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Interpreting Articles 28(2) and 29 of Regulation (EU) 2018/848 in accordance with the recognized principles of the EU organic legislation[6]

I. Introduction

On 1 January 2022, Regulation (EU) 2018/848 of the European Parliament and the council, governing organic production in Europe, came into force as the "New EU Organic Regulation". That same day, the previous EU Organic Regulation (EC) No. 834/2007, was repealed.

Articles 27, 28, and 29[7] have already led to intense debate among organic operators, control bodies, and competent authorities.[8] According to *Alexander Beck*, the way the "*subject matter of this revision process"* was addressed in these rules was *"very controversial"*[9].

Nevertheless, the dedicated reader of these three articles will quite readily understand the basic structure of these three rules: Articles 27 and 28 are directed at organic operators, while Article 29 is directed at the competent authorities or their delegated bodies, i.e., the control authorities or control bodies. Otherwise, Article 27 and its corresponding Articles 41 and 42 are to be understood by nature as lex generalis; the provision, for which there is no equivalent in general food law, defines an action programme that must be respected in all conceivable cases of non-compliance by the operators.

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[6] The present text summarizes the results of the authors' preliminary work on Article 27 et seq. of Regulation (EU) 2018/848. To that extent, it builds on some publications written with the involvement of the authors on topics surrounding the subject of Article 27 et seq. of Regulation (EU) 2018/848. In that regard, please refer to *Beck*, LMuR 2018, 221 et seq.; *Beck/Stumpner/Wallau***,** LMuR 2021, 257 et seq.; *Beck/Guhrke/Milan*, LMuR 2022, 93 et seq.; *Neuendorff/Wallau*, LMuR 2022, 288 et seq. inter alia.

[7] In terms of legal systematics, Articles 41 and 42 of Regulation (EU) 2018/848 similarly fall within this context because they prescribe the procedural approach to be taken by the competent authorities or control bodies whenever non-compliance is suspected.

[8] Please refer to *Beck*, LMuR 2018, 221 et seq.; *Beck/Stumpner/Wallau***,** LMuR 2021, 257 et seq.; *Beck/Guhrke/Milan*, LMuR 2022, 93 et seq.

[9] *Beck,* LMuR 2018, 221 (224).

Article 28(1) requires a precautionary approach by operators to avoid contamination of organic products by substances or products not authorised for use in organic production. Article 28(2) lays down how the organic operation shall proceed if the presence of a non-authorised product/substance is suspected. Article 28 thus stipulates in lex specialis terms, the special case of when nonconformity is suspected involving the presence of a product or substance, not authorised for organic production and holding the potential of being the result of contamination.

Article 29 regulates what the competent authorities and control bodies must do in the event of a suspected case of contamination caused by the presence of products or substances in organic products which are not authorised for use in organic production.

Despite their respective differences, all three articles pursue a mutual objective: ensuring the integrity of organic products.[10]

That said, the aim of this essay is to interpret the requirements of Articles 28(1) and (2) and 29(1) and (2) substantively and in the spirit of Regulation (EU) 2018/848. This is necessary, not least, for various practical reasons.

II. The two sides of the coin called integrity - precautionary measures and response programmes

Article 28(1)[11] very impressively achieves the objective laid down in recital (24) of Regulation (EU) 2018/848[12].

1. Precautionary measures pursuant to Article 28(1)

The way to understand the concept of "precautionary measures" can be found in the legal definition given in Article 3(5) of Regulation (EU) 2018/848

In turn, the products or substances which are authorised for use in organic production are summarized in Article 9(3) sub-paragraph 1 of Regulation (EU) 2018/848.

Article 28(1) states that "In order to avoid contamination […] operators shall take the following precautionary measures […]: (a) … identify the risks of contamination … and (b) put in place […] measures to avoid risks of contamination…". In both steps, these measures are sufficient for organic certification when they are proportionate as well as appropriate. In consequence, firstly, this means that risks of contamination that have not been identified will not result in precautionary measures - until the contamination has been detected the first time. Secondly, it also means that operators take

[10] See the recitals (67) et seq.

[11] Article 28(1) identifies two types of cases: precautionary measures as described under points (a), (b) and (c) which deal with the avoidance of contamination risks; then there are the precautionary measures as defined in point (d) which ensure the "classical" principle of separation into organic, in-conversion and non-organic products.

[12] The "undertaking by the operator" is defined in point (c) of Article 63(1) of Council Regulation (EC) No. 889/2008 as: "The precautionary measures to be taken in order to reduce the risk of contamination by non-authorised products or substances." And Council Regulation (EC) No. 889/2008 stipulates above in Article 26(2) and (4): "(2) Operators producing processed feed or food shall establish and update appropriate procedures based on a systematic identification of critical processing steps.
(…)
(4) "Operators shall comply with and implement all the procedures referred to in paragraph 2. In particular, operators shall:
(a) take precautionary measures to avoid the risk of contamination by non-authorised substances or products".

measures to avoid risks of contamination within their own sphere of influence, said otherwise "under their control".

Contamination and integrity: what's in a name?

Maybe the most fundamental question of all is related to the term "contamination". It is used 17 times in Regulation 2018/848 without a definition. It's common knowledge that rainwater contains traces of chemical substances, the soil may contain residues that were used 30 years ago, domestic tools and equipment spray chemicals in the atmosphere, products and substances used in livestock management, and so much more. There is an important difference between the presence of such "unavoidable" contamination and the presence due to ignorance, negligence, accidental use, or even fraudulent activities which are more generally "avoidable" sources of contamination.

Integrity is defined in the new organic Regulation (Art 3(74)) and it states that the product does not exhibit non-compliance which, in any stage of production, preparation and distribution affects the organic characteristics of the product or is repetitive or intentional.

Precautionary measures to ensure separation between "organic" and "conventional" products and production

Critical readers who summarize these statements against the backdrop of the objectives anchored in the recital (24) will themselves realize how narrowly circumscribed the scope of the compulsory precautionary measures is and take them with a grain of salt. The precautionary measures are designed and intended to ensure the separation between "organic and conventional" and thereby ultimately the "dualism of organic versus conventional": operators producing organic products are not only prohibited from actively using certain substances or products authorised for the field of conventional, but not for that of organic food production; indeed, their duties extend further. Above and beyond this, they are also obligated to take precautionary measures to minimize risks of contamination of organic production by substances or products authorised for the field of conventional, but not authorised for the field of organic food production[13]. To put it briefly and concisely: the prohibition on the use of non-approved substances has been supplemented by precisely defined precautionary measures[14] which already existed according to Article 63 and Article 26 of Regulation (EC) No. 889/2008.

However, it is not the aim of the precautionary measures under discussion to establish a legal requirement for "residue-free organic products" and subject the organic operator to a one-size-fits-all contamination prevention programme – which by its all-inclusiveness – would be disproportionate in the legal sense. Consideration should be given to the fact that the parallel production (i.e. simultaneous organic and conventional production practices on the same farm) and preparation of organic and conventional products throughout all stages of production and distribution, including agriculture, remains possible under the new EU Organic Regulation. The pivotal objective of the

[13] Practical examples are cited in *Rombach/Schigulski*, LMuR 2020, 68: "Such items might include, for example, sowing and harvesting machines subject to shared use among conventional undertakings or even third-party equipment that is used on a temporary basis (for example dryers, cleaning systems) and that may contain residues of non-authorised substances or products. Conceivable sources of contamination include storage premises that were treated with non-authorised substances or conveyance and transport equipment that was contaminated by conventional products. Thought should also be given to the commissioning of third parties with the running of operations and the use of their own machinery. All types of dust should be taken into account that originate from conventional products and the residues of which remain due to insufficient cleaning."

[14] In this context, the restriction of the company's or operator's duties is important in terms of process control.

requirements is to have internal processes at the operator level designed in such a way that any contamination and mixing of organic and conventional products is avoided during parallel production.

Precautionary measures and their limitations in coverage/scope

Accordingly, even the terminology of the precautionary measures is not directed against general environmental contaminants such as heavy metals, dioxins and furans, nor against any potentially contaminating substances like mycotoxins or lubricants for agricultural machinery[15] that are the subject of other EU food safety rules and regulations[16,17]. Both conventional, as well as organically produced products, must be produced in accordance with such legal requirements. Neither are environmental contaminants subject to the authorisation proviso pursuant to Regulation (EU) 2018/848. By contrast, plant protection agents, ingredients, processing aids or products for cleaning and disinfection, for example, are subject to the authorisation proviso pursuant to Regulation (EU) 2018/848. In other words, the precautionary measures need to be designed by operators to manage the risks of contamination of organic products by substances and products whose use is allowed in the conventional sector but not in organic production[18] and which may occur under their responsibility.

Precautionary measures are proportionate

As recital (68) unequivocally states, the precautionary measures to be taken by operators must be "proportionate and appropriate" and "under their control," i.e., manageable and controllable. In terms of practical implementation, as described by Article 28(1)(a), the identification of risks of contamination shall include "systematic identification of critical procedural steps", as part of the prevention programme established by this provision and aligned along specific operational "bio-critical control points", similar to HACCP systematics.[19]

The overriding principle that the precautionary measures should be "proportionate and appropriate" is consistent with the principle of proportionality anchored in Union law as laid down in Article 5(4) of the treaties of the European Union[20] and national law by Article 20(3) of the Basic Law for the Federal Republic of Germany[21]. Accordingly, the legislature is bound by the constitutional order, executive power, and the judiciary by law and justice. Pursuant to the principle of proportionality emanating therefrom, the following applies in general: proportionate and appropriate measures are subject to the principle of prohibition of excessive measures. They serve a legitimate purpose and are suitable, necessary, and reasonably practicable (appropriate).

Precautionary measures are appropriate

Appropriateness is an element of proportionality. The fact that the EU legislators specifically emphasize appropriateness in the rule shows that the measure not only must be appropriate in

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[15] Please refer to Working paper of the BioKKP Project, p. 5.
[16] Please refer to Article 2(4) of Regulation (EU) 2018/848.
[17] Please refer to *Schmidt/Haccius 2020*, Das Recht der Bio-Lebensmittel [The law on organic food], p. 71: "The EU Organic Regulation limits the scope of the operator obligation to take precautionary measures to those substances that are not approved to be used in organic production, but according to its set-up would have to be authorised in order for them to be able to be used in organic production."
[18] Contamination risks usually arise as a function of operator activities; please refer to the examples cited in the working paper published by the BioKKP Project, p. 6.
[19] Please refer to the practical guides for implementing Article 28 (1) of Organic Regulation (EU) 2018/848, available at https://orgprints.org/id/eprint/42876/. With regard to the differences, please refer to *Schmidt/Haccius*, Das Recht der Bio-Lebensmittel [The law on organic food], p. 80.
[20] Please refer to *Trstenjak/Beysen*, EuR 2012, 265 et seq. with further references.
[21] Please refer to *Klatt/Meister*, JuS 2014, 193 et seq. with further references.

general, but also in each individual concrete case. It, therefore, follows the principle of proportionality, of which limits are set according to the obligatory precautionary measures pursuant to Article 28(1) Regulation (EU) 2018/848. This is especially evidenced in recital (68), where the measures to be taken are limited to those under the operator's own sphere of influence. Only such measures are reasonable (appropriate). All precautionary measures to be taken by the operator pursuant to Article 28(1) must therefore be aligned to this principle.
In practice, this means that each case must always be weighed on its merits. A precautionary measure is appropriate if the disadvantages associated with it are not entirely disproportionate to the benefits it confers. Therefore, operators do not have to exert influence on third parties in order to force them to comply with the rules applicable to their sphere of influence. Operators are also not required to conduct research in order to ascertain whether these third parties comply with the rules or not. For that reason, they do not need to conduct any lawsuits to enforce third-party compliance, e.g., the obligation to avoid drift from conventionally farmed neighbouring land. Likewise, they are not required to maintain any special buffer zones to conventionally farmed neighbouring land or plant hedges. All of that would not be reasonable or appropriate, solely based on the fact that such measures go beyond the measures that are under the operator's sphere of influence, but also because the expenditure is disproportionate to the benefits. Indeed, drift to the agricultural area of the operator can occur over long distances despite hedges, tree rows, buffer strips, or even a combination of all those. Moreover, it is neither reasonable nor sustainable or proportional to try to avoid ubiquitous environmental toxins in the organic parcels of land by building greenhouses on the parcels.

2. Suspicion-based response programme in accordance with Article 28(2)

While Article 28(1) deals with the establishment of precautionary measures, Article 28(2) lays down a suspicion-based response programme: Article 28(2) sets requirements for operators to follow when dealing with suspected non-compliance. It thereby stipulates how to proceed when and where presence of prohibited products or substances has arisen despite the compulsory avoidance of which is required by Article 28(1).

In this regard, Implementing Regulation (EU) 2021/279 specifies the rules of Article 28(2) of Regulation (EU) 2018/848, laying down their practical measures[22]. The relevant recital (2) presents the intention and purpose of this part of the Implementing Regulation, which states: "...*it is appropriate to establish procedural steps to be followed and the relevant documents to be provided in case operators suspect, due to presence of non-authorised products or substances, that the product that is intended to be used or marketed as an organic or in-conversion product, does not comply with Regulation (EU) 2018/848*."

[22] B*eck/Stumpner/Wallau*, LMuR 2021, 257.

a) The basic four-step model of Articles 27 and 28(2)

The four-step[23] response programme[24] laid down in Article 27 provides the basic model for the response programme of Article 28(2): as defined in point (a) of Article 27, the operator shall identify and separate the product based upon a "suspicion concerning a possible non-compliance". The next step in accordance with point (b) of Article 27 is to check whether the suspicion is "substantiated" or not. During the suspicion check, the product may not (no longer) be placed on the market, see point (c) of Article 27. The relevant control authority or control body must be informed immediately (only) where the suspicion has been substantiated; this likewise applies where the suspicion cannot be eliminated, see point (d) of Article 27.

First, an explanation is required as to when a "suspicion" of "non-compliance" is present.

According to Article 3(57), the term "non-compliance" is broadly defined. *Alexander Beck*[25] summarizes the situation as follows "*The term 'non-compliance' thus comprises everything ranging from minor labelling deficiencies (for example when stating incorrectly the code number of the CB), which do not impact the compliant production process of an organic product, to nonconformities in the compulsory production process that place the organic status of a product into question*". Reg (EU) 2021/279 Article imposes on competent authorities to adopt a national catalogue of measures containing at least three types of non-compliances: minor, major, and critical based on fixed criteria. Accompanying measures vary from submission of a corrective action plan to withdrawal of the certificate.

Reversal of the conclusion to be derived from Article 41(2)[26] of Regulation (EU) 2018/848 would suggest (accordingly) that any legally relevant non-compliance within this meaning would have to affect the integrity of the produce or product in terms of it being organic. From this, it follows that any nonconformity is predicated on the legal definition given under Article 3(7) of Regulation (EU) 2018/848, according to which there must be a certain degree of integrity impairment[27] involved:

Furthermore, it must be clearly stated which conditions are to be satisfied in order for there to be a "suspicion" at all. This term is not defined in the EU Organic Regulation. Mere information as such does not constitute a "suspicion"; that statement also applies to the initial information about the possible presence of a non-authorised substance. One cannot speak of a "suspicion" until evidence like the analytical findings, for example, prove to be legitimate in terms of being correct and robust and have relevance within the meaning of the EU Organic Regulation[28].

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[23] As defined in point (d), Article 27 of Regulation (EU) 2018/848 stipulates the maxim that operators are in principle required to cooperate with the control bodies and control authorities.

[24] Article 27 of Regulation (EU) 2018/848 and Articles 41 and 42 of Regulation (EU) 2018/848 must be read "together".

[25] *Beck*, LMuR 2018, 221 (224). Please also refer to Article 3(57) of Regulation (EU) 2018/848: "Non-compliance: 'Non-compliance' means non-compliance with this Regulation or non-compliance with the delegated or implementing acts adopted in accordance with this Regulation."

[26] "(*2) In the event that the results of the investigation referred to in point (a) of paragraph 1 do not show any non-compliance affecting* ***the integrity*** *[authors' boldface] of organic or in-conversion products, the operator shall be allowed to use the products concerned or to place them on the market as organic or in-conversion products."*

[27] In this regard, please also refer to the previous rule in Article 30(1) of Council Regulation (EC) No. 834/2007, which posed the significant question as to whether "the (nonconformity) would be proportionate to the relevance of the requirement that has been violated and to the nature and particular circumstances of the conformity."

[28] *Beck/Guhrke/Milan*, LMuR 2022, 93 et seq.

b) The specific requirements of Article 28(2)[29]

Whilst Article 27 describes the general requirements in the event of suspicion of non-compliance, the follow-up actions are described in Article 41 and in 42 in cases, where the non-compliance affects the integrity of organic products, Article 28 (2) specifically addresses the requirements when the operator's suspicion is related to the presence of not authorised products or substances in organic products under his responsibility. In addition, supplementing regulation (2021/279) describes more in detail how operators shall proceed in this particular situation; the follow-up actions, involving the competent authority, control authority or control body, are described in Article 29.

Contrary to what's stated in Article 28(2), in real-life situations, the suspicion itself does not arise solely based on the "presence" of "a" non-authorised substance in an organic product.[30] Rather, the "presence" triggers a series of quick checks among which, for example, is one to see if there is a functional relationship between non-authorised substance or product on the organic product pointing towards a possible non-compliance with the requirements of the EU Organic Regulation:

For example, where an analysis has established the presence of a non-authorised substance, the first step is to check whether the sampling was performed and documented in compliance with the requirements[31]. A testing laboratory accredited in the respective analysis method according to DIN EN ISO/IEC 17025[32] should determine the analytical result so far as possible, which should be above the limit of detection. Ultimately, it should be evaluated whether the detected substance or product concerns a substance that is subject to the authorisation proviso of the EU Organic Regulation.

In other words, two conditions must thus be met: a non-authorised product or substance must in fact be present in the organic product in a quantifiable way expressed as x mg/kg, excluding "traces". At the same time, its presence leads to the assumption that the organic product was not produced or processed in accordance with the production rules laid down in the EU Organic Regulation. Once this is established, "the presence of a product or substance" results in a "suspicion of non-compliance" and the requirements in accordance with Article 28(2) are to be initiated.

Very similar to Article 27, Article 28(2)(a) stipulates that the operator identifies and separates the organic products concerned (Article 28(2)(a)).

Next, the operator must check whether the suspicion is "substantiated" (Article 28(2)(b)). Parallel to this, Article 1 of Implementing Regulation (EU) 2021/279 lays down the procedural steps that must be followed in the least by the operator to "substantiate" the level of suspicion of non-compliance.

Firstly, the organic certificate of the supplier must be verified against validity and coherence with the suspicious products that have been delivered or purchased. Secondly, a determination must be made as to whether the suspicious organic product has been properly labelled; and additionally, whether the accompanying documents meet the requirements of the EU Organic Regulation and match with the

[29] In reference to the following, please also refer to the practical recommendations given in the FIBL Quality Management Guide entitled "How do I proceed in case of a possible non-compliance with the Organic Regulation (Regulation (EU) 2018/848) according to Article 27 or Article 28 (2)?", p. 9 et seq.

[30] Differently nuanced *Beck/Guhrke/Milan*, op. cit., 93 (96).

[31] Please refer to, inter alia, 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 (text with EEA relevance), Commission Regulation (EC) No. 152/2009 laying down the methods of sampling and analysis for the official control of feed alongside Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) 1830/2003.

[32] DIN EN ISO/IEC 17025:2018 General requirements for the competence of testing and calibration laboratories.

product concerned. For products that have already passed the check-in, the effectiveness of the internal precautionary measures must be verified to be able to rule out that the contamination has arisen in an area that lies in the operator's own sphere of influence. This includes a check as to whether non-authorised substances or products used at the operator's own undertaking might have caused the contamination (for example, when storing conventional farm products next to organic products at the operator's own holding or when performing "contract farming for conventional agricultural holdings"). Effective instruments to detect issues are the mass balance calculation, i.e., a reconciliation of the incoming and outgoing goods and a check of the traceability of the organic products concerned. These instruments are particularly helpful for processing and trading companies in order to establish whether, for example, any non-authorised -or not intended- mixing with conventional products has occurred.

Operators can draw upon a large number of factors to help them determine whether the presence of a non-authorised substance or product justifies a "substantiated" suspicion or allows the suspicion to be "eliminated".[33] By way of example, such an "elimination" is rather easy in the case of plant protection products that have no longer been in use for many years now (like DDT, dieldrin) or their use in the concerned organic products would not make any sense (as in the case of anthraquinone in tea).

To sum up: as discussed above, the review of the level of substantiation of the suspicion does not merely deal with the suspicion as to whether a non-authorised product or substance is present in the organic product. Rather, what matters is the suspicion that the organic product may not comply with the rules of Regulation (EU) 2018/848 *due to* that presence.

Neither is it a trivial matter to clarify cases concerning "multi-purpose substances" or "multiple source substances" like phosphonic acid or phthalimide, whose presence can be attributed to a wide range of causes – sometimes outside the purview of the EU Organic Regulation.[34] In practice, sworn experts regularly have to evaluate the likelihood of several sources and causes in the case of such "multi-purpose substances" or "multiple source substances".

Where it is not possible to establish a non-compliance with the EU Organic Regulation or the non-compliance appears very improbable, the EU legislators allow the concerned products to be marketed with reference to organic production. At this point as well, it becomes clear again that legislators did not intend to anchor the likes of a special "organic German purity law for beer" in the EU Organic Regulation.

While the operator is investigating the level of suspicion in accordance with Article 28(2)(b), Article 28(2)(c) stipulates that the operator shall not place the organic products concerned on the market and not use in organic production unless the suspicion can be eliminated.

An example of a case where suspicion can be eliminated is a packing site for fruits and vegetables where products are washed before packing. Washing with water of drinking water quality is allowed. Therefore, if the water supplying company disinfects the water, and confirms this in writing, then the suspicion of non-compliance with the organic production rules can be eliminated and the products

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[33] https://orgprints.org/id/eprint/43004/2/Guideline_FiBL_BLQ_Residue_Handling_Operators_Art27-28_ENG_final.pdf
https://www.aoel.org/wp-content/uploads/2021/12/Guideline_FiBL_BLQ_Residue_Handling_Operators_Art27-28_ENG_final.pdf

[34] With regard to phosphonic acid, for example, please refer to the results of a seminar offered by the Anti-Fraud-Initiative on 13 October 2020, available at https://www.organic-integrity.org/meetings/afi-14-2020/. Regarding phthalimide, please refer to the position paper published by the Society of Food Chemistry, available at www.gdch.de.

concerned may be placed on the market as organic, provided, of course, that horizontal legislation (MRLs) are also complied with.

Article 28(2)(d) states that, where the suspicion has been substantiated or where it cannot be eliminated, the operator must immediately provide the control body with the information specified in Article 1(2) of the Implementing Regulation (EU) 2021/279.

This information relates to all points previously mentioned: certificate of the supplier and documents accompanying the product; information confirming traceability, lab results, sampling details as well as relevant information about previous non-compliances and other relevant information to clarify the case.

Finally, Article 28 (2)(e) sets the standard that the operator must fully cooperate in verifying and identifying the reasons for the presence of non-authorised products or substances (while Art 27e requires full cooperation in verifying and identifying the reasons for the suspected non-compliance).

As laid down in point (d) iii of Article 39(1), there is also an obligation to inform buyers whenever the suspicion of a case of non-compliance is substantiated or the suspicion of non-compliance cannot be eliminated. This obligation to provide information shall not be confused with any obligation to undertake a recall in accordance with Article 19 of Council Regulation (EC) 178/2002. In fact, in the event of suspected non-compliance that has been substantiated or cannot be eliminated, the organic Regulation only refers to informing the buyers and does not refer to a recall. Operators receiving such information are invited to assess the situation.

3. Suspicion-based response programme of authorities and control bodies in accordance with Article 29

Essentially, information about the presence of a non-authorised product triggers suspicion of non-compliance with the production rules of the EU Organic Regulation and may reach the competent authorities, control authorities and control bodies in three ways: from the official monitoring of food or animal feed, from the operator's in-house quality assurance itself or the sampling performed by the authorities in the organic control system themselves.

It is also obligatory for the competent authorities and control bodies to initially evaluate the reliability of the information received. Was the sampling performed and documented in compliance with the requirements? Is the analysis laboratory accredited in the method used and is the analytical result above the limit of detection? Was a substance identified that is governed by the authorisation proviso of the EU Organic Regulation? Not until these investigative clarifications provide positive proof are the authorities and control bodies legally obligated to conduct an “official investigation”[35]. At the same time, they must prohibit the concerned organic products from being marketed as such until the investigation has been concluded. Of course, this is only required if the operator himself does not refrain from organic marketing and blocks the lots concerned. Otherwise, the measure would constitute an onerous administrative act; indeed, the amended German law on organic farming does not allow the control bodies to perform such acts in Germany unless they have been authorised to do so in the Federal State concerned[36].

[35] With regard to the procedures laid down in Article 28(2) and Article 29, please refer to the results obtained by the RESCUE Network coordinated by the Anti-Fraud-Initiative (AFI), available at https://www.organic-integrity.org/afi/activities/

[36] Article 3(1) of the German Law implementing the legal acts of the European Union in the area of organic production.

The requirement of carrying out an official investigation also applies to other cases of suspected non-compliance (Article 27) followed up by actions prescribed in accordance with Article 41 of Regulation (EU) 2018/848, although there are at least two fundamental differences in the procedure of Article 29 and 41.

In cases, where the operator is the source of the information, as it has been already explained, the operator shall fully cooperate in the verification and identification of the reasons for the presence of the non-authorised products and substances (Art 28(2)(e)). The aim of this official investigation is expressed more explicitly in Article 29(1)(a) which states that the official investigation shall be carried out so as to determine the source and cause of the present products and substances.

In the event that the information comes after sampling by the control body itself, operators must be given the opportunity to ask for an analysis of the counter sample. In real life, the analytical results of the second test may differ from the first. In such cases, internal procedures of the control bodies may prescribe to drop the case and thus not start the official investigation. As there are no detailed prescriptions for such cases (in the Regulations or accreditation standards), it is reasonable to expect that there are differences between control bodies in how to proceed in case "second" analytical results do not confirm the finding of the first.

The supplementing Regulation (EU) 2021/279 describes more details about the official investigation in relation to Article 29 and accepts in Article 2 (2), with regard to the methodology of this official investigation all "appropriate methods and techniques, including those referred to in Article 14 and Article 137(3) of Regulation (EU) 2017/625 of the European Parliament and the Council". This legislation has sensibly handed over to the competent authorities and control bodies a variety of methods to help them clarify the facts of each matter in contention. This does not necessarily mean that on-the-spot inspections have to be involved[37]. Nevertheless, Article 29(1)(a) requires that the investigation must be conducted within a timeframe that appropriately takes the durability of the product and the complexity of the suspected case into account.

As it has already been explained, that in the event of operators informing the competent authority, control authority, or control body, it is the company's duty to clarify the traceability and mass balance of the organic lot concerned where this makes sense. One example of this is when the suspected non-compliance arises at a trading or processing company. If no irregularities can be identified, the suspected non-compliance is passed on to the competent authorities or control bodies in descending order of stages through the supply chain for further investigation. If the information needs to be passed on in a cross-border chain of control, this is done via the Organic Farming Information System (OFIS).

Controls and sampling in organic production are risk-based. When samples are taken, it is crucial to identify what the sample represents. Samples taken in one field of wheat, while the farmer grows wheat on other fields as well, may trigger an investigation on the field where the sample was taken, but it's equally important to decide beforehand what shall be done with the outcome of the official investigation, particularly in relation to the wheat growing/grown on the other fields. Therefore, the representativity of the sample, indicated in the sampling protocol is a very important source of information for official investigations on farms where organic production takes place.

In the event of the presence of prohibited substances, the operator shall be given the opportunity to comment on the results of the investigation and thus after the blocking of the products. Especially in the event of sampling and testing carried out by the control bodies themselves, in the first months of 2022, lots of operators were surprised by the obligation to provisionally block organic products while the control body started up an "official investigation". The surprise is due to the creation of specific

[37] See recital (69) of Regulation (EU) 2018/848.

requirements in the event of presence of prohibited substances, while this was not the case under the previous Regulation (more in particular Art 91.2 of Commission Regulation 889/2008).

If, at the end of the official investigation, it should be established that either non-authorised products or substances were used, that the precautionary measures pursuant to Article 28(1) of the EU Organic Regulation were not effectively implemented, or that previous requests by the control body or authority to avoid contamination events were not followed, the organic products concerned may not be marketed as such (Article 29(2)(a), (b) and (c) of Regulation (EU) 2018/848).

Supplementing Regulation 2021/279 Article 2(3) prescribes the minimum requirements for the conclusion of the official investigation. The conclusion shall indicate if the integrity of the organic products is affected or not, as well as the source and cause of the non-authorised products or substances and it should relate to the three possible sources mentioned in Article 29(2).

As indicated above, identifying the source and cause to explain the presence of the prohibited substance requires specific capacities and skills, and sometimes it is not possible at all. As the scientific-technical viewpoint would dictate, in many cases, the best possible approach is to assess the plausibility and probabilities relating to the causes of the contamination.

It can also be expected that, due to the complexity of cases and lack of expertise, a lot of sources and causes will be "invented". This is due to the high pressure on control bodies to come up with a source and cause for any "official investigation".

It goes without saying that when the operator will be given the opportunity to comment only after concluding the investigation, a lot of time may be lost. On the other hand, operators who chose to use their right to get a second expert opinion (Reg 2017/625 Art 35) will have the possibility to drag the official investigations even longer and complicate the work of the control bodies even more.

Under the new organic regulation, Article 28 and 29 also apply -as such- in third countries. It can be expected that the challenges to properly investigate, and reach reliable results and conclusions are another level up for both operators and control bodies.

The competent authority or control body must draw up a final report for each official investigation. Supplementing Regulation 2021/279 Article 2(4) prescribes the minimum content thereof.

The first fundamental difference in the procedure of Article 29 and 41 is the timing of opportunity for the operator to comment: in the event of presence of prohibited substances, the operator shall be given the opportunity to comment on the results of the investigation. Thus, after blocking the products while in the event of another reason for suspicion, Article 41(1)(b) requires that the competent authority, control authority or control body shall give the operator the opportunity to comment before blocking of the concerned products.

The second fundamental difference between Article 29 and 41 lies in the legal requirements after the closure of the investigation: Article 29(2) only prescribes the mandatory decertification of the products in relation to one (or a combination) of the three possible reasons indicated without prescribing what is to be done in case the present products or substances -which are prohibited for use in organic production- have another source and cause. This is different from Article 41(2) which states that "In the event that the result of the investigation […] do not show any non-compliance affecting the integrity of organic products, the operator shall be allowed to use the products concerned or to place them on the market as organic products."

One should not neglect, at this juncture, the principle of proportionality[38] that is to be applied to every official measure/onerous administrative act.

Under all circumstances, the measures laid down in Article 29(1) and (2) inherently serve a legitimate purpose, namely, to ensure compliance with the processing rules for organic production.

These are generally suitable to attain this purpose as well. An official investigation as well as a provisional or definitive prohibition on marketing products with references to organic production all ensure that only products enter the market as organic that have been produced/manufactured in accordance with the processing rules of Regulation (EU) 2018/848.

A measure is required when there is no less restrictive measure available by means of which the objective can be attained with the same success and comparable expenditure. The authority is therefore required to resort to the least restrictive of available measures suitable to attain the objective. Another, less restrictive measure than the official investigation along with a (provisional) prohibition on marketing is not evident for ensuring that no foods are placed on the market as organic that do not comply with the processing rules laid down in the EU Organic Regulation. When doing so, the investigation should be performed using generally accepted and reliable (technical) methods and with what is considered the usual expenditure. Therefore, the newest technically feasible laboratory analysis cannot be relied upon, e.g., if it is considerably more complicated, particularly in terms of being time-consuming. That said, because foods have limited durability, the time factor involved with an investigation could constitute a particularly burdensome factor for the operator. A (provisional) prohibition on marketing is only required if the operator does not voluntarily refrain from (provisionally) marketing the food as organic. A non-provisional prohibition on marketing in accordance with Article 29(2) must generally leave the option open for the operator to demonstrate that previous conditions that resulted in non-compliance with the processing rules of the Regulation have been definitively eliminated to have the prohibition on marketing or obtaining a new certification in accordance with Regulation (EU) 2018/848 lifted.

Finally, each measure by the authority must be appropriate (reasonable). This is the case if the disadvantages associated with the measure are not entirely disproportionate to the benefits it confers. Therefore, an individual analysis is always necessary in such cases.

As defined in point (a) of the Regulation's Article 29(1), the official investigation should be completed as soon as possible, within a reasonable period of time, while considering the durability of the product and the complexity of the case. From this, and this is also confirmed by Regulation 2017/625, Article 9(5), it can be concluded that the burden on the operator should be kept as minimal as possible. Moreover, the concerned food should be prevented from getting wasted at the end, because the investigation took so long that the food has become unmarketable, especially where the investigation results have not determined any non-compliance with the processing rules of the Regulation. As described above, this aspect comes into play when the need to prohibit excessive measures is considered; at the latest, finding its limits in the context of doing justice to proportionality and reasonableness. In the context of proportionality/reasonableness, it must be additionally considered that the reliability of the test result of a laboratory analysis based on the use of recognised analytical methods is ensured and recognised in order to avoid further, complicated follow-up tests becoming necessary. The speed at which the authorities work on the official investigation also plays a role in this context. The authorities may need to find substitutes to represent potentially absent staff who must be immediately ready to work and drive the investigation forward. Indeed, authorities as well as official laboratories must always reserve sufficient capacity for such investigations described as urgent and

[38] Please refer to footnotes 19 and 20 above.

postpone other tasks for the time being, if necessary. This impacts the provisional prohibition on marketing. It must not be upheld any longer than absolutely necessary, whilst a reliable investigation result is being attained within an appropriate period of time which, in the best case, concludes in the repeal of the provisional prohibition on marketing.

The standards of appropriateness/reasonableness are even stricter when considered in relation to a permanent prohibition on marketing. This measure places a disproportionately more severe burden on the operator than a provisional prohibition. For this purpose, Article 29(2) lays down certain conditions (use of non-authorised products or substances, failure to take precautionary measures referred to in Article 28(1), or failure to respond to relevant previous requests from the competent authorities, control authorities, or control bodies). If any one of these conditions is met, a permanent prohibition on marketing will usually not constitute an excessive measure once all circumstances of the individual case have been taken into account and do not lead to a different result when weighed together. A prohibition on marketing that is only provisional will often fail at this point. Such a measure can only be appropriate and reasonable when either non-authorised substances are used, precautionary measures pursuant to Article 28(1) are not taken or a failure to respond to relevant previous requests from the competent authorities, control authorities or control bodies has been reliably demonstrated.

Although in derogation from the rules, the authorities are sometimes very quick to assume in practice that the presence of a non-authorised substance has been demonstrated (e.g., allowing a laboratory analysis result to stand without taking additional factors into account). This is particularly the case when the operator concerned does not seek legal representation in advance of such a measure. A permanent prohibition on marketing nevertheless represents an administrative act that can be subject to review by the competent administrative court.

In most cases, non-compliance with the processing rules of Regulation (EU) 2018/848 does not mean that a foodstuff is harmful to health and not suitable for consumption. Indeed, many substances not allowed for use in organic food, are certainly permitted in conventional foods. Although the mere suspicion that the EU Organic Regulation has been violated initially triggers a suspension or provisional prohibition on the marketing, it does not justify the ordering of a recall or destruction as a matter of course. First of all, further investigations to eliminate the suspicion or to deem the non-compliance as substantiated are required prior to any recall or destruction. In accordance with the requirements of Regulation (EU) 2018/848, a positive analytical result may trigger the suspicion of the presence of a non-authorised substance/product. A laboratory analysis is nevertheless nothing more than a laboratory analysis. It lacks an evaluation and classification of the concrete analytical result with respect to the circumstances of that concrete individual case. Obviously, the measured value must be evaluated by taking all the facts into account. This includes answering several additional questions relating to the particular substance or product. For example, the sampling circumstances and, particularly the issues defined in Article 29(2) are significant. Have non-authorised products or substances been used? Were sufficient precautionary measures taken? Were relevant requests from the authorities and control bodies not implemented? Finally, the nature, scope and extent of the (potential) non-compliance are otherwise to be taken into account during the required weighing of the facts.

4. Outlook

Regulation (EU) 2018/848 defines the term “organic” in a process-orientated way: a product is labelled “organic” if it has been produced or processed in compliance with the requirements of the EU Organic Regulation. This quality promise based on process compliance does not only claim to be valid for the

question of “scope”, i.e., but also the fulfilment of the conditions laid down in the EU Organic Regulation; rather, it likewise applies to the question as to what is deemed non-compliance with the Organic Regulation. Indeed, the interpretation of Articles 28(2) and 29 of Regulation (EU) 2018/848 as discussed herein is entirely in that spirit: when viewed objectively, these rules are nothing more than a normative extension of the prohibition on the use of certain substances laid down in the EU organic legislation. The hope remains that such an understanding of these provisions will establish itself in legal practice; the understanding of establishing an “organic German purity law for beer” through these provisions, finds no basis in existing law.