch size. All this information is known by the FBOs, but it is not always available for the officials when taking samples. Therefore, the situation is different for FBOs and enforcement authorities when taking samples. The choice of the sampling method is part of the responsibility of the FBOs to ensure food safety of their products. Due to the detailed information available FBOs are in the position to choose the most appropriate method of sampling for the concrete batch. They need to make sure that the individual sampling method applied leads to a representative sample which is at least as reliable as samples taken according to official sample methods. In fact, such individual sampling methods result in even more representative samples.

➔ Article 2 (16)

"Authorised person for sampling means a person trained in sampling procedures and, where required, authorised by the appropriate authorities to take samples."

Comment

Who carries out the training and ensures that there is a standardised understanding of implementation throughout the EU? Are there standardised training documents or guidelines?

Specific remarks on Annex of PLAN 2023/636 Rev.6

→ Part A.1; Scope

"Samples intended for the control of the levels of pesticide residues in food products of plant and animal origin shall be collected in accordance with the methods described in this Annex. Compliance with MRLs laid down in Regulation (EC) No 396/2005 shall be established on the basis of the levels determined in the laboratory samples."

Comment

See Comment on Article 1.

→ Part B2; Table 3

Comment

We question the feasibility of this proposal, when taken the example of tea or herbal infusions raw materials:

One quickly reaches a high number of samples: e.g. 5 samples for 4 bags of tea (100 kg) - from a practical point of view, this makes no sense for pesticides if the goods are homogeneous, and it is assumed that a substance is homogeneously distributed. For contaminants, a high number of samples can make sense, as spot contamination is often assumed.

In addition, every single sample, e.g. in a warehouse of a storage service provider, causes costs. E.g. at a price of 10 € per sample, the price per batch will quickly amount to 400 €. And in practice, storage service providers will reach its capacity regarding personnel and cannot provide the manpower who does the necessary bagging, labelling etc. of the samples.

With regard to the equivalence of sampling done by the FBO we therefore propose to take into consideration if preliminary analysis of the batch has been done and a lot has been classified as "non-suspect-lot". Then a risk-orientated reduced sampling procedure should apply.

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➔ Part B.3; Preparation of the aggregate/reduced sample

"The aggregate sample shall be made up by combining the incremental samples."

Comment

This is in general acceptable but problematic with a large number of samples, e.g. 40 incremented samples of 100 g each, which need to be mixed, homogenised and then made a representative aggregate sample. This will be difficult for enforcement authorities as well as for FBOs. Several of the FBOs will lack the manpower and machine to do this.

And what happens to the remaining 3.8 kg after 200 g have been sent to the lab? Is this procedure in line with the target to avoid food waste?

➔ Part B.3; Preparation of the aggregate/reduced sample

"Where mixing to form the aggregate sample is inappropriate or impractical, the following alternative procedure may be followed. Where units may be damaged (and thus residues may be affected) by the processes of mixing or subdivision of the aggregate sample, or where large units cannot be mixed to produce a more uniform residue distribution, the units should be allocated randomly to replicate laboratory samples at the time of taking the incremental samples. In this case, the result to be used should be the mean of valid results obtained from the laboratory samples analysed"

Comment

This could possibly be applied to finished tea bag packs, which would not all be opened (boxes and bags) to obtain a sample, but a certain number of boxes or finished packs would be analysed. This procedure is often a practice which is often described in companies' specification or QA-documents to check whether there are divergences of final products. How can this be implemented by the enforcement authorities?

➔ Part B.4; Preparation, packaging, sealing and transport of the laboratory sample

"In this case, the result to be used should be the mean of the results obtained from the laboratory sample analysed"

Comments

Sizes should be specified. Would this provision also apply to final packages for consumers?

→ Part B.4; Table 5, 7.2

Comment

According examples for tea (*Camellia sinensis*) are speciality teas like Matcha, garden teas, etc.

→ Part B.5; Replicate sample

"Replicate sample is formed from the aggregate sample, unless such procedure conflicts with a Member State's rules. Replicate samples are prepared in the same way as laboratory samples."

Comment

We ask for clarification on this point, with regard to the following questions:

- How do the enforcement authorities intend to realise this on site?
  - Usually, a sealed official sample in the sense of a replicate sample remains on site where the sample was taken for a possible counter-expertise. This is common practice in laboratories but how shall that be done on site?

- How should the sampling of finished products take place?
  - To date, one unit has been deposited for inspection and one as a retained sample. This approach is practical and easy to implement.

TEA & HERBAL INFUSIONS EUROPE

Formerly: European Tea Committee (ETC) and European Herbal Infusions Association (EHIA)

Hamburg, 19 August 2024

Position paper on autocontrols –

Sampling methods as well as pesticide residue and contaminants analysis and interpretation of results

- EU legislation harmonizes pesticide MRLs and contaminants MLs and has set a common EU assessment scheme for all agricultural products for food and feed to achieve the basic objectives of facilitating trade whilst protecting the consumer.
- The purpose of these controls is to ensure food safety and compliance. According to Art. 19 of Reg. (EC) 178/2002 the Food Business Operators (FBOs) are responsible for the safety of the food.
- It is a requirement of all FBOs to ensure they have appropriate food safety risk management processes and systems in place.
- To obtain qualified data for all kinds of pesticide residues and contaminants in food and feed, "sampling" as well as "analysing" are crucial but general steps in safety/quality control. In the preparation of rules, the various material and analyte combinations should be considered in an overall context.
- Rules for sampling as well as methods of analysis are technical rules. Both shall contribute to deliver a meaningful analytical result representative for the load present in the batch/product analysed. The practical and technical challenges are independent of whether the assessment is done by the FBOs or officials.
- THIE welcomes the approach to set a framework for sampling, sample preparation and methods of analysis (including method performance criteria) and measurement uncertainty for FBOs and enforcement authorities, which recognises the risk management processes and controls FBOs have in place by accepting equivalent sampling strategies.
- The FBO's risk management processes would include risk assessment, expert knowledge, historical data (inc. surveillance) and appropriate testing to ensure a safe product is released to the market. This may consider product types, origin, supply chain, pesticides

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where used, possible contamination, suppliers pre-sale testing and FBO's pre-shipment testing.

- The FBO's sampling strategy may vary from those as laid down in the official controls, however, they are equivalent as requested in the respective provisions and are designed to ensure product safety and integrity.
- Laboratories analysing for pesticides and contaminants should be able to demonstrate they are capable of achieving the required standards as described in official methods, guidance documents or regulations.
- Legal provisions should apply equally to enforcement bodies and FBOs. A harmonized and consistent approach in the interpretation of analytical results between Member States but also with FBOs supports the functioning of the single market and delivers a common approach to food safety.

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Responsibility for food safety

Reg. (EC) 178/2002[1] states that the primary responsibility for ensuring compliance with food law - and in particular the safety of the food - rests with the food business operators (FBOs). To complement and support this principle, the competent authorities of the EU Member States must ensure adequate and effective controls are in place. It is a requirement of FBOs to ensure they have appropriate food safety risk management systems in place e.g. BRC, IFS or FSSC. Beneath traceability, transparency, emergency management, prevention and cooperation, "product control" is a crucial aspect for ensuring Food Safety. This refers holistically to various processes that are relevant to ultimately bringing a safe and legal product to the market. These include development processes and product design, product labelling, allergen handling, packaging design, purchasing processes, systems to ensure product authenticity, laboratory product inspection and testing etc. In the context of food safety, the sampling and the analytical testing for pesticides and contaminants plays an important role for the tea, herbal- and fruit infusions sector as well as for all FBOs dealing with natural agricultural products. As only the FBOs know specifics like type of product, type of (possibly) used pesticides, options for contamination from field to cup, processing status of the product, origin of the good, packaging, batch size etc., a risk-based sampling and testing regime needs to be in place to ensure product safety.

It is imperative that the sampling process is representative of the entire batch. The sampling procedure must be based on a rational scheme that includes risk analysis results as well as statistical criteria and sampling carried out by trained personnel to ensure adherence to the specified sampling procedures including preparation, packing and documentation. The samples should then be sent for analysis for the residues/contaminants as identified by the FBO's risk management process.

Laboratories analysing for pesticides and contaminants should be able to demonstrate they are capable of achieving the required standards as described in official methods or guidelines e.g. EU Guidance Document SANTE 11312/2021 v2[2] (pesticide analysis), Reg. EC 333/2007[3] (various contaminants), EU Reg. 2023/2782[4] (Mycotoxins) or EU Reg. 2024/1045[5] (Nickel). Although the FBOs contract laboratories mostly are accredited to ISO 17025, according to Art. 37 para 5 of Reg. (EU) 2017/625 an accreditation is only mandatory when it operates as an official laboratory. Proficiency Tests showed that it is the fulfilment of the analytical performance criteria which leads to reliable and comparable analytical results. The accreditation does not necessarily increase the comparability and quality of the analytical results. The comparability is influenced due to statistical reasons and therefore method performance criteria are a crucial point for this purpose.

[1] Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[2] Analytical quality control and method validation procedures for pesticide residues analysis in food and feed; SANTE 11312/2021 v2.
[3] 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.
[4] REGULATION (EU) 2023/2782 of 14 December 2023 laying down the methods of sampling and analysis for the control of the levels of mycotoxins in food and repealing Regulation (EC) No 401/2006.
[5] Regulation (EU) 2024/1045 of 9 April 2024 amending Regulation (EC) No 333/2007 as regards the methods of sampling and analysis for the control of levels of nickel in foodstuffs and amending certain references.

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To demonstrate a high level of quality in their own food safety and quality control, the FBOs should take the definitions of the respective Regulations for example Reg. (EU) 2017/625[6] (sampling) and Commission Directive 2002/63/EC[7], Reg. (EC) 396/2005 (pesticide analysis) or contaminants analysis e.g. Reg. (EC) 333/2007, EU Reg. 2023/2782 or EU Reg. 2024/1045 into account. Any risk-orientated and product-specific sampling by the FBO must be representative of the entire batch and comply with the official requirements.

The FBO's risk management processes would include risk assessment, expert knowledge, historical data (inc. surveillance) and appropriate testing to ensure a safe product is released in the market. This may consider product types, origin, supply chain, pesticides where used, possible contamination, suppliers pre-sale testing, FBO's pre-shipment testing. The appropriate number of samples may differ from requirements in official provisions.

To safeguard high quality in analytical procedures and building a sound basis for monitoring and controlling pesticide residues in food and feed, the EU has published a "Guidance Document" SANTE 11312/2021 v2 (referred to as 'The Guidance' below). It is a technical guideline of the Commission Services and is intended for enforcement authorities involved in the official control of pesticide residues in food and feed across the European Union. The key objectives are to provide a harmonized, cost-effective quality assurance and quality control system across the EU, to ensure the quality and comparability of analytical results, to ensure that acceptable accuracy is achieved, and that false positives or false negatives are avoided.

As the primary responsibility for food safety lays with the FBOs, quality assurance checks of the purchased materials and produced products are conducted by them at different stages (e.g. pre-shipment testing, incoming goods inspection) according to the FBO's risk management. In addition, official food control checks by food inspection services ensure that products and companies are complying with the legal provisions. It seems obvious within this system that a harmonized approach based on practical rules or proven comparable strategies - between EU Member States and between Member States and FBO shall be the best basis for a consistent supply chain of safe food products from field to the consumer.

THIE would therefore like to advocate harmonization of the interpretation of pesticide and contaminants analysis results if the preceding monitoring, sampling and analytical testing steps done by official food control or FBOs quality control are comparable.

Basic principles for sampling

When it comes to ensuring the quality and safety of food products through representative sampling, specific principles are essential to follow. Standards according to which sampling

[6] Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

[7] COMMISSION DIRECTIVE 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC

should be oriented are, for example in the general guidelines on sampling from CODEX.[8] These principles are specified in some EU-Regulations such as Regulation (EU) 2023/2782 or Regulation (EU) 2024/1045. General principles for representative sampling for quality assurance of food are:

- Have a clearly defined and documented sampling procedure.
- Sampling shall be performed by trained staff. Appropriate sampling equipment and techniques shall be used.
- The sampling process must ensure no contamination of samples is possible during sampling, preparation and packaging.
- The sample must be stored in a clean invert container or bag, should be sealed and labelled correctly.
- A clear chain of custody shall be maintained for samples to ensure their integrity and traceability throughout the sampling, transportation, and analysis process. Proper documentation of sample collection, labelling, and storage is essential.

The sample for analysis should be delivered to the laboratory in due time. The laboratory contracted by the FBO is responsible for the further processing of the sample e.g. preparation of the analytical sample and analysing.

Basic principles for analytical quality in pesticide analysis

Basic principles for pesticide analysis laid down in the analytical "Guideline" refer to sampling, transport, traceability and storage of the samples, sample analysis with preparation, processing, extraction, clean-up, concentration/reconstitution, the chromatographic separation and determination, the calibration for quantification, the identification of analytes and confirmation of results as well as the reporting of results. The analytical method must be validated and criteria like specificity, recovery and precision have been set to ensure the performance acceptability of the method.

The criteria in the Guideline for "recovery" (for each spike level) is 70-120% average recovery rate. Precision (RSDr) of an acceptable method should be lower or equal 20% for each spiked level or ongoing method validation/verification. Although procedures are well described and criteria have been fixed it is clearly described that even in a "spiked" sample, no "true" value will be found but all accepted results will be in a well described range around the mean value.

The guideline also states how to report results of an analytical testing, e.g. the rounding of data or the very crucial aspect of measurement uncertainty (MU). The result from the analyte measured must be reported as mg/kg (ppm). As explained before, technically the measured value should be seen as a value in a range defined by the recovery and precision of the analysis and MU of the analytical method. It is therefore said in the guideline that the result shall be reported together with the expanded MU. "A default expanded MU of 50% (corresponding to a 95% confidence level and a coverage factor of 2) has been calculated from

[8] CODEX, 2004, CXG 50-2004; General Guidelines on Sampling

EU proficiency tests. In general, this 50% value covers the inter-laboratory variability between the European laboratories and should be reported together with the analytical results.[9]"

Compliance Evaluation

The evaluation of compliance is a legal decision based on the relevant EU regulations, in this case based on Article 18 (1) of Reg. (EC) 396/2005. As described, a +/- 50% expanded MU in analytical results is acceptable if a routine analytical method is applied. In the case of MRL compliance, the analytical result (value X +/- 50%) must be compared with the relevant MRL specified in Reg. (EC) 396/2005 for the specific substance-crop-combination. Compliance with the MRL must be checked by assuming that the MRL is exceeded significantly if the measured value exceeds the MRL by more than the expanded uncertainty (x – U > MRL)[10]. When the lower limit of the +/- 50% tolerance of the measured value is below the relevant MRL, it can be concluded that the MRL is not clearly exceeded. As such, if an exceedance has not been proven the product is legally regarded as compliant.

Interpretation of analytical results according to Guidance document SANTE 11312/2021 v2

According to the Guidance, results should be reported together with the expanded measurement uncertainty. In case of pesticide residues, the recommended +/- 50 % default measurement uncertainty should be applied when evaluating the compliance of a sample, if the expanded measurement uncertainty of the laboratory is less than 50 %.

For example:

A sample is considered to exceed significantly the MRL if X – U > MRL. Where X is the lab result and U is the expanded measurement uncertainty. Where a lab result (X) is 2.2 then the expanded measurement uncertainty (U) is 1.1.

If the MRL is 1, then 2.2 – 1.1 = 1.1 which is greater than MRL.

Ideally analytical results would lead to a precise figure reflecting the level of residues, but in reality, the analytical result reflects an interval in which the true value can be found with defined or given confidence value. Therefore, the interval must be compared to the legal MRL to evaluate whether there is an exceedance according to Art. 18 (1) of Reg. (EC) NO 396/2005.

The guideline explains different cases in table and figure D1 in appendix D:

[9] Analytical quality control and method validation procedures for pesticide residues analysis in food and feed; SANTE 11312/2021 v2, E12
[10] Analytical quality control and method validation procedures for pesticide residues analysis in food and feed; SANTE 11312/2021 v2, E14

Reported results with respect to their uncertainties:

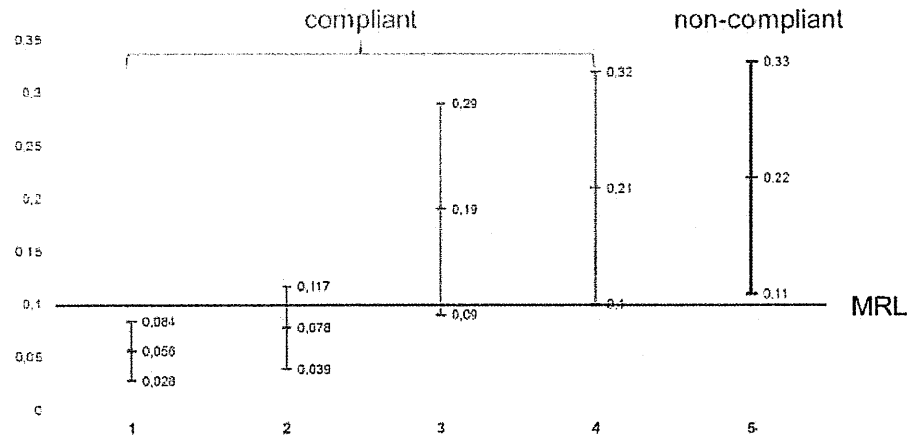

Figure D1. *Example of compliant and non-compliant results*

A similar interpretation of results for compliance assessment is shown in the "Guidance Document on Measurement Uncertainty for Laboratories performing PCDD/F and PCB Analysis using Isotope Dilution Mass Spectrometry"[11].

Conclusion

EU legislation for pesticides and contaminants, and in accordance with the general principles laid down in Reg. (EC) No 178/2002, addresses authorities and FBOs in the same way as far as compliance with maximum residue levels (MRLs) is concerned.

A harmonized approach across Europe is essential for generating reliable data on residues and contaminants in food and for a common understanding in the interpretation of the results found (e.g. measurement uncertainty) in the compliance evaluation by the competent authorities and FBOs. This is extremely important as there are already ambiguous cases between authorities and FBOs. For example, when an FBO imports tea from a third country into a country in Europe, the consignment is analysed by an official laboratory at the Border Control Point (BCP). Based on the analysis carried out by an official laboratory, taking into account the measurement uncertainty, the consignment is considered compliant. If the tea is then placed on the market in a second country in Europe and tested by the national authority there, which follows a different strategy in interpreting the results (e.g. not taking the measurement uncertainty into account), this product would be considered non-compliant.

[11] https://food.ec.europa.eu/document/download/8e974557-3720-4bac-be6e-d0d641349600_en?filename=animal-feed-guidance_document_pcdd-f_pcb_en.pdf

In order to obtain reliable analytical results for a batch, representative sampling is necessary. Sampling rules for FBOs and for official controls should follow the same principles and/or be of equivalent quality as laid down in the respective provisions.

The EU Guidance Document SANTE 11312/2021 v2 is a technical guideline which describes the current state of the art in pesticide analysis of food and feed and was intended for use by Official Controls. The document states basic principles for analytical quality and described that the analytical result reflects an interval in which the true value can be found. Therefore, the document includes guidance on the use of measurement uncertainty, highlighting that an uncertainty of +/- 50% can be applied on the analytical results for pesticide residues for the evaluation of compliance with the EU Pesticide Residue Reg. (EC) 396/2005. This is particularly relevant for products with difficult matrices, such as tea and herbal infusions. The technical rules on the interpretation of analytical results should apply in the same way to all analytical results for pesticide residue analysis. The decision on compliance is a legal evaluation based on EU legislation. FBOs should have the opportunity to challenge results through the appropriate application of the EU guidance on measurement uncertainty and this is in line with EU legislation. A different approach to the application of measurement uncertainty between Official Control labs, National Authorities and when interpretating the results of tests conducted as part of an FBOs Quality Assurance program will lead to unnecessary and undesirable legal uncertainty.

FBOs shall ensure that sampling is representative for the monitoring of pesticides and contaminants and that the contracted laboratories provide excellent performance for the respective analytical method, regularly participate in independent proficiency tests with corresponding results and have implemented state of the art analytical quality assurance measures.

Under the conditions described above, it should therefore be possible for FBOs to take the measurement uncertainty into account in the same way as the official food control when assessing the regulatory compliance of a product regarding maximum levels for pesticides and contaminants.

The analytical values should be reported in the same way by all parties: as measured, together with the measurement uncertainty but without deducting measurement uncertainty. This will eliminate the inconsistencies described above and has no negative impact on consumer safety, which is the FBOs top priority and responsibility.

A harmonized and consistent approach in the interpretation of analytical results between Member States but also with FBOs strengthens the principles of the single market within the EU, avoids trade barriers across Europe and beyond and reduces food waste and cost burdens along the supply chain.

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- It is a requirement of all FBOs to ensure they have appropriate food safety risk management processes and systems in place.
- To obtain qualified data for all kinds of pesticide residues and contaminants in food and feed, "sampling" as well as "analysing" are crucial but general steps in safety/quality control. In the preparation of rules, the various material and analyte combinations should be considered in an overall context.
- Rules for sampling as well as methods of analysis are technical rules. Both shall contribute to deliver a meaningful analytical result representative for the load present in the batch/product analysed. The practical and technical challenges are independent of whether the assessment is done by the FBOs or officials.
- THIE welcomes the approach to set a framework for sampling, sample preparation and methods of analysis (including method performance criteria) and measurement uncertainty for FBOs and enforcement authorities, which recognises the risk management processes and controls FBOs have in place by accepting equivalent sampling strategies.
- The FBO's risk management processes would include risk assessment, expert knowledge, historical data (inc. surveillance) and appropriate testing to ensure a safe product is released to the market. This may consider product types, origin, supply chain, pesticides

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where used, possible contamination, suppliers pre-sale testing and FBO's pre-shipment testing.

- The FBO's sampling strategy may vary from those as laid down in the official controls, however, they are equivalent as requested in the respective provisions and are designed to ensure product safety and integrity.
- Laboratories analysing for pesticides and contaminants should be able to demonstrate they are capable of achieving the required standards as described in official methods, guidance documents or regulations.
- Legal provisions should apply equally to enforcement bodies and FBOs. A harmonized and consistent approach in the interpretation of analytical results between Member States but also with FBOs supports the functioning of the single market and delivers a common approach to food safety.

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Responsibility for food safety

Reg. (EC) 178/2002[1] states that the primary responsibility for ensuring compliance with food law - and in particular the safety of the food - rests with the food business operators (FBOs). To complement and support this principle, the competent authorities of the EU Member States must ensure adequate and effective controls are in place. It is a requirement of FBOs to ensure they have appropriate food safety risk management systems in place e.g. BRC, IFS or FSSC. Beneath traceability, transparency, emergency management, prevention and cooperation, "product control" is a crucial aspect for ensuring Food Safety. This refers holistically to various processes that are relevant to ultimately bringing a safe and legal product to the market. These include development processes and product design, product labelling, allergen handling, packaging design, purchasing processes, systems to ensure product authenticity, laboratory product inspection and testing etc. In the context of food safety, the sampling and the analytical testing for pesticides and contaminants plays an important role for the tea, herbal- and fruit infusions sector as well as for all FBOs dealing with natural agricultural products. As only the FBOs know specifics like type of product, type of (possibly) used pesticides, options for contamination from field to cup, processing status of the product, origin of the good, packaging, batch size etc., a risk-based sampling and testing regime needs to be in place to ensure product safety.

It is imperative that the sampling process is representative of the entire batch. The sampling procedure must be based on a rational scheme that includes risk analysis results as well as statistical criteria and sampling carried out by trained personnel to ensure adherence to the specified sampling procedures including preparation, packing and documentation. The samples should then be sent for analysis for the residues/contaminants as identified by the FBO's risk management process.

Laboratories analysing for pesticides and contaminants should be able to demonstrate they are capable of achieving the required standards as described in official methods or guidelines e.g. EU Guidance Document SANTE 11312/2021 v2[2] (pesticide analysis), Reg. EC 333/2007[3] (various contaminants), EU Reg. 2023/2782[4] (Mycotoxins) or EU Reg. 2024/1045[5] (Nickel). Although the FBOs contract laboratories mostly are accredited to ISO 17025, according to Art. 37 para 5 of Reg. (EU) 2017/625 an accreditation is only mandatory when it operates as an official laboratory. Proficiency Tests showed that it is the fulfilment of the analytical performance criteria which leads to reliable and comparable analytical results. The accreditation does not necessarily increase the comparability and quality of the analytical results. The comparability is influenced due to statistical reasons and therefore method performance criteria are a crucial point for this purpose.

[1] Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[2] Analytical quality control and method validation procedures for pesticide residues analysis in food and feed; SANTE 11312/2021 v2.
[3] 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.
[4] REGULATION (EU) 2023/2782 of 14 December 2023 laying down the methods of sampling and analysis for the control of the levels of mycotoxins in food and repealing Regulation (EC) No 401/2006.
[5] Regulation (EU) 2024/1045 of 9 April 2024 amending Regulation (EC) No 333/2007 as regards the methods of sampling and analysis for the control of levels of nickel in foodstuffs and amending certain references.

To demonstrate a high level of quality in their own food safety and quality control, the FBOs should take the definitions of the respective Regulations for example Reg. (EU) 2017/625[6] (sampling) and Commission Directive 2002/63/EC[7], Reg. (EC) 396/2005 (pesticide analysis) or contaminants analysis e.g. Reg. (EC) 333/2007, EU Reg. 2023/2782 or EU Reg. 2024/1045 into account. Any risk-orientated and product-specific sampling by the FBO must be representative of the entire batch and comply with the official requirements.

The FBO's risk management processes would include risk assessment, expert knowledge, historical data (inc. surveillance) and appropriate testing to ensure a safe product is released in the market. This may consider product types, origin, supply chain, pesticides where used, possible contamination, suppliers pre-sale testing, FBO's pre-shipment testing. The appropriate number of samples may differ from requirements in official provisions.

To safeguard high quality in analytical procedures and building a sound basis for monitoring and controlling pesticide residues in food and feed, the EU has published a "Guidance Document" SANTE 11312/2021 v2 (referred to as 'The Guidance' below). It is a technical guideline of the Commission Services and is intended for enforcement authorities involved in the official control of pesticide residues in food and feed across the European Union. The key objectives are to provide a harmonized, cost-effective quality assurance and quality control system across the EU, to ensure the quality and comparability of analytical results, to ensure that acceptable accuracy is achieved, and that false positives or false negatives are avoided.

As the primary responsibility for food safety lays with the FBOs, quality assurance checks of the purchased materials and produced products are conducted by them at different stages (e.g. pre-shipment testing, incoming goods inspection) according to the FBO's risk management. In addition, official food control checks by food inspection services ensure that products and companies are complying with the legal provisions. It seems obvious within this system that a harmonized approach based on practical rules or proven comparable strategies - between EU Member States and between Member States and FBO shall be the best basis for a consistent supply chain of safe food products from field to the consumer.

THIE would therefore like to advocate harmonization of the interpretation of pesticide and contaminants analysis results if the preceding monitoring, sampling and analytical testing steps done by official food control or FBOs quality control are comparable.

Basic principles for sampling

When it comes to ensuring the quality and safety of food products through representative sampling, specific principles are essential to follow. Standards according to which sampling

[6] Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)

[7] COMMISSION DIRECTIVE 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC

should be oriented are, for example in the general guidelines on sampling from CODEX.[8] These principles are specified in some EU-Regulations such as Regulation (EU) 2023/2782 or Regulation (EU) 2024/1045. General principles for representative sampling for quality assurance of food are:

- Have a clearly defined and documented sampling procedure.
- Sampling shall be performed by trained staff. Appropriate sampling equipment and techniques shall be used.
- The sampling process must ensure no contamination of samples is possible during sampling, preparation and packaging.
- The sample must be stored in a clean invert container or bag, should be sealed and labelled correctly.
- A clear chain of custody shall be maintained for samples to ensure their integrity and traceability throughout the sampling, transportation, and analysis process. Proper documentation of sample collection, labelling, and storage is essential.

The sample for analysis should be delivered to the laboratory in due time. The laboratory contracted by the FBO is responsible for the further processing of the sample e.g. preparation of the analytical sample and analysing.

Basic principles for analytical quality in pesticide analysis

Basic principles for pesticide analysis laid down in the analytical "Guideline" refer to sampling, transport, traceability and storage of the samples, sample analysis with preparation, processing, extraction, clean-up, concentration/reconstitution, the chromatographic separation and determination, the calibration for quantification, the identification of analytes and confirmation of results as well as the reporting of results. The analytical method must be validated and criteria like specificity, recovery and precision have been set to ensure the performance acceptability of the method.

The criteria in the Guideline for "recovery" (for each spike level) is 70-120% average recovery rate. Precision (RSDr) of an acceptable method should be lower or equal 20% for each spiked level or ongoing method validation/verification. Although procedures are well described and criteria have been fixed it is clearly described that even in a "spiked" sample, no "true" value will be found but all accepted results will be in a well described range around the mean value.

The guideline also states how to report results of an analytical testing, e.g. the rounding of data or the very crucial aspect of measurement uncertainty (MU). The result from the analyte measured must be reported as mg/kg (ppm). As explained before, technically the measured value should be seen as a value in a range defined by the recovery and precision of the analysis and MU of the analytical method. It is therefore said in the guideline that the result shall be reported together with the expanded MU. "A default expanded MU of 50% (corresponding to a 95% confidence level and a coverage factor of 2) has been calculated from

[8] CODEX, 2004, CXG 50-2004; General Guidelines on Sampling

EU proficiency tests. In general, this 50% value covers the inter-laboratory variability between the European laboratories and should be reported together with the analytical results.[9]"

Compliance Evaluation

The evaluation of compliance is a legal decision based on the relevant EU regulations, in this case based on Article 18 (1) of Reg. (EC) 396/2005. As described, a +/- 50% expanded MU in analytical results is acceptable if a routine analytical method is applied. In the case of MRL compliance, the analytical result (value X +/- 50%) must be compared with the relevant MRL specified in Reg. (EC) 396/2005 for the specific substance-crop-combination. Compliance with the MRL must be checked by assuming that the MRL is exceeded significantly if the measured value exceeds the MRL by more than the expanded uncertainty ($x - U > MRL$)[10]. When the lower limit of the +/- 50% tolerance of the measured value is below the relevant MRL, it can be concluded that the MRL is not clearly exceeded. As such, if an exceedance has not been proven the product is legally regarded as compliant.

Interpretation of analytical results according to Guidance document SANTE 11312/2021 v2

According to the Guidance, results should be reported together with the expanded measurement uncertainty. In case of pesticide residues, the recommended +/- 50 % default measurement uncertainty should be applied when evaluating the compliance of a sample, if the expanded measurement uncertainty of the laboratory is less than 50 %.

For example:

A sample is considered to exceed significantly the MRL if $X - U > MRL$. Where X is the lab result and U is the expanded measurement uncertainty. Where a lab result (X) is 2.2 then the expanded measurement uncertainty (U) is 1.1.

If the MRL is 1, then $2.2 - 1.1 = 1.1$ which is greater than MRL.

Ideally analytical results would lead to a precise figure reflecting the level of residues, but in reality, the analytical result reflects an interval in which the true value can be found with defined or given confidence value. Therefore, the interval must be compared to the legal MRL to evaluate whether there is an exceedance according to Art. 18 (1) of Reg. (EC) NO 396/2005.

The guideline explains different cases in table and figure D1 in appendix D:

[9] Analytical quality control and method validation procedures for pesticide residues analysis in food and feed; SANTE 11312/2021 v2, E12
[10] Analytical quality control and method validation procedures for pesticide residues analysis in food and feed; SANTE 11312/2021 v2, E14

Reported results with respect to their uncertainties:

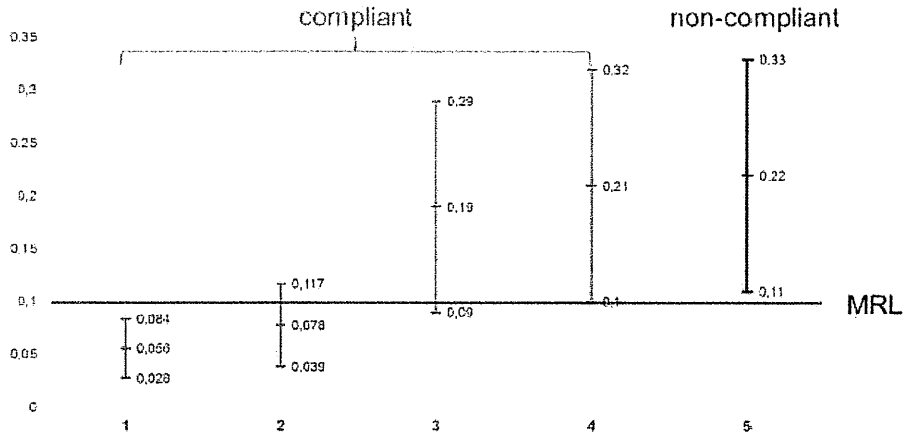

Figure D1. *Example of compliant and non-compliant results*

A similar interpretation of results for compliance assessment is shown in the "Guidance Document on Measurement Uncertainty for Laboratories performing PCDD/F and PCB Analysis using Isotope Dilution Mass Spectrometry"[11].

Conclusion

EU legislation for pesticides and contaminants, and in accordance with the general principles laid down in Reg. (EC) No 178/2002, addresses authorities and FBOs in the same way as far as compliance with maximum residue levels (MRLs) is concerned.

A harmonized approach across Europe is essential for generating reliable data on residues and contaminants in food and for a common understanding in the interpretation of the results found (e.g. measurement uncertainty) in the compliance evaluation by the competent authorities and FBOs. This is extremely important as there are already ambiguous cases between authorities and FBOs. For example, when an FBO imports tea from a third country into a country in Europe, the consignment is analysed by an official laboratory at the Border Control Point (BCP). Based on the analysis carried out by an official laboratory, taking into account the measurement uncertainty, the consignment is considered compliant. If the tea is then placed on the market in a second country in Europe and tested by the national authority there, which follows a different strategy in interpreting the results (e.g. not taking the measurement uncertainty into account), this product would be considered non-compliant.

[11] https://food.ec.europa.eu/document/download/8e974557-3720-4bac-be6e-d0d641349600_en?filename=animal-feed-guidance_document_pcdd-f_pcb_en.pdf

In order to obtain reliable analytical results for a batch, representative sampling is necessary. Sampling rules for FBOs and for official controls should follow the same principles and/or be of equivalent quality as laid down in the respective provisions.

The EU Guidance Document SANTE 11312/2021 v2 is a technical guideline which describes the current state of the art in pesticide analysis of food and feed and was intended for use by Official Controls. The document states basic principles for analytical quality and described that the analytical result reflects an interval in which the true value can be found. Therefore, the document includes guidance on the use of measurement uncertainty, highlighting that an uncertainty of +/- 50% can be applied on the analytical results for pesticide residues for the evaluation of compliance with the EU Pesticide Residue Reg. (EC) 396/2005. This is particularly relevant for products with difficult matrices, such as tea and herbal infusions. The technical rules on the interpretation of analytical results should apply in the same way to all analytical results for pesticide residue analysis. The decision on compliance is a legal evaluation based on EU legislation. FBOs should have the opportunity to challenge results through the appropriate application of the EU guidance on measurement uncertainty and this is in line with EU legislation. A different approach to the application of measurement uncertainty between Official Control labs, National Authorities and when interpretating the results of tests conducted as part of an FBOs Quality Assurance program will lead to unnecessary and undesirable legal uncertainty.

FBOs shall ensure that sampling is representative for the monitoring of pesticides and contaminants and that the contracted laboratories provide excellent performance for the respective analytical method, regularly participate in independent proficiency tests with corresponding results and have implemented state of the art analytical quality assurance measures.

Under the conditions described above, it should therefore be possible for FBOs to take the measurement uncertainty into account in the same way as the official food control when assessing the regulatory compliance of a product regarding maximum levels for pesticides and contaminants.

The analytical values should be reported in the same way by all parties: as measured, together with the measurement uncertainty but without deducting measurement uncertainty. This will eliminate the inconsistencies described above and has no negative impact on consumer safety, which is the FBOs top priority and responsibility.

A harmonized and consistent approach in the interpretation of analytical results between Member States but also with FBOs strengthens the principles of the single market within the EU, avoids trade barriers across Europe and beyond and reduces food waste and cost burdens along the supply chain.

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