A VADE MECUM ON OFFICIAL INVESTIGATION IN ORGANIC PRODUCTS

Good implementation practices for Articles 28 and 29of Regulation (EU) 2018/848

By: Nicolos Verlet and Jochen Neuendorff

Abstract

During the development of the new EU Organic Regulation, the issue of non-authorised substances, particularly pesticides, in organic products was a major concern. If such substances are discovered, an official investigation must be carried out to identify the source and determine the cause of contamination. A product can only be labeled and sold as organic if no non-compliances affecting the integrity of the product are found. A useful guide: "Vade mecum on official investigation in organic products" has recently been published to assist in conducting effective and efficient official investigations. This document guides investigation methods and techniques.

The starting point

Biofach, February 2023. The main focus of this year's conferences and panels is the implementation of the new organic regulation (EU) 2018/848, specifically Article 29. That Article requires official investigations to be conducted if non-authorised substances, such as pesticides, are found in organic products. These products cannot be marketed as organic until the investigation determines the source and cause of the contamination.

Some concerns raised include the widespread presence of pesticides, difficulties in determining the origin, the burdensome and expensive nature of systematic investigations, potential blockage of goods due to residual findings, and the risk that traders may only accept residue-free organic products.

An evening discussion over a beer in old Nürnberg. “Okay, but where does this leave us? Is the goal to anticipate a reconsideration of these provisions by the Commission for a more business-friendly Regulation? To advocate for more lenient interpretations of the current legal provisions?”

Article 29 was the outcome of challenging negotiations that lasted over four years. The circumstances that led to the compromise have not changed, making it difficult to envision an alternative solution that would garner consensus today. It is unlikely that there will be a short-term amendment to the legislative framework, at least not before the Commission presents a report on these measures by the end of 2025. Therefore, whether one likes it or not, the current regulatory framework will remain in effect until at least 2026.

The compromise reached should represent a middle ground between economic constraints and the robustness of the control system. On the one hand, it is possible to label a product as organic even if it contains pesticide residues below MRL; on the other hand, it is crucial to identify the source and the cause of the contamination and establish, based on strong evidence, that pesticides have not been used. Additionally, the operator must have implemented proportionate and adequate precautionary measures to minimise contamination. Easing the conditions for official investigations would upset the balance between these two imperatives. After discussing over a second beer, it was concluded that exploring investigation methods is the most obvious approach to resolving a significant portion of the challenges encountered while still adhering to the legislative framework. This is how the idea of the Vade mecum was born.

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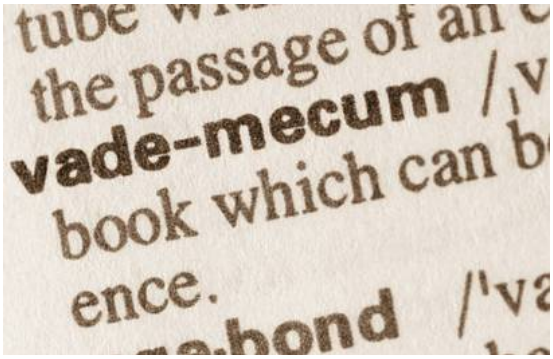

The vade mecum, a technical tool for the organic sector

The EU Organic Regulation allows flexibility in selecting and implementing investigation techniques to determine the source and cause of suspected contamination. It provides wide discretion for official control methods and techniques. The objective was to create a technical document based on the extensive experience of 25 authors from 8 different countries in all aspects of organic production. A steering committee closely monitored the elaboration and publication of this document.

The Vade mecum is available for free download from www.anti-fraud-initiative.org.

The main issues covered by the Vade mecum

The official investigation begins with "substantiated" information regarding presence of non-authorised products or substances. First, the analysis report sent to the control authority or body (CA/CB) must be reliable. Ideally, the analytical result should be quantifiable, meaning it should be above the limit of quantification (LOQ).

Chapter 2 of the Vade mecum aims to provide an understanding of the analytical requirements and limitations that laboratories encounter. The investigation begins with evaluating the laboratory results and forming hypotheses about the potential sources and reasons for the contamination. **Chapter 3** suggests to base these hypotheses on 16 types of sources, categorised into 5 main groups: "use of non-authorised substance," "commingling with non-organic products," "cross-contamination," "environmental contamination," and "natural presence." The source investigation looks at how the contamination occurred, while the cause investigation delves into organisational and motivational factors behind the contamination event. Unlike the source investigation, it's not possible to provide an exhaustive list of all potential causes, there are several "root causes" to consider, including "intentional," "insufficient or neglected precautionary measures," "lack of knowledge," and "external factors."

In order to conduct an effective and efficient investigation, it is important to use the most effective methods and techniques. **Chapter 4** offers a comprehensive toolbox based on the authors' field experience. This chapter emphasizes the importance of documentary analysis, mass balance, and traceability as the starting point for an investigation. Inspectors undertaking an official investigation must thoroughly prepare themselves before the on-site visit, define a strategy, and decide which questions to ask, and in what order. During the inspection, they mainly ask open technical questions (why, when, how, etc.).

All the elements of the preceding chapters have been put into context in **Chapter 5** to propose a structured and systematic approach to official investigation. The objective is to provide an effective and efficient systematic approach to official investigation, finding the right balance between cost and result. The starting point is the ranking of hypotheses on the possible sources of contamination listed in Chapter 3, based on several factors: the non-compliance history of the operator, the type of activity and the operator structure, the types of substances identified, and the concentration.

As a result, the hypotheses are classified into three groups: ***"Probable," "Possible," and "Excluded,"*** to be confirmed or eliminated by the most effective investigation techniques. A risk analysis model determines the intensity of the official investigation, that is, if the evaluation can be achieved based on a documentary review, or if an on-site visit should be conducted, possibly unannounced.

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The chapter also deals with recurring contamination cases, the timing and duration of an investigation, and an important question: what degree of certainty must be achieved for identifying the source and the cause?

Chapter 6 serves as a reality check regarding how investigations are conducted in practice and to what extent the principles of the systematic approach are already being implemented. Operators are facing a new challenge: the implementation of Article 28 of Regulation (EU) 2018/848, which provides an option to assess whether suspicions can be eliminated at their level. The chapter offers an overview of the regulations with tools to support the effective implementation of the legal requirements. The Chapter also explains how to apply a systematic approach to official investigations by control bodies and authorities. An investigation should be tailored to the specific case, considering aspects such as the organic production activity (e.g., farm/processing/trade), the (organic) product concerned, the detected plant protection product or non-agricultural ingredients or processing aid, and the context. This may also include traceability of the lot, field observations, additional sampling of foliage, soil, equipment, or crops, literature review for environmental behavior of the substance leading to technically unavoidable contamination, alternative sources for the presence of the residue, and concentration or dilution factors in the case of processed food. Competent authorities play an important role in the supervision of the official investigations. Chapter 6 presents the survey results providing a first factual overview of the main elements which structure operator assessment and official investigations in 21 EU Member states, followed by concrete case studies from Germany, Denmark, and France.
Decision making is an integral part of the official investigation process. **Chapter 7** summarised the decisions which need to be made on: whether to launch an official investigation and provisionally block the product, ,the source and the cause of contamination, the status of the product (organic or conventional), the operator's certification status, and to follow up on the investigation. All decisions made shall be supported by factual evidence collected through appropriate methods and techniques for official controls, and should be proportionate to the suspected non-compliance.

The Vade mecum focuses on the actions to be taken in the event of the presence of a pesticide. This particular attention paid to contamination must not overshadow a fundamental point: organic products generally have much lower levels of pesticide residues compared to conventional products, as shown in Chapter 1: lower frequency of positive samples, fewer combinations of substances, and lower level of contamination which very rarely approaches or exceeds the maximum residue limit (MRL). The low level of contamination is a direct result of compliance with the EU Organic Regulation.
It is important to emphasize that the Vade mecum is purely technical and operational and does not have legal or regulatory significance. Its practical implementation is not obligatory. The implementation will be successful if the stakeholders perceive benefits for their specific situation. By voluntarily adopting a similar approach and best practices, this initiative may lead to improved harmonisation of investigation practices and decision-making, even though we recognise that the Vade mecum does not cover all issues and challenges.