Heads of Food Safety Agencies

Private Assurance Schemes Working Group

Position Paper

Mapping of Legislation and the Importance of Unannounced Visits (Inspections / Audits)

This paper was taken forward under the Heads of European Food Safety Agencies (HoA) by a working group of 10 Member States, chaired and coordinated by the Federal Agency for the Safety of the Food Chain (FASFC) **BELGIUM** and Federal Office of Consumer Protection and Food Safety (BVL) **GERMANY**.

Responsibility for the information and views set out in this document lies entirely with the authors.

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The purpose of this document is to provide the position of the Heads of European Food Safety Agencies about the mapping of legislation and importance of unannounced visits (inspections/audits) when considering information from private quality assurance schemes for the planning of official controls.

This document does not intend to change regulatory requirements, replace regulatory oversight, outsource official inspection work, impose the use of private quality assurance by industry; nor does it constitute any approval or recognition of private quality assurance schemes.

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INTRODUCTION

Collaboration between Competent Authorities (CAs) and Private Assurance Schemes (PAS) can offer significant advantages[1], such as improved resource efficiency, reduced duplication of audits, and the possibility for risk-based, more targeted official controls. By sharing information and aligning monitoring efforts, both efficiency and food safety can be strengthened.

Various approaches are already in use across the EU for integrating PAS into official control planning, offering opportunities to enhance regulatory effectiveness and food safety assurance.

The Heads of Food Safety Agencies (HoA) working group on PAS has identified several options for incorporating PAS into official controls, as discussed in the online workshop "How Private Assurance Schemes can be taken into account for official controls"[2].

From the European perspective, private certification can be taken into account in the performance of official controls, where appropriate, pursuant to EU legal framework (Official Control Regulation (EU) 2017/625 Art. 9[3], Commission Notice on the Implementation of the OCR[4]).

The Codex Alimentarius document on voluntary Third-Party Assurance (vTPA)[5] provides further guidance on how CAs can monitor and integrate these schemes into their risk-based control strategies.

This position paper aims to provide guidelines for comparing key aspects of PAS requirements with EU regulations. It focuses on two main topics: (1) mapping of legislation, which includes areas such as microbiology, traceability and HACCP, and (2) the importance of unannounced inspections, highlighting the benefits and challenges of unannounced visits (inspections/audits). From the HoA's perspective, it is reasonable to compile these aspects into one position paper that addresses the requirements of EU regulations and PAS specifications.

[1] HoA Position Paper – "Benefits for food business operators implementing private quality assurance schemes" (2021)
[2] HoA Workshop Report – "How Private Assurance Schemes can be taken into account for official controls" (2023)
[3] 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 https://eur-lex.europa.eu/eli/reg/2017/625/oj
[4] Commission Notice on the Implementation of Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C_202406481
[5] Codex Alimentarius – "Principles and guidelines for the assessment and use of voluntary third-party assurance programmes" (CXG 93-2021) https://www.fao.org/fao-who-codexalimentarius/sh-proxy/es/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B93-2021%252FCXG_093e.pdf

1. Mapping of Legislation

1.1. General Remarks

1.1.1 Rationale

CAs may choose to incorporate certain PAS into their official control mechanisms. To determine whether or not a PAS can be integrated and how it should be considered, an assessment of the PAS is required. This assessment should cover the scope of the PAS, its relationship to relevant legislation (whether it has gaps, overlaps, or extends beyond legal requirements), and the confidence CAs can place in PAS-based certifications. The Heads of Food Safety Agencies (HoA) working group on PAS has identified several options for incorporating PAS into official controls[6].

Currently, some CAs take into account the PAS results for risk classification of FBOs[6, 7], though this happens at different levels and often in a non-harmonized manner, leading to duplication of efforts. Better coordination, exchange of experience and identification of best practices are needed to facilitate the consideration of PAS in the official control process.

The purpose of this document is not to provide a detailed mapping framework, but to highlight key points of attention when performing such a mapping.

1.1.2 Considerations

The evaluation of PAS must take into account various factors, including the type of scheme and its intended purpose. Specific considerations include:

- **Compliance:**
  International vs. national schemes and their relationship with EU or national legislation.
- **Market Access:**
  Whether the scheme is designed primarily to ensure legal compliance or to facilitate market access.
- **Sector:**
  For which sector of the food chain is the standard intended.

[6] HoA Position Paper – "Benefits for food business operators implementing private quality assurance schemes" (2021)
[7] HoA Workshop Report – "How Private Assurance Schemes can be taken into account for official controls" (2023)

1.1.3 Questions

The following questions should be taken into account when conducting a mapping exercise:

- **Who will conduct the mapping of the PAS?** (e.g., EU authorities, CA, International benchmarking organizations (IBO), PAS owner)
- **What part of the food chain is covered by the PAS?**
- **What elements should be assessed?** (e.g., compliance, FBO requirements, Certification Body (CB) requirements, auditor qualification and competence)
- **At what level will the PAS be assessed?** (e.g., IBO-level or PAS-specific requirements)
- **Is the intention to provide formal acceptance in relation to Art. 9 d of the Official Control Regulation (EU) 2017/625?**

1.2. Conducting a Mapping Exercise

1.2.1 Who should conduct the mapping?

While there is no obligation for the CA itself to evaluate PAS, a well-founded decision by the CA can only be made if the CA has an understanding of the value of PAS in question before deciding to take them into account.
There is no requirement that the mapping should be done by a particular organization. But sometimes there exist useful initiatives on mapping that can be valorized.

The mapping of PAS requirements against legal frameworks could be performed by different entities, such as:

- European Commission
- Competent Authorities
- International benchmarking organizations
- International Accreditation Forum (IAF)
- Self-assessment by PAS owner
- others

In the context mentioned above, all PAS which will be considered should demonstrate that they cover at least a significant part of the EU legal requirements through ongoing mapping efforts.

The depth and scope of the PAS assessment should be consistent with the intended use of the PAS information/data.

1.2.2 How to perform the mapping?

Several methods are available for conducting a mapping exercise. The following three approaches can be applied individually or combined for better results.

1.2.2.1 Comparison of Requirements (Legislation vs. PAS) [See example in Annex I.]

The first method for the mapping of legislation is the comparison of the legislation with the requirements of the PAS. At the EU level, higher-level benchmarking is possible, and collaboration between CAs. At the national level, mapping can be handled by national CAs.

For each provision in the legislation, the comparison with PAS could lead to the following results:

- not covered
- partially covered
- fully covered
- implicitly covered

It is important to recognize that legislation and PAS are often expressed differently. As a result, determining whether a legislative provision is covered in the PAS typically requires a more nuanced analysis than a simple “yes” or “no” answer. Additionally, the level of detail in PAS requirements can vary significantly: some are highly detailed, while others are more generic. A single paragraph in the legislation may be addressed by multiple articles in the PAS, adding to the complexity of the comparison.

Although mapping the requirements can provide an indication of the value of a PAS, its effectiveness depends on how it is implemented by the FBO and, more importantly, on the quality of the audits conducted.
The competence of the auditor plays a crucial role in this process, especially when a legal provision is determined to be only implicitly covered by a PAS requirement. In such cases, the auditors’ ability to assess compliance accurately becomes even more critical. Therefore, the qualification of auditors is essential – if not mandatory – to ensure their competence and impartiality.

1.2.2.2 Comparison of Inspection Results (Legislation vs. PAS-Certified)

A second method involves comparing CA inspection results between PAS-certified and non-PAS-certified FBOs. Since the data on inspection results is owned by the CA, it is more practical for this comparison to be conducted by the CA.

However, this method also has its limitations. For instance, it is crucial to ensure that FBOs in the CA's database are properly linked to those that are PAS-certified, ideally through a unique identifier that accurately matches the FBOs. This step is essential for the effective incorporation of PAS into the evaluation process.

In a PAS evaluation exercise, various factors or distortions may arise that could impact how the results are interpreted. For example, the evaluation outcome could be influenced by an FBO holding multiple PAS certifications, with the result reflecting only one of those certifications. Additionally, external factors unrelated to the exercise, such as the size of the FBO or the timing of the visit, could also affect the results. Therefore, it is important to consider the broader context and any peripheral comments during the comparison and incorporate them into the interpretation.

This method can also complement the approach of comparing legislation with the requirements of the PAS, as described above. After conducting the initial comparison as a "desktop" exercise, this method can be used to further refine the analysis and complete the results. This enhances the understanding of how the PAS is applied at FBOs, beyond merely examining how the requirements are structured.
Another option is to conduct this comparison a few years after implementing a system to consider PAS in official controls. This would involve assessing the system's effectiveness, specifically determining whether PAS-certified FBOs perform better – or at least as well – as non-certified FBOs. The comparison would focus on the compliance levels of both groups in official controls.

1.2.2.3 Monitoring Visits [See example[8] in Annex II.]

The CA conducting monitoring visits could be a third option in the mapping exercise. These on-site assessments complement the previous comparisons of legislation and inspection

[8] The questions and the number of FBOs surveyed are for informational purposes only. Each CA can assess for itself what is relevant based on its own situation.

results. Once a PAS meets the required pre-assessment criteria, monitoring visits verify its effectiveness in safeguarding legal requirements.

Rather than conducting detailed inspections for full regulatory compliance, monitoring visits focus on assessing whether a PAS effectively upholds essential legal components. During these visits, the CA verifies how the PAS operates in practice at certified FBOs and evaluates whether specific legal requirements – such as hygiene conditions, construction standards, traceability, and microbiological criteria – are adequately safeguarded. Based on structured research questions, the CA determines its level of confidence in the PAS's ability to ensure compliance with these requirements. If a PAS effectively safeguards a particular legal component, the FBO may undergo less frequent inspections. However, if weaknesses are identified – such as in microbiological criteria – ongoing oversight may be necessary. The findings from monitoring visits ultimately inform risk-based supervision and ensure that regulatory efforts are focused on areas where additional assurance is needed.

1.3 Conclusion

Mapping of legislation in relation to PAS is an important step to determine how PAS can be integrated into official control mechanisms. The different mapping approaches – comparing PAS requirements with legislation, analyzing inspection results, and conducting monitoring visits – provide complementary insights into how well PAS align with legal requirements and support regulatory goals.

Comparing requirements provides a basic understanding of PAS coverage, while the comparison of inspection results and monitoring visits help validate its practical implementation and effectiveness. Each method has its strengths and limitations, which is why a balanced assessment based on multiple sources of information is necessary.
For example, safeguarding microbiological criteria presents a greater challenge compared to areas such as traceability or HACCP, as it often requires more rigorous verification and scientific assessment. PAS may face difficulties in fully integrating EU microbiological regulations into their control systems, which is why continued oversight in this area is needed.

Ultimately, the mapping exercise enables CAs to make informed decisions about the role of PAS in risk-based supervision. A structured and harmonized approach to mapping can help to avoid duplication of work, improve regulatory efficiency, and ensure that supervision efforts focus where they are most needed – especially in areas where PAS coverage remains insufficient.

2. The Importance of Unannounced Visits (Inspections / Audits)

2.1 General Remarks

2.1.1 Rationale

Regulation (EU) 2017/625 establishes the framework for official controls, which include various methods such as inspections and audits (Article 14). According to Article 9(4), official controls must generally be carried out without prior notice, unless prior notification is necessary and duly justified.

During the preparation of this position paper, the European Commission was contacted and requested to provide guidance regarding this issue. In its response, the Commission stated that the Regulation does not provide a specific definition of 'unannounced' controls. However, in line with the literal interpretation of “without prior notice”, the Commission considers an official control to be announced when the CA provides prior notice – regardless of the length of time between the notification and the actual control[9].

While Article 9(4) of Regulation (EU) 2017/625 emphasizes that inspections should generally be unannounced unless justified otherwise, Recital 33 acknowledges that audits often require prior notification to allow for necessary preparation by both the auditors and the audited entities. Nevertheless, Regulation (EU) 2017/625 does not explicitly categorize inspections as predominantly unannounced and audits as predominantly announced.

The decision of whether prior notice is necessary lies with the CAs, who must assess on a case-by-case basis whether providing prior notice is justified, considering the risks associated with doing so or not.

2.1.2 Considerations

Different forms of supervision – announced and unannounced – have their own benefits and are suited to different objectives:

[9] The Commission plans to discuss prior notice in the third review of the Commission Notice on the Implementation of Regulation (EU) 2017/625 of the European Parliament and of the Council (Official Controls Regulation) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:C_202406481

- **Announced Visits:**
  An announced visit is a scheduled and pre-planned evaluation of the compliance of a FBO with food safety regulations, standards, or certification requirements. The FBO is notified in advance about the date, scope, and expectations. Announced visits can be conducted by CAs, third-party certification organizations, or internal quality assurance teams.
  When the auditing entity focuses on assessing the organization and preconditions necessary for a sound production process, announced visits could be preferable. Both the FBO and the auditing entity can prepare properly, ensuring that relevant employees and necessary information are available for a thorough review.

- **Unannounced Visits:**
  An unannounced visit is a spontaneous or surprise evaluation by CAs, third-party auditors, or internal compliance teams to assess a FBOs adherence to food safety laws and standards. The FBO is not given prior notice, ensuring that the visit reflects the facility's normal operating conditions without special preparation.
  If the auditing entity aims to evaluate the actual implementation of production processes, unannounced visits are the most effective method. The unpredictability of these visits gives auditors a more accurate view of everyday practices.
  It is preferable to prioritize areas or departments that are most sensitive to the element of unpredictability. For example, inspections should begin with on-site work areas rather than starting with document reviews.

Given that both forms of supervision provide valuable and complementary insights, a combination of announced and unannounced visits is desirable from a policy perspective. Unannounced visits, in particular, remove the element of predictability, encouraging FBOs to maintain compliance throughout the year. This approach is intended to act as one of several safeguards within the overall compliance system.

2.1.3 Questions

In the context of supervision, the following questions regarding the nature of the visit (announced vs. unannounced) could be considered.

- **What is meant by an "unannounced" visit?** (e.g., without any prior notice, or with minimal notice, such as a short period of time in advance? depends on the likelihood

of relevant personnel being present on the farm in question (e.g., farmer *vs.* slaughterhouse), depends on the time to potentially improve the degree of compliance before the visit)

- **Which FBOs should be subject to these unannounced visits?** (e.g., all FBOs across the entire food chain or only those within a specific sector? Within a given sector, should all FBOs be subject to unannounced visits, or only a certain percentage? Or does it depend on a trigger (e.g. previously identified non-conformities)?)
- **What frequency of unannounced visits is desirable?** (e.g., same frequency as announced audits, or should they be conducted in addition to them? And, should follow-up inspections or controls triggered by suspicions always be unannounced?)
- **What should be the scope of unannounced visits?** (e.g., a comprehensive review of all requirements or a focused assessment of selected areas, such as activities in the production facilities rather than documentary compliance)

2.2 Benefits of unannounced visits

- **Continuous Compliance:**
  Unannounced visits help ensure that FBOs maintain continuous compliance with food safety regulations throughout the year, rather than only during scheduled audits.

- **Improved Accuracy:**
  These visits provide inspectors with a clearer picture of actual operational practices, reducing the chances of superficial compliance.

- **Improvement of Food Safety Culture:**
  Unannounced visits ensure that FBOs consistently adhere to established food safety protocols on a daily basis. This helps raise awareness and strengthen the focus on food safety culture.

- **Increased consumer confidence:**
  Unannounced visits provide a more realistic view of daily operations and increase the credibility of oversight. This offers consumers additional assurance regarding food safety. It also contributes to a transparent image of the sector.

2.3 Challenges of unannounced visits

- **Logistical Difficulties:**
  Ensuring that the right personnel and information are available during unannounced visits can be challenging, as preparation is limited.

- **Potential for Resistance:**
  FBOs may view unannounced visits as disruptive or unfair, especially if they feel unprepared to meet the audit's requirements.

2.4 Conclusion

A balanced approach that combines both announced and unannounced visits is essential to ensure comprehensive compliance.

Announced visits allow for thorough preparation and a structured evaluation, enabling a detailed assessment of compliance frameworks and organizational elements. They provide an opportunity for FBOs to demonstrate compliance under optimal conditions. However, these visits alone may not always reflect actual day-to-day operations.

Unannounced visits, in contrast, offer a more accurate assessment of real working conditions. Their unpredictability discourages temporary adjustments made in anticipation of inspections and promotes continuous adherence to food safety regulations. This makes them a crucial tool in ensuring regulatory compliance.

The same principle applies to PAS audits. To achieve reliable results comparable to unannounced visits by CAs, unannounced PAS audits must be implemented. Many PAS audit schemes already offer FBOs the option to choose unannounced audits or even impose them, reinforcing the importance of this approach.[10]

As the importance of unannounced audits grows for both CAs and FBOs, incorporating both announced and unannounced visits ensures continuous compliance. This ultimately strengthens food safety oversight and enhances consumer protection.

[10] However, certain PAS describe a possible time window for the FBO when the visit can happen.

ANNEX

I. Example: Comparison of Requirements (Legislation vs. PAS)

				PAS 1			PAS 2		
	Legislation text	**Legislation and article**	**Comment**	**Contains requirement**	**Require-ment**	**Comment**	**Contains requirement**	**Require-ment**	**Comment**
Traceability	Food or feed which is placed on the market or is likely to be placed on the market in the Community shall be adequately labelled or identified to facilitate its traceability, through relevant documentation or information in accordance with the relevant requirements of more specific provisions.	178/2002, article 18.4	This is for example batch number, or best-before that can be used to trace the product.	no	N/A	Have been discussed with standard owner.	yes	6.4	In 6.4 there are requirements of internal and external traceability.

	2. Food and feed business operators shall be able to identify any person from whom they have been supplied with a food, a feed, a foodproducing animal, or any substance intended to be, or expected to be, incorporated into a food or feed. To this end, such operators shall have in place systems and procedures which allow for this information to be made available to the competent authorities on demand. **3.** Food and feed business operators shall have in place systems and procedures to identify the other businesses to which their products have been supplied. This information shall be made available to the competent authorities on demand.	178/2002, article 18.2 and 18.3	They must know who they bought raw materials from, and who they supply to.	yes	18.1		yes	4.11 8.5	4.11 requires an updated list of approved suppliers. 8.5 requires traceability to suppliers and customers.
HACCP	Food business operators shall put in place, implement and maintain a permanent procedure or procedures based on the HACCP principles.	852/2004, article 5.1		yes	2.3		yes	4	Chapter 4 is about HACCP and follows the principles in Codex.

	The HACCP principles referred to in paragraph 1 consist of the following: **(a)** identifying any hazards that must be prevented, eliminated or reduced to acceptable levels	852/2004, article 5.2a		yes	6.3		yes	3.8.1	
	(b) identifying the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or to reduce it to acceptable levels; **(c)** establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards; **(d)** establishing and implementing effective monitoring procedures at critical control points;	852/2004, article 5.2 b,c,d		yes	7.2 and 7.3		yes	5	Chapter 5 contains this in detail
	(e) establishing corrective actions when monitoring indicates that a critical control point is not under control;	852/2004, article 5.2e		yes	4.2		yes	3.12	2.12 contains requirements of corrective actions when a critical control point is not under control.

	(f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively	852/2004, article 5.2f	This can for example be internal audits.	yes	7.6		yes	2.123.4	2.12 requires verifying procedures. 5.4 requires yearly internal audits that covers the entire standard.
	(g) establishing documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).	852/2004, article 5.2g		yes	4.4		yes	chapter 4	
	When any modification is made in the product, process, or any step, food business operators shall review the procedure and make the necessary changes to it.	852/2004, article 5.2		yes	8.2		yes	1.12	1.12 requires the HACCP is validated yearly and when changes are made.

II. Example: Monitoring Visits

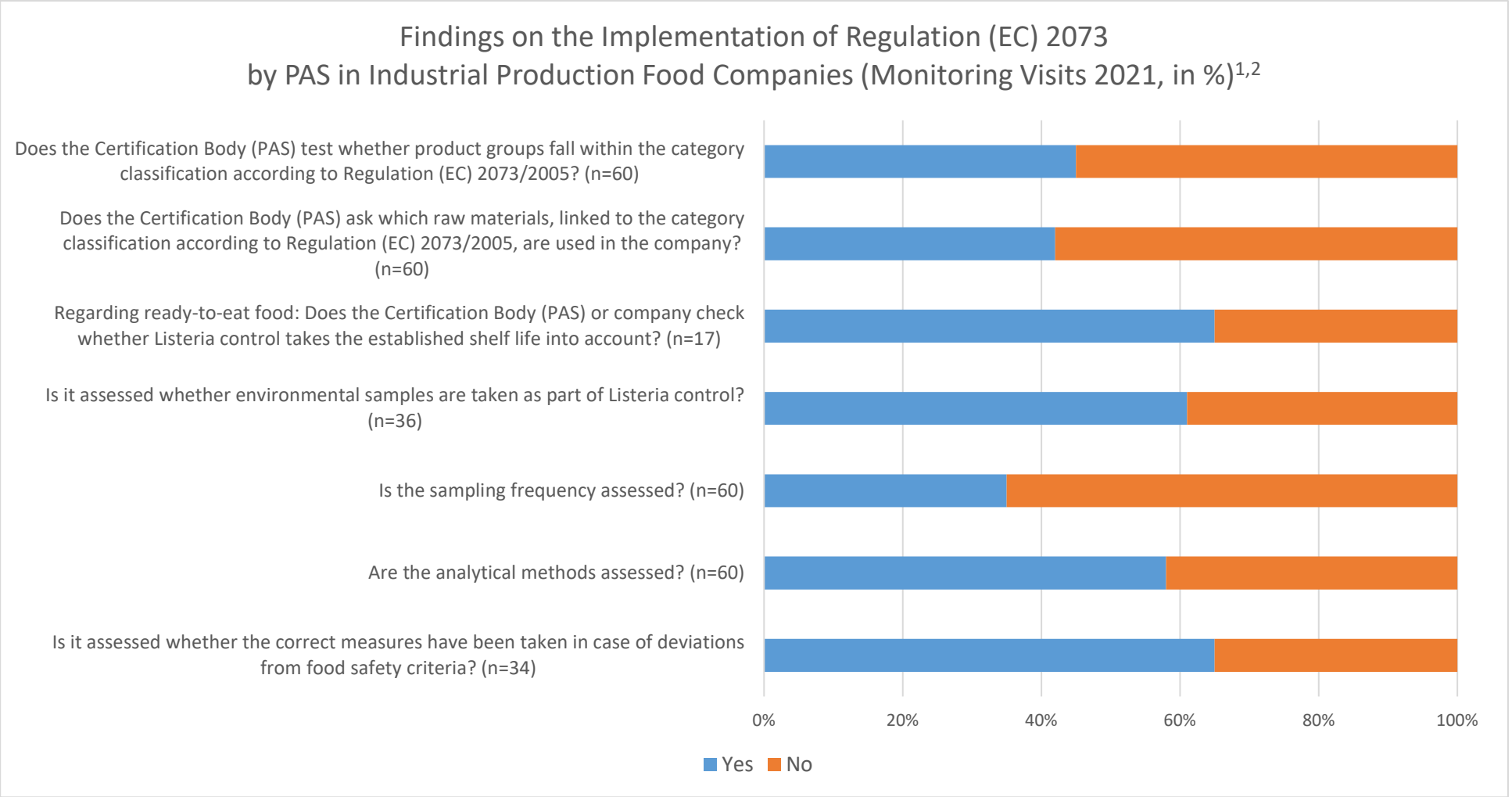
The [Authority] has an acceptance program for PAS in place. If intake-criteria are met, a monitoring program is set up. Part of the monitoring program are monitoring visits to the certified FBO. During these monitoring visits the [Authority] verifies the operation of the PAS in practice.

The visits/audits conducted by the [Authority] are not assessing coverage of regulation in detail but have a focus on the effectiveness of the private assurance scheme.

Based on research questions, the degree of safeguarding of legal components has been assessed. Based on this assessment per legal component, the CA decides whether there is confidence that the assurance of the assessed component is or is not properly carried out by a PAS. This information is then used in setting up risk-oriented supervision. Legal components that are demonstrably well safeguarded by a PAS are not or less frequently included during a regular inspection/audit by the [Authority].

The following legal components have been assessed for the PAS that are active in the production of food: Basic Hygiene Conditions, Basic Construction Conditions, Tracing and Microbiological Criteria.
It has been established that there is sufficient confidence in the safeguarding of the basic conditions of hygiene, basic conditions of construction and tracing. But that the CA has insufficient confidence in the safeguarding of the microbiological criteria because the EU regulations have not been sufficiently implemented in the control system of the PAS.

Below is an example of how the CA assesses the effectiveness of the PAS control per legal component. An example of the questions asked during monitoring visits (2021) to certified FBOs is provided, topic microbiological criteria.



[1] Conclusion of the visits: The findings from the monitoring visits with regard to the assurance of compliance with the microbiological criteria do not yet provide sufficient trust. For all questions the execution was below 80%. Three questions even scored below 50%.
[2] The questions and the number of FBOs surveyed are for informational purposes only. Each CA can assess for itself what is relevant based on its own situation.