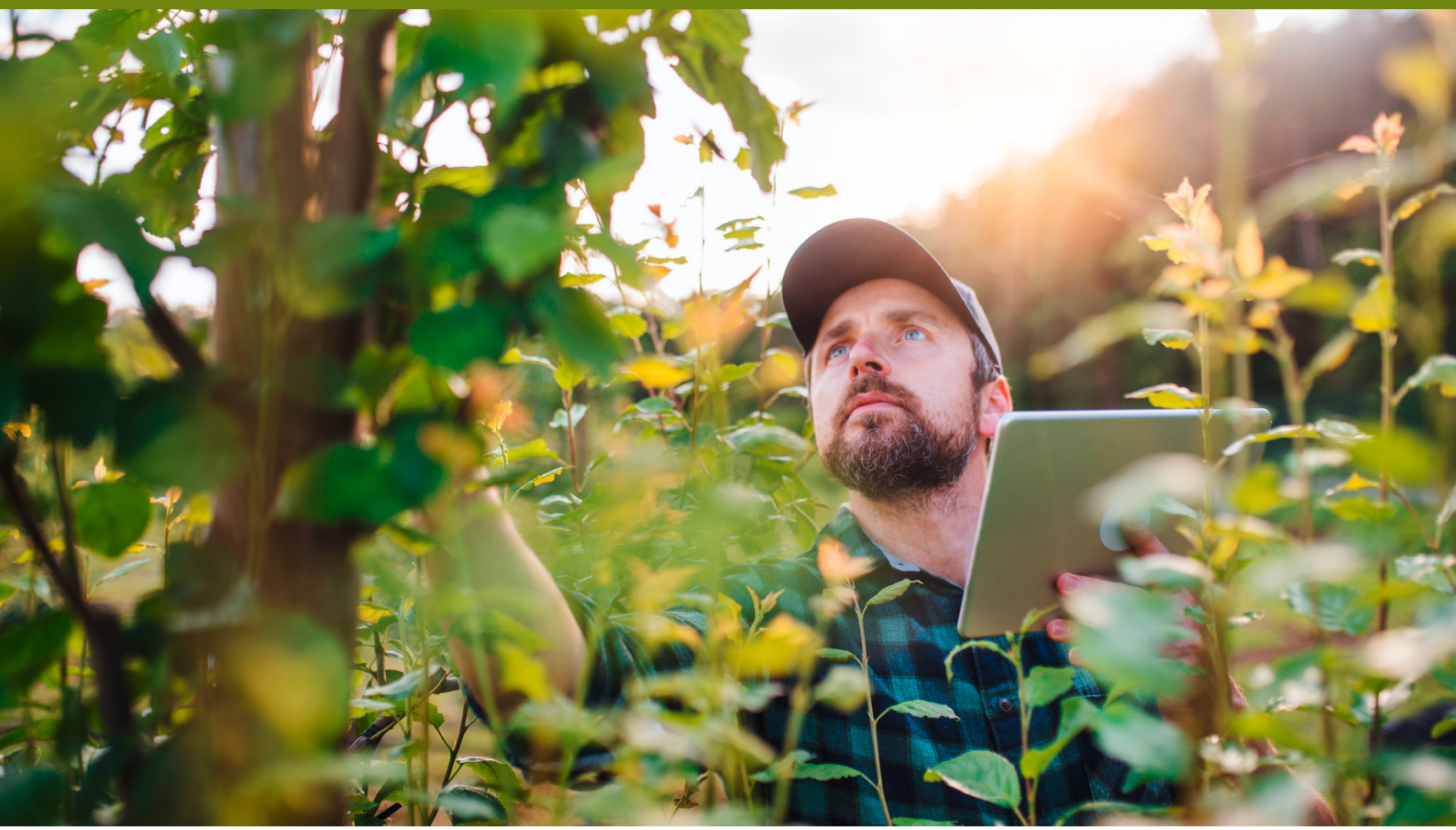
Martin Rombach, Dr. Günter Lach, Albrecht Friedle, Dr. Georg Eckert, Sascha Schigulski

MANUAL

Laboratory analysis and pesticide residues in the control procedure for organic farming



PRÜFGESELLSCHAFT ÖKOLOGISCHER LANDBAU mbH

VERARBEITUNG . HANDEL . IMPORT

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%	percent
‰	per thousand
< QL	“below the limit of quantification”
ADI	acceptable daily intake, parameter for the assessment of possible chronic toxicological effects
ARfD	acute reference dose
BAC	benzalkonium chloride
BNN e.V.	Bundesverband Naturkost Naturwaren (BNN) e. V., Berlin (German Association of Organic Processors, Wholesalers and Retailers, Berlin, Germany)
CVUA	chemical and veterinary investigation office (German abbreviation)
DAkkS	Deutsche Akkreditierungsstelle GmbH (German Accreditation Body)
DDAC	didecyldimethylammonium chloride
dt/ha	deci tonne per hectare
e.g.	example given / for example
FOSFA	Federation of Oils, Seeds & Fats Associations Ltd.
g	gram
g/mol	gram per mol
GAFTA	Grain and Feed Trade Association
GMO	genetically modified organism
ha	hectare
kg	kilogram
l	litre
LD	limit of detection
LFGB	Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch (Lebensmittel- und Futtermittelgesetzbuch – LFGB); German Food and Feed Code
LLE	legal limit exceedance
LoQ	limit of quantification
m	meter
m²	square meter
mg	milligram
mg/kg	milligram per kilogram
mg/l	milligram per litre
MitÜbermitV	Mitteilungs- und Übermittlungs-verordnung; German national regulation on notification and transmission obligations for substances hazardous to health
n.d.	not detected
ng/kg	nanogram per kilogram
OCR	regulation on official controls (EU) 2017/625 – Official Controls Regulation
PAK	polyaromatic hydrocarbons
RL	reporting limit
t	ton(s)
u	uncertainty (of measurement)
µg/kg	microgram per kilogram

Glossary

acaricides Chemical active against mites.

AMPA Aminomethylphosphonic acid, metabolite of glyphosate.

analysis Investigation of a sample regarding contents of chemical or biological substances or other properties of the sample itself.

analyte Chemical substance that is subject to an analytical investigation.

biocide Active that is used to fight plagues (mainly insects) in storage, transport and processing of food and feed.

bulk sample (collective sample) Total volume of samples taken from a single lot or charge.

carry-over Generally unwanted or unintentional transmission of, or cross-contamination with a substance from one product to another.

charge / lot / batch An amount of a food product, which is homogenous in regard to origin, producer, field, harvest, strain, packager, packaging, labelling and so forth.

clean-up Preparation of a sample during an analysis for the purpose of removing interfering substances.

compliance Here: Compliance with the requirements of regulations such as regulation (EC) No. 396/2005 or others.

compliance-sample A sample taken for the purpose of checking for compliance with food regulations such as (EC) No. 396/2005 or others.

conjugate Reaction product of a pesticide that exists as a result of a chemical reaction with a plant substance within or on the treated plant.

contaminants Substances that are not intentionally added to a foodstuff, but nonetheless are added during production or processing or are present as impurities from the environment.

contamination Process by which contaminants get added to a foodstuff.

counter sample/ arbitration sample Possibly sealed sample(s) that is stored for a certain amount of time and that has to be similar to the lab sample. The counter sample / arbitration sample has to be handed over to other parties involved in the control procedure.

CS_2 Carbon disulphide

DDT Dichlorodiphenyltrichloroethane, organic chlorine pesticide, use forbidden in Germany due to its properties since 1977.

desiccation Chemical drying by killing a plant before harvest using a herbicide, e.g. glyphosate.

electron spin resonance Physical measuring technique for the purpose of analysing the molecular structure of a substance.

ester Transformation product of acids (that are used as pesticides); can themselves be used as active agents.

GC Gas chromatography, analytical method for separating chemical substances to qualitatively identify them.

GC/MSMS Gas chromatography/Mass spectrometry / Mass spectrometry, coupling of several analytical measurement devices for identification and quantification of pesticides and other organic substances.

geogenic A characteristic, which is the result of natural processes (as opposed to anthropogenic, influenced by humans).

HACCP-concept Quality assurance concept for hazard analysis and identification of critical control points when handling food.

homogenate A puree prepared by a laboratory from the delivered food products.

hot-spots Describes a point or area in a batch or lot, a field or larger area with unusual properties, such as a higher than normal pesticide contamination compared to the immediate surroundings.

inert substrate A substrate that does not itself contain nutrients.

integrity Cf. Article 3 (74) organic regulation (EU) 2018/848; Cf. point (a) of Article 1 (2) OCR (EU) 2017/625.

lab sample The sample that is handed over to the lab. This sample contains a representative amount of the material from the gathered sample.

Lauterkeit German term. Cf. point (a) of Article 1 (2) regulation (EU) 2017/625, s. also “Integrity”.

LC Liquid chromatography, analytical separation method for the determination of chemical substances.

LC/MSMS Liquid chromatography / mass spectrometry / mass spectrometry, coupling of analytical instruments for the detection and quantitative determination of pesticides and other organic substances.

marker substance Lead substance that is typical for a group of substances and can be used as a surrogate analyte.

MCPA Methyl Chlorophenoxy Acetic Acid; herbicide (chemical agent against weeds).

metabolite Degradation product of a substance (mainly linked to pesticide metabolism).

monitoring sample A sample taken within a framework for regular controls of compliance to requirements or for surveillance of specific product characteristics or process parameters.

MRM Multi-Residue-Method; analytical method for the simultaneous identification of several pesticides and/or other substances within one analytical run.

MS Mass spectrometry.

MS/MS-Technik Tandem-mass spectrometry.

PCDD Polychlorinated dibenzodioxins, colloquially referred to as “dioxins”.

PCDF Polychlorinated dibenzofurans, a group of dioxin-like compounds that often can be found with dioxins.

Photon-stimulated luminescence Physical measuring method to prove treatment of food with ionising radiation.

POP Persistent Organic Pollutants; chemical substances that are regarded to be especially harmful due to their properties, such as persistence in the environment.

QAC Quaternary Ammonium Compounds; a group of substances that are used as disinfectants, especially for the cleaning and disinfection of surfaces.

QuEChERS “Quick, Easy, Cheap, Effective, Rugged, Safe”, abbreviation for an analytical multi-residue-method for the identification of numerous pesticides in a single analytical run; it has been published as an EN-norm and in Germany as an official analytical method (EN 15662 / ASU §64 LFBG, L 00.00-115).

radiolysis product Molecule formed as a result of the application of ionising radiation splitting another substance.

rain-out-effect Washout of pesticides and other substances that are present in the gaseous phase in the atmosphere or sticking to dust particles by rain events.

recital Laying out the purpose and the thought process behind the introduction of a law (e.g. a regulation).

run-off-effect Influence of chemicals (e.g. pesticides) on untreated areas (e.g. organically farmed fields) by means of washout or other effects from treated areas during or after rain events.

sampling Taking of a sample for the purpose of laboratory analysis.

scope The number and kind of substances included in an analytical method.

screening Checking of a maximum number of pesticides or other substances in a given time without specific indications.

single sample A sample taken from a single point of a lot / charge / batch.

specificity Being applicable for a specific trait or characteristic.

suspect sample A sample that is taken due to a suspicion. This can be a primary sample after a hint of non-conformity or a repeat sample meant to, for example, verify the results of a previous sampling and analysis.

thermoluminescence Physical measuring method to prove treatment of food with ionising radiation.

triage (Medicine) Method for a quick classification as a risk group.

undercover samples Sample with known pesticide contents or other substances are being sent to laboratories as part of an unannounced ring test, disguised as a routine sample. This is meant to test the performance of labs under routine conditions. Announced ring test samples tend to be analysed with increased care outside of routine operations.

Introduction

The integrity of food and feed, as it is described by the new European Official Controls Regulation (OCR), is an important good. Only those products with integrity can justify the higher prices that many consumers are willing to pay for organic products. To add to this, the biosystem services provided by organic farming practices only come to bear when the regulatory framework is being complied to. This manual is aiming to provide control bodies, public offices or ministries and private businesses with devices and tools necessary in proving the integrity of organic products in an environment that is defined more and more by the fallout from conventional, chemical-industrial agriculture.

The inception of this manual was not only caused by new regulatory frameworks, but also by the experiences that were gathered during countless pesticide residue analyses that have been conducted by private businesses, controls bodies and public offices over the course of the last 25 years. Recent studies about the ever-presence of residues in agricultural products and in untouched natural environments contributed to this inception as well. These studies in particular show beyond a doubt that the pesticides, being brought out yearly, don't just disappear as is hoped and often hypothesised. Instead they are, over time, being distributed somewhat evenly throughout the environment. Other recent studies have found that this dilutive effect has since been exhausted, in large part due to the cyclical introduction of chemical substances each year, meaning that a sensitive analytical method is going to find background levels in almost every sample. As an example, studies from Switzerland and Southern Tirol prove this for samples from the alpine meadows, far away from agricultural areas. In 2018 a nation-wide monitoring of tree bark in Germany came to comparable results in trees that were also far removed from any conventional agriculture.

For a long time, it was seen as predictable and assured that a conventional product would be clearly identifiable as such based on residue analysis and that organic products and untouched or natural areas would be free from such detectable residues. Based on the doubt cast upon this paradigm by recent analyses, this manual is going to posit the central problem of distinguishing organic products from the conventional kind.

Organic food control bodies and the responsible agencies need to be able to navigate the tensions between the justified expectations of consumers that organic products should have little to no residues, the reality of global pesticide contamination, the legal security necessary for producers (farmers), manufacturers and distributers of organic products and, last but not least, their responsibility to provide official oversight and to unmask and prevent fraud effectively and efficiently.

Sample gathering, lab analysis and result interpretation are becoming ever more relevant in the sector: While the first organic regulation in 1991 only mentioned sample gathering as a side note regarding control requirements "samples for testing of products not authorized under this regulation may be taken", in 2013 a general quota of five percent was set for those controls, meaning that samples had to be taken from five percent of the surveyed businesses (Reg. (EU) 392/2013). The trend of increasing the scope of sample gathering was continued in 2015 with the "Guidelines on additional official controls on products originating from Ukraine, Kazakhstan, Moldova and Russian Federation", that mandated additional controls for imports from these countries both in the country of origin and after arrival in the EU, as well as with a similar regulation in November 2018 for specific types of products from China. This manual will discuss the results of this in a later chapter.

The manual will be relying, where possible, only on the new legal framework: the regulation for official controls (EU) 2017/625 from March 15th 2017 and valid since December 14th 2019 as well as the regulation for Organic Products (EU) 2018/848 from May 30th 2018 and valid after January 1st 2021. For improved readability the Official Controls Regulation (EU) 2017/625 will be referred to as OCR while the regulation for organic products (EU) 2018/848 will be referred to as organic regulation. All other laws and regulations will be referred to according to the appendix. The links are static links to the generally consolidated regulation papers, to be found on the website of the European Union at https://eur-lex.europa.eu/homepage.html?locale=en.

Any gender specific terms used in the paper are used for the sake of readability and refer to both their male and female versions.

Part 1: Fundamentals for the discussion on undesirable substances in products from organic farming

1.1. Residue-free food as fiction – the ever-presence of chemical resources from conventional agriculture

Conventional agriculture is in large parts shaped by its reliance on a heavy use of synthetic active substances, most of them being pesticides. They are not only supposed to fight various vermin and illnesses in plants, but are rather aimed at reducing human and machine labour as a factor of production in a cost-oriented economic model. These active substances are spread on the fields where they are meant to take effect. However, they get spread through the whole ecosystem in a variety of ways, piggybacking on soil processes like erosion and ground water flow and being spread through the air. The chemical and biological breakdown of these chemicals can only be tracked to their respective analytical limits. Nonetheless, they remain present and active below these limits for a long time. Additionally, renewed application of these active substances year after year prevents concentration decline and rather instead leads to a continuous increase of contamination of many natural habitats and especially in soil. There they become detectable in time. Organically grown products too are grown in these "natural" habitats, where organic agriculture is particularly coined by the abstention from the usage of synthetic chemical pesticides and fertilizers. Agrochemical substances can and have been identified in all naturally occurring organisms and natural products as a necessary consequence of their decades-long application.

The European regulation on organic production (EU) 2018/848 defines in paragraph 28 and 29 as a threshold for further actions the "presence of non-authorised products and substances". Without doubt this is referring to pesticides first and foremost.

The term "presence" is closely coupled with the analytical method of measurement, with which the "present" substance is detected. Depending on how finely tuned the analytical methods are, singular substances can be measured independently from one another. Every improvement in measurement technology improves the scope of detectable substances. This basic principle doesn't end at the limit of detection. Not without reason, since theoretically it generally includes all possible substances. In the end it is just a question of the capabilities of analytical methods: In minute concentrations almost, every imaginable substance is included in every sample. "Presence" is therefore a rather unsuitable term.

As a result of the decade-long intensive deployment of chemical substances in agriculture, animals and plants living in "free" nature (that being not in agricultural use) as well as organic produce cannot live up to the expectation of being free of such substances.

The idea that organically farmed produce could be produced, processed and transported is therefore far removed from reality and plainly unscientific. It is based on the paradox that this produce can reasonably be expected to be, in a sense, cleaner than the natural environment. This is to be regarded, if organic agriculture is to coexist with conventional, chemical agriculture.

1.1.1. Which substances are banned from organic farming by the organic regulation?

Banned are all substance that are not explicitly listed as positive in the provision on organic farming or its respectively valid annexes (e.g. additives, adjuvants and flavours). Analysed objectively this can only apply to substances which are generally subject to approval. Contaminants like mycotoxins or other toxins are thereby not included in the spectrum of possible substances.

Hence, the following considerations will mostly focus expediently on pesticides as the most relevant and most studied group of substances. Albeit, in recent times another group of substances have started to crop up in food stuffs – both conventional and organic – and have been vividly discussed. The substances being referred to are those chemical substances that are used as technical additives or adjuvants in operational supplies (inputs), but can also be present in disinfectants and other cleaning supplies, as well as in drinking water. Examples are chlorates (as a by-product from the chlorination of drinking water or sprinkler systems) or quaternary ammonium compounds (QAC, surface disinfectants). The position paper of the laboratory quality circle relana® [1]. provides a good overview of relevant substances. Many of these substances are used in a wide range of use cases (e.g. both as a disin-

1 Cf. http://www.relana-online.de/wp-content/uploads/2019/04/relana-pos.-paper-19-01-Sources-of-Contaminations-20190412-final.pdf ((Accessed 30.07.2019).

fectant and as a fungicide or pesticide), they are therefore referred to as "Dual-Use"- or "Multiple-Use"-substances. Oftentimes, it is difficult to identify the cause and/or source of the measured concentrations of these substances in food stuff.

1.1.2. Presence vs. detectability

When is a chemical/physical substance present?

Here a distinction has to be made between presence and detectability. A substance is present, if it is contained in a sample in any concentration. It is however only detectable, when the concentration in the sample is high enough to trigger a positive result in a suitable chemical-physical analysis. When analysing for pesticide residues, these analyses can only provide a quantitative verification upwards from a few micrograms per kilogram of sample (µg/kg). In substantive terms, this is about equivalent to 1015 molecules for many substances, meaning a number with 15 zeros. This shall be exemplified using glyphosate (molar mass = 169 g/mol):

A successfully quantified concentration of glyphosate of 0.01 mg (= 10 µg) in a kilogram of sample material is equal to roughly 35 quadrillion (35 × 1015) molecules. Even a 1000 times smaller concentration of 10 nanograms per kilogram (ng/kg) would still come out to around 35 trillion molecules of glyphosate per kilogram of sample material.

What can laboratory analyses technically accomplish presently?

In the analysis of drinking water quantitative detection of pesticides and other chemicals up to 0.1 µg/l is common (figuratively speaking: one black kernel in a sea of 10 billion differently coloured ones). As a consequence, more and more analytical detections of many different substances such as, for example, pharmaceutical products are catalogued. In the analysis of polychlorinated dibenzodioxins and furans (PCDD/PCDF) qualitative detection is possible down to around 0.1 ng/kg (one black kernel in 10 trillion differently coloured ones).

In chapter 1.3 – "Increasing sensitivity – progress in instrumental analysis" – this will be discussed in more detail.

Proportionality of effort and usefulness/significance

The already mentioned measurement sensitivity regarding the analysis of drinking water and dioxins cannot be replicated in the analysis of pesticides and contaminants of food stuff.

This is predicated on two preconditions:

1. Drinking water is, analytically speaking, the "easiest" sample. It contains no disturbing substances that could hinder the analysis. Without these hindrances the analysis is consequently optimally sensitive.
2. The dioxin analysis is limited to a total of 17 stringently defined chemical compounds from the chemical group of polychlorinated dibenzodioxins (PCDD) and the polychlorinated dibenzofurans (PCDF). For these substances it was possible to create "isotopically labelled" reference material. Using these in combination with high resolution mass spectroscopy, it is possible to detect extremely low concentrations.

Both preconditions are not given in the case of pesticide and environmental contaminant analysis. On the one hand, there are hundreds of compounds (more than 1300 known pesticides[2] and several hundred potential contaminants). With few exceptions no "isotopically labelled" reference material is available. On the other hand, the wide spectrum of food stuff and agricultural produce is enormous and often contains substances, which hinder the analysis (e.g.: fats, proteins, sugars, natural colourants and antioxidants).

In many cases, a concentration of a pesticide or contaminant can be reliably measured upwards from 0.01 mg/kg under optimal conditions. In rare cases and extraordinary good conditions, concentrations upwards from 0.01 mg/kg or 1 µg/kg can be reliably measured. Often however, the opposite is the case and a sample contains many "hindering substances", that cannot be separated. In those cases, reporting limits of 0.05 mg/kg or, in rare cases, 0.1 mg/kg are the result.

The limit of detection is dependent on the employed method and specific to a substance in a single sample type. Additionally, laboratories have different measurement uncertainties. Therefore, setting the term "presence" equal with the term "limit of detection" is not meaningful, especially considering that this term acts as a threshold.

Conclusion

Even when employing optimal analytical techniques, a qualitative detection, never mind a quantitative one, of pesticide or contaminant concentrations below 0.01 mg/kg is not reliably feasible. The result of an analysis is only possible upwards from an analytical limit (reporting limit). The question of whether this represents a verification limit, a limit of detection or of quantification is of an academic nature and in practice neither solvable nor relevant. What matters is, if a substance is conclusively detected and if its concentration can be quantified.

Regarding (pesticide-)contaminants, another problem arises. A contamination is often by chance, rather than intentional (at least not deliberately). Even though some kind of contamination is to be expected (f. ex. driftage), the exact place and scope is not predictable.

2 Cf. The Pesticide Manual© BCPC (British Crop Production Council), 2014.

Therefore, the circumstances are as a general rule untraceable as well: duration, Intensity, means of transport (air, water, soil), punctual or large-area influence, direct influence (driftage during application on the neighbouring field) or large-scale influence (long-distance transport of pollutants, e.g. bound to dust particles), weather conditions (wind, rain, severe weather, drought and dust) and other parameters lead to the fact that contamination over an examination material is not evenly – neither randomly nor statistically – distributed. In a very unfavourable situation, there are so called "Hot-Spots", which pretend a high exposure, but which are not distributed across the entire batch of tested items. In such cases, a causal deduction is not possible from a single sample, even if the sample was collected in a representative manner according to common guidelines. In this context, one should pay heed to the official sampling procedure regarding the import of dried fruits and nut products to identify a possible contamination of these goods with mycotoxins and to take them out of the supply chain if necessary (see the following box).

Official sampling procedure for import control of dried fruit and nut products

Mycotoxins often form nests when they occur in food stuff, and these nests would not be detected in a typical representative sampling. Therefore, according to Reg. (EU) No. 401/2006[i] for example for dried figs one has to take a sample of 30 kg that is separated into 3 samples of 10 kg each for analysis and have to be prepared accordingly. For nuts, other oil seeds and a few other goods, collective samples of 20 kg are to be taken. This exemplifies the enormous efforts necessary when dealing with unevenly, non-randomly distributed contaminants, in order to reliably quantify the average contamination level of a particular batch of goods. However, this method too doesn't solve the underlying problem of potentially dangerous highly contaminated nests being diluted to the point of being below detection limits.

i Cf. Reg. (EC) No. 401/2006, last amended by Reg. (EU) No. 519/2014.

In order to be able to make a conclusion regarding the marketability of a product, the sampling and analysis need to enable an inference regarding the whole lot. In case the residue was the result of an uneven or punctual contamination, a representative sample is not able to paint a picture of the overall situation.

To justify a suspicion and, if necessary, further sanctions solely with a singular laboratory result, may not be appropriate due to the aspects mentioned above and, in case of doubt, not reliable.

1.1.3. International case studies from agricultural production

Germany

In the federal republic of Germany with an area size of 357,168 km² 30,000 to 35,000 tons of agrochemical substances (active substances without adjuvants) are used per year (2011: 43,000 t; 2012: 45,527 t, including inert gases for storage protection)[3,4]. The area in agricultural use amounted to 16.663 million hectares in 2013 according to the federal statistics administration, that being 166,630 square kilometers.

This amounts to between 180 and 210 kg of agrochemical substances per km² agricultural land or 180 to 210 mg per square meter of area per year.

The actual amount used depends however in large part on the intended use case. In organic farming and on extensively used areas such as orchards or pastures, the usage of these substances is system-related low and/or limited to natural substances. This contrasts with high entries for conventional intensive crops and horticultural companies, so that a multiple of the application rate calculated above must be expected here.

Why then is it that there are still agricultural products that show little to no residues? To explain this phenomenon, several factors will have to be considered:

1. The applied national number of agrochemicals averaging 180 to 210 mg per square meter of agricultural land, is distributed over 270 individual approved substances (2016)[5]. Due to this distribution over many different substances, the individual substances quickly fall below the technical limit of detection due to degradation and dilution processes.
2. Immediately after application of agrochemical substances, several processes kick in, distributing, diluting, degrading and chemically modify the substances. First and foremost, rain is washing the substances from the plants' surface. Physical processes in the atmosphere distribute the substances far and wide through wind and water both on the entire surface and in the soil. Light and chemical

3 Cf. Federal Environment Agency (2018) of Germany: Plant protection products in agriculture. Available online: http://www.umweltbundesamt.de/themen/boden-landwirtschaft/umweltbelastungen-der-landwirtschaft/pflanzenschutzmittel-in-der-landwirtschaft (accessed on 30.07.2019)

4 Cf. Federal Office of Consumer Protection and Food Safety (2013) of Germany: Sales of crop protection products in the Federal Republic of Germany. Available online: http://www.bvl.bund.de/SharedDocs/Downloads/04_Pflanzenschutzmittel/meld_par_19_2012.pdf?__blob=publicationFile&v=3 accessed on 30.07.2019).

5 Cf. Federal Environment Agency (2018) of Germany.

processes decompose the substances or modify them. Biogenic processes in the ground and the entire biosphere break down that substances or bind them into their own substance. Both through physical processes and microorganisms, the substances can be adsorbed or absorbed in reversible and irreversible ways.

3. All processes named above directly lead to a measurable significant reduction of the contamination level, especially in the short period after substance application. With a linear reduction rate of 90% per unit time and an initial concentration of 1018 molecules the reduction is however only one decimal power per unit time.
4. As long as an affirmed detection is only possible upwards from one microgram of a single substance per kilogram of sample (often upwards from 10 micrograms or higher), multiple residues and degradation substances disappear quickly from perception, although they are present in large quantities from a molecular scale.

The example of Germany is easily transferred to other European countries or extrapolated to the global scale, since there is an international market for agrochemical substances and nature conditions are also somewhat similar everywhere. Every year huge amounts of agrochemical substances are applied. Even though trace analysis has undergone rapid progress, it is still far away from being able to show actual concentrations and distributions in the entire biosphere. However, it can be deduced with the help of rather simple mathematical methods, that agrochemical substances and their metabolites have to be present throughout the total environment, in soils, water, plants and animals.

Brazil (endosulfan)[6]

The intensified application of the insecticide "endosulfan" in conventional agriculture in Brazil has led to contaminant drift, through – including but not limited to – rain and air. As a result, significant amounts of endosulfan traces have been found in analysed samples of organic soy.

The sale of agrochemical substances and especially of endosulfan-containing pesticide formulations in Brazil had increased considerably between 2007 and 2009. Consequently, big amounts of endosulfan got into the environment (plants, soil, air, water). This situation was confirmed by data from chemical-industrial farmers and cooperatives. In the season 2009/2010 the use of endosulfan in Brazil increased by two and a half. Considering the weather conditions, especially the precipitation and air temperature and the increased use by the chemical-industrial farmers of Brazil, a significant correlation can be seen, which increased the danger of a contamination with endosulfan for organic soy. The results of the conducted analyses showed a measurable increase in endosulfan content in organic soy from the 2009/2010 season. While in the 2008/2009 season the average concentration was at 0.028 mg/kg it increased to 0.059 mg/kg in the 2009/2010 season. When comparing the increase in endosulfan use by a factor of 2.5 with the increase in average concentration in organic soy, a factor of 2.1, the correlation is apparent.

As a result, a concentration of 0.05 mg/kg of endosulfan in Brazilian soy beans was constituted to be

6 Cf. Lach&Bruns Partnerschaft (2010): Breport "Endosulfan: Environmental circumstances in Brazil 2010 and assessment of its impact on organic soy bean production", on behalf of Gebana AG Zürich.

Case study on long-distance transport using pendimethalin and prosulfocarb in Brandenburg as an Example

In a project titled "Durchführung einer Bioindikation auf Pflanzenschutzmittelrückstände mittels Luftgüte-Rindenmonitoring, Passivsammlern und Vegetationsproben" (performance of a bioindication for pesticide residues using air quality bark monitoring, passive collectors and vegetation samples), executed by TIEM Integrierte Umweltüberwachung GbR[i] on behalf of the State Administration for Environment, Health and Consumer Protection Brandenburg (LUGV), the long-distance transport of pesticides was examined using the herbicides pendimethalin and prosulfocarb as an example. Citation from the study (translated):

The findings lead to the following summarising conclusion:

- The results of the screening regarding immission contamination show a significant contamination over not only isolated places but rather a contamination of the whole region for both Herbicides, pendimethalin and prosulfocarb.
- The data from our and other research allow for the congruent conclusion that an undesirable and prolonged distribution especially of pendimethalin over a large area in the environment.
- Herein concentrations are reached that lie close to those of POPs such as lindane and DDT, which are both classed as problematic.

i Cf. Hofmann, Frieder, Schlechtriemen, Ulrich (2015): Durchführung einer Bioindikation auf Pflanzenschutzmittelrückstände mittels Luftgüte-Rindenmonitoring, Passivsammlern und Vegetationsproben. Fachbeiträge LUGV Brandenburg Nr. 147. http://www.bioland.de/fileadmin/dateien/HP_Dokumente/Pressemitteilungen/LUGV_BB-Studie_Ferntransport_Pestizide.pdf (accessed on 30.07.2019).

unpreventable, which was confirmed both by the responsible control bodies[7] as well as a public position paper of the BNN e.V.[8] for the 2009/2010 and the 2010/2011 season.

USA/Canada (glyphosate)[9]

The herbicide glyphosate is applied globally for the chemical control of weeds and in part replaces the mechanical techniques[10]. for this purpose in chemical-industrial agriculture. Furthermore, it is used intensively for the purpose of chemical desiccation (chemical drying, increase of ripening activity) of pulses and sometimes cereals. In a project taking inventory and analysing the situation of findings of glyphosate in organic wheat, organic farmers in Montana (USA) and Saskatchewan (Canada) were visited and interviewed. Additionally, the business premises and cultivated fields were inspected and soil as well as wheat samples were taken. Where ever possible, samples were also taken from neighbouring fields, which were being farmed in a chemical-industrial way. Rainwater samples collected by farmers as specified were also analysed.

The causes for the generally random and often irreproducible glyphosate findings between 0.01 mg/kg and 0.076 mg/kg (mean around 0.035 mg/kg) were identified as follows:

1. Local contamination by means of drift and cross-contamination from harvesting machines by neighbouring chemical-industrial fields during application of glyphosate, or during the harvest after previous chemical dessiccation treatment with glyphosate;
2. missing barriers in the form of shrubs, bushes or other partitions;
3. long-distance transport of contaminated dust particles through erosion and weather or wind conditions;
4. long-distance transport of contaminated dust particles through disturbance during harvest and shipment to higher layers of air during the harvest of dessiccation-treated products.
5. environmental influences through rain, containing or washing contaminated dust particles out of the atmosphere.

Most of these effects occur randomly and unpredictably, so that a forecast is impossible regarding if and which areas might potentially be contaminated. Due to the illustrated situation regarding the intensive, global application of glyphosate, a production of organic products with glyphosate concentrations of less than 0.01 mg/kg has already become hardly possible anymore.

Control bodies in North America (US and Canada) confirm regularly occurring background concentrations of glyphosate of up to 0.05 mg/kg and thus consider the goods as equivalent to the legal regulations for organic farming. Thereby, based on bilateral recognition, all further restrictive policies in Europe are restricted, even if similar concentrations in European products would lead to reclamations.

2018/2019 studies

In 2019, a number of studies on general background pollution in the environment with pesticides were published. For further research on this we recommend:

- Umweltinstitut München e. V. (2019): Vom Winde verweht, Messung von Pestiziden in der Luft im Vinschgau 2018; online at: http://www.umweltinstitut.org/aktuelle-meldungen/meldungen/2019/pestizide/vom-winde-verweht-luftmessungen-im-vinschgau.html (accessed 30.07.2019);
- TIEM Integrierte Umweltüberwachung GbR (2019): Biomonitoring der Pestizid-Belastung der Luft mittels Luftgüte-Rindenmonitoring und Multi-Analytik 2014-2018; online at: http://enkeltauglich.bio/wp-content/uploads/2019/02/Bericht-H18-Rinde-20190210-1518-1.pdf (accessed on 30.07.2019);
- Labor Quanta d.o.o. Kroatien (2019): Projekt "Sanjas Garten"; online at: https://www.heuschrecke.com/sanjas-garten-2/ (accessed on 30.07.2019);
- Ségolène Humann-Guilleminot, Łukasz J. Binkowski, Lukas Jenni, Gabriele Hilke, Gaétan Glauser, Fabrice Helfenstein (2019): A nation-wide survey of neonicotinoid insecticides in agricultural land with implications for agri-environment schemes. In: Journal applied ecology (in press); online at: https://besjournals.onlinelibrary.wiley.com/action/doSearch?ContribAuthorStored=Humann-Guilleminot%2C+Ségolène (accessed on 09.08.2019);
- Sarah Bögli and Bernhard Speiser, Agrarforschung Schweiz 10 (9): 344-345, 2019: Mögliche Rückstände von Phosphonaten auch nach der Umstellung auf Bioweinbau.

7 Cf. Bächi, Rainer; Vido, Laurence; Harkaly, Alexandre (2010): Statement about residues of Endosulfan detected in organic soy beans from Brazil in 2010. Available online: https://n-bnn.de/sites/default/dateien/bilder/Downloads/statement_endosulfan_21052010_0.pdf (accessed on 30.07.2019).

8 Cf. Schmitt, Meinhard (2011): Öffentliche Stellungnahme zur Anwendung des BNN-Orientierungswerts bei Endosulfan-Nachweisen in (brasilianischen) Sojabohnen. Available online: http://www.n-bnn.de/sites/default/dateien/bilder/Downloads/OeffentlicheStellungnahme_Soja_August2011.pdf (accessed on 30.07.2019).

9 Lach&Bruns Partnerschaft (2015): Report and Conclusions related to glyphosate levels in organic wheat of origin Montana, USA and Saskatchewan, Canada".

10 Personal Information from farmers in Montana (USA) and Saskatchewan (Canada) gathered by Lach&Bruns Partnerschaft, August 2014.

1.1.4. Conclusion

As long as conventional, chemical-industrial agriculture operates with large amounts of pesticides, the presence of these substances in organic products will not be preventable and does not constitute a sign of irregularity. A single lab result on a trace level can thereby not give reason to doubt a compliant mode of operation according to organic regulation requirements. Only a gapless and problem-oriented process control can ensure the integrity of products from organic agriculture.

1.2. More than just “leaving out“ – the basic elements of organic agriculture

A both beautiful and comprehensive definition for organic agriculture can be found in recital 1 of the basic European regulation on organic agriculture (EC) 834/2007:
“Organic production is an overall system of farm management and food production that combines best environmental practices, a high level of biodiversity, the preservation of natural resources, the application of high animal welfare standards and a production method in line with the preference of certain consumers for products produced using natural substances and processes. The organic production method thus plays a dual societal role, where it on the one hand provides for a specific market responding to a consumer demand for organic products, and on the other hand delivers public goods contributing to the protection of the environment and animal welfare, as well as to rural development.”
This definition includes all target dimensions that the original pioneers of organic agriculture had in mind: the market, the environment and the society.

1.2.1. Roots and origins of organic agriculture

The agriculture of the 19th century in central Europe was characterised by the need to supply a growing population and a massively growing number of workers in industrial areas with enough food. In the aftermath of the great famines at the beginning of the 19th century, an increasing number of agricultural schools were founded aiming to ensure the nutrition by improving agriculture.
This was achieved by increasing the area of farmable land through land reclamation (drainage of large peat areas, cultivation of “wasteland areas”, privatised use of commons) and cultivation of the fallow with clover and potatoes. With the insights of Justus von Liebig regarding the fertilisation of plants (1840) the demand for external fertilisers began to increase: Guano as a phosphor and nitrogen fertiliser was imported in increasing numbers (for Saxony from 22.5 thalers worth in 1842 to 272,000 thalers worth in 1859), the German extraction of potassium rose from 2,300 t (1861) to 670,000 t. The crop yields increased respectively. Having been at around ten dt/ha for centuries, the yield of wheat doubled in less than a century to 20 dt/ha in 1900, the same went for livestock and milk production[11]. The

11 Cf. Schuster, Gerd (1983): Im Schweiße deines Angesichts. Natur, Booklet 4 1983, Biederstein.

nutrition situation of the population improved steadily (except during war). With Fritz Haber's "process to synthesise ammonia from elements", patented in 1908 and the therefrom derived Haber-Bosch process, the first industrial installation converting ammonia from nitrogen out of the air was brought online by BASF in Ludwigshafen. "Bread from air", meaning food security by means of artificial fertilisers and technologically bound rather than biologically bound nitrogen was the catchphrase of the era. Agricultural practice seemed to be reduced to the correct and sufficient application of fertilisation, choice of variety and plant protection.

There were however early doubts. Liebig himself wrote in 1856 about the art of the farmer:

"This art comes to an end when the farmer, seduced by ignorant, unscientific and stupid teachers, puts all his hopes on universal means that do not exist in nature if, blinded by temporary successes, he relies on their application, forgets the and loses sight of its value and influence."[12]

The discovery of nitrogen-binding bacteria by Hermann Hellriegel and Hermann Wilfahrt and the upcoming "agricultural bacteriology" (through Felix Löhnis and others) had by turn of the 20th century already laid the groundwork for an ecological understanding of soil fertility, whose center of attention was the life inside the soil and humus budgeting with the respective build-up and degradation processes.

Rudolf Steiner (1861-1925) "invented" the biological-dynamic agriculture in 1924 in eight speeches to anthroposophical farmers (resp. east Elbe landowners) and initiated a rethinking of agriculture with his listeners. His ideas, inspired by anthroposophical ideas, were aimed at bringing the soil and the products, as well as the entire economic (agricultural) production organism to life. After only a couple of years, Steiner's impulses had sparked the inception of the biological-dynamic agriculture and the shared use of the trade mark Demeter.

Sir Albert Howard was, after studying natural sciences in Cambridge, a lecturer at the Imperial Department of Agriculture in Barbados. While he originally was thinking only through a lens of chemistry, he realised that the indigenous population there was able to achieve with crop rotation and compost management exceedingly high and sustainable yields, even without chemical fertilizers. In 1905 Howard became a "botanist of the empire of the Indian government". In Indore, India, Howard started cultivating plants without the use of pesticides and artificial fertilisers, exclusively with compost from plant waste and animal excrements. Over time, Howard optimised the composting process and formulated the so called "Indore-Mixture", named after the place of its conception – a special type of compost. Howards test fields remained free of disease. The cattle that were being fed exclusively with the plants grown in this way, were free from foot-and-mouth disease. Today Howard is seen as one of the pioneers of organic agriculture in Great Britain.

The correlation postulated by Howard that "the health of soil, plant, animal and man is one and indivisible" was ground-breaking for an increasingly wholistic view of agricultural production systems. The method known as the "Indore-method", coined by its application of compost, the nurturing of soil life and the abstention from pesticide, was already known and widely accepted by that time[13].

Hans Müller as leader of the Swiss Bauern-Heimatbewegung (Farmer's Homeland Movement) realised the opportunity to be able to retain and further develop a farming-centric Christian life style by means of organic agriculture, even in a modern, industrialised world. Organic agriculture enhanced the scope of traditional Christian goals, the preservation of family and farm, of the home and tradition by adding to it a responsibility for nature and the consumer. Müller met **Hans-Peter Rusch**, in 1951, the inventor of the concept of the natural balance, depicted for example in "Der Kreislauf der lebendigen Substanz" [14] (cycle of living substances). This provided the theoretical basis and the "Rusch-test" for biological activity in soil became the instrument of success measurement in organic agriculture. Rusch coined the term "Kreislauf der lebendigen Substanz" (cycle of living substances) as the basis for all biological thinking and acting and together with Hans Müller and his wife Maria Müller developed the school of organic-biological agriculture, based in large part on Rusch's work regarding soil tenure and the retention of its long-term fertility[15].

1.2.2. Constitutionalising of organic standards

The requirements set for food grown by means of organic resources were high: a low degree of processing and high amounts of whole grains. By abstaining from the use of questionable substances (Nitrite curing salt), as well as substances deemed unnecessary during food processing, it was hoped that the health benefits of the food be retained. At Bioland and Demeter the focus on health benefits was especially pronounced: Alcohol and flour products were taboo. For a long time, they were not allowed to carry the associations' labels.

12 Cf. Liebig, Justus von (1856): Ueber Theorie und Praxis in der Landwirthschaft. Braunschweig.

13 Cf. Die Zeit (1949): Sir Albert Howard schriebt… In: Die Zeit vom 10.03.1949. Available online: https://www.zeit.de/1949/10/sir-albert-howard-schreibt (accessed on 10.01.2019).

14 Cf. Allgemeine homöopathische Zeitung (1952), Vol. 157, p. 5-6.

15 Cf. Rusch, Hans Peter (2014): Bodenfruchtbarkeit: Eine Studie biologischen Denkens.

While many different forms of organic agriculture were leading a niche existence without much economic reach or impact, the amount of criticism regarding the ever more intensive chemical-industrial agriculture increased steadily, leading to statements such as this one from a DLG notification (German Agriculture Association, DLG) regarding a conference about soil machining:
"Anyone who thinks that he can use modern chemistry to compensate for errors or inadequate care in tillage and floor maintenance is cheating himself. The floor – with and without chemicals – will take revenge."[16]
The American Zoologist Rachel Carson too depicts the application of pesticides and the consequences of these on the whole food chain in her book "Der stumme Frühling"[17] (the silent spring).
Livestock farming was long regarded a lesser aspect of organic agriculture: Animals were to be fed the feed crops that were necessary for a healthy crop rotation and were meant to close the procedural nutrition loop, while simultaneously providing quality food and natural fertilizers.
Even today conventional chemical-industrial agriculture is coined by a increasing degree in the division of labour, the continuing splitting up of animal and plant production and growing feed imports. The amount of animal produce were growing steadily, livestock farming was optimized industrially: with the emergence of cage husbandry and the creation of hybrid strains for egg-laying hens completely new dimensions of animal husbandry opened up. Other types of animal husbandry too became subject to public scrutiny. Television shows such as Horst Sterns "Bemerkungen über das Haushuhn" (Comments regarding the domestic fowl) and "Bemerkungen über das Hausschwein" (comments regarding the domestic pig) wanted to inform about modern types of animal husbandry and the connection between these and consumerist behaviours from the 1970s onwards, without accusatory underpinnings. These shows sparked consideration in viewers and fuelled the public debate.
This public debate regarding mass animal husbandry lead to the inception of a concept for species-appropriate husbandry within the framework of organic agriculture in the 80s and 90s. The by then established organic agriculture associations (In Germany mainly Bioland, Demeter, Naturland) began defining rules for husbandry, feeding practices and health maintenance of animals. These concepts were integrated into the European organic regulation through (EEC) 1804/1999 in 1998 and were consequently further developed since then.

1.2.3. Characteristics of organic agriculture

In the vein of the recital mentioned at the beginning of this chapter organic agriculture to this day is grounded in and coined by:

- A biological understanding of soil fertility.
- The goal of maintaining or improving soil fertility by using a sensical combination of plant and soil-bound animal farming.
- Respecting and maintaining the natural processes of biodiverse ecosystems.
- The application of biological substances (aided by organisms) and organic farming practices (Synergies or agricultural and cultivation measures) in order to maintain the agricultural ecosystem.
- Species-appropriate animal husbandry, maintaining a high level of animal protection.
- Keeping of livestock that is well adjusted to environmental factors.
- Health maintenance of animals by selection of adjusted breeds, species-appropriate husbandry conditions and species-specific and appropriate feeding.
- A high degree of animal protection also in the interaction with animals up to and including slaughter.

The goal behind this is to provide consumers with high quality food items.
Under consideration of these goals and demands of organic agriculture (and the official assurance by European law) it is obvious that the scope is much larger than a simple abstinence from chemical-synthetic adjuvants (pesticides and fertilizers). This is especially true for the core areas of soil fertility, biodiversity, stability of the agricultural ecosystem and species-appropriate husbandry.
Organic agriculture therefore demands a conscious decision for these systems and a goal-oriented acting, design and investment in agricultural operations.
Particularly in regard to soil, plant, animal and human health this also includes the abstinence from mineral fertilizers, chemical-synthetic pesticides, genetically modified organisms (GMOs) and numerous other additives and adjuvants. "Abstinence" (from pesticides and fertilizers) alone however is by far insufficient however for organic agriculture.
It has been common knowledge for a while that the qualities and advantages of organic agriculture lie in the means of production and the goal-guided design of agricultural production processes. Evidently however organic agriculture has to take place in the natural environment of the 21st century. Trace contaminants such as lindane, DDT, dieldrin and endosulfan but also the ever-present glyphosate and other substances, some

16 Warum heute eine Tagung über Bodenbearbeitung? In: Mitteilungen der Deutschen Landwirtschaftsgesellschaft 79 (1964), p. 1241-1242; p. 1241.
17 Cf. Carson, Rachel (1963): Der stumme Frühling (Silent Spring), Biederstein Verlag.

even having been banned for years in the European Union are unavoidable. To add to this there are those pesticides that are not illegal, such as prosulfocarb and pendimethalin, that are brought out in chemical-industrial agriculture and get distributed over large areas.
With considerable foresight earlier definitions and regulations have not focused on products having to be uncontaminated and weren’t written around abstinence from adjuvants, but have always focused on the production process. This starts with the application of organic dynamic compounds and ends with the treatment of animals and their appropriate husbandry. The production process defines the organic quality rather than the quite random presence or absence of specific substances.

1.2.4. System-intrinsic barriers and constraints

Only the substances that are to be abstained from are accessible for a chemical-physical analysis. Crop rotation, free ranging, grazing and soil health or rather the impacts of these on the final product are (so far) not analytically detectable. The food analysis regarding pesticide residues has developed in conjunction with the usage of pesticides and parallel to the development of residue threshold regulations: the official procedures from sample collection, starting with regulation 76/895/EEC in 1976, followed later by 2002/63/EU, up to the analysis and interpretation of results were always designed around threshold concentrations. They regulate and analyse what ends up in the hands of consumers, in the sense of a product sample. That the regulations that are effective towards this purpose are ill-equipped to deal with organic production processes can be proven to an assuring degree, is undoubtedly true.
Sample collection within the framework of controlling organic agriculture need therefore be done and interpreted in the light of these systemic constraints: while they are able to shed light on the small area of “illegal substances”, they do not do justice to the wholistic system of organic agriculture.
To add to this there is no regulations regarding processing of organic produce in European law per se. Goals and values of the processing are only described in very loose terms and regarding processing methods there are only very few restrictions, such as the irradiation with ionising radiation., very specific wine curing procedures and genetic editing. Central to processing of food and feed is the stipulation that (almost) only organic substances are used and a reduced number of allowed adjuvants.
When disallowed substances are found in processed products the cause is often quickly identified. A contamination with pesticides can however have many causes: application or cross-contamination in production, purposeful or accidental mixing with conventional products, impurities or “carry-over” in storehouses, in transport or in processing facilities. The analytical result is often unable to identify these causes.

For further reading:

Aubert, Claude (1981): Organischer Landbau / von Claude Aubert. Bearb. Von G. Kahnt. Stuttgart, Ulmer.
Crookes, William (1898): Address of the President before the British Association for the Advancement of Science, Bristol, 1898. In: Science. 1898, p. 561–575.
Heckman, J. (2006): A history of organic farming: Transitions from Sir Albert Howard’s War in the Soil to USDA National Organic Program. Renewable Agriculture and Food Systems, 21(3), 143-150.
Hermann, A. (1965): Haber und Bosch: Brot aus Luft – Die Ammoniaksynthese. In: Physik Journal. 21, 1965, p. 168–171.
Kahnt, Günter (1986): Ökologischer Pflanzenbau: Möglichkeiten und Grenzen ökologischer Anbausysteme. Stuttgart, Ulmer.
Klapp, Ernst (1971): Wiesen und Weiden, Eine Grünlandlehre. Paul Parey, Berlin.
Liebig, Justus von (1856): Ueber Theorie und Praxis in der Landwirthschaft. Braunschweig, F. Vieweg und Sohn.
Steiner, Rudolf (1924): Geisteswissenschaftliche Grundlagen zum Gedeihen der Landwirtschaft, (Landwirtschaftlicher Kurs), 8 speeches, cited according to http://anthroposophie.byu.edu, 4. Auflage 2010. summarised here: https://www.lebendigeerde.de/index.php?id=steiners-kurs-fuer-landwirte.
Vogt, Gunter (2001): Geschichte des ökologischen Landbaus im deutschsprachigen Raum [History of organic agriculture in the German-speaking region]. Ökologie & Landbau 118 (2/2001):47-49 (Teil 1) and 119 (3/2001):47-49 (Teil 2).

1.3. Increasing sensitivity – Progress in instrumental analysis

Regarding methods and instruments within the screening of organic products, pesticide and contaminant lab analyses play a special and significant role. This is due to OCR art. 37 paragraph 1 mandating ministries to appoint laboratories that, in addition to being accredited according to EN ISO/IEC 17025, are capable to provide "expertise, equipment and infrastructure required to carry out analyses or tests or to make diagnoses". The responsible authorities are required to test and assess this regularly.

Art. 34 paragraph 4 of the OCR goes as follows: "Wherever possible, methods used for laboratory analyses shall be characterised by the relevant criteria set out in Annex III".

Characteristics of the analytical methods according to Annex III of the OCR are:

"(a) accuracy (trueness and precision),
(b) applicability (matrix and concentration range),
(c) limit of detection,
(d) limit of quantification,
(e) precision,
(f) repeatability,
(g) reproducibility,
(h) recovery,
(i) selectivity,
(j) sensitivity,
(k) linearity,
(l) measurement uncertainty,
(m) other criteria that may be selected as required."

In the following the terms of the corresponding letters a, c, d, i, j and l will be more closely discussed, since these are of relevance especially during interpretation of analytical results.

1.3.1. Accuracy of analytical results

The accuracy of analytical results is a qualitative descriptor of the scope of convergence between measured results and the "true" value. Therein the accuracy describes the total deviance, which is comprised of the systemic error (correctness) and the random error (precision). The systemic error (Figure 1, top right bull's eye) can only be corrected by removing its cause, the random error (Figure 1, lower left bull's eye) can be statistically reduced by doing multiple analyses.

The challenge laboratories face is to achieve a high degree of accuracy of analytical results in day to day operations, so that the measures that are grounded in them are justified, as these can have a significant economic impact.

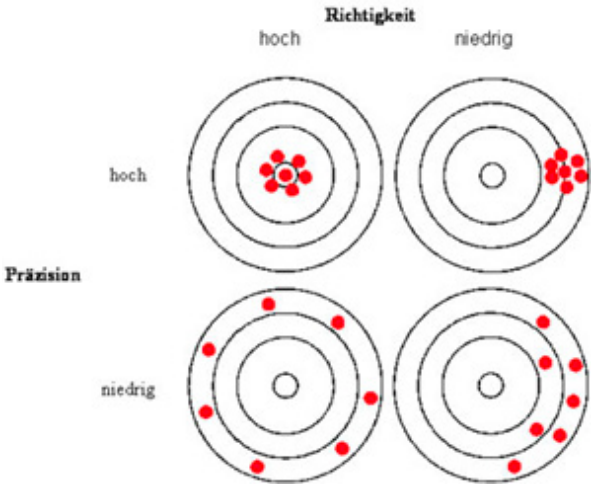

Figure 1: Relationship of correctness and precision

As an external quality assurance measure to test the accuracy of their analytical methods, laboratories should regularly participate in ring test and other competency tests (refer chapter 3.1: Selecting laboratories and service providers).

1.3.2. Limit of Detection (LD)

The limit of detection is the concentration threshold above which a substance is regarded to be present in a sample. Substances with concentrations below the detection limit are defined as not detectable (short: n. d.)

The calculation of the detection limit can for example be done according to the guidelines published as DIN 32645 (German standard). In chromatographic practice the detection limit is – for purely pragmatic reasons – set as the standard deviation from the mean of the chemical and electronic noise multiplied by three:

$$\text{detection limit} = \bar{y}_N + 3 \times N_\sigma$$

$\bar{y}N$ = mean $\bar{y}$ of the noise
$N\sigma$ = standard deviation σ of the noise

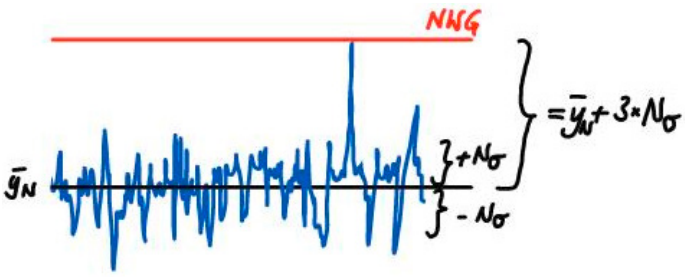

Figure 2: Determination of the detection limit

1.3.3. Limit of Quantification / Quantification Limit (LoQ)

The limit of quantification is the smallest concentration of a substance in a sample that can be quantified. Only concentrations at or above the limit of quantification are quantifiable (e.g.: 0.36 mg/kg). The limit of quantification is the concentration at which a measurement can provide a specific level of precision, for example a relative standard deviation of ±25 % in case of pesticide residue analysis.
Analogously to the detection limit, the limit of quantification is set as standard deviation from the mean of the chemical and electronic noise, but multiplied by nine:

$$\text{Limit of Quantification} = \bar{y}_N + 9 \times N_\sigma$$

$\bar{y}N$ = mean $\bar{y}$ of the noise
$N\sigma$ = standard deviation σ of the noise

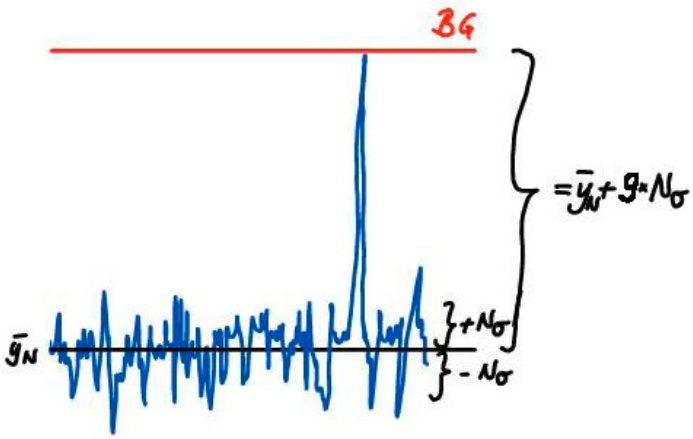

Figure 3: Determination of the limit of quantification

The concentration of a substance present between the detection and the quantification limit is designated as < LoQ or "below limit of quantification". In different terms this means that the substance, albeit being qualitatively detected, cannot be quantified reliably regarding its concentration.
The "reporting limit" is an important term in day to day operations. In the document SANTE/11813/2017 "Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed" the term "reporting limit" is described as a reference value for statements regarding the specific quantifiable concentration of a substance that can be ensured by a lab over the course of 12 months[18].
The reporting limit isn't actually a technical trait, but rather a "pragmatic limit" that can be achieved in routine operations. Thereby, it is important that the reporting limit must be equal or greater than the detection limit. Usually it is greater than, rather than equal, the limit of quantification set by a standard (e.g.: DIN 32645).
The reporting limit is therefore the lowest concentration value that a laboratory can guarantee in its routine work, e.g. for the determination of pesticides in food and feed.

1.3.4. Selectivity

Selectivity, also known as specificity, describes the level of vulnerability of an analytical method to disruption. A method is seen as selective, if it is able to capture the substance in question undisturbed by other components present in the sample. The higher the selectivity of an analytical device, the smaller the chance to get a wrong measurement. The commonly employed tandem mass spectrometry (MS/MS-method) is a highly selective and similarly a highly sensitive method of measurement. Therein the tandem mass spectrometer serves as a detector for the gas chromatograph (GC) or liquid chromatograph (LC).

1.3.5. Sensitivity

Sensitivity, according to the German standard DIN 1319, is defined as the change in the value of the output variable of a measuring device in relation to the change in the value of the input variable that causes it. In every day practice of residue and trace analysis this equates to the gradient of the calibration line, as well as the respective signal to noise ratio (S/N; relationship between size of the substance's signal and the baseline noise).
The following chromatograms impressively show the quantitative detection of the fungicide Cyprodinil with a concentration of 0.004 mg/kg in fruit samples in figure 4 from the year 2010 (S/N ≈ 10:1) and in figure 5 from the year 2019 (S/N ≈ 100:1). The drastically improved sensitivity gained from technological advancements is striking.

18 Cf. European Commission (2017): SANTE/11813/2017, Guidance document on analytical quality control and method validation procedures for pesticide residues and analysis in food and feed. Appendix D, p. 40. Available online: https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_wrkdoc_2017-11813.pdf.

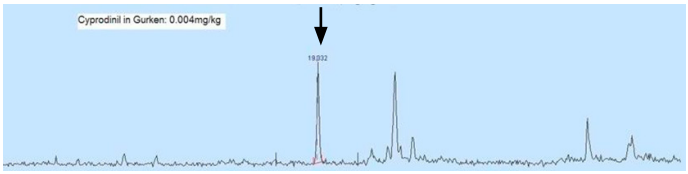

Figure 4: Detection of 0.004 mg/kg cyprodinil using GC-MS, measured in 2010 (matrix cucumber)

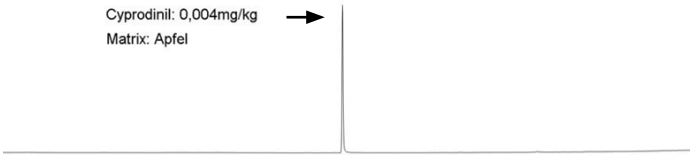

Figure 5: Detection of 0.004 mg/kg cyprodinil using GC-MS/MS, measured 2019 (matrix apple)

1.3.6. Measurement uncertainty

The reporting of results in test reports normally happens in the form of a measured concentration in combination with a dimension. However, measurements are not inherently fixed numeric values, but rather subject to typical fluctuation. Way back in 1982 William Horwitz[19] found a relationship between the level of substance concentration and the variability coefficient VC (figure 6). In this figure for instance the relative standard deviation at a measured concentration of 0.050 mg/l is about 25%, meaning that in a repeated analysis the measured concentration is likely to be between 0.038 mg/l and 0.063 mg/l. At a concentration of 0.010 mg/l the variability coefficient is already at around 32%.

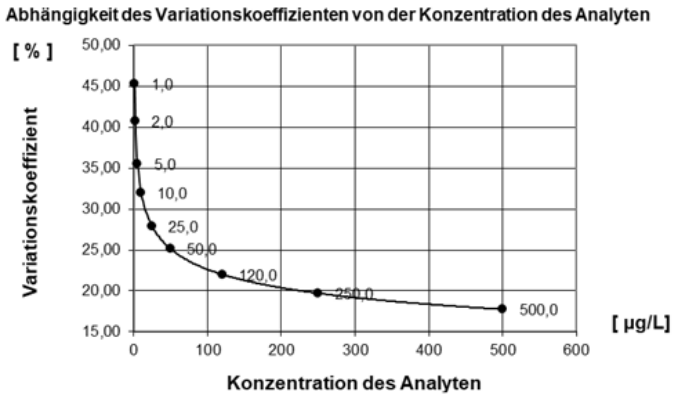

Figure 6: Dependency of VC on the concentration of the analyte according to Horwitz

Despite the great advances of instrumental technology this relationship remains unchanged, as the mostly non-automated sample preparation in the lab is a main factor for measurement uncertainty. As confirmed by the variability in current method ring tests, the Horwitz formula is still a reliable way of approximating measurement uncertainty.

The uncertainty of measurement u describes the precision of a measured value. However, this uncertainty is not restricted to measurement, but rather includes all identifiable and assessible influences of the whole analytical method to the highest degree of accuracy that is possible. This includes

- sample preparation (partitioning, homogenisation, weighing, etc.)
- sample processing (digestion, extraction, clean-up, enrichment)
- measurement and analysis.

The result with its statement of uncertainty in the test report doesn't consider uncertainties in sample collection however, but rather only the specific uncertainties of the sample once arrived at the lab ("lab sample").

The measurement uncertainty for the whole process can only be calculated by determining the specific uncertainties of precision data (e.g. from ring tests, control cards, calibration and multiple analysis). The basics of uncertainty calculation and determination can be extracted from the "Guide to the Expression of Uncertainty in Measurement" (GUM). The NORDTEST-concept20 has proven to be a practical approach for residue analysis laboratories in determining measurement uncertainties.

Measurement uncertainty is not a fixed value, but rather undergoes constant change. It is especially linked to the technical state of analytical devices, the qualifications of employees and the frequency with which the method in question is being used at the lab.

19 Cf. Horwitz, William (1982): Evaluation of analytical methods used for regulation of foods and drugs. Anal Chem 54 (1): 67A-76A.

20 Cf. NORDTEST Report TR 537 (2004): Handbook for Calculation of Measurement Uncertainty in Environmental Laboratories, http://www.nordicinnovation.net/nordtestfiler/tec537.pdf, 2nd edition, Espoo.

Example for measurement uncertainty
The standard measurement uncertainty assumes a confidence interval of 68%, meaning that repeated measurements would be within the scope of this uncertainty with a probability of 68% (result ± uncertainty). If required by the client the lab can also state the level of confidence in addition to the uncertainty:
"0.048 mg/kg Fludioxonil were measured in the sample. The measurement uncertainty of the result covering the whole analytical process is 25% at a confidence interval of 68%."

Laboratories that have specialized in residue analysis tend to achieve a measurement uncertainty u (confidence interval: 68%) of around 25% when testing for pesticides in food and feed. Uncounted amounts of method ring tests of European laboratories confirm this.
In order to be able to compare lab test results in one and the same matrix (≙ homogenate) the confidence interval is expanded to 95%, so that the **expanded uncertainty U** is increased to 50%. (see fig. 7).

U = 2 * **u**

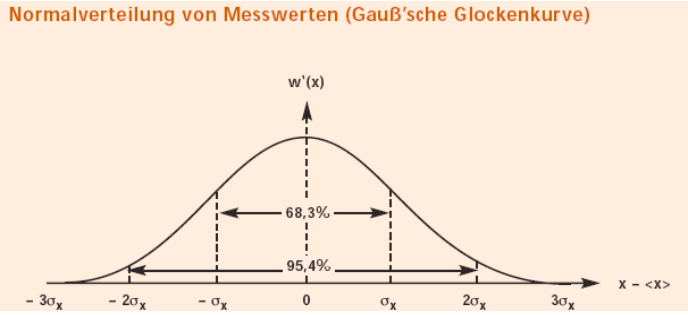

Figure 7: Standard uncertainty u, expanded uncertainty U[21].

Especially when talking about legal limit exceedances and the resulting legal consequences such as enforcement actions, the expanded uncertainty of the result is taken into account:

1) assured LLE
2) non-assured LLE
3) no LLE
4) no LLE (assured)

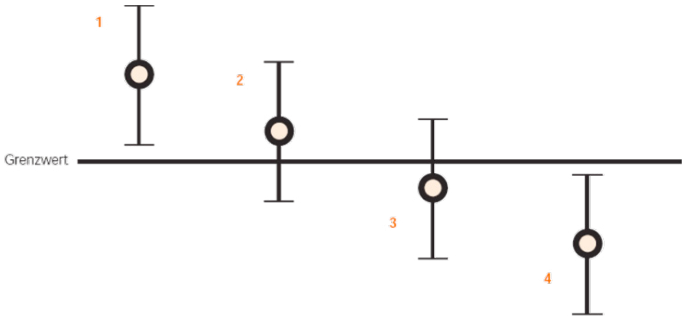

Figure 8: Consideration of expanded uncertainty U[22].

Case 1) In figure 8 the test report clarifies:
"The maximum residue level (MRL) for the active substance … has been exceeded in the sample, including under consideration of the expanded measurement uncertainty of ± 50% (document no. SANTE/11813/2017). According to the regulation (EU) No. 396/2005 in its currently valid version, the sample is thereby not marketable."
Case 2) In figure 8 the test report clarifies:
"Under consideration of the expanded measurement uncertainty of ± 50% (document no. SANTE/11813/2017) the maximum residue level (MRL) for the active substance … is not clearly exceeded. Within the scope of the conducted analyses the sample conforms to the regulation (EU) No. 396/2005 in its currently valid version and is still to be regarded as marketable."

1.3.7. Increasing sensitivity – present and future

Rapid improvements in instrumental analysis, the miniaturisation of methods (e.g. the pesticide multimethod QuEChERS, see chapter 3.2.1.) and the continued automatization have led to faster, more accurate and more selective methods in residue analysis over the last two decades. Today labs a routinely able to detect and reliably quantify analytes in the lower µg/kg range. Especially the MS/MS-method with its high selectivity allows the detection of a large range of substances in basically any matrix in a single run. At the beginning of

21 M. Jezussek (2017): Krisenkommunikation: Handhabung von Befunden, joint workshop 26.04.2017 in Frankfurt a.M.

22 M. Jezussek (2017).

the 2000nds the parameter scope of the multimethod DFG-S19 was at about 150 to 200 pesticides, today the multimethod QuEChERS includes up to 700 substances (see fig. 9).
Especially the developments in the coupling of liquid chromatography and the tandem mass-spectrometry (LC-MS/MS) were a large step for residue analysis and have significantly increased the scope: Now even small polar compounds such a for example metabolites of pesticides or Phosphonic acid and the Chlorate-ion are analytically detectable.
However, in the view of the author it is not likely that analytical devices are to become significantly more sensitive in the near future. This is based on the fact that the reagents, vials and tools in the lab are generally contaminated in small trace amounts. In this way they create blind levels at the same level as the contaminant that is to be detected in the samples. It is however likely that instead the accuracy of residue analyses will still increase in the future.
Optimization potential exists in the chromatographic phases, which are used in the LC-MS/MS-coupling. This could, amongst other things, establish a “polar multimethod”, allowing an even greater spectrum of substances to be analysed in a way analogous to the QuEChERS-multimethod.
With the consecutive development of the Time-of-flight mass spectroscopy it will be possible in future to identify the structures of unknown compounds (pesticides, metabolites, contaminants) in ultra-low trace concentrations. In this way more and more substances will be brought into the scope of surveillance and adulterations or non-declared compounds will be easier to identify.
The mantra of the future is therefore: faster, more accurate and more comprehensive.

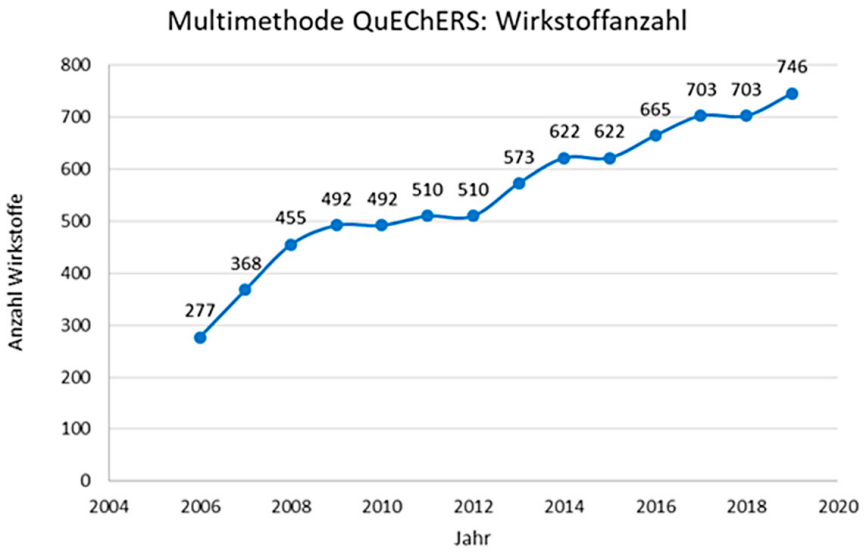

Figure 9: Typical development of the multimethod in a residue analysis lab.

1.4. Non-normalised mass wares – regarding the inhomogeneity of agricultural produce

Agricultural products are resources for food and feed. These are products whose development is influenced by various factors: the soil, the weather and the climate, the near and the far environment and many others. To add to this There are also small-scale and practically unquantifiable influences: uneven distribution of contaminants in the soil, as well as traces of pesticides and other chemicals that are spread via wind and rain, via dust particles or ground water. Thus, each plant integrates the environmental effects of its specific location during the growing season, whereby certain substances can accumulate strongly in the different parts of the plant (e.g. volatile pesticides in oils and essential oils, cadmium in flowers, chlorinated hydrocarbons in seeds). Since soil conditions, air and drift currents, precipitation events and soil erosion/entry are never completely homogeneous over large areas, this initially causes considerable inhomogeneity within the population. Additionally, there is the possibility of unauthorised substances and contaminants maybe introduced into the products during harvest, transport or storage, for example grain residues from a previously harvested lot in the combine harvester, or dust from previous transport in trucks, or conveyor equipment. Transport or transfer operations often lead to segregation of particles of different sizes due to shocks or vibrations, so that particles from paints or surface coatings are concentrated at the bottom of containers.

Therein follow two assumptions: agricultural products are generally not homogenous and the inhomogeneities as well as unauthorised substances are unevenly distributed in larger batches or lots.

These conclusions are valid first and foremost for the "field sample" (chapter 1.4 and 1.5). In experiments Carlsen et al.[23] found drift in an area of 150 meters around a treated field between zero and ten percent of the application amount for ten different herbicides. This shows: a field-population will almost never be homogenous regarding pesticide drift. Sampling close to production on the farm prior to mixing by relocation, batch formation, transport etc. thus initially maps the inhomogeneities within and between the different fields. The unpredictable contaminations of harvested crops from peripheral locations is not eliminated by incomplete mixing during reloading by harvesting machines (e.g. combine harvesters) onto trailers and during goods movements in the warehouse and during transport (storage, transfer and removal from storage).

The known inhomogeneities have an impact on sampling and are a recommendation for risk-oriented sampling in the near-production area: in that way grain samples, which are taken near storage walls or dust samples in warehouses can indicate insufficient cleaning procedures (for example after application of "chemical" storage protection agents). While representatively taken and mixed samples (in accordance with directive 2002/63/EC) could disguise these insufficient cleaning procedures, a non-representative edge sample in conjunction with another non-representative sample from the centre of the storage unit can give a clearer statement. In the case of already known trace entries of plant protection products, drift can be determined by field edge samples in comparison to samples taken in the middle or away from drift sources. Unfortunately, there is little scientific knowledge about the specific conditions and inhomogeneities in agriculture, so that intuition and experience in sampling are primarily required.

1.4.1. Example GMO-contamination: Why sampling is hardly reproduceable

Many sampling procedures in the past have assumed that contaminations in agricultural bulk materials as well as in solid batches were more or less equally and randomly distributed. This was examined thoroughly in the so-called KeLDA (Kernel Lot Distribution Assessment) study[24].

This project analysed the circumstance, that GMO analyses with high specificity measurement methods simultaneously showed very high measurement uncertainties for several years. The KeLDA study addressed the question of whether the reason for the high error rate might be the inhomogeneity of the initial goods. The results are summarised in concise abstracts:

"The reliability of analytical testing is strongly affected by sampling uncertainty. Sampling is always a source of error and the aim of 'good' sampling techniques is to minimize this error."

"[...] Generally, the distribution of genetically modified (GM) material within a sample is assumed to be random [...]. This assumption was never verified in practice [...]."

23 Cf. Carlsen, S.C.K.; Spliid, N.H.; Svensmark, B. (2006): Drift of 10 herbicides after tractor spray application. 2. Primary drift (droplet drift), Chemosphere, Volume 64, Issue 5, 2006, p. 778-786, ISSN 0045-6535. Available online: https://doi.org/10.1016/j.chemosphere.2005.10.060.

24 Cf. Paoletti, Claudia et al (2006): European Food Research and Technology 224, Available online: https://link.springer.com/article/10.1007/s00217-006-0299-8 (accessed on: 16.12.2019)..

An examination of 15 lots of soya in 100 individual samples each in chronological order resulted in: *"[...] All the lots display significant spatial structuring, indicating that randomness cannot be assumed a priori [...]."*

Thus, when if inhomogeneity in spatial structures has to be assumed for a batch of an agricultural product this has consequences for the reliability of assessments of complex batches based on analytical results. The following figures this has consequences for the reliability of assessments of complex batches based on measurement results (see figure 10 and 11).

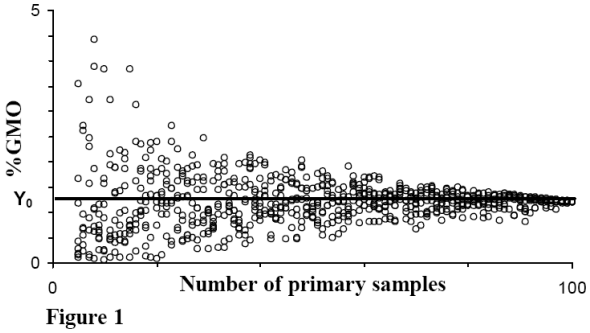

Figure 10: Correlation between measurement values and number of primary samples.

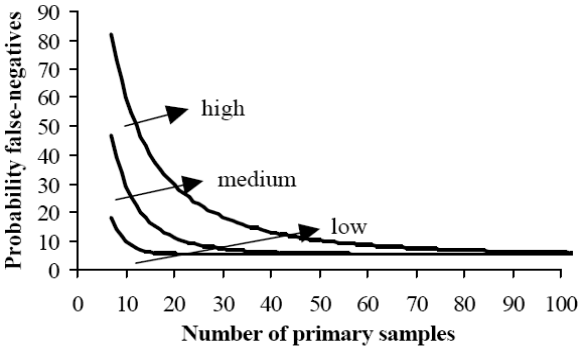

Figure 11: Correlation between measurement values and degree of heterogeneity.

If the number of primary samples is too small, the probability of error in relation to the indication of average quality will increase significantly. Is the number of primary samples is sufficient, the result will be highly indicative of the average exposure. Nevertheless, the pointwise load can deviate considerably from the average value.

In cases where a high degree of spatial inhomogeneity must be assumed, both positive and negative results may therefore not be representative. Paoletti et al. become even more clearer here. They conclude that "in general, impurities in bulk material batches are not randomly distributed and therefore, the common assumptions for sampling lead to errors". [25]

The above results refer to GMO impurities in bulk materials. They therefore deal with a very specific quality of both impurities and detection methods. Nevertheless, the conclusions regarding spatial inhomogeneity in bulk solids can be extrapolated to other impurities that are introduced accidentally and unnoticed. Examples would be accidentally adding a small number of conventional crops to organic crops or for other bulk agricultural products. If the deviation from average quality is bound to discrete particles, then these can occur in spatial structures. A single grain is either organic or conventional, GMO or non-GMO. Contamination of organic products in the field (for example by drift) now leads to overlapping problems: all grains in the organically cultivated field have been produced correctly, but nevertheless they were contaminated with pesticides in different ways depending on exposure. In the harvest there is on the one hand no perfect mixing in the crop and on the other hand, contaminated crops still remain organically produced. For the sampling this means: if the sample is representative for the total harvest, usually only smallest traces of drifted pesticides will be found. A later sample from sub-batches however may show a level of pesticides, supporting a suspicion of conventional methods being employed or of a mixing with conventional crops despite our example being completely in line with organic regulations.

1.4.2. Variability of pesticide residues

A publication of the EFSA Journal deals with the variability of pesticide residues from active application.[26] AIn response to a request from the European Commission the *"Wissenschaftliche Gremium für Pflanzengesundheit, Pflanzenschutzmittel und ihre Rückstände"* (scientific panel on plant health, plant protection products and their residues) evaluated corresponding data. The guiding question was whether the spread of pesticide residues would require special consideration for food products with a high consumption volume (fruit and vegetables). This was triggered by the fact that the quantified residues within a batch could show a surprising high variability (variability factor of 7 or more)

25 Cf. Paoletti, C., Donatelli, M., Kay, S., Van den Eede, G. (2003): "Simulating kernel lot sampling: the effect of heterogeneity on the detection of GMO contamination", Seed Science and Technology 31(3), 629-638.

26 Cf. The EFSA Journal (2005): Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a re-quest from Commission related to the appropriate variability factor(s) to be used for acute dietary exposure assessment of pesticide residues in fruit and vegetables" Vol. 177, p. 1-61.

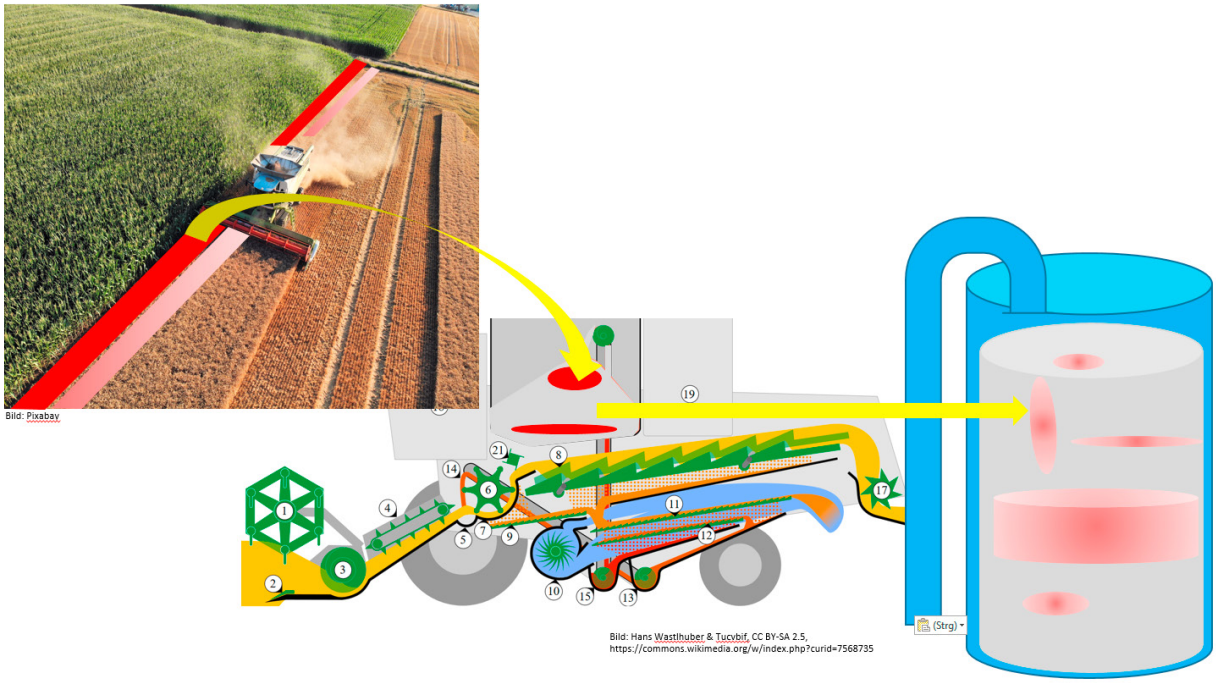

Figure 12: Mixing of contaminated and uncontaminated subsets by threshing on the neighbouring conventional field

for two consumption units of conventional fruit or vegetables.

Based on the inhomogeneity of the raw material, the level of pesticide residues will practically never be the same everywhere. Areas with significant levels could be situated right next to areas where no levels can be detected.

A solution to this would be the creation of a homogenous mixing of raw materials, a task that is practically hardly achievable. Mixing a delivered batch 25 tonnes cereals in a way so that it becomes homogenous is technically already almost impossible, in practice such batches are almost never mixed.[27]

In the case of agricultural products in medium to large units (e.g. pumpkins, fruit or potatoes), it is easy to understand that even with a technically good pesticide application (due to different exposures, the location on the tree or bush, coverage by foliage or variations in spraying equipment due to soil unevenness) the locally applied amount of pesticides will differ. Regarding cereals and other bulk material, a closer look is required.

Inhomogeneity due to harvesting procedures

If a farmer starts threshing a crop along the border of a conventionally cultivated neighbouring field, he will harvest the "most heavily loaded" lot with the first harvest width of the combine (see Fig. 12). It is then stored at the bottom of the combine's bunker. From there the yield will be transferred to transport vehicles, meaning that this part will also be the first to be unloaded. During this process the highly loaded and the less loaded subsets of the yield will be mixed slightly, obscuring the border between the highly contaminated parts and the less contaminated one. A complete mixing during transport and stock transfer operations however does not take place. If a sample is then taken from warehouses, there is always the risk of randomly sampling correspondingly contaminated areas and thus not showing the entire batch in a representative way.

But in the end, the expectation of a homogenous spread throughout charges is still unlikely at best.

In addition, it can be surmised from general rules in chemistry, that as the concentration decreases, the number of substances present increases. Considering the increasing sensitivity of analytical methods and the ability to detect even small traces, it is unavoidable that more and more unwanted substances will be detected in future.

27 Cf. Rombach, Martin (2015): Manual "Risikomanagement von Pflanzenschutzmittel-Rückständen in Lebensmitteln aus Ökologischem Landbau", published in GfRS Gesellschaft für Ressourcenschutz mbH (Hrsg.), Göttingen/Karlsruhe, supported by Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (BMELV) within the federal program Ökologischer Landbau Forschungs- und Entwicklungsvorhaben 03OE461.

1.4.3. Summary

For sampling of solid products in warehouses or in production processes should be considered: Sampling methods that are designed to provide an average sample which is as representative as possible as a composite sample will often paint an inaccurate picture of the actual exposure at a specific place. When selecting the samples, a decision shall be made as to whether representative or targeted sampling is to be used. The purpose of the sampling determines the sampling method and must be documented. The evaluation of the analytical result must take into account the purpose and method of sampling.
For the sampling in the field or close to the place of production: Since the harvested units are not homogenous, the term batch refers here mainly to delimit able characteristics such as species, variety, date of harvest and field / region, but not to characteristics that can only be identified by analysis. These include factors such as water and protein content, but also geogenic heavy metals and contaminations by pesticides and mycotoxins There may be gradients in levels or “hotspots” that cannot be realised. This can be compensated for by sampling, which is as representative as possible, which in turn will not detect “hotspots” and zones of impurities.
Regarding liquids in tanks a higher degree of homogeneity is to be expected.

1.5. What does the representative sample represent? Sampling in the dilemma between ideal average and single control point

Reliable analytical results are a basic requirement to use lab analyses within the framework of the organic control procedure. Badly matched and hardly retraceable results can lead to unjustified action and in the worst case to irreparable reputational damage and financial harm.
Diverging analytical results of samples taken from the same charge or lot of a food item can have several reasons. It is only seldomly the fault of the laboratory.[28]
In addition to the technical factors surmised in chapter 1.4 the time factor can also affect results from the same charge differently: As many pesticide compounds change their chemical make-up over time (metabolization, breaking down, evaporation) the pesticide concentration tends to trend downwards over time if analysis does not happen immediate after sampling.
An usable lab result crucially depends on the employment of meaningful methods and strategies during sampling. The task at hand and the situation one finds themselves in at the place of gathering decide on the sampling approach: as representative samples or as risk-oriented single samples. It is important for the lab to know the purpose of the sampling and what questions are to be answered by the analysis.
Only then it is possible to implement a meaningful sampling strategy. In addition to the sample approach resp. type (representative, risk-oriented, single sample in response to inconsistencies) the gathering method is relevant. A sample devoid of purpose or any kind of specification is not useful in the context of the organic control procedure (see also chapter 1.7).

1.5.1. Why is the sampling so important?

Analytical results are often pivotal during important decisions along the food supply chain and during official controls of food and feed.
While the validation methods and analytical competence schemes focus on the analytics, other important steps such as sampling, sample transport and sample preparation (partitioning, grinding, homogenisation) are often disregarded.
Meanwhile the influence of sampling on the variation of the final analytical results is often greater than expected. The relevance of single factors of influence on the measured result declines from the sampling

28 Cf. relana® Position Papers 19-01, 19-02 und 19-03 at http://www.relana-online.de/position-papers/.

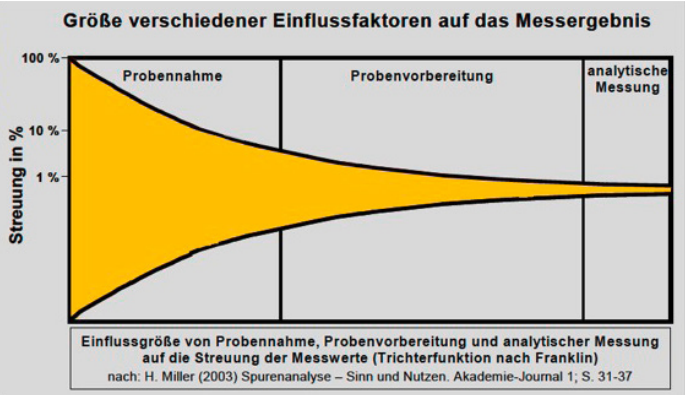

Figure 13: Influence of "sampling" (Probenahme), "sample preparation" (Probenvorbereitung) and "analytical measurement" (analytische Messung) on the variation of analytical results ("Streuung" = variation).

over the sample preparation towards the analytical measurement (see fig. 13). Any mistake during sampling has a high chance of leading to a questionable if not at worst useless result.

1.5.2. Purpose of sampling

The basic responsibilities of official controls are defined in the official controls regulation (OCR) (EU) no. 2017/625 in article 1, paragraph 2a as follows:
"food and food safety, integrity and wholesomeness at any stage of production, processing and distribution of food, including rules aimed at ensuring fair practices in trade and protecting consumer interests and information, and the manufacture and use of materials and articles intended to come into contact with food".
The areas of food safety as well as health innocuousness are covered by respective measures (official food monitoring among others) by the official food safety administration for all food items and therefore also for organically produced ones (see box).
For this purpose, sampling and lab analysis is conducted in yearly programs on the federal and state level in Germany. The method that is defined by official norms is mostly focused on the surveillance of residues (after application of legal pesticide formulas in conventional agriculture under the rule of the "good agricultural practice") and contaminants. The goal is to identify if the batch or lot is compliant with the legal requirements and specifications.
Relating back to the "organic production and labelling of organic products;" mentioned in article 1 paragraph 2i only the verification and confirmation of the product's integrity can be the goal of an official sampling. The other areas and goals of the OCR (food safety, health innocuousness) are covered otherwise (see box "Aims and legal framework of monitoring").
But what questions can be derived from the criterium of integrity for the sampling?
During production, processing and storage of organic produce sampling should only occur if a suspicion regarding the integrity of the respective product (relating to one or a number of lots) is present. At that point it has to be clarified what specifically gives cause to this suspicion:

- Is the suspicion relating to a supposed use of illegal adjuvants (agriculture inputs) such as pesticides, it is meaningful to take a representative sample. With conventional produce there is a good chance of a somewhat even distribution of the substance under suspicion, as the application of the substance is aimed at having the most effective influence on the crop.
- If the suspicion relates to pesticides or other contaminants that are likely to have come from external sources it is important to investigate whether the contamination can be traced back to the environmental factors of wind (including dust) or water (surface water, rainfall, flooding, run-off effects). If this is the case a slew of different substance should be identifiable, spread inhomogenously in the harvested lot or field. This is to be taken into account for the sampling strategy.
- If a suspicion regarding contamination during food processing can be reasoned for (for example contamination with smoke gases, which contain Biphe-

Aims and legal framework of monitoring

Monitoring serves the purpose of preventative consumer health protection. With the help of monitoring health risks for the consumer posed by substances inside and on food, cosmetic items and commodities can be identified beforehand and can be eliminated through specific action. Included in these substances are residues such as pesticides, pest control substances, mycotoxins, heavy metals, other contaminants and microorganisms. The monitoring is carried out as an independent legal requirement within the framework of official controls according to paragraph 50 to 52 of the German Lebensmittel- und Futtermittelgesetzbuch (LFGB).[i]

i Cf. Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (2018): Lebensmittelsicherheit 2018 in Deutschland. Available online: https://www.bvl.bund.de/DE/01_Lebensmittel/01_Aufgaben/02_AmtlicheLebensmittelueberwachung/04_Monitoring/lm_monitoring_node.html;jsessionid=1EE23EA1BF817CECE75527FAA0C8D351.1_cid340#doc1399894bodyText1 (accessed on 30.07.2019).

nyl, Anthraquinone or PAHs) the concentrations are hardly predictable or traceable to a source as the extent of contamination varies strongly between products and processing cycles. Here it can be advisable to take single samples from different steps of the production cycle or from different places, in case a contamination is brought into the product from the outside while it is being processed in barrels or other containing devices.

- Another cause of suspicion can be improper storage, where correctly farmed organic produce gets mixed with conventional produce during transfer procedures or is possibly even diluted with conventional produce intentionally. The application of chemical storage protection agents (Biocides) too can lead to singular contamination spikes, necessitating a proper sampling.
- If sampling proceeds due to other reasons (for example testing of soil contamination with persistent pesticides such as lindane, DDT and HCB or contaminants such as dioxins or heavy metals) it can be necessary to adjust the sampling procedure to the specific situation at hand.
- Depending on aim and purpose of the question not only food and feed are potential objects to be sampled, but rather also packaging material, plants, soil, fertilizers and others.

Depending on the specific issue at hand different sampling methods offer themselves up. A holistic method for sampling that can answer all questions does not exist however. For surveillance of food safety (for example adherence to maximum residue levels in conventional produce) and health innocuousness (for example testing of mycotoxin contaminations) representative samples are the most meaningful option. In regard to the integrity of organic produce or processed foods a representative sample is only rarely effective, only when there is a suspicion of illegal use of adjuvants (agriculture inputs). In most cases this type of sampling is not productive. Here the importance of the development of specific strategies cannot be overstated (for the different sampling strategies see chapter 3.3.2.).

1.5.3. Example cases

Small Scale Agriculture

Description of case 1:

Organic cereal field, size three hectares, 100 m × 300 m, neighbouring field along one of the long sides (300 m) with conventional (chemical) agriculture production. The neighbouring farmer is applying a fungicide shortly before harvest of the organic crop without considering the unfavourable wind conditions (strong wind in direction of the organic cereals) and without using any equipment that reduce drift.

Assumption: The organic crop field is contaminated with the fungicide 2 meters deep and 300 meters wide. This is representative of 2 % of the whole field.

Typical application rates of fungicides are around 2 l of active substance per hectare. Assuming a conventional, 5-meter-wide side-strip a length of 300 meters results in 0.15 hectares of treated area. This is equivalent to a substance amount of around 0.3 l. Under the assumption that around 0.1% of this cross-contaminates the organic field, the contamination of the organic field would come out to 0.0003 l. At a density of 1 this translates to a substance amount of 0.0003 kg or 0.3 g (300 mg).

These 0.3 grams are distributed over an area of 600 m^2 (0.06 ha) of the organic field. Assuming a 50% intake of the fungicide into the harvested crop and a yield of roughly 5 t of crop (resulting in 0.3 t or 300 kg per 0.06 ha) this results in a concentration of 0.15 g / 300 kg or 0.0005 g/kg coming out to

0.5 mg fungicide per kg of organic crop.

Which sampling strategy leads to which insights?

a) edge-row sampling
b) representative sample over the whole area
c) sampling from a silo after the harvest

to a) edge row sampling

The sampling takes place in at least six places (50 m apart), afterwards the samples are put together to form a single sample. The analysis indicates a fungicide concentration of 0.5 mg/kg or lower.

Result: The contamination was confirmed and respective measures can be taken (for example separate harvest of the side strip with conventional merchandising).

to b) representative sample over the whole area

A representative sample is taken of the whole field. The analytical result shows a fungicide concentration of less than 0.01 mg/kg (assuming the other 98% of the field show no contamination).

Result: No hints of any inconsistencies or irregularities despite part of the yield being contaminated.

to c) sampling from a silo after the harvest

The whole field is harvested with a harvester and the yield is stored (assumedly 15 t from 3 ha). The contaminated crops (roughly 300 kg) won't be distributed evenly in storage. These 300 kg will be harvested as a side strip and will be present inside the storage unit as a streak or cloud. During sampling (with access hatches or plunging pipes at different heights) the amount of contaminated material in the sample will differ substantially, depending on whether the contaminated part of the yield is "hit" or not. The analytical result will likely vary strongly from undetect-

able to many µg/ kg. As the contaminated part of the yield is distributed unevenly in the lot, the results of different samples will differ significantly. Additionally, the analytical competence of the labs will be put into question due to the assumption of homogeneity.
Result: Unclear. After a positive analytical result (detection of small concentrations of the fungicide) more sampling procedures will be enacted to verify the results. The following results will likely vary extremely and therefore cause more questions than they answer. The tool of sampling and analysis is generally not productive for processed or stored products if the respective lot is partially contaminated or mixed in with conventional wares.

Traceability of large shipments
The case discussed above is augmented by another dimension for extremely large batches. Lots in the magnitude of many thousands of tons are no rarity in the areas of cereals and oil seeds. During a representative sampling procedure of such large lots, sub-batches that are contaminated can often neither be detected nor identified. This is also true for fraudulent produce, where conventional products are mixed in intentionally, as through the effects of dilution the analytical reporting limits are undercut.
With lots that are sub-divided, the likelihood of detecting irregularities is increased however. When a lot of 5000 t of cereals or oily seed is transported in cargo hatches that can hold 500 t each it is possible to take samples of every sub-batch during loading or unloading. When some of these 10 sub-batches show pesticide contaminations this is in important hint towards possible irregularities. Additional inquiries can then be initiated by the control body responsible. It is important thereby to store the sub-batches separately even after unloading.
The sampling procedures that have been published by organisations such as GAFTA (Grain and Feed Trade Association) or FOSFA (Federation of Oils, Seeds & Fats Association) have the purpose of evaluating a whole batch in regard to its qualitative characteristics (for example oil content of a lot of oil seeds) and in regard to its specifications (this can also include the adherence to maximum residue levels). Since sampling fulfils a completely different role in the context of the organic control process, these procedures are not suitable towards this purpose and should therefore not be employed.

Contamination or mixing during processing and storage

Description of case 2:
50 kg of conventional cereals from a previous batch (in a company that deals with organic and conventional produce) are carried over into an organic lot due to deposits in pipes, etc. and are transported into a silo for organic products. The 50 kg of conventional crop show pesticide contaminations of four different active substances (three fungicides and one herbicide) between 0.05 mg/kg and 0.2 mg/kg.
Specifically:
Fungicide 1: 0.05 mg/kg equivalent to 2.5 mg in 50 kg.
Fungicide 2: 0.1 mg/kg equivalent to 5 mg in 50 kg.
Fungicide 3: 0.2 mg/kg equivalent to 10 mg in 50 kg.
Herbicide 1: 0.1 mg/kg equivalent to 5 mg in 50 kg.
Assuming an ideal mix with the following batch of 10 t of organic crop the measured levels would lie somewhere between 0.00025 mg/kg and 0.001 mg/kg. This is so low that an analysis of a representative sample would show no contamination. Such an ideal mix does however not take place. Rather a sample taken from near the bottom of the silo will show pesticide contamination while further up no pesticide contamination will be measurable.
Result: If there is reasoned suspicion that insufficient cleaning procedures are employed before the processing of an organic batch, it is meaningful to take simple risk-oriented samples from the storage unit. A representative sample is not particularly useful here.

Description of case 3:
A silo is treated with a biocide (normally an insecticide) after cleaning. The biocide sticks to the inside walls of the silo. Afterwards a batch of organic crop is stored in the silo. The cereals in contact with or near the wall are contaminated while the parts at the centre remain uncontaminated. A sampling using plunging pipes at different levels of the silo that focus only on the centre of the silo will not identify such a concentration.
Sampling after packaging in big-bags will lead to highly variable results, depending on how many grains from the vicinity of the wall are contained in the specific big-bag.
A preventative measure is the sampling of storage units before the storage or processing of organic crops, especially after renovations or cleaning. Here it is meaningful to take dust samples as well as swipe samples, to identify all possible applications of biocides as well as emissions from building materials or adjuvants (for sampling using dust and swipe samples see chapter 3.4.7.).
For other contamination scenarios similar examples can be consulted. There is no hidden mechanism at work that ensures a homogenous spread of contaminations inside a batch. Inhomogeneities and spatial structures are the rule rather than the exception.

1.5.4. Conclusion

As demonstrated by the examples a representative sample often does not verify a suspicion. Without up-

front research regarding the specifics of the case at hand it is difficult to define a workable and effective sampling procedure. Figure 13 shows clearly that an unfitting and un-reflected sampling procedure can lead to analytical results with extreme variances and as a consequence confuse rather than clarify.

If sampling is done in a representative manner the likelihood of obscuring point-like errors in organic food production is massively increased. Reason for this is the dilution effect, caused for the 2 m wide side strip by the uncontaminated rest of the lot in case 1 described above.

Risk-oriented sampling or focused single samples can help in identifying the causes of contamination or suspicion in many cases. Sanctions such as decertification of the product as non-organic or even banning however cannot be reasoned based on this in a legally sound manner. In such cases sampling and analysis can only be one piece of a mosaic in the repertoire of the organic control process.

Through sampling it is only possible to determine average contamination of an ideally mixed sample or the concrete value of the specifically sampled place, but never within reason, both simultaneously.

The different sampling methods all have their place and their respective uses, assuming the purpose of the sampling is known and considered. A single standardised sampling method for controls would not be effective, as individual cases can be fundamentally different from one another.

1.6. Who owns the analysis? Legal status of operational sampling

Preface: This chapter relates to the legal regulations for food and feed. As long as no special regulations for feed apply this chapter will only mention food or food product for the sake of readability, albeit these legal regulations apply to feed as well.

Whoever produces or brings a food product to market has to ensure that all legal requirements are met. This is true for both conventional and organic products and relates to a wide variety of parameters. It not only concerns questions regarding food safety but also labelling. Additionally, specific requirements are in place for some food categories. The requirements for organic products are based on a special set of criteria, too. Only if those criteria are satisfied, the product is marketable as being of organic agriculture resp. production.

Possible starting points for controlling marketability are physical characteristics of the item as well as the production process, the packaging and the labelling of a product. Towards investigation of this many different methods offer themselves up. These methods are constantly being developed further due to scientific progress in analytics or by new regulations.

In order to ensure compliance with the regulations, a food business operator has to get his products tested and evaluated regularly. More and more this includes sampling and lab analysis. Therefore, it can be classified as a self-control procedure as the investigation is done by a private lab on behalf of the business operator.

Self-controls belong to the scope of preventative measures that have to be taken by a business operator of organic produce.[29]

At this point the question of whether or not the business operator is obliged to provide the results of his self-controls to the organic control bodies and as a consequence to the related competent authorities?

To answer this question, one has to look at the rights and duties of the control bodies, which are granted to and imposed on them by law. The rights of the control bodies within organic food regulations is based on two pillars, one being the OCR, the other the organic regulation itself. The OCR posits that official controls include the reliability and results of self-controls of the food business operators.[30] Furthermore, the methods and techniques of official controls include investigation of self-controls implemented within the businesses and the results of these respectively.[31]

Mirroring these control regulations, businesses are obliged to comply and contribute in official controls.

29 Cf. Art. 28 organic regulation.
30 Cf. Art. 9 (1) d) OCR.
31 Cf. Art. 14 (a) OCR.

This follows from art. 15 of the OCR and states, that for example the food business operator has to permit access for the competent authorities to their electronical information management systems[32] and has to provide access to documents and factual information.[33]
The above-mentioned rights are also available to the control bodies in organic law. Because it determines that for the control bodies the requirements of the Control Regulation are applicable in addition to the regulations on organic agriculture. [34, 35]
As a conclusion, control bodies are in general permitted to get access to the self-control activities of food business operators. Access here means, that control bodies are entitled to be shown the analyses relevant to organic regulations that the business operator has access to. This might include analyses conducted on behalf of the business operator themselves but also results from third parties that the business operator was given access to, such as the analyses conducted by a supplier or client.
As a consequence, the analytical results regarding the requirements of organic agriculture have to be handed over by the business operator on demand. Demand here means, that the control body not only has the right to look on the results but can also take a copy in a physical or electronic format. At the same time ,it is made clear that the business operator is not obliged to immediately provide the results of their self-control activities to the control body without such a demand.[36]
Generally, a business operator of an organic product has to self-investigate any suspicion of non-conformity to organic requirements themselves. In case of the suspicion being justified and not easily cleared, they are required to immediately notify the responsible control body.[37]

1.6.1. Reasoned suspicion or clear case of violation?

Does this mean that a business operator is to report every suspicion of a violation of the legal requirements of the organic regulation to his control body? And what if the suspicion is confirmed and not just a suspicion anymore? Is the duty to report still valid at this point?
Here one has to differentiate. The corrective resp. guideline for reporting has to be, whether the integrity of the organic product is in question (see chapter 2.2). This teleological frame is reasoned based on the legal requirements described by article 41 paragraph 2 of the organic regulation. It states, that violations that don't endanger the integrity of the organic product don't prohibit a product from being marketed as organic. Such cases – some examples are mentioned in Chapter 1.1. – are e.g. the introduction of chlorate via drinking water or low levels of phosphonic acid in fruit or substances that are not covered by the regulation like mycotoxins. In such cases a report to the control bodies is not necessitated.
If, however, the violation is more severe than these examples, the business operator has to start an investigation. If the operator is not able to do this on their own, they will have to employ third parties to do so. He can also contact the control body, even though this in effect results as a reporting. In article 2, no. 74 of the organic regulation, characteristics that define a product as organic are listed. These characteristics must not be violated, if the integrity of the product is to be protected. In case of such a violation or the suspicion thereof, one has to heed the activities in the company itself as well as the duty to report and the proceedings of the control body, as described in articles 27 to 29, 41 and 42 of the organic regulation. Whether a violation is qualified to impact the integrity of the product can often only be decided under consideration and balancing of the pros and cons. It is however incompatible with a well-functioning control process, if every small violation is forwarded to the responsible control bodies resp. authorities for assessment, as these will have to make their own official inquiries. At this point the organic regulation puts both inquiry and assessment in the hands of the business operator. Instead of reporting every small violation and setting of an official inquiry each time the organic regulation assumes a competent, diligent business operator with assessment related skills.
So how about the question, if a violation is also to be reported when this is not demanded by the organic regulation? In a foregone conclusion the duty to report is to be assumed for violations where the law demands a report in case of suspicion. This is due to a violation also positing a reasoned suspicion which always is subject to duty to report. Analogously to the duty to report in case of suspicion the business operator should always inquire whether the violation has the potential to impact the integrity of the product.

1.6.2. What are private laboratories required to report?

At that point, the duty to report for private laboratories according to article 44 paragraph 4a of the German LFGB (German food and feed code) comes to mind. If the person in charge of a laboratory that is dealing with food product analyses has reason, due to an analysis

32 Cf. Art. 15 (b) OCR.
33 Cf. Art. 15 (d) OCR.
34 Cf. clarification in Art. 37 organic regulation.
35 Article 38 organic regulation specifically refers to the already mentioned Art. 9 OCR.
36 Cf. expressed formulation of Art. 15 OCR.
37 Cf. Art. 27 (d) organic regulation.

conducted by the lab, to assume that a product from within the country would be subject to a market ban according to article 14, paragraph 1 of reg. (EC) no. 178/2002, they are required to inform the responsible competent authority of the time and result of the analysis, the analytical method employed and the client of the analysis either on paper or electronically. This regulation does not apply to samples taken before harvest as plants are not food before harvest.[38]

This duty to report for private laboratories only applies, if the lab has suspicions regarding food safety in a sample taken from within country borders. It is therefore important to note, that only findings relating to a product that is unsafe to consume or a health hazard according to article 14 of the German basic food regulation are subject to a duty to report by the person in charge of a lab. Other non-conformities such as microbiological guideline values being exceeded in a way that is not a health risk, labelling mistakes or detection of non-approved substances are not subject to duty to report.

Regarding maximum residue levels (MRLs of pesticides f. ex.) one has to differentiate however: Only exceedance of the legal limits is not enough to trigger duty to report. This is only the case when the result of a risk assessment leads to a conclusion of the exceedance of the limit posing a health risk or is unfit for consumption. For this, acceptable daily intake (ADI) or acute reference doses (ARfD) have to be calculated. In such a case, an individual assessment is necessary.

1.6.3. Duty to report for business operators

This is to be separated from the duty to report as regulated in article 44a. This duty to report relates not to the person in charge of a laboratory but rather to the business operator themselves. The duty to report according to article 44a LFGB relates to substances that are undesirable regarding human health. This area of application, which seems to be quite encompassing at first, is however restricted strongly by other laws. This is due to duty to report only applying to those substances that are listed in specific legal regulations. The legal act being referred to here is the German national regulation on notification and transmission obligations for substances hazardous to health (Mitteilungs- und Übermittlungsverordnung – MitÜbermitV). § 1 MitÜbermitV lists only dioxins and substances similar to dioxins at the current time, and therefore only those are subject to duty to report.

Duty to report for laboratories and for business operators differ in one significant way. The duty to report that applies to laboratories according to § 44 paragraph 4a LFGB comes into effect when a specific circumstance is positively verified, in this case the presence of an unsafe food product. The duty to report that applies to business operators according to § 44a LFGB relates to every result regarding the relevant substances. This means that even analyses that show no dioxin contaminations are subject to duty to report. The duty to report for laboratories is meant to enable control bodies to immediately be able to take a product out of the supply chain if deemed unfit for consumption. The duty to report for business operators however serves merely a monitoring purpose.

Another case of duty to report for business operators in organic regulations is a reasoned suspicion of the presence of a substance that is not allowed for use in organic food production.[39] In these two cases the duty to collaborate is turned into a duty to report.

Strictly speaking, only a (confirmed) suspicion is to be reported. However, the term suspicion here has to be interpreted to include the reasons for the suspicion, meaning that a duty to actively cooperate regarding analytical self-control results of business operators can be present in effect.

1.6.4. Requirements regarding self-controls

Official sampling is nested in a rigorous and constrictive legal framework. Article 34 of the OCR contains a whole catalogue of requirements for official sampling (see chapter 1.7.). Furthermore article 35 of the OCR regulates the right of the food business operator to demand the taking of a counter sample in case of an official sampling as confirmed by the German Supreme Court.

These strict regulations do not apply to the investigations done by the business operator themselves. Of course, the business operator also has a legitimate interest in valid and, if necessary, credible analyses. Therefore, they will regularly instruct an accredited lab that has a certain level of expertise regarding specific parameters (see chapter 3.1).

However, this doesn't change the fact that the legal requirements for official controls do not apply to self-controls.

This opens up the question if results from self-controls can be regarded as equal to official sampling procedures and the analytical results thereof. Specifically, the question is whether the results of self-controls can be made the focus of official inquiries and measures.

Rightly one has to differentiate once again. Of course, the credibility of self-controls has to be assessed sci-

38 Cf. Art. 2 (3c) of Reg. (EC) No. 178/2002 laying down the general principles and requirements of food law.

39 Cf. point (d) of Art. 28 (2) organic regulation.

entifically. In case they show significant deviation from the requirements for official controls the relevance of their results is to be put into question. Depending on the degree of deviation the results of the self-control cannot be taken as sufficient reason for the implementation of official measures. Restrictions are therefore likely for non-representative samples, non-accredited labs or methods, commercial quick-tests or screenings as well as other deviations from the official methods.
When no scientific mistakes are identified however, which is generally the case, the analytical results from self-controls can be used to their full extent by control bodies. They can therefore trigger the duty to report in case of suspicions in the context mentioned above. This conclusion is supported by the legal code. Nowhere it is mentioned however, neither in conventional nor organic food regulations, that business operators have to follow article 34 of the OCR when conducting self-controls.
The authorisation of control bodies does, as shown previously, not include a restriction that only the results of official samplings have to be handed over on request.
Article 29 of the organic regulation regulates how control bodies resp. authorities have to proceed based on suspicions reported by a business. In order to identify the origin and cause of a violation or deviation the control body have to immediately initiate an official investigation.[40] At the same time they are obliged to prohibit the placing on the market of the product until conclusion of the official investigation.[41]
This shows an appropriate course of action by the legislator. In order to ensure the accuracy of the results from the self-controls another investigation is to be conducted. This doesn't however need to be an official sampling and analysis with consecutive official investigation. The control bodies should verify the situation with the tools available to them. At the same time, it is possible and might be necessary to immediately implement measures based on the self-controls by the business operator.
In food related court cases the question if official measures such as product recalls are to be based solely on official analytical results is not controversial. In fact, there are documented court cases where official measures were based on self-controls either by the business operator themselves or somewhere else in the supply chain. The credibility and legal validity of the analytical results commissioned by private (business) order were neither questioned nor rejected by courts.[42]

1.6.5. Legal consequences of credible self-controls

One has also to consider that food regulations might give reason for civil disputes between different business operators. A company can allege that their supplier has not supplied them in a way that conforms with the related regulations. In this constellation there tends to be no official investigation. Only the business operators' own investigative results are able to provide any legal basis for such allegations or to dismiss them.[43] However, both parties have the right to an official evaluation of the evidence against them.
Using self-investigative results for this purpose is by no means a new development or specific to the organic food industry. A comparison with general food regulations clarifies this. According to article 19 paragraph 1, first sentence of the European basic food regulation (EC) no 178/2002 the food business operator has to take measures to take a product out of the supply chain if he has reason to suspect a non-conformity with food safety regulations
TThe precondition necessary to pull a product out of the supply chain is then a sufficient amount of suggestive data regarding a violation of food safety. The suggestive data here is often derived from self-investigations. In practice this leads to many cases of food products being recalled based on self-investigations by a business operator. In these cases, where the business operator complies with his duty to report to the competent authorities and simultaneously pulls the product proactively, official measures are not necessary. Instead the competent authorities restrict themselves to supervise the diligent execution of the proactive recall.
To conclude, self-controls or self-investigation both in the organic as well as in the conventional food industry can trigger official measures.
Therefore, the business operator should always differentiate the objectives of their self-controls. If then their own controls can become the subject of official inquiries, they should ensure to use a scientifically sound sampling and analysis method as mentioned by the official controls regulation (OCR).
The basis for an assessment regarding maximum residue levels always has to be a representative sample.[44] Towards this purpose the food business operator should always take representative samples in accordance with official methods and should let them be analysed by an accredited lab in order to produce credible results that, if necessary, are able to withstand judicial scrutiny.

40 Cf. Art. 29 (1a) organic regulation.
41 Cf. Art. 29 (1d) organic regulation.
42 Cf. Verwaltungsgerichtshof München (2019): Ruling from 07.02.2019, Az.: 20 BV 17.1560; but also: Verwaltungsgericht Augsburg (2017): Ruling from 04.07.2017, Az.: Au 1 K 16.1531.
43 Cf. e.g.: Bundesgerichtshof (2014): Ruling from 22.10.2014, Az. VIII ZR 195/13.
44 Cf. Art. 27 (1) first sentence of Reg. (EU) No. 396/2005 or Appendix III No. 3 of directive 2002/63/EC.

Process controls, for example to verify procedures, often don't occur in a representative manner but rather a risk oriented one. If then the business operator wants to attain specific process analyses for single specific questions, then they should clarify this in the analysis order. This should also be apparent in the lab's report, so that the result can be correctly interpreted. The results of such process controls don't give any insight into the marketability of the product. They can however cause suspicion or give reason to an already existing suspicion, which then has to be handled in accordance with the criteria mentioned above.
This different approach to self-controls also has to be applied by the competent authorities when answering the question of how to deal with suspicious results from self-controls.

1.7. The official controls regulation (EU) 2017/625

The official controls regulation (EU) no. 2017/625 (here: OCR) is valid since December 14th, 2019 and replaces the previous regulation (EC) no. 882/2004 and other legal documents.
What is new is, that the new OCR specifies, that it is also valid for organic products and the labelling thereof, unlike the previous version.[45]
In the following individual articles of the OCR will be discussed:
Regulations for official controls are to be found in chapter II in articles 9 and following. These articles contain general provisions regarding all types of official controls, including those for organic food controls. Article 9 paragraph 1 stipulates, that controls have to be performed risk-oriented and have to be of sufficient frequency.
Article 10 describes the business operators under official control, including their processes and operations. Official controls have to be transparent according to article 11; for example, type, number and results of official controls and violations are to be published.
Articles 12 and 13 stipulate that control methods have to be documented in written form.
Finally, article 14 describes the methods and techniques of controls. These can include:

- An investigation of the self-controls of a business operator and the results thereof.
- An own investigation.
- Hygiene controls.
- Assessment of the HACCP-concepts and other proceedings.
- A testing of supply chain traceability.
- Conversations with the business operator and their employees.
- Assessment and double-checking of measurements made by the business operator and other test results.
- Sampling, analyses, diagnoses and tests.
- Audits of the business operator.
- Other measures necessary to verify violations have occurred.

Mirroring the official control authorities, article 15 stipulates a duty to comply and assist on behalf of the business operator. This includes, for example, that they have to provide the competent authorities access to their equipment, transport devices and property, as well as computer-based information management systems, animals and goods under their supervision, their documents and other relevant information.

45 Cf. Art. 1 (2i) OCR.

1.7.1. Other requirements for official controls

The articles 16 and following contain additional requirements for official controls in specific areas. This concerns the areas in food and feed law specified in article 1 paragraph 2. Regarding organic agriculture these additional requirements are to be found in article 25, which is however restricted to granting the commission the right to decree implementing acts. At the time of writing this manual these implementing acts do not yet exist or are at least not yet known.
Interesting is however, that the granting of the right to decree implementing acts in line with article 25 letter d) can include methods for sampling and lab analyses of organic produce. Excluded however are all stipulations that define threshold values for pesticides and other contaminants.
Provisions regarding sampling, analyses, tests and diagnoses are to be found in chapter IV, articles 34-42. One also has to pay attention to Annex III.
The general requirements for sampling are to be found in article 34 paragraph 5. Samples have to be taken, handled and labelled such that the legal, scientific and analytical validity is guaranteed (compare chapter 1.6.).
As before, food business operators whose produced or marketed food is subject to official sampling, shall have the right to obtain a second expert opinion. The legal basis for this is mentioned in article 35.
What is new is, that article 35 paragraph 3 of the regulation grants food business operators the right to request at their own expense a review of the documents relating to the original analyses, tests or diagnoses by another official laboratory. The extent to which this new provision will become significant will only become clear in practice.
Requirements for the official laboratories can be found in article 37 paragraph 4. The official laboratories must:

- Have the expertise, equipment and infrastructure necessary to analyse, test or diagnose samples.
- Have a sufficient number of appropriately qualified, trained and experienced staff.
- Ensure that the tasks assigned to them as official laboratories are performed impartially and that they are free from any conflict of interest in carrying out their duties as official laboratories.
- Being able to provide within a reasonable timeframe the results of analyses, tests or diagnoses on samples taken in the course of official controls and other activities.
- Operate in accordance with standard EN ISO/IEC 17025 and be accredited by a national accreditation body operating in accordance with regulation (EC) no. 765/2008.

Whether and under which conditions private laboratories, in particular for the organic controls procedure, can also be qualified as official laboratories was discussed in the individual German states as of August 2019, but without result so far.
Furthermore, Art. 38 paragraph 1 stipulates that in the case of analyses, tests or diagnoses that indicate a risk to human, animal or plant health or, in the case of GMOs and plant protection products, also to the environment, laboratories must immediately inform the responsible authorities (see Chapter 1.6.)

1.7.2. What responsibilities apply to control bodies in the organic food industry?

The question now arises, as to what controls the organic control bodies must carry out under the new OCR. In the provisions on the scope of application in Article 1 paragraph 2 letter a) of this regulation, food safety, integrity and health safety at all stages of production are also mentioned. In article 14 of the OCR, for example, the HACCP-concept is expressly mentioned as the subject of official controls, along with a large number of other areas. Controls in the area of organic agriculture must, however, be limited to ensuring that the provisions of the organic regulation itself and the associated implementing acts are complied with. Thus, it is not issuing of food safety or health innocuousness that can be subject to the control procedure for organic agriculture, but the integrity of the entire production method and of the products.
This basically already follows from the definition of the “control body for organic production” in Art. 3 no. 4 of the OCR. According to this definition it is an administrative organisation of a Member State for organic production and labelling of organic products to which the responsible authority has delegated all or part of its tasks in connection with the implementation of regulation (EC) no. 834/2007. The organic control bodies, which operate on the basis of Art. 3 par. 5 of the Control Regulation, can therefore by definition only be entrusted with the tasks related to the implementation of the organic regulation. This is confirmed by the rule of jurisdiction in Art. 4 paragraph 3 of the OCR, according to which the authority responsible for verifying compliance with organic legislation may delegate certain responsibilities in connection with official controls and other official activities to one or more control bodies. However, the responsible authority cannot delegate responsibilities that did not apply to them in the first place. Due to the explicit limitation to the verification of compliance with organic legislation, it can therefore only be these responsibilities.
Therefore, the requirements of the OCR must always be seen in the context of the organic regulation and of organic agriculture. The question is therefore whether a requirement for the food business operator to be

checked by the organic control procedure has its origin in organic law.

For this reason, the content of the controls in organic law is essentially derived from article 38 of the organic regulation. According to this article, the controls that verify compliance with this regulation include in particular the following:

- The verification of the application of preventive and precautionary measures by operators at each stage of production, preparation and distribution (letter a).
- The clear and effective separation between organic production units, production units in conversion and non-organic production units and their respective products (letter b).
- The verification of records and existing measures, procedures or arrangements to ensure that organic and in-conversion products are at all times identified and separated from conventional products (point c).
- A review of the establishment and functioning of the internal control system for groups of operators (point d).
- Verification of compliance with the requirements for the exemption of certain operators and products (point e).

Furthermore, article 38 paragraph 2 of the organic regulation links essential contents and principles to official controls in accordance with article 9 of the OCR. The first sentence of Article 38 paragraph 2 stipulates that official controls at all stages of production, preparation and distribution are to be carried out on the basis of the likelihood of violations of organic legislation. In addition to the control elements under Article 9 of the OCR, the list in Article 38 paragraph 2 of the organic regulation adds essential elements. These include, among others:

- The type, size and structure of the companies.
- The duration of the period during which the enterprises are engaged in organic production or processing.
- The date and results of the inspections carried out by the inspection body.
- The categories of products, the nature, quantity and value of the products and their evolution over time.
- The possibility of mixing of products and contamination with unauthorised products or substances.
- The application by operators of derogations or exceptions to the rules.
- Critical points for non-compliance and probability of non-compliance at each stage of production, preparation and distribution.

Activities carried out under subcontracting arrangements must also be taken into account. In addition, there are regulations on the frequency of controls, which are not relevant to the questions of the manual.

1.7.3. How do the OCR and the organic regulation complement each other?

The following conclusions can be drawn for this manual from the linking of the OCR and organic regulation:

1. An inspection must record and assess the probability of violations already at the inspection planning stage, which is why the inspection will have to be planned and structured.
2. As a result of this planning, possible applications and uses of prohibited substances and processes must be recorded, as well as unintentional input possibilities and contamination.
3. For sampling and analysis, this means that they must be risk-oriented and contain precisely targeted questions. Representative sampling to assess the marketability of entire batches is not the focus here.

According to point (a) of article 1 paragraph 2, the objectives of the OCR in the concrete implementation of organic controls include product integrity. Where the German text of the Regulation uses the term “Lauterkeit” (fairness), the English version uses the term “integrity”. A further look at the various language versions of the control regulation shows that this term appears eleven times in the English language version. In the German version, the term “integrity” is translated twice as “Lauterkeit” and nine times as “Integrität”.

If one takes into account that the term “integrity” from the OCR should be better understood as used in the organic regulation itself and the integrity of the products means that they have been produced in accordance with the rules on organic farming, the OCR and the organic regulation fit together harmoniously.

1.8. The presence of unauthorised substances in the focus of the new organic regulation

One aspect of the new organic regulation is the "avoidance of the presence" of unauthorised products or substances in food and feed from organic production. To this end, the organic regulation now imposes precautionary measures on companies along the entire supply chain. In addition, it defines further measures to be taken in case of the presence of such unauthorised products or substances.

1.8.1. Terminology of the organic regulation

At various points the organic regulation refers to the *"presence of unauthorised products and substances".*[46] Elsewhere however, the *"unintentional presence of unauthorised products and substances"* is mentioned.[47] Finally, the regulation also uses the term *"contamination".* [48]

In the German language version, the term *"Verunreinigung"* (= pollution) can also be found in Annex III, point 7.1 of the organic regulation. Whether this could just be an unfortunate German translation is open to discussion. This is because the English version of Annex III, point 7.1, refers to "contamination". Nevertheless, it is required at this point by the German version that "any mixing with or pollution resulting from products not complying with the organic production rules shall be avoided". Is it possible that this particular usage of the term pollution in the German version may be given a desirable clarification from the definition of "contamination" in the contaminants regulation (EEC) No 315/93 quoted below? More on this later.

Now the question has to be asked, whether the European legislator, when using the terms "presence of unauthorised substances" and "unintentional presence..." compared to the term "contamination", is only imprecisely formulated and basically describes the same facts, or whether the use of the different terms is deliberately chosen and different circumstances have to be considered separately. There is much to suggest that the latter is the case.

Despite their considerable number of definitions – article 3 of the new organic regulation contains no less than 75 different ones – unfortunately neither the terms "presence of unauthorised products or substances" nor the term "contamination" itself are explained. There is also no reference to the terms that are certainly present and known from other regulations or directives.

1.8.2. Definition of the term "contamination"

The term contamination is defined in food law in Article 1 paragraph 1 of regulation (EEC) no. 315/93, the regulation laying down community procedures for contaminants in food (European Contaminants Regulation[49]), According to this, a contaminant is any substance that is not intentionally added to food but is present in food as a residue of the cultivation (including methods of treatment in agriculture, livestock breeding and veterinary medicine), manufacture, processing, preparation, treatment, presentation, packaging, transport or storage of the food in question or as a result of contamination by the environment. The term does not include the remains of insects, animal hair and other foreign matter.

Accordingly, contaminants and the impurities to be designated as such as a result of their presence are always incidental and unintentional. When the organic regulation speaks in recitals 72 and in article 29 paragraph 7 of "the unintended presence of non-authorised products and substances", the definition of contamination is thus precisely fulfilled. Thus, if the concept of contamination is to be understood as accidental and unintentional presence, the precautionary measures described in Article 28 paragraph 1 of the regulation and to be taken by the food business operator attain their proper meaning, namely the prevention of the accidental and unintentional introduction of unauthorised substances and products.

1.8.3. Identification of contaminants in practice

Taking into account the principle of proportionality, the food business operator, comparable to their HACCP approach in terms of hygiene, must identify the risks of contamination of their organic products and systematically critical points in the processing steps they set up.[50] In addition, the food business operator must take proportionate measures to avoid the risk of contamination of organic food.[51] These measures have to be reviewed regularly, adapted where necessary and are to ensure the separation of organic food from products in conversion and conventional food.[52]

In more specific terms, this means that the operator must check at which points in the production process

46 Cf. Recitals 69, 72 and 114, Art. 28 (2) and Art. 29 (1,6) organic regulation.

47 Cf. Recital 72 and Art. 29 (7) organic regulation.

48 Cf. e.g.: Recitals 68, 69, Art. 28 (1), Art. 29 (3) organic regulation.

49 Reg. (EC) No. 315/93 of the council from 08.02.1993 laying down Community procedures for contaminants in food. Available online: https://eur-lex.europa.eu/legal-content/DE/TXT/?qid=1576510270172&uri=CELEX:01993R0315-20090807.

50 Cf. point (a) of Art. 28 (1) organic regulation.

51 Cf. point (c) Art. 28 (1) organic regulation.

52 Cf. point (c, D) of Art. 28 (1) organic regulation.

contamination is conceivable and possible or even likely. Such points could be, for example:

- Sowing and harvesting machines used jointly with conventional enterprises.
- Other machinery and equipment (plant protection), but also third-party equipment that is used occasionally (e.g. dryers, cleaning equipment) and which may contain the remains of unauthorised substances.
- The commissioning of third parties with operations and machinery (machinery rings, contractors, grinding and mixing plants).
- Storage facilities which may have been treated with non-approved substances and which may, from time to time, dispose of them again (flat stores, timber stores, absorbent building materials).
- Conveying and transport equipment contaminated by conventional products (e.g. potato sorting plants).
- Mixers, transport equipment (elevators, screws, blowers), filling lines, but also tanks and silos.
- Dust of any kind that comes from conventional products and is left behind due to poor cleaning.
- Flue gases/exhaust gases from drying facilities

The analysis therefore always focuses on the risks of accidental and unintentional entry, i.e. the risk of contamination in the broadest sense, but not the intentional or grossly negligent use of unauthorised substances in the company.

Difference between unavoidable and intentional use of non-authorised substances using the example of preservatives

If an operator uses an authorised natural flavouring that contains a (non-labelled) preservative in the formulation, this entry is unintentional and even unavoidable when using this specific flavouring preparation. Nevertheless, precautionary measures can identify this risk and lead to the use of another product without this preservative in the future.

The deliberate use of the identical preservative by the entrepreneur in order to improve the shelf life of the final product is prohibited by the regulation itself and is therefore a violation of the requirements of the organic regulation. In this case, the preservative is not a contamination and is also not subject to the precautionary measures. In this case, even a ban on marketing with the organic label would be possible and appropriate. The intention is decisive.

The term “pollution” used in the German translation (see Chapter 1.8.1.) becomes relevant and meaningful here: No. 7 of Annex III of the organic regulation describes the requirements for the storage of organic products or products from conversion operations. Avoidance of mixing and contamination in this context therefore means that measures must be taken to avoid the unintentional introduction of all unauthorised substances and products. In concrete terms this means that prior to the processing of organic products, a plant must be cleaned of the conventional primary product to such an extent, that no “significant” residues are carried over into the organic products. The technical equipment must not introduce lubricants or flue gases into the organic products. The organic regulation itself does not define the quantities above which contamination is still present. Molecular considerations are unlikely to be applicable here (see chapter 1.1.2.). It follows from the context that there can be no percentage figure for assessing whether a non-authorised substance has accidentally and unintentionally entered the product. Rather, the aim can only be to prevent contamination or pollution through appropriate precautionary measures and, if present, to clarify whether it was unintentional and unavoidable (because precautionary measures have been taken and implemented). However, caution is advised: it is very easy to find oneself in an insoluble dilemma as described for sampling (see chapter 1.5.4). Common sense or life practice suggest that no absolute standards should be applied here. There is a high risk of introducing pesticides into organic products, e.g. via previously processed conventional products for which these have been approved. For this reason, the organic regulation also consistently follows the principle of process control. If the measures to prevent contamination and contamination have been observed to be effective, then the still detected presence of non-authorised substances is a contamination, but not a violation of the regulation and thus not detrimental to the organic labelling of the products.

Unavoidable contamination
Grain fennel, which is threshed in November, may have been contaminated with the herbicide pendimethalin from atmospheric inputs in rape growing areas. The analysis will determine the presence of pendimethalin, but the status of fennel as an organic product will be maintained, as its presence is incidental, unavoidable and cannot be influenced by measures taken by the farmer. Organic labelling will not be restricted. However, as it will not be possible for the farmer to market the fennel, e.g. for baby food, and his customers may therefore not buy the product, he may still suffer considerable damage due to the use of pesticides by his neighbours, which may result in disputes under neighbourhood law.

The analysis of the critical points mentioned above is an ongoing process that must be carried out and documented at regular intervals, e.g. annually, or at least when processes and procedures change.

1.8.4. Responsibilities of food business operators

As we have seen, the entire field of occupational precautionary measures is tailored to the unintentional or negligent entry of unauthorised substances. The operator must ensure that the risk of entry is continuously minimised from this side. The entire system has been known and familiar to operators for years from the regulations and measures aimed at minimising the entry of GMOs.
The task for the operator is clearly formulated in article 28 paragraph 1 of the organic regulation:

1. The first step is the risk analysis, i.e. consideration of the critical points.
2. Then they take measures to avoid contamination.
3. They check these measures regularly and adapt them.

In the first two points, the legislator has inserted the word pair "proportionate and appropriate". According to recital (24), operators should take "where appropriate, proportionate precautionary measures under their control" to prevent contamination. In concrete terms, this means that the operator must, as part of his risk analysis, deal with the sources of contamination within their business. They may rely on the fact, that contamination which is unavoidable (because it is ubiquitous, from the atmosphere, from the past or from the neighbourhood or simply not known to date) does not restrict the organic status of their production.
The legislator is aware of the fact that organic farms do not work under a glass bell in a "pollutant-free" room, but have to live and manage with all residues just like their non-organic neighbours.
Thus, the legislator remains consistent with the existing regulations in the new set of rules, according to which products are considered organic if the production rules have been observed. And this is independent of contamination caused from outside (e.g. by drift).[53] This limitation to one's own farm and area of responsibility relieves the operator of the need to impose special care on his neighbour or even to create protective strips, hedges, safety and restricted zones around his organic areas. For the feared conflict situations arising from German neighbourhood law, this means that the all-clear is given: the organic farmer does not have to force his neighbour to refrain from using pesticides. Their behaviour is not subject to their influence. Nevertheless, it is to be feared that new areas of conflict may arise (see box "Unavoidable contamination").
The focus of the preventative measures in the organic enterprise is on the own farm. And here again, it is necessary to check where relevant and avoidable sources of contamination may be located: starting with soil (e.g. no cultivation of Cucurbitaceae on soils known to be contaminated with DDT/Dieldrin) and production facilities (no storage of organic grains in wooden silos or flat stores, which have been treated very intensively with storage protection agents in the past, f. ex. as happened by the "nitrofen" scandal), via machinery and equipment (sowing machines, which may transfer large quantities of seed treatment residues/dust or plant protection equipment without thorough and proper cleaning), to washing water (chlorate, disinfectants) and packaging materials (migration of softeners, preservatives, fungicides).
This assessment itself must be proportional and appropriate. The operator may restrict himself to risks and procedures that are generally known to him and those that are customary in practice and may identify risks using the analyses known to him.

53 Cf. also Verwaltungsgericht Koblenz, Ruling from 15.03.2017, Az.: 2 K 885/16.KO.

Proportionate examination by the entrepreneur
The operator may also use drinking water from the public drinking water supply if it has been treated with chlorine to reduce germs and there is a risk that chlorine compounds will be present in the product, for example in the infusion liquid or in a drink. These chlorine compounds must not give rise to action by the inspection body or the inspection authority, even if they are not authorised as additives for organic products, as drinking water is not covered by this regulation. It is beyond the operator's control how the public drinking water supplier treats the water; any possible contamination is therefore unavoidable. The same applies to unavoidable inputs of certain substances not authorised for organic production by permitted conventional additives and processing aids, flavourings and authorised conventional ingredients.

1.8.5. Handling of other unauthorised substances by the food business operator

Against this background, what is the situation regarding the "presence of unauthorised products and substances", to which the regulation attaches specific measures? The absence of unauthorised substances is not to be expected in practice (see chapter 1.1. and the examples in this chapter). So, what is at stake?
To be separated from the concept of contamination, understood as the accidental and unintentional presence of certain substances, is another "presence of unauthorised substances", which must be intentional or at least avoidable by applying the principles found so far. Otherwise, the legislator could have spoken of the concept of contamination or unintended presence in this case as well. We are therefore dealing here with unauthorised substances which, after the necessary review of the own area of responsibility of the operator, are suspected of having been introduced intentionally, negligently or against their better judgment. What criteria could the operator, inspection body or inspection authority take into account for this presumption?
First of all, pesticides which, by type and quantity, are commonly found in conventional production. However, lower pesticide levels can also give rise to a suspicion after thorough examination, for example if

- The sample was taken close to production and in the unprocessed crop.
- The pesticides detected could be used meaningful in the corresponding crop.
- Typical active ingredients from conventional storage protection are present in the product.
- The pesticide or the amount found is unusual for organic products based on extensive experience.
- The product has (possibly multiple) interfaces with conventional production lines, i.e. in harvesters, warehouses, trading companies, etc.
- The market situation is tense.
- Price, appearance, colour or other characteristics are unusual.
- The supplier is new, unknown, or of poor reputation.
- The supply chain is not transparent.
- The agricultural origin is not yet known for ubiquitous residues.
- If there are doubts about the integrity of the goods.

The legal consequences of such an understood avoidable presence of substances are described in the organic regulation in article 28 paragraph 2 and article 29 paragraph 1. If the operator suspects, that a substance not approved for use in organic food is present in a foodstuff, that has been produced as an organic food or a product in conversion and the foodstuff therefore does not comply with the regulation, they are to proceed as follows:

- They are to identify and isolate the product in question.
- They check whether the suspicion is well-founded.
- They do not market the product in question as an organic product or product in conversion and does not use it in organic production until the suspicion can be eliminated.
- Where the suspicion is well-founded or cannot be eliminated, they shall without delay inform the competent authority concerned or, where appropriate, the control authority or control body concerned, providing them with the relevant available information.
- They are to fully cooperate with the responsible authority or, where appropriate, the control authority or control body concerned in establishing and verifying the reasons for the presence of the unauthorised products and substances.

If one compares Articles 27 (suspicion of non-conformity) and 28 paragraph 2 of the organic regulation, it is striking that the procedure of the operator in letters a) to e) of the two articles is identical. The two cases described in Article 27 and Article 28 paragraph 2 thus lead to the same consequences. Nevertheless, the legislator has refrained from merging the articles.
Article 27 describes how the operator must proceed if he suspects that the product (in whatever form it has come to him) does not comply with the regulation.
Article 28 paragraph 2 is much more complex in wording and only at first glance is it as clear as Article 27, because here a further relation is introduced and at the same time the terminology is slightly changed. Once again, we have the operator, who must have a suspi-

cion. This suspicion relates to the fact that the product, which only has to be used or marketed here, does not comply with the regulation. Now, however, suspicion must arise in a number of decision-making stages due to the presence of unauthorised products and substances in relation to the regulation. The article does not stipulate that the presence (of unauthorised products and substances) necessarily leads to suspicion. Such an automatic mechanism is explicitly not provided for. Rather, the operator must go through three decision-making steps:

1. Are unauthorised products and substances present in the product they intend to use or market?
2. Are the products and substances covered by the scope of the regulation?
3. Are the type and quantity of their presence likely to give rise to a suspicion that the product does not comply with the regulation?

Only if all three questions are answered in the affirmative, the operator has to follow steps a) to e).

There are good reasons to deal intensively with the formulations in Art. 28 paragraph 2, as the extraordinarily complex and difficult questions concerning the presence of unauthorized products and substances are dealt with in detail there.

First of all, it should be noted that the decision on suspicion is the responsibility of the operator, who must therefore be competent and able to judge. If they are not in a position to answer the questions, they must either contact his competent authority or control body and thus de facto apply the provisions of the article. Or they may seek outside expert advice and then make a well-founded decision on whether or not there is any suspicion.

Secondly, if it is present, it must be decided whether the substance that has been reliably detected falls within the scope of the regulation and whether, as an unauthorised substance, it may affect conformity with the organic regulation. Microorganisms, mycotoxins, heavy metals and technical substances that are not regulated by the organic regulation are therefore classified as not relevant here.

Finally, the operator or assessing body must decide whether the presence of the detected and controlled substances is likely to give rise to a suspicion that the product does not comply with the requirements of the organic regulation. If the cause for the presence is to be classified as contamination (see chapter 1.8.2.), suspicion is not justified. This means that, for example, flue gases, Phenols, Bromides and Chlorate can be classified as unavoidable contamination according to expert judgement, if it is considered to be certain that the substances have not been used.

However, if an unauthorised use or mixing is an immediately apparent cause, then a suspicion with all necessary procedural steps is unavoidable.

1.8.6. Responsibilities of control bodies and competent authorities

Article 29 of the organic regulation regulates the tasks of the control bodies/competent authorities in the presence of unauthorised substances. A basic description of the tasks is provided in paragraph 1: “Where the competent authority, or, where appropriate, the control authority or control body, receives substantiated information about the presence of products or substances that are not authorised (…) for use in organic production, or has been informed by an operator(…), or detects such products or substances in an organic or an in-conversion product”, the control body or authority must act.

The basic requirement for the information is that it must be substantiated. This means that the information usually obtained from analyses must be reliable and unambiguous. This includes that information on the sampling procedure (see also chapters 1.5. and 1.6.) and on the analytical reliability (see chapter 1.3.) must be available and must allow for substantiated judgement.

If this is the case, article 29 paragraph 1 requires of the control body resp. authority that:

a) It shall immediately carry out an official investigation in accordance with regulation (EU) 2017/625 to determine the sources and the cause in order to verify compliance with the first subparagraph of Article 9 paragraph 3 and Article 28 paragraph 1; this investigation shall be completed as soon as possible within a reasonable period of time, taking into account the shelf life of the product and the complexity of the case.

b) It shall provisionally prohibit both the placing on the market of the products concerned as organic or in conversion and their use in organic production pending the results of the inquiry referred to in point a).

The “official investigation” referred to in point a) is described in recital 69 of the organic regulation: “Such investigations should be propor¬tionate to the suspected non-compliance, and therefore should be completed as soon as possible within a reasonable period, taking into account the durability of the product and the complexity of the case. They could include any method and technique for official controls which is considered appropriate to efficiently eliminate or confirm, without any unnecessary delay, any suspicion of non-compliance with this Regulation, including the use of any relevant information that would permit the elimination or confirmation of any suspicion of non-compliance without an on-the spot inspection.”

The main points are as follows:

- The reasonable relationship to suspected violations.
- The shelf life of the products.
- The design of the investigation.

Example of an official investigation
The discovery of traces of chlormequat in organically produced mushrooms does not justify a month-long investigation into the theoretical sources of the residue, as it has long been known that traces of chlormequat cannot be completely excluded in the production of mushroom substrate and that the mushrooms absorb and accumulate chlormequat. Since knowledge of corresponding findings in the case of documented substrate origins and raw materials proves a large number of possible entry routes (dust, drift, conventional poultry dry manure) and the origin could not be clarified in numerous specific cases, no batches would have to be blocked here as the available information is not sufficient to substantiate suspicion.

However, in all cases where the official investigation has to be carried out in a more detailed manner, possibly with further controls and/or sampling and analysis, because a suspicion is well-founded and the origin of the contamination is not clear, the corresponding lot should be provisionally excluded from marketing with references to the organic production method.
As this is done provisionally, this only concerns the product stored at the company concerned. A recall of already delivered goods would only be appropriate and proportionate if required by consumer health protection, in which case the responsibility lies with the food control authorities.
Article 29 paragraph 2 shall exclude the labelling of products with indications referring to organic production methods only, if it can be demonstrated that the operator:

a) has used products or substances not authorised for use in organic production in accordance with the first subparagraph of Article 9 paragraph 3
b) has not taken the precautionary measures referred to in Article 28 paragraph 1, or
c) has not taken action in response to previous relevant requests from the competent authorities, control authorities or control bodies.

Case a) requires no further explanation. If the producer has used unauthorised pesticides or the processer has used unauthorised additives, i.e. deliberately and intentionally added or applied them, organic marketing shall be excluded.
Case b) is already more difficult: according to this, organic marketing would be excluded if the operator has not taken precautionary measures against impurities and contamination within his sphere of influence. In principle, a certificate should not be issued to a business that has not taken any precautionary measures at all. It can therefore only be a matter of the necessary measures not having been taken or not having been implemented. For this decision to be made, however, the source of the contamination must be known, because only if the source is known (within the company's sphere of influence?) can a decision be made as to the extent to which a corresponding preventive measure would have been appropriate and proportionate. In principle, it can be assumed that preventive measures against unknown sources are not possible. An example: after lengthy investigations, chlorpropham detection in organic potatoes could be traced back to cross-contamination by rubber bands in sorting plants. Only since this source became known, preventive measures were possible. As a rule, the greatest challenge will be to identify the source of the presence and subsequently prove that preventive measures were necessary, but were not taken in the specific case.
Case c) is more obvious: in this case, pollution is due to sources which were known and which the operator has already been requested by control bodies or authorities to avoid. If he has not complied with these requests, the reasons for the presence are attributed to the operator as if they had been actively applied.
In any case, the operator must be given the result of the investigation and the opportunity to comment. According to article 35 of the OCR, the operator has the right to a second expert opinion.
The uncertainties and thus the requirements for determining the operator's responsibility are numerous. In many cases, it will be just as difficult to prove application as it will be to prove that the presence was caused by a lack of preventive measures. There is a lot of room for legal uncertainty and litigation in the area of conflict between the foreseeable effect, the adequacy and proportionality of precautionary measures up to the sphere of influence of the operator.

1.8.7. National maximum limit values for contaminations

Article 29 paragraph 7 authorises Member States to establish additional rules "to avoid the unintended presence in organic agriculture of products and substances not authorised pursuant to the first subparagraph of Article 9 paragraph 3 for use in organic production". In concrete terms, this refers to the maximum limits for organic production introduced, for example, in Italy or Belgium. However, these measures must not impede the free movement of goods within the Community, so that goods from Member States which have not introduced maximum limit values may not be decertified or excluded.

Legislation on methods of detection and assessment of the presence and exchange of information is currently being drafted.

1.8.8. Summary

As there can be no limits or thresholds for products from organic production on a scientific basis (see chapter 1.1.), a detected presence of non-authorised substances leads to a series of investigations which can only be carried out with a high level of experience and competence. They start with the company where the detection was made and its own company precautionary measures. If these checks reveal that the presence of an unauthorised substance or product is incidental and unintentional and therefore unavoidable, the foodstuff remains compliant and the operator does not need to take any further action. However, they must continuously maintain their monitoring of critical points and react to changes in the process if necessary. If, on the other hand, the application of article 28 paragraph 2 of the organic regulation shows that a suspicion is justified or irrevocable and the product does not comply with the regulation due to the presence of unauthorised products and substances, the operator is to carry out the procedural steps in accordance with letters a) to e) of this article and report the suspicion to their control body or control authority (see chapter 1.8.4.). From here, the suspicion can fall upon the previous stage of trade, where the inspection starts again, if necessary up to the agricultural production of the primary product. Under certain circumstances, the official inspection according to article 29 of the organic regulation will also use this procedure. The complexity of the process alone makes it necessary to set high standards for the conclusiveness of a suspicion due to the presence of unauthorised substances. This applies all the more to a definitive ban on marketing as an organic product.

Part 2: The control procedure – elements – results – verification

2.1. Elements of a risk-oriented control procedure – indicators of the application of unauthorised substances and procedures

In future, the control procedure for organic products will be defined and structured by the relevant provisions of the OCR and the organic regulation (see chapter 1.7. for objectives and contents). In the first sentence of Article 38 (2), the organic regulation sets out the direction for controls: official controls at all levels of production, processing and distribution shall be based on the probability of non-compliances with the organic legislation. In Article 42 (1) of the organic regulation, the use of unauthorised products and substances as well as unauthorised processes and mixing with non-organic (i.e. colloquially "conventional") products are mentioned as examples of violation of organic law. It is therefore by no means just a question of analyses for unauthorised pesticides. Thus, there is the necessity to carry out audits and spot audits in accordance with organic legislation in a planned and structured way.
This requires the most detailed knowledge possible of the company and its processes in order to identify and evaluate the risks associated with the use of illegal substances and processes. Only on this basis can sampling and the selection of the parameters to be investigated be used sensibly. Without this prior knowledge, the control procedure will not take sufficient account of the specific risks and will therefore be more random in its results.
In the following, we would like to show and evaluate exemplary processes and substances. The key question here is to what extent, based on current knowledge, statements can be made by sampling and analysis as to whether impermissible substances or processes have been used.

2.1.1. What are prohibited procedures?

Use of genetically modified processes, substances or organisms (article 11 organic regulation):
The use of genetically modified organisms (GMOs) and of substances produced from and by GMOs is prohibited. The organisms themselves as well as substances from GMOs are generally easily detectable by analysis. Heavily processed substances and substances produced by a GMO organism (e.g. organic acids) usually do not contain any DNA residues that can be detected analytically. This means that the smallest traces of GMOs in primary agricultural products can be detected with a high degree of certainty, even if the origin is only dust contamination. For all other substances, precise knowledge of the production chain is necessary to be able to substantiate the suspicion of GMO production. For this reason, the organic regulation generally requires a seller's declaration. In order to be able to analytically exclude the use of genetic engineering methods in suspected cases, the buyer should contact an analytical service laboratory, which has proven expertise in GMO analysis. Recommendations for laboratories can be found at the "Verband Lebensmittel ohne Gentechnik" (Association "food without genetic engineering; VLOG).[54]

Irradiation with ionising radiation:
The organic regulation refers to ionising radiation.[55] According to the quoted directive, ionising radiation "means energy transferred in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less (a frequency of 3×10^{15} hertz or more) capable of producing ions directly or indirectly" (directive 2013/59/Euratom).
Accordingly, metal detectors do not fall within the scope of the requirements for ionising radiation within the meaning of the organic regulation.
In article 5 of the organic regulation the requirement "the exclusion from the whole organic food chain of ionising radiation" is formulated.
Ionising radiation is used in the preservation or disinfection of meat, fruit, spices and dried products. In the European Union, there are high technical hurdles to this technology and to the approval of the plants.[56] Only aromatic herbs and spices may be treated with ionising radiation in the EU. However, there are exceptions for Belgium, France, Great Britain, Italy, the Netherlands, Poland and the Czech Republic. These countries have irradiated other foods before EU legislation came into force and may continue to do so. Depending on the Member State in question, fruit, vegetables, meat, fish, mussels, frogs' legs, camembert from raw milk, cereals, rice flour, protein and blood products may be irradiated there. In Germany, drinking water, surfaces of fruit and vegetables and hard cheese may be treated with

54 https://www.ohnegentechnik.org/standard001/, Link under keyword "Laboren".
55 Specifically, Recital 23, in the definitions after Art. 3 (67), as well as Art. 5 (i) "Allgemeine Grundsätze".
56 Cf. directives 1999/2/EC and 1999/3/EC

UV radiation for disinfection during storage. Due to exceptions, this is also permitted for shell eggs (including chicken eggs).
Irradiation detection is used to determine radiation-induced changes in food. Due to the different chemical compositions of the food, radiolysis products are formed to varying degrees. So far, no generally valid marker substance exists. Foods poor in water, e.g. dried herbs, are analysed by electron spin resonance, where the free radicals primarily formed are detected. By means of thermoluminescence, e.g. spices, fresh fruit and vegetables, seafood, which contain mineral accompanying substances (salts, minerals, dust) are analysed. Fatty foods can be analysed by means of gas chromatography, which detects volatile hydrocarbons formed secondarily and 2-alkylcyclobutanones. A further method for the detection of ionising radiation is photon-stimulated luminescence.

Agricultural production methods:
Various methods of cultivation are not permitted under organic law. These are mainly hydroponics, i.e. the cultivation of land plants on inert substrates, in which the nutrient supply is exclusively via water and added fertilizers. Cultivation without "soil contact", i.e. in closed tubs or pots, is also generally excluded, as long as the delivery to consumers does not take place together with the pots (potted herbs). Landless animal husbandry, as well as recirculation systems in aquaculture and the keeping of poultry in cages are also not permitted. These inadmissible methods of agricultural production cannot be verified analytically or cannot be checked reliably. However, they can be clearly and reliably detected during an on-site inspection.

Oenological practices:
In the previous organic regulation (EC) 2007/843, the implementing rules for wine production distinguish between permitted and prohibited practices for the production of organic wines. If the process control finds indications of the use of prohibited procedures, this information should be forwarded to the competent wine monitoring authority of the federal state (federal state here being a state inside Germany) concerned. In this case, an official examination according to article 29 of the organic regulation by the specialised control bodies for wine control is provided for.

2.1.2. What are prohibited products and substances?

As a general rule, the organic regulation is subject to authorisation requirements for certain functional groups of products and processes. This includes pesticides, fertilisers, food additives, feed additives, disinfectants and others. On the other hand, substances and functional groups that are not subject to approval reservations (e.g. biocides in storage protection or plant strengthening agents in agriculture, wood preservatives for pasture fences, coatings for silo systems or stables, etc.) can be used, unless their use is explicitly excluded by the organic regulation or other legislation.

Agricultural inputs:
According to Article 24 (1) of the organic regulation, the Commission may authorise certain products and substances for use in organic production for specific purposes and includes all such authorised products and substances in restrictive lists:

a) Active substances to be used in plant protection products.
b) Fertilisers, soil conditioners and nutrients.
c) non-organic feed material of plant, algal, animal or yeast origin or as feed material of microbial or mineral origin.
d) Feed additives and processing aids.
e) Agents for cleaning and disinfecting ponds, cages, tanks, flow channels, buildings or installations for animal production.
f) Products for cleaning and disinfecting buildings and installations used for plant production, including storage on an agricultural holding.
g) Products for cleaning and disinfection in processing and storage facilities.

Detection of nitrogen
Analyses are only possible with regard to nitrogen (N) fertilisation. Here conclusions can be drawn about fertilisation on the basis of the N isotope distribution. However, it is not always possible to distinguish clearly between organic and other products, so that further information from the control procedure is required. Furthermore, the stable isotope methods are limited to agricultural products containing nitrogen (protein). Oils, fats or sugars are beyond the scope of this analytical method, as they contain (almost) no protein and therefore (almost) no organic N. The method is therefore not suitable as a routine method at present, but can be helpful in special situations. Especially when reference samples of organically produced crops from the same region are available or when batches are to be checked for identity. Particular risks are posed by enterprises which, in the context of crop rotation, have neither a weed strategy with forage cropping nor an adequate supply of N to the populations through legumes. Here, in-depth studies of weed management and nutrient strategy are necessary, which can be supplemented by sampling in individual cases.

Handling of surface-active substances

In summer 2012, the surface-active substances didecyldimethylammonium chloride (DDAC) and benzalkonium chloride (BAC) in food in general, but also in organic products, were the subject of discussion. These substances are used in disinfectants and cleaning agents and are classified both as biocide and pesticide active substances.[i] Currently, the following regulations apply to quaternary ammonium compounds (often declared as cationic surfactants): Regulation (EU) No 1119/2014 from October 23, 2014 regarding maximum residue levels of BAC and DDAC: According to this regulation specific maximum residue levels for DDAC (C8, C10, C12) and BAC (C8, C10, C12, C14, C16, C18) of 0.1 mg/kg each have been established for all types of goods according to Annex I of Regulation (EC) No 396/2005. Regulation (EU) No 1119/2014 has been applicable since November 12, 2014, and a reassessment of these maximum residue levels by the EU is foreseen for the end of 2019.

The organic regulation does not provide specific regulations for DDAC/BAC. As a guideline for the handling of these substances, the orientation value of 0.01 mg/kg for primary plant products of the "Bundesverband Naturkost Naturwaren" (BNN) can be used.[ii] It also provides for an investigation of the cause of DDAC or BAC in the case of evidence exceeding 0.01 mg/kg, in order to rule out a violation of the legal regulations for organic farming.

i Cf. Bundesinstitut für Risikobewertung (2013): Gesundheitliche Bewertung der Rückstände von Didecyldimethylammoniumchlorid (DDAC) in Lebensmitteln. Available online: https://www.bfr.bund.de/cm/343/gesundheitliche-bewertung-der-rueckstaende-von-didecyldimethylammoniumchlorid-ddac-in-lebensmitteln.pdf.

ii Cf. Bundesverband Naturkost Naturwaren (2012): Stellungnahme des BNN zum Umgang mit DDAC- und BAC-Rückständen. Available online: https://n-bnn.de/aktuelles/26072012-stellungnahme-des-bnn-zum-umgang-mit-ddac-und-bac-r%C3%BCckst%C3%A4nden.

Legal acts on these "specific products and substances" has not yet been adopted, so the specific substances are not yet known. With regard to plant protection products and fertilisers, according to the Commission's notification, the current Annexes I and II to regulation (EC) 889/2008 are to be adopted.

Regarding a): Plant protection products and pesticides are in principle subject to analysis. However, since analyses only show the presence and level of pesticides, but do not identify the source of the impurities, it is absolutely necessary to check the organisation regarding the use (of pesticides) or inadequate precautionary measures (see also chapters 1.7., 1.8. and 3.2.).

Regarding b): Fertilizers and soil conditioners and their use are difficult to detect analytically in the agricultural products. Here, in general, on-site inspections are more meaningful and better suited to establish their plausibility (see box on previous page).

Regarding c): Non-organic feed materials can usually only be analysed secondarily, if certain patterns of exposure to pesticides or feed additives can be attributed to them.

Regarding d): Feed additives and processing aids are hardly ever used in the production sector. Sampling and analysis are therefore preferable in processed feed. They are therefore not indicated as routine tests in the agricultural sector.

Regarding e) and f): With regard to cleaning agents and disinfectants in agricultural production, only the list in Annex VII of Regulation (EC) 889/2008 exists to date. Due to the large number of substances that can be used, analytical testing for the use of other cleaning agents and disinfectants is only appropriate in exceptional cases. In addition, there are many substances from other sources in stables and housing facilities, e.g. paints, wood preservatives, biocides, cleaning agents for milking installations, veterinary medicines, care products for animals and cosmetic and disinfectant substances from human use. Other control techniques are also suitable here, e.g. records, stocks, visual inspection or, where appropriate, animal health.

Regarding g): At present, the organic regulations' positive list for permissible cleaning and disinfecting agents in processing and storage is still empty. This situation would mean that from 2021 onwards all agents used for these purposes would no longer be permitted, as no substances have (yet) been permitted. It can therefore be expected that the Commission will publish a regulation here in good time.

Since 2006, the Research Institute of Organic Agriculture (Forschungsinstitut für biologischen Landbau, FiBL) has published the input list for organic farming in Germany. The list also contains cleaning and disinfection agents for the agricultural sector.[57]

The Association of Organic Food Producers (Assoziation ökologischer Lebensmittelhersteller, AöL) has compiled a list of cleaning and disinfection agents used in organic farming. According to the AöL, the substances on the list are used in organic farming as well as in processing and storage.

The AöL prefers a negative list instead of a positive list for detergents and disinfectants and has already notified the Commission of this.

57 Cf. Forschungsinstitut für biologischen Landbau (2019): Betriebsmittelliste. Available online: https://www.betriebsmittelliste.de/de/bml-info.html.

Additives and processing aids for food and feed are listed individually in the organic regulation in positive lists and, if necessary, with further information. Only a few substances also have maximum levels, such as nitrate/nitrite for meat processing or sulphur dioxide for wine. In these cases, it is useful to monitor the maximum levels by means of sampling and analysis. It is advisable to sample finished products for analysis, as the maximum levels refer to the products ready for consumption. If the use of unauthorised additives or processing aids is suspected, laboratories or state laboratory can provide information.

In some cases, safe methods exist for the detection of *colourings, preservatives and sweeteners,* provided that the group of substances can be narrowed down in the test order. A particular risk of using undeclared substances exists for the following product groups:

- Sweet drinks, lemonades, cold filling of beverages: so-called cold sterilisation using Velcorin or as an additive peracetic acid; use of colouring agents as (possibly undeclared) additives; preparations for colour, flavour, lees declared as natural flavourings.
- Gourmet and fresh products for counter distribution: Preservatives such as sorbic acid.
- Oils, fish, animal feed: antioxidant ethoxyquin.

If not expressly prescribed, the state laboratories can be asked for information or administrative assistance in the event of suspected use of *vitamins, minerals and micronutrients.* In practice, it will be difficult to establish proof of unauthorised use.

Whether *flavourings* are actually natural flavourings in accordance with the requirements of article 16 of the Flavour Regulation (EC) 1334/2008, as required by the organic regulation, will hardly be able to be verified by the inspection body in the course of sampling and analysis. Even the differentiation from flavourings preparations or other flavour mixtures is only possible for a few experts. In the German federal states there are specialised state offices for this purpose, which can be asked for administrative assistance if there is a justified suspicion.

Conventional ingredients may or may not be permitted. Inadmissible conventional ingredients can basically only be uncovered through process controls. Permissible conventional ingredients are not required to be residue-free and may be the cause of considerable residues in an otherwise organic product. Permissible additives can also contain other substances such as preservatives, solvents or carriers.

As *packaging materials, containers and wrappings* are not subject to approval as products and substances, they are not subject to the organic regulation. However, even in this case there may be a considerable transition from e.g. preservatives or technical additives from packaging to organic products.

2.1.3. Other unauthorised substances

In addition, there is an almost infinite number of unauthorised substances such as industrial chemicals in the broadest sense (e.g. benzene). This also includes technical substances and materials used as tools, machines, containers, building materials, paints and coatings or fuels. The same applies to natural substances such as soil, pollen (if not used for beekeeping), bacteria and fungi and their metabolic products (if not defined as contaminants). If these substances are not covered by the organic regulation, e.g. as plant protection products or additives, they are not subject to this Regulation. However, the delineation of products and substances outside of the approval reservation is likely to be difficult in individual cases as long as there has not been a rejected approval procedure. For this reason, if the presence of non-authorised substances is certain, it must always be examined whether this may be unintentional and technically unavoidable contamination.

The large number of basically possible unauthorised substances and processes suggests that there can be no one-sided focus, for example on the group of pesticides. A close product-risk coupling in the sense of a risk matrix, that assigns defined risk substances to certain products must also be viewed critically. This is because every impermissible substance is equally important and can be a reason for an official investigation and, if necessary, the withdrawal of organic certification. There is also no analytical method that can be used to identify all or at least most of the risks in the sense of a screening. A thoroughly prepared and competently performed process control is still the best way to monitor compliance with legal regulations in a structured way.

For the purposes of this paper, three questions are particularly important for the preparation and implementation of controls:

1. At what point in the controlled company's process is there a risk that unauthorised substances or processes are used?
2. How high is the risk that this will actually happen?
3. What is the probability that the confirmed presence is a consequence of precautionary measures not taken or not implemented?

Only when these questions have been answered the next step can be taken to decide whether and to what extent sampling and analysis can provide valuable information.

2.2. Suspicion as a result of the control

The basic principle of organic control as an official control procedure results from the interaction of the organic regulation and the OCR. The organic regulation regulates the minimum requirements for food and feed to be labelled with references to organic farming and to be allowed to carry the European organic logo (EU logo). In this context, the European Union logo for organic production is "an official attestation in accordance with Articles 86 and 91 of Regulation (EU) 2017/625". As a prerequisite, companies wishing to label and market organic products in this way must register with the responsible authority (or the control bodies responsible for this) and submit their activities to the certification system. Exceptions are made only for retail sale of packaged products and out-of-home catering. The certification system in turn regularly checks compliance with the regulations and thus the integrity of the offer, labelling and advertising in accordance with the requirements of the OCR. The safety and health safety of the products is also continuously checked in accordance with the OCR, but by the general food and feed control body and outside the certification system for organic farming. This connection is important for the understanding of the control: not the inspection is the basis for the right to market organic products, but rather the continuous effective maintenance of the entire control system. The control can now check compliance with the regulation at any time and at any point within its area of responsibility, not only during the annual inspections. And the entrepreneur in the certification system can, unless other conditions are imposed on him, label and market products with the European logo without restriction within the notified and certified area. There is no separate product release.

2.2.1. Which determinations can be made by the certification system?

In essence, official controls under the OCR distinguish between three types of results: conformity, non-conformity and suspicion.

Determination of conformity: The controlled processes, procedures, products and substances comply with the organic regulation. Even though it is never possible to check all processes, procedures and substances in an inspection, there is no reason for further action.

Determination of non-conformity: If non-conformities are determined, the Regulation has two stages:

- The non-conformity impairs the integrity[58] of the product/conversion product.
- Or the non-conformity does not affect the integrity of the product/conversion product.

In general, the organic regulation distinguishes between serious infringements, where the integrity of the entire product is affected, and less serious cases, where, for example, there are only formal infringements, which otherwise do not affect the integrity of the product. In cases where the integrity has been compromised, article 42 of the organic regulation regulates the necessary procedures. These serious cases include the use of unauthorised substances.

Specific measures are therefore provided for in the control procedure (certification/disqualification) to establish conformity as well as to detect infringements.

Suspicion of non-conformity: Suspicion of non-conformity is a key outcome of the control procedure, as both the operator and the control body are obliged regularly check whether there are indications of a suspected violation. The procedure in the event of a suspected infringement is dealt with in many places in the organic regulation.

2.2.2. Specifics of suspicions regarding non-conformity

In article 39 (1) (d) (iii), the organic regulation contains the following peculiar wording for a declaration by the entrepreneur to which he must commit himself with his signature:

"[...] to inform in writing and without undue delay buyers of the products and to exchange relevant information with the competent authority, or, where appropriate, with the control authority or control body, in the event that a suspicion of non-compliance has been substantiated, that a suspicion of non-compliance cannot be eliminated, or that non-compliance that affects the integrity of the products in question has been established, [...]".

First of all, it should be noted that certainly not every suspicion of a lack of labelling or a formal irregularity should have the same serious consequences as identified violation that affects integrity. Must this obligation therefore be understood in such a way that, of course, even if there is a suspicion, it must be checked whether it affects integrity? Otherwise, the entrepreneur would only have to report a violation if it compromises (i.e. could not only impair it) the integrity of the product, but any suspicion of a violation below this threshold if it is justified or cannot be eliminated. If the suspicion were to be confirmed when the violation was discovered, it would again no longer have to be reported, since the integrity is not affected by this violation. The strict interpretation would mean that the company would be better off not suspecting rather uncritical violations in order to avoid stricter measures.

58 In the definition of no. 74, art. 3 Organic Regulation.

The heading of article 27 of the organic regulation reads: "Obligations and actions in the event of suspicion of non-compliance". This article also obliges companies to take measures in the event of suspicion, which will lead to the goods being blocked and reported in the control procedure if the suspicion is justified or cannot be dispelled. In this respect, the associations "Bund Ökologische Lebensmittelwirtschaft" (BÖLW), the German Farmers' Association and the Food Association of Germany have stated in an interpretation in 2019[59] that, from a legal logic point of view, this only applies to infringements that are likely to impair the integrity of the product.

For the presence of unauthorised substances, an uncritical reading of the wording in articles 27 to 29 would have serious consequences: either in the case of a well-founded suspicion of the presence of unauthorised substances or in the case of a suspicion, which need not be well-founded but cannot be dispelled. In any case, the goods would have to be blocked and the control body/authority would have to be informed and, as a result of the voluntary commitment, the buyer/buyers would also have to be informed. This means that any suspicion that is justified or cannot be removed would have the same legal consequences as an identified use of these substances.

Therefore, if each presence is assessed indiscriminately as an application, then the entrepreneur would have to prove that no application has taken place for each presence. But what does proof that something has not taken place look like? The result is an irrevocable scepticism and therefore a suspicion could hardly be systematically dispelled, whereas the determination of an application must first be proven under criminal law. After all, a non-application cannot be proven at the moment. The consequence would always be a (permanent) blockage and the notification of the buyer and the control body/authority with the result that the goods can no longer be marketed. This in turn would be contrary to the expressed will of the legislator, who mentions the organic regulation as recital (17):

"This Regulation should provide the basis for the sustainable development of organic production and its positive effects on the environment, while ensuring the effective functioning of the internal market in organic products and fair competition, thereby helping farmers to achieve a fair income, [...]".

For this reason, well-founded and comprehensible standards must be developed for the point at which "presence" constitutes a suspicion (see Chapter 1.8).

In his late work: "Über die Gewissheit" (about certainty) Ludwig Wittgenstein turned against scepticism, which, in fact, doubts everything. Wittgenstein states that there must be reasons for doubt, i.e. firm convictions about which doubt can only arise in the first place. Applied to cases of suspicion in the field of ecological control, this consideration means that there must be at least two certainties:

1. The presence of unauthorised substances (analytically proven) is always at the same time proof that these substances were used in the production of the sampled batch.
2. Residues of these substances are always detectable in conventional products that have been produced with (for organic production) unauthorised substances.

There is a lot of evidence that both statements are not true. Regular publications on this subject are, for example, the annual reports on organic monitoring of the Chemical and Veterinary Investigation Office (Chemischen- und Veterinäruntersuchungsamts, short: CVUA) Stuttgart.[60]

In the absence of such certainties, a doubt about the compliant production method must have reasons for it to be condensed into a suspicion or even a well-founded one. The presence of non-authorised substances is neither a necessary nor a sufficient justification for a suspicion of active use. An application is not necessary for a presence, because there are many reasons and ways of entry (see chapter 1.1.). Conversely, the presence is not sufficient evidence for a violation of the regulation and not even in every case a reason for suspicion. Conversely, the "non-presence" is also not proof of organic production, as numerous unauthorised substances (e.g. fertilisers, but also pesticides) do not leave any detectable traces.

It is therefore very important how the operator, control body or control authority comes from a laboratory finding to a well-founded suspicion. Examples of this can be found in chapters 3.4 and 3.5, as well as a list of questions for the evaluation of laboratory findings.

59 Cf. www.boelw.de.

60 Cf. Vgl. Ministerium für Ländlichen Raum und Verbraucherschutz (MLR) (2018): Ökomonitoring 2018. Available online: http://www.untersuchungsaemter-bw.de/pdf/oekomonitoring2018.pdf.

2.3. Suggestions for the application of new control methods

This chapter presents control methods developed on the basis of the manual for the organic control procedure. Since, by nature, there is no experience in dealing with the new regulations and the application of this manual, the following methods are first recommendations. In the future it is planned to regularly present further proposals for control methods in the online version of the manual. On the one hand, control methods must be aimed at recording possible violations and, on the other hand, they must consider the probability of violations. Guidelines can be found in the OCR in articles 9, 10 and 12 to 15 and in the organic regulation in article 38.

An indispensable component of previous organic controls were detailed descriptions of the companies (company name, contact persons, addresses, areas, buildings, machinery, products and processes) and the documentation of work processes and inputs (seeds, fertilisation, plant protection, ingredients, production processes). This also includes documentation obligations for all procedures and processes in the company with which the purpose of the business is to be achieved: good professional practices, hygiene, traceability, hazard analysis and others. Sampling and analysis have played hardly any role in this so far. Sampling was planned only as an exception and in cases of suspicion and had little significance in practice. In the meantime, the control procedure has developped further and sampling has become a routine instrument. Accordingly, quotas for sampling are also planned for the future.

Article 14 of the OCR is entitled "Methods and techniques for official controls". The organic regulation itself contains no control methods for specific control procedures in organic farming. Therefore, organic control methods and techniques must refer to the list in article 14 of the OCR. Although this article describes control instruments rather than methods, the list in points a to j provides for the first time an overview of approved and tested techniques in process control.

2.3.1. Control procedure: preparation and planning of the control – prioritisation of control points

Objective: The objective of the control method is the effective use of the limited resource "control time on site" and the focus on activities that influence the integrity of the products. The method described can ensure that the selection of control contents is systematic.

Legal reference: Article 38 (2) of the organic regulation links essential contents and principles with official controls according to article 9 of the OCR. Sentence 1 of article 38 (2) stipulates that official controls at all stages of production, processing and distribution are to be carried out on the basis of the likelihood of violations of organic legislation. A control must therefore always be targeted and justified and be based on the probability of violations.

Procedure: In preparation for the inspection, the inspector categorises the company's activities into three priority levels (in medicine this method is called "triage"):

1. Quality determining steps, which are essential for the integrity of the products: Precautionary measures, separation of activities for organic and conventional products or production methods, procurement and use of products and substances (e.g. operating materials, ingredients, adjuvants), import from third countries, batch separation, measure description, self-control system, QM concepts, traceability, etc.
2. Quality assurance steps: labelling, testing of guaranteed properties (e.g. GMO-free), activities on purely organic farms, documentation, sales, export to third countries, employee training, etc.
3. Activities with no direct impact on integrity: all activities not covered by 1. and 2., e.g. farm sales of commercial products, factory sales, packaging materials, by-products that are not marketed, waste management, energy, transport.

The total planned control time is divided approximately in the ratio 3:2:1. For the inspection of quality determining steps (1.) about 50% of the planned time is used. Quality assurance steps (2.) are audited about one third of the time, while activities without direct impact on integrity (3.) take the remaining time (about 15%).

Advantages of the procedure: Prioritisation during preparation ensures that a sufficiently large amount of time is planned for the quality-determining steps at the beginning of the inspection. Less important points are dealt with at the end of the inspection if there is either already time pressure or if concentration is waning. Since the critical steps have already been checked, a good overview of the company is available at this point in time, so that even marginal topics can be dealt with in the necessary depth of detail.

It goes without saying that during the inspection, the inspector must at all times address any conspicuous features and particularities of the situation, modify his planned programme and, if necessary, set new or additional priorities.

Documentation: For the evaluation of the inspection and the planning of the follow-up inspection, it is important that information on the areas inspected is recorded. This necessity also results from the fact that a control can usually not be fully comprehensive.

2.3.2. Control procedure: Sample planning for controls of agricultural production

Objective: Sampling in the production sector is intended to confirm, substantiate or eliminate suspicions of the use of unauthorised products or substances. It can also help to check precautionary measures and their effectiveness (for general aspects of sampling see chapter 3.2).

Procedures:

- Sampling can be planned based on known or suspected risks. This can be based on information on plant health[61], other information from plant protection services, or advisory media from conventional agriculture.
- Sampling must always be carried out if suspicions of the use of unauthorised substances are detected during the inspection. Ideally, sampling should be carried out in the field. Sampling should be representative if an extensive application is suspected. So-called "hotspots" (i.e. areas with perceived or suspected application or anomalies in the crop) should be sampled if anomalies are found in the crop or if application is suspected at certain points. Bleaching may indicate herbicides from the bleacher group (clomazone), twisting and twisted growth and changes on stems of dicotyledonous species on the other hand may indicate growth promoters (e.g. 2,4 D-preparations). An application of fungicides or insecticides is not directly visible on the crop, only the absence of damage can give an indication.
- If the application of mineral nitrogen fertilisers is suspected, plant samples for isotope analysis are possible. However, these are not effective for all crops and require a reference sample from an undoubtedly biologically cultivated site as close as possible. It is advisable to take appropriate samples in case of suspicion, but to have them analysed only after consultation with an appropriate laboratory.
- It may be possible to take samples from storage containers of plant protection equipment or fertiliser spreaders, tanks or mixing containers for irrigation in order to check them for impermissible mixtures.
- Where there is a suspicion that precautionary measures have not been taken or are not effective, targeted sampling can also be carried out. This sampling must be planned and carried out in such a way, that the result of the analysis can confirm or dispel the suspicion. Examples may be the use of polluted/contaminated storage facilities or the suspicion of insufficient batch separation in storage and processing. In case of suspicion of insufficient cleaning of storage facilities in flat stores/silos, samples should preferably be taken from the peripheral areas of the storage facilities.
- Sampling in livestock production is generally limited to feed. Animal products (meat, eggs, milk) usually do not give rise to analytical results that would allow conclusions to be drawn about violations.

Documentation: Documentation is provided as part of the sampling protocols and, if necessary, in the description of the suspected or detected deviation. All relevant supporting documents must be enclosed.

61 e.g.: warning services for Phytophtora, Peronospora: e.g.: http://www.vitimeteo.de

Part 3: From sample to assessment – tips for implementation in practice

3.1. Selecting laboratories and service providers

Sampling with subsequent laboratory analysis, if carried out properly and appropriate, provides important information within the process of organic controls, food law controls ("compliance") as well as for the quality assurance of producers and enterprises (for the proper and appropriate performance of sampling see chapters 1.6. and 3.3.). Following sampling, the reliability of the results of the laboratory analyses is of decisive importance. Today, analytical service laboratories are all accredited according to the international standard ISO 17025 (current version ISO 17025: 2018) by the respective national accreditation bodies, in Germany this is the Deutsche Akkreditierungsstelle GmbH (DAkkS).

3.1.1. Quality-indicating characteristics of analytical service laboratories

The criterion "accredited laboratory" does not represent a particular quality characteristic with regard to the actual analytical competence of a laboratory in the control routine. The accreditation does not at all cover the assessment competence of laboratories with regard to conformity with food law requirements ("compliance"), such as the correct assignment and verification of the results in the analysed samples to the respective MRLs of regulations (EC) No. 396/2005 or (EC) No. 1881/2006. Verifications of competence with regard to assessment and interpretation analogous to analytical "interlaboratory comparisons" (laboratory competence tests, interlaboratory comparisons, etc.) are hardly offered so far.
A first assessment competence test was offered by the Lach & Bruns Partnership 2018[62] and carried out with a total of 16 participants from Germany and Austria. Pesticide residues and contaminants in the following foodstuffs had to be evaluated:

- tomatoes, fresh.
- organic black tea.
- organic goji berries, dried.

In addition to an evaluation based on food regulations, a toxicological evaluation and a classification according to organic criteria, if applicable, were required. A second assessment competence test – this time at European level – was offered and carried out in October 2019. Unfortunately, the analytical competence of the laboratories is also insufficiently verified in the accreditation procedure. Although laboratories must participate in a minimum number of method ring tests, the results usually do not allow conclusions to be drawn about the performance of the laboratories in routine testing. Method ring tests are carried out with a completely different effort (e.g. several repeated analyses) and additional confirmation steps compared to routine samples. A further point of criticism is the fact, that in many cases the test reports of the laboratories lack basic and essentially important information on the samples investigated (e.g. weight/volume/number of pieces of the sample received) and on the test methods used (commonly, only abbreviations are used or only the instrumental measurement technology is listed).
As a consequence of the insufficient significance of an accreditation in relation to the daily or actual analytical performance of a laboratory, various private sector systems have been set up to compensate for this shortcoming. These include the laboratory approval systems of QS GmbH[63] salmonella, feed, residue analysis), various, partly closed laboratory circles of the food retail trade and, in the field of organic food, the laboratory approval system of the Bundesverband Naturkost Naturwaren (BNN).[64] The members of the laboratory quality circle relana®,[65] dgo one step further by voluntarily submitting themselves to controls by the independent operator of this circle.

3.1.2. Choosing of analytical service laboratories for organic product controls

Helpful advice on the selection of a laboratory is provided by the private sector laboratory approval systems

62 Cf. Lach & Bruns Partnerschaft (2018): Competence test LB 18-01 "Beurteilung von Analysenergebnissen – Rückstände und Kontaminanten", May/June 2018.

63 Cf. QS Qualität und Sicherheit GmbH: Labore: Grenzwerte und Höchstgehalte im Blick. Available online: https://www.q-s.de/zertifizierungsstellen-und-labore/labore.html (accessed on 15.01.2020).

64 Cf. Bundesverband Naturkost Naturwaren: Laboranforderungen. Available online: https://n-bnn.de/qualitätsarbeit/laboranforderungen (accessed on 15.01.2020).

65 Cf. quality circle of laboratories relana®: Laboratory clients. Available online: http://www.relana-online.de/laborkunden/ (accessed on 17.03.2020).

mentioned above. Under the BNN laboratory system, laboratories can undergo the recognition procedure for different food groups (e.g. fruit/vegetables and/or grains/oily seeds and/or tea/spices) and for different parameters (e.g. pesticides and/or contaminants). Within the framework of this procedure, not only the analytical competence of the laboratories is tested, but also their assessment competence. Laboratory competence tests are carried out regularly (at least annually), each time specifically for the individual food groups. These tests are organised differently from the usual method ring tests, namely either as "unannounced" ring tests (the test sample arrives unexpectedly at the laboratory and has to be analysed and evaluated within a short period of time) or even as "hidden" samples submitted to the laboratories via BNN member companies. The laboratory tests of the BNN are based on the particularities that can occur with organic samples. These are e.g. very low levels of pesticides (e.g. < 0.01 mg/kg), which are spiked into the test material, or metabolites (degradation products of pesticides), which are not part of the residue definition according to Regulation (EC) No. 396/2005, but which can provide important information for an evaluation within the organic control procedure (e.g. AMPA as main metabolite of glyphosate). Laboratories that undergo these tests within the framework of the BNN laboratory approval procedure and achieve good results thereby demonstrate their special competence with regard to the requirements in the organic food sector. Once a BNN laboratory approval has been granted, it is generally limited to three years. Thereafter, a re-approval is necessary, which includes, among other things, as a main criterion the evaluation of the results achieved by the laboratory in the BNN competence tests during the previous three years.

For laboratories with a special demand on the quality of their services, the laboratory quality circle relana® has been established, which on a voluntary basis questions a broad spectrum of the services of laboratories. Above-average requirements are set up, which are subject to permanent checks. These checks include unannounced laboratory visits and the regular introduction of so-called "hidden" samples. These hidden samples (also called "white samples" or "undercover samples") are food products spiked with pesticides, which are sent in via customers of the respective laboratories. Thus, the laboratories do not recognise the samples as test samples and analyse them in their routine procedure, i.e. not with the additional effort and increased attention with which the official method ring test samples are analysed. In this way, weak points can be identified and improvement measures can be initiated to optimise the analytical quality of the laboratory in routine operations. The participants of relana® have committed themselves to actively participate in addressing emerging challenges and improving existing analytical methods. This results in regularly published position papers[66] which are made available to the public without exception. The current members of the laboratory circle belong to five different European countries and are available online.[67]

Qualitative differences of laboratories

Using the example of so-called "Acidic Herbicides", the qualitative differences of laboratories can be well illustrated. In many laboratories the representatives of the "Acidic Herbicides" are included in the active substance scope of the multimethod QuEChERS (EN 15662, see chapter 3.2.1.), e.g. 2,4-D, dichloroprop, fluazifop, haloxyfop, MCPA and others as so-called free acids. Some esters of these active substances are also included in the scope of the multimethod (e.g. haloxyfop methyl ester). However, both the free acids and the esters represent only a limited part of the total content of the "Acidic Herbicides". By far the largest part is present in biological material as conjugates, e.g. as haloxyfop glucoside. The multimethod is not sufficient to detect these conjugates analytically. An alkaline hydrolysis must be carried out as an additional step. This allows the total content of the herbicides to be recorded and a correct result to be obtained. Without this alkaline hydrolysis, the contents of the acid herbicides are usually determined to be clearly too low.

However, many laboratories do not point out this particularity and only use the multimethod for analysis. As this usually leads to significantly lower results, a correct evaluation of the analytical results is neither possible for checking compliance with maximum levels nor for an organic control procedure.

All laboratories in the relana® quality circle use alkaline hydrolysis if a corresponding question is posed. Likewise, the BNN laboratory approval procedure is used to check whether the laboratories have established this procedure. If not, this has to be done within a given period.

In principle, laboratories which offer residue analyses of organic products should be able to provide the following proofs of competence:

- Recognised laboratory in a laboratory approval system focused on the requirements for organic products such as that of the BNN e.V.
- Member of a quality laboratory circle with comprehensible and transparent criteria such as relana®.

66 http://www.relana-online.de/position-papers.
67 http://www.relana-online.de.

- At least regular and successful participation in method ring tests of commercial operators, with pesticide contents in the range < 0.01 mg/kg.

In addition to these proofs of competence, "soft" factors that can be considered when selecting suitable service laboratories include the following:

- Structure and comprehensibility of the test reports, especially with regard to complete information on the sample and clear, comprehensible information on the test methods used (no in-house method abbreviations or incomplete information such as LC/MSMS; see chapter 3.2.1.)
- Advising customers on a meaningful and appropriate scope of testing.
- Advice on how to deal with a positive finding, in particular with regard to the assessment of the finding in the overall context of the laboratory's experience with comparable pesticide-food combinations, both conventional and organic.
- Active information of the client, if the laboratory becomes aware of new risks for the product group under investigation.

The evaluation of analytical results for the organic products investigated should be agreed between the testing laboratory and the client. This avoids that the laboratory incorrectly assesses findings with regard to the requirements of EU legislation on organic farming (e.g. suspect sample, monitoring sample, compliance sample, etc.). If the laboratory is not informed about the purpose of the sampling, it should not give an assessment or interpretation of the results.

Especially if residues are found, expert advice for companies as well as control bodies and authorities is indispensable. If there is no contact person available in these cases or if the contact person is not able to give helpful advice, misinterpretations can be the result. Within the BNN laboratory recognition procedure the competence of the laboratories in this respect is checked and is part of a successful approval. For the laboratory quality circle relana® the continuous examination of the assessment competence is an essential part of the activities as well as the examination of reasonable examination proposals.

3.1.3. Choosing a suitable sampling service provider

An improperly performed sampling has the consequence that the results of the subsequent laboratory analysis are not or only partially usable. The greatest contribution to the variance and uncertainty of analytical results is caused by inadequacies in sampling (see chapter 1.5.). Samples should always be taken by people trained in sampling procedures (see chapter 3.3.) and who have the necessary equipment and aids at their disposal. *Consequently, a professional service provider should be commissioned to carry out sampling unless trained and experienced personnel are available.*

In the field of sampling organic products, it seems reasonable to commission companies for sampling that are also familiar with the overall context of sampling in the control procedure. These can be e.g. sampling companies or departments of laboratory service providers who offer the analysis, the evaluation of the analysis results and also the upstream sampling from one source. In such cases it is guaranteed that the necessary knowledge and practical experience from the involved areas of sampling, analysis and evaluation is available and coordinated in the sense of a purpose- and objective-oriented approach. For the sampling of microbiologically sensitive products or frozen goods, special techniques are applied, for which skilled personnel are at all times required.

3.1.4. Independent experts

For the overall assessment of sampling, laboratory analysis and the pre-defined purpose of these measures, it might be helpful to draw on the expertise and experience of external, independent specialised experts. These should be able to demonstrate in-depth knowledge and as much practical experience as possible in the relevant areas, such as

- Organic farming (production, storage, processing, trade).
- Sampling of food and raw food materials, soils, etc.
- Laboratory analysis.
- Food law with special focus on organic food.
- Food chemistry, general chemistry and geology.
- Biology and hydrology.
- Commodities science.
- Biological plant protection.
- Chemical plant protection.

It is important to be able to put individual aspects into an overall context. There are now a certain number of independent experts – usually self-employed consultants – who cover at least one, but often several of the above-mentioned areas competently. As a rule, these experts have extensive experience from previous activities in the fields of food production, processing, trade, analytical service laboratories, professional associations or other institutions or companies with a relevant connection to the subject of food.

3.2. Choosing examination parameters

Which parameters are to be examined in a sample taken, depends decisively on the question that triggered the sampling. In most cases, the issue is a possible contamination or a suspected illegal use of products that are not permitted in organic farming. The focus is particularly on pesticides, i.e. substances that are used in conventional agriculture as insecticides, acaricides, fungicides, herbicides or with other modes of action. The unauthorised use of genetically modified organisms (GMOs) should also be mentioned, although this aspect will not be discussed here, as the analysis is unambiguous and the limit of 0.9% for accidental and unavoidable contamination is clearly defined.[68]

As a matter of principle, care must be taken to ensure that the valid residue definitions (according to regulation (EC) no. 396/2005) of the respective pesticides or pesticide groups are taken into account when determining the scope of the analysis or the analytical methods. If, for example, it is suspected that herbicides have been used illegally or there is contamination with herbicides, it is not sufficient to commission a standardised multimethod (e.g. the QuEChERS method, EN 15662, see chapter 3.2.1.) for sampling and subsequent analysis. The reason for this is, that these standard tests may only detect a fraction of an herbicide. After their application in plants and soils, herbicides are often present as a mixture of acids, esters and conjugates, as most herbicides form conjugates with plant-own components (e.g. herbicide-glucosides or herbicide-glucuronates) quite quickly. It is therefore imperative to use a specific analytical method for their quantitative detection. For this purpose, a method that includes alkaline hydrolysis as an additional step is suitable. Otherwise there is a considerable risk that the herbicide content actually present in the sample will be underestimated. This in turn can lead to misinterpretations when evaluating the laboratory findings.

3.2.1. Overview analyses (screenings)

It is not always possible to correlate the questions that trigger sampling with a concrete suspicion or indication of certain pesticides from the outset. In these cases, it is useful to cover a range of pesticides as broad as possible by selecting a multimethod, supplemented by additional specific methods if necessary. This approach is often referred to as “screening” or “screening analysis”: Screening of the largest possible number of potential pesticides without specific advance information.

With the exception of some fats and oils and some herbs and spices, which require special sample preparation, a multi-residue method (MRM) is used for almost all food products, which was first published in 2005: the so-called “QuEChERS” multimethod.

QuEChERS stands for “Quick-Easy-Cheap-Effective-Rugged-Safe”. This method was jointly developed by Michelangelo Anastassiades of the Chemical and Veterinary Investigation Office (CVUA) Stuttgart and Steven Lehotay (U.S. Department of Agriculture, Pennsylvania, USA). Later on, two somewhat different analytical methods developed from this, which are now used worldwide. In Europe, the version of Anastassiades has become generally accepted, which was published in 2008 as European norm “EN 15662”. Since this method is constantly being optimized and refined, corresponding amendments to the standard are also being drafted. As of July 2019, the current version is the norm EN 15662:2018. Innovations and publications on the QuEChERS method can be followed on the website of CVUA Stuttgart.[69]

Often the abbreviations “GC/MSMS” and/or “LC/MSMS” are wrongly quoted as “applied methods”. These are by no means analytical methods, but instrumental measurement techniques used at the end of the analytical process. As a general rule, extracts obtained from the sample after comminution, homogenisation, extraction and purification are analysed by chromatography in order to successively determine the pesticides possibly contained in the sample according to their retention time (time in the separation column). Depending on the type and properties of the pesticides, gas chromatographs (GC) or liquid chromatographs (LC, for liquid chromatography) are used for this purpose. After the chromatographic separation, the pesticides are identified and their concentration is determined (quantification). Today, this is typically done with the help of mass spectrometry (MS). In order to achieve the necessary specificity and detection sensitivity, with which levels in the range of a few µg/kg can be reliably determined, several mass spectrometer units connected in series (MSMS) are used.

For a comprehensive overview analysis with the multimethod it is necessary to use both measurement techniques, GC/MSMS and LC/MSMS, to analyse the sample extracts.

68 Cf. Reg. (EU) No. 1829/2003, Art. 12.

69 Cf. Chemisches und Veterinäruntersuchungsamt (CVUA) Stuttgart (2016): QuEChERS und QuPPe – die Multimethoden in der Pestizidanalytik. Available online: http://www.untersuchungsämter-bw.de/pub/beitrag.asp?subid=1&Thema_ID=5&ID=2200&Pdf=No&lang=DE (accessed on 19.07.2019).

In addition to the multimethod mentioned above, the group of *"polar pesticides"* has been in focus for some time now and is in many cases part of a survey analysis in case of unclear questions. The group of polar pesticides comprises – as the name suggests – active ingredients that generally have polar properties and thus have positively and negatively charged components in the molecule. This prevents that these polar pesticides can be determined in one analysis run with the so-called non-polar pesticides, which are covered by the multimethod QuEChERS. Polar pesticides include chlorate (and perchlorate, which is not a pesticide), ethephon, fosetyl and phosphonic acid, but also glyphosate (and its main degradation product AMPA) or maleic acid hydrazide. These also include the growth regulators chlormequat and mepiquat as well as the herbicides diquat and paraquat. Which of these polar pesticides should be covered in a general analysis depends on the respective food product and its origin. Here, laboratories can usually give appropriate advice as to which analysis combinations of food/pesticide(s) make sense from their point of view.

3.2.2. Indirect (sum-)parameters

Some pesticides cannot be analysed directly or only with disproportionate effort. This is usually due to their particular physical-chemical properties (e.g. high volatility, low stability under normal conditions) or to the lack of analytical methods. In these cases, substitute parameters, also called indirect parameters, are used. This will be discussed using the two most important representatives.

Dithiocarbamates

The group of dithiocarbamates consists of numerous fungicides developed by the chemical industry which – with a few exceptions – cannot be analytically detected directly. However, since all these fungicides release carbon disulfide (CS_2) under appropriate conditions, this property is exploited: carbon disulfide is released by a chemical reaction and quantitatively measured. The measured carbon disulphide content is then compared with the maximum residue level ("dithiocarbamates, calculated as CS_2") of Regulation (EC) no. 396/2005.

The following problem arises: In many vegetables and also in some fruits, the plant's own ingredients containing carbon disulphide are present, which also release CS_2 during the analysis. These varieties include in particular leek and cabbage plants, but also papaya, for example. If such ingredients are naturally present in a food, they are measured as CS_2 in a laboratory analysis and thus simulate a possibly non-existent or too high dithiocarbamate level. This fact is described in detail in a document of the Bundesverband Naturkost Naturwaren e.V. (BNN).[70]

Inorganic total bromide

Like chloride or fluoride, inorganic bromide is the anionic (negative) part of mineral salts and occurs naturally in varying quantities in soil, water and plants. An overview of the natural content of bromide (and many other elements) in nuts and shell fruits was already published in 1979 by Keith Furr et.al.[71] DThere, a value of 16 mg/kg is given for pistachios, 20 mg/kg for almonds, 76 mg/kg for walnuts and 87 mg/kg for Brazil nuts.

It is also known that salt aerosols can drift from the sea into the interior of the landmass. The amount of these, that can be detected, depends on how far away agricultural fields are from maritime coastlines (see M.A. Short et.al.[72]). Sea salt aerosols show a typical chloride/bromide ratio where the proportion of bromide is increased compared to the ratio of these anions in soils. If sea salt aerosols are transferred to agricultural soils and the crops growing there, the bromide content increases, in some cases significantly, depending on the absorption properties of the respective plants.

This effect can be observed in Italy, for example, where the extreme length of the coast means that many tomato growing areas are exposed to such sea salt aerosol inputs. Regularly, correspondingly elevated bromide levels are therefore found in Italian field-grown (organic) tomatoes.

So why does one analyse inorganic bromide in food products and especially in those from organic farming? The analysis of total inorganic bromide can give an indication of an unauthorised application of bromine-containing agents through fumigation. These are substances such as methyl bromide or dibromoethane, which convert very quickly into inorganic bromide after use. Thus, the proof of a treatment is usually not provided by the analysis of the fumigants themselves, but indirectly via the bromide. For this reason, a maximum content for inorganic bromide is also regulated (see Regulation (EC) No 396/2005). However, when setting the maximum level, the specific basic content of inorganic bromide in individual plants and fruits was not taken into account, but a flat-rate value for various groups (e.g. nuts, salads, vegetables) was used as a basis.

70 Cf. Bundesverband Naturkost Naturwaren e.V. (2009): Interpretationshilfen zum BNN-Orientierungswert für Pestizide. See point 3) "Dithiocarbamat-Nachweise in Bio-Produkten". Available online: https://n-bnn.de/sites/default/dateien/190409_Interpretationshilfen_OWert.pdf (accessed on 22.07.2019).

71 Cf. Keith Furr, A.; et.al. (1979): Elemental Composition of Tree Nuts, Bull.Environm.Contam.Toxicol. 21, p. 392-396.

72 Cf. Short, M.A.; P. de Caritat, D.C. McPhail (2017): Continental-scale variation in chloride/bromide ratios of wet deposition, Science of the Total Environment 574, p. 1533-1543.

On this flat-rate basis, the maximum levels for the individual foodstuffs were set in such a way, that if they were exceeded, there would be concrete evidence of the use of fumigants containing bromine. This quite sensible approach is to be applied in principle to a plant or fruit, regardless of whether the plants or fruits are conventionally or organically grown. The background level of bromide will be reflected in the plant, regardless of the cultivation method used.

The use of methyl bromide has also been banned for a long time for conventionally produced products (see Montreal Protocol[73]), so here too the focus is on proving (circumstantial evidence) that a banned bromine-containing fumigant has been used when setting maximum levels. In this respect, there is no conclusive reason to set a separate or particularly low bromide content for organic products as an indication of possible illegal fumigation.

As the "phase-out period" for methyl bromide agreed under the Montreal Protocol also ended in 2015 in all so-called "developing countries" (2005 already for the "developed countries"), the use and thus also the proof of illegal use of methyl bromide is becoming increasingly unlikely. The author is not aware of a single case from the last ten years in which an analytical finding on bromide is available which could be used as an indication of the illegal use of a bromine-containing fumigant. Taking into account the natural bromide occurrences discussed above and the possible influence of sea salt aerosols, it seems fundamentally worth considering not to analyse inorganic bromide. This is at least true when it comes to proving the integrity of organically produced food. Irrespective of this, random checks on compliance with the maximum residue level for bromide in accordance with Regulation (EC) no. 396/2005 should not be omitted.

3.2.3. Choosing analytical methods and parameters (pesticides)

As already mentioned at the beginning of the chapter, the selection of the parameters to be investigated must be based on the particular problem that triggered the sampling. Nevertheless, the question of fundamentally sensible investigation scopes arises. Often there is little or no detailed information available that would enable the scope of the investigation to be clearly defined after sampling has been initiated for whatever reason.

Table 2 at the end of the chapter therefore contains recommendations which – in relation to the respective product group under investigation – provide information on which analytical methods (e.g. pesticide multimethod) or which parameter groups (e.g. acid herbicides) or individual pesticide determinations are useful. These recommendations are based on many years of knowledge and experience of the authors in various analytical service laboratories and in the preparation of numerous expert opinions on the evaluation of pesticide contents in organic products.

It should be clearly pointed out at this point that such a list always represents only a snapshot based on the current state of knowledge and that these recommendations may become obsolete due to new pesticides, analytical developments and findings. In particular – as the recent past has just shown – new parameters can suddenly become relevant which were previously unknown or were not considered relevant. Examples are the parameters chlorate, perchlorate, phosphonic acid, phthalimide or nicotine. Especially parameters that are used as so-called "multiple use" active ingredients are always in focus. An overview of such substances or parameters has been published in a position paper of the laboratory circle relana® [74] (s. table 1).

Other relevant sources of information for the search for meaningful investigation scopes are the annual monitoring reports of the official food control authorities. Particularly worth mentioning is the "Ökomonitoring Baden-Württemberg", which has been examining selected organic foods on an annual basis since 2002. The results are published in detailed reports.[75]

Of course, large database records on pesticide findings in organic products are also available from private service laboratories, so that these laboratories also represent an important source of information for their customers. Above all, laboratories that have been recognised within the framework of the laboratory approval system of the BNN e.V., and in particular those laboratories that carry out or have carried out the analyses of the BNN monitoring for fruit and vegetables, can offer a high density of information and specific detailed knowledge.

For imported goods from non-EU countries, the *"Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third*

73 https://www.admin.ch/opc/de/classified-compilation/19870179/201901010000/0.814.021.pdf (accessed on 23.12.2019).

74 Cf. relana®Position Paper No. 19-01"Sources of contamination of samples for analysis" version 2019/04/12. Available online: http://www.relana-online.de/wp-content/uploads/2019/04/relana-pos.-paper-19-01-Sources-of-Contaminations-20190412-final.pdf (accessed on 06.09.2019).

75 Cf. Ministerium für ländlichen Raum und Verbraucherschutz Baden-Württemberg (2018): Ökomonitoringberichte. Available online: https://oekomonitoring.ua-bw.de/berichte.html (accessed on 06.09.2019).

Source	Possible compounds (examples)	Remarks
Repellents and insecticides against moths	• naphthalene • pyrethroids (like permethrin, phenothrin, synergist piperonylbutoxide (PBO)) • chlorpyrifos	• Occurrence also in carpets, wool, lambskin etc. possible.
Veterinary biocides against ticks, fleas etc.	• biocides such as propoxur, diazinon, imidacloprid, flumethrin, fipronil	• For use with pets (dogs, cats), for example as shampoos or in collars.
Antibiotics and veterinary drugs	• tetracyclines • sulfonamides	• carry-over into plants via manure.
[…]		
Cleansers and disinfectants	• hypochlorite (→ chlorate) • quaternary ammonium compounds (DDAC, BAC) • 2-phenyl phenol	• Check any cleansers used in factories, transport vessels, labs etc.; 2-phenyl phenol also used in air nebulisers.
Carry-over contamination via substrates	• chlormequat/mepiquat in mushrooms • nicotine in mushrooms	• transfer via contaminated straw or substrate. (f.ex. by presence of tobacco stems or feathers of hens being treated with nicotine).
Open fires, firesides, bonfires, heating, drying with exhaust fumes, open waste incineration incl. waste incinerating plants	• PAH • biphenyl • anthraquinone • dioxins • MOSH/MOAH • heavy metals (such as mercury)	• high risk products: • dried food and feedstuff (herbs, spices, tea etc.) • products with large surfaces (fresh herbs).
Drinking water/washing irrigation water	• chlorate/perchlorate • bromide	
Tobacco users (smoking, chewing), **tobacco cultivation**	• nicotine *** • PAH • cadmium	*** direct contact with smoke; contamination via hands (esp. after rolling of tobacco products for chewing); nicotine through air and dust (if close to tobacco plantations) …

Table 1: Excerpts from the relana® position paper 19-01

countries (...)" should be taken into account.[76] This implementing regulation sets out in detail the measures to be taken for temporarily increasing official controls on certain food and feed of non-animal origin from third countries, where maximum levels of pesticide residues are exceeded or where there is a risk of contamination by mycotoxins (in particular aflatoxins), germs or other undesirable substances.

In addition to the product, the country of origin, the hazard (e.g. pesticide residues, specified if necessary, or mycotoxins) and the frequency of physical checks or identity checks are mentioned. Even though this regulation was not explicitly drawn up for organic products, but in principle for all food and feedstuffs of the respective product type from a particular country of origin, it is advisable to observe the current risk parameters listed there and, if necessary, to include them in a scope of analysis.

76 Cf. European Commission (2019): Implementing Provision (EU) 2019/1793 of the Commission. Available online: https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32019R1793&qid=1572447390106&from=DE (accessed on 30.10.2019).

Product group	pesticides (multimethod)	acidic herbicides	chlormequat, mepiquat	glyphosate/AMPA	ethephon	fosetyl/phosphonic acid	chlorate, perchlorate	maleic acid hydrazide	nicotine	dithiocarbamates (as CS_2)	fumigants	Remarks
1. FRUITS, FRESH or FROZEN; TREE NUTS												
Citrus fruits	x	x		x		x						
Tree nuts	x	o									o	*acidic herbicides: peanuts (4-chlorophenoxyacetic acid) fumigants: vacuum-packed cardboard goods (especially phosphine)*
Pome fruits	x		o			x				o		*chlormequat: pears dithiocarbamates: apples*
Stone fruits	x					x				x		
Berries and small fruits	x	x	o	x	o	x				o		*chlormequat: table grapes of India ethephon: red table grapes dithiocarbamates: Table grapes, overseas goods*
Miscellaneous fruits	x	x			o		x					*ethephon: pineapple, mangos*
2. VEGETABLES, FRESH or FROZEN												
Root and tuber vegetables	x							x				
Bulb vegetables	x					x	x	x				
Fruiting vegetables	x				o		o					*ethephon: sweet peppers, tomatoes chlorate and perchlorate: melons*
Brassica vegetables	x											*dithiocarbamates not meaningful (mustard oil glycosides)*
Leaf vegetables, herbs and edible flowers	x						x			x		
Legume vegetable	x											
Stem vegetables	x											
Fungi	x		x	o		x			o			*glyphosate: cultivated fungi nicotine: edible boletus*
3. PULSES	x			x								
4. OILSEEDS AND OIL FRUITS	x	x		o							o	*glyphosate: flaxseeds fumigants: goods (stock) from third countries (especially phosphine)*
5. CEREALS	x	x	x								o	*fumigants: goods (stock) from third countries (especially phosphine)*
6. TEES and HERBAL INFUSIONS	x	x		x					x			
7. SPICES	x										o	*goods (stock) from third countries (especially ethylene oxide)*

(x) recommended (o) consider notes

Table 2: Recommendations on analytical methods and parameter groups or specific pesticides (as of September 2019).

3.3. Sampling as an element of the control procedure

The inspection must be carried out on the basis of the probability of violations of the applicable organic legislation (see Chapter 1.7.). Therefore, depending on the task in the organic control procedure, a representative sample is often not the method of choice. If during the inspection or assessment of organically farmed agricultural areas conspicuous features are identified (e.g. plant damage that is only spatially limited; partial weed clearance of areas), alternative sampling strategies adapted to the specific situation are necessary. The same applies, if there are indications that a batch of organic goods is not sufficiently or carefully protected from contamination or contamination during storage or processing (e.g. suspicion of the use of stock protection agents or of inadequate cleaning of conveyor lines and pipe systems on mixed-processing farms). These strategies can be e.g. side-row sampling, risk sampling, spatially dispersed sampling of bulk materials or dust sampling (see also chapter 3.4.).

3.3.1. Official requirements for sampling procedures

Depending on the analyte[77] and the objective of the sampling, a suitable sampling procedure must be selected in advance.
For samples to be tested for maximum levels of pesticides, the EU directive 2002/63/EC contains the requirements for official controls *("Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin").* Since its publication in 2002, the directive has neither been

77 For example, a suspicion of herbicides used in previous charges, instant action fungicides or insecticides, a possible presence of heavy metals, mycotoxins, alkaloids, process-contaminants like Chlorate and others.

Tabelle 4

Pflanzenerzeugnisse: Beschreibung der Primärproben und Mindestgröße der Laborproben

	Warenklassifikation (1)	Beispiele	Art der zu entnehmenden Primärprobe	Mindestgröße der einzelnen Laborproben
Primäre Lebensmittel pflanzlichen Ursprungs				
1.	Frisches Obst Frisches Gemüse, einschließlich Kartoffeln und Zuckerrüben, jedoch ausgenommen Kräuter			
1.1.	Kleine Frischerzeugnisse Einheiten i. d. R. < 25 g	Beeren, Erbsen, Oliven	Ganze Einheiten oder Packungen oder mit einem Probenahmegerät entnommene Einheiten	1 kg
1.2.	Mittelgroße Frischerzeugnisse, Einheiten i. d. R. 25-250 g	Äpfel, Orangen	Ganze Einheiten	1 kg (mindestens 10 Einheiten)
1.3.	Große Frischerzeugnisse, Einheiten i. d. R. > 250 g	Kohlköpfe, Gurken, Trauben (Büschel)	Ganze Einheit(en)	2 kg (mindestens 5 Einheiten)

Table 3: Extract from Table 4 "Primary products: Description of primary samples and minimum size of laboratory samples" from directive 2002/63/EC

transposed into national (German) law nor replaced by an EU regulation (directly and in all EU member states). In the case of official controls to verify compliance with maximum residue levels of pesticides in accordance with regulation (EC) no. 396/2005, the administrative bodies are obliged to apply this directive.

The recitals of that regulation state, that MRLs for pesticides should be set taking into account, among other things, good agricultural practice:

"Accordingly, in the interest of free movement of goods, equal competition conditions among the Member States, as well as a high level of consumer protection, it is appropriate that maximum residue levels (MRLs) for products of plant and animal origin be set at Community level, taking into account good agricultural practice." [78]

It also explains once again, that the starting point is the legal use of plant protection products (pesticides), considering good agricultural practice and integrated plant protection:

"Directive 91/414/EEC provides that Member States, when issuing authorisations, are to prescribe that plant protection products be used properly. Proper use includes the application of the principles of good agricultural practice as well as the principles of integrated control." [79]

Accordingly, the sampling methods described in directive 2002/63/EC pursue a specific objective. They are intended to monitor the correct application of good agricultural practice with regard to the application of chemical pesticides by checking whether the maximum residue levels of regulation (EC) no. 396/2005 are met. For other tasks such as the one just described, the directive is only partially applicable.

Directive 2002/63/EC goes into detail on the necessary definitions (e.g. unit, primary sample/individual sample, bulk sample/aggregate sample, laboratory sample, analytical sample, etc.) and describes different sampling procedures in order to take representative samples from a lot. For food of animal and plant origin, for example, the number of primary samples and the minimum size of individual laboratory samples are specified (see Table 3).

A publication of the FAO (Food and Agriculture Organisation of the United Nations) is also important as a further document.[80]

Appendix V of this document describes in detail sampling procedures which serve as a basis for meaningful and representative analytical results. In terms of content, this FAO document – as well as directive 2002/63/EC – aims at the deliberate and planned application of pesticides by applying the guidelines of Good Agricultural Practice. At the same time, however, they are also relevant with regard to a valid "representative" statement regarding a possible pesticide or contaminant load of a field (field impact) or a bulk lot.

3.3.2. Recommendations for sampling strategies

Depending on the question resp. objective within the scope of application of the organic regulation, different sampling strategies for primary agricultural products (field plants) must be chosen.

1. *Specific suspicion of non-compliant or unauthorised use of a pesticide during growth in the field or on the tree/bush or suspicion of non-compliant or unauthorised post-harvest or storage protection treatment:*
   In these cases, it is usually useful to carry out representative sampling, considering the procedures described in the two documents mentioned above (EC 2002/63/EC and FAO 2016). Contamination of a field or cultivation area due to the background contamination of the environmental compartments water, soil and air with pesticides, which are transported over long distances (atmospheric input), can also be recorded in this way.
2. *Suspected contamination due to direct drift from neighbouring crops:*
   After prior assessment of possible inputs from neighbouring areas managed with conventional chemical methods, a risk sampling of marginal rows or marginal areas is useful. This risk sampling can be carried out in different ways. Primary samples can be taken from a boundary strip at several locations, which, when combined to form a total sample, allow a representative statement to be made on the contamination of a boundary strip along the boundary to the potential source of the drift. However, in certain cases it may also be useful to take individual samples at several locations, e.g. to identify a gradient (decreasing loading of the samples from the side-strip towards the centre of the field). However, it should be noted that influences from neighbouring fields are generally not within the organic farmer's sphere of influence.[81]
3. *Suspicion of (partial) mixing with conventional goods:*
   In this case, a strategy of dividing the total lot into sublots that are as small as possible, but which must be physically distinguishable (e.g. by separate storage), is meaningful. This is the only way to identify parts of the total batch that may contain non-con-

78 Regulation (EU) no. 396/2005: Recital (3), second sentence.
79 Regulation (EU) no. 396/2005: Recital (7).
80 Cf. FAO (2016): Submission and evaluation of pesticide residues data for the estimation of maximum residue levels in food and feed, Rome.
81 Cf. Recital 68 organic regulation.

forming (conventional chemical) components. A representative sampling of the total batch will usually not be able to detect an admixture of non-conforming fractions due to the dilution process taking place. This has to be considered especially for very large bulk material lots (e.g. grain lots of several hundred or thousand tons).

3.3.3. Devising a sampling scheme

Depending on the analyte and purpose, an appropriate sampling scheme must be established to obtain a meaningful sample. It should include the following provisions:

- Number of sub-samples (from the field, lot, silo, pre-packages, etc.).
- Location of sampling points ("Z" or "S" scheme, start-centre-end for loading, selected sample(s), etc.).

sample(s), etc.).

If there are doubts about the conformity of a product (batch, lot) with the requirements of regulation (EU) 2018/848, the following possible cases, among others, must be considered:

1. The entire crop/goods have not been grown and/or processed in conformity.
2. A part of the crop/goods has not been grown and/or processed in a compliant way and has been intentionally (deliberately) or unintentionally (e.g. unknowingly contaminated goods due to insufficient rinsing after processing or transport of conventional chemical goods) mixed with organically compliant goods.
3. The goods have been grown and processed in a way that is in conformity with organic standards, but have been contaminated by diffuse inputs from the environment (e.g. background contamination of environmental compartments, dry and/or wet deposition, indoor dust) during production or during transportation and processing.

In *case 1,* sampling that is exclusively representative would lead to a valid and traceable analytical result which can serve as a basis for further evaluation in the control procedure.

In the case of goods of a batch which is only partially non-compliant *(case 2),* representative sampling leads to an analytical result which, due to the compliant part of the batch as a whole, indicates low levels of the pesticide or other substances in question. As a rule, this does not reveal whether the measured content is evenly distributed over the entire product or whether only individual parts of the total batch are affected (see also chapter 1.5.3.). In this case, the representative sample must be supplemented by individual samples in order to identify the possibly non-conforming parts of the batch. These individual samples are then characterised by significantly higher contents compared to the representative sample.

If organically grown and processed goods have been contaminated by diffuse environmental inputs *(case 3),* a uniform distribution of the contaminations cannot generally be assumed (only in the case of atmospheric inputs can a homogeneous distribution be expected across the area/field). In this case, the same procedure as described in case 2 makes sense in principle. The higher number of positive findings on average (in the lower concentration range, i.e. untypical for conventionally chemically treated goods) can represent an important part of the plausibility chain.

Independent of this, external factors can limit the possibility of carrying out a representative sampling:

- Available time (before loading, packing, processing, etc.).
- In such a case, efforts should be made in advance to ensure that the shipper, packer, processor, etc. has a sufficient time window.
- Technical possibilities (availability of sampling equipment, suitable sampling bags, protective clothing when sampling in refrigerated or deep-frozen environments, etc.).
- The commissioning of professional service providers generally avoids the deficiencies men-tioned above (for the selection of sampling service providers see under 3.1.3.)
- Lack of trained personnel.
- The commissioning of professional service providers generally avoids the deficiencies men-tioned above (for the selection of sampling service providers see under 3.1.3.)
- Accessibility of the lot (fully packed containers, pallets on high shelves, sterilised containers that would become unsterile during sampling, freezer storage, etc.).
- Extreme weather conditions for outdoor sampling (e.g. continuous rain: fields not accessible or samples cannot be taken; heavy rain with wash-outs, thunderstorms with hail).

In general, a reasonable effort should be made to obtain a meaningful sample. Any deviations from the specifications must be carefully documented and justified in the sampling protocol.

Sampling can be carried out at various locations along the supply chain, which may differ according to conditions such as accessibility, temperature, humidity, etc. at the respective sampling points:

- In the field or in a plantation.
- In warehouses (storage uncooled, cooled or frozen).
- At retail level.
- In large bags, containers, silos, etc.
- In transport vehicles (lorries, tankers, ships, etc.).

Sampling is not limited to food and feed, but may also include leaf samples, water, soil, growths of neighbour-

ing untreated areas (blank samples for "background contamination"), inputs (fertilisers, plant fortifiers, etc.), contact and wipe samples (search for sources of contamination, see also chapter 3.4.).

3.3.4. Experience, independence and training of personnel

Samples should be taken by persons trained in sampling procedures. Whether or not official permits are required for sampling is governed by any applicable legislation (e.g. for drinking water, where there is a particular risk of contamination). There are no known restrictions for control authorities or control bodies on the sampling of products that fall within the scope of the organic regulation.
Since the number of possible errors in sampling is high and defined standards must be observed, sampling should always be carried out by qualified personnel who have experience in sampling.
Another relevant factor is the independence of the personnel, as they must be free from any economic or other interests that could influence the sampling. Therefore, the production manager of the controlled company may not be the best person to carry out the sampling. In any case, the independence of the organic inspector must be guaranteed. In order to ensure the independence of the sampling, an external person or company may also be appointed.

3.3.5. Time component of sampling

As not all analytes (especially pesticides) are stable over a significant time period, the timing and duration of sampling is of great importance. Large time intervals between individual sampling and the arrival of the samples at the laboratory can significantly change the original pesticide content. It is therefore essential that samples already taken, are immediately kept at least refrigerated (e.g. in cool boxes with a sufficient number of cooling elements or electrical cooling) and stored in the dark. Transfer to the laboratory should take place as soon as possible. This applies not only to fresh products such as fruit and vegetables, but also to dry products such as grain or oilseeds. Pesticides may be present on the surface of these food products, for example, and these may evaporate during improper transport and storage. High temperatures not only favour direct loss through evaporation, but also a possible degradation to metabolites (which may not be detected analytically) can be accelerated.

3.3.6. Traceability

Usual sampling procedures in the context of checking compliance with maximum residue levels or threshold values under food law as well as health safety requirements are aimed at obtaining a representative sample, i.e. to represent the properties of an entire batch (also charge or lot).
However, it must be questioned whether the "lot" from which the sample is taken always corresponds to the official definition of a "lot" as formulated in the following two documents.

Regulation (EC) No 401/2006, Annex I, Chapter A.2.1:
"Lot" means a distinguishable quantity of food delivered in a consignment which, according to official examination, displays common characteristics such as origin, variety, type of packaging, packager, dispatcher or labelling.

Directive 2011/91/EU, Art. 1 para. 2
For the purposes of this directive, "lot" means a set of sales units of a foodstuff, which has been produced, manufactured or packaged under practically identical conditions.

In practice, however, a wide variety of aspects can be used to define a lot:
- Varieties (types) of food and feed.
- Producers and/or sellers (particularly in the case of cooperatives consisting of a large number of small businesses or producers).
- Different fields or plantations.

Often batches or lots are defined by commercially divided deliveries or settlement units. The products then have to be tested for their characteristic properties.
If the batch is of uniform quality, sampling by obtaining a representative sample is useful. Examples of this are sugar or edible oils.
Otherwise, several random samples are necessary, which are analysed separately. An example: Deliveries of raisins from different primary producers are combined into one batch (lot).
Where the product is unlikely to be a homogeneous unit, the methods described in regulation (EU) No 691/2013 may be used to obtain a meaningful sample, in particular as regards the number of incremental samples to be taken.[82]
Although this regulation refers to the official testing of feed *("laying down the methods of sampling and analysis for the official control of feed"),* the intention and the resulting sampling instructions correspond to the

82 Cf. Reg. (EU) No. 691/2013, Appendix I, Paragraph 5.2.

issue discussed here with regard to unevenly occurring undesirable substances or contaminants.
Sampling of a selection or, in the extreme case, of all individual batches delivered by primary producers may also be useful, especially if knowledge of product qualities from the past is available (e.g. repeated suspicion of non-conformities).

3.3.7. Deficiencies in sampling and technical errors

Examples of defects and technical errors that can occur are:
- Insufficient sample size.
- Number of individual samples is too small.
- Samples are only taken at one location (unless explicit sampling is intended).
- Missing or unsuitable sampling equipment or containers.

The following "rules of thumb" should always be observed when sampling after harvesting:
- Never just one crate / box / big bag (unless there is a clear indication of "this" one crate).
- Never sample a pallet stack or silo only "from above".
- Cut open/break open crates or de-stack pallets.
- Only take samples of clearly identified goods.
- Do not mix different lots/batches (origins, producers, production units).

3.3.8. Contamination of samples by personnel, during storage or due to unsuitable containers

Personnel performing the sampling may be a cause of cross-contamination, for example by
- Transmission of repellents against mosquitoes containing DEET or icaridin.
- Contamination with nicotine (smoking, chewing tobacco).
- Use of laboratory gloves or other disposable gloves containing carbon disulfide releasers (thiurams, dithiocarbamates) as vulcanization accelerators or other unsuitable chemicals.
- Veterinary medicines used in the pet industry (e.g. products against fleas and ticks) for pet owners.
- Disinfecting hands after going to the toilet with soaps and creams containing quaternary ammonium compounds (QAV).

Careful consideration of storage conditions is also very important, as there are many sources of cross-contamination:
- Contamination with repellents if used indoors or if persons touching samples have been treated with repellents prior to sample contact.
- Use of insecticides as biocides (e.g. pyrethroids, pyrethrin's, organochlorine pesticides, etc.) against insects, moths, cockroaches, etc.
- Cross-contamination with pesticides, surface treatment agents, disinfectants (quaternary ammo-nium compounds, chlorate formed from hypochlorite) via water, surfaces (such as conveyor belts), etc.
- Contamination with wood preservatives (e.g. PCP) through the wood or wooden crates used to make storage boxes.
- Contamination with plastic additives, monomers and polymers (phthalates, POSH etc.) from sur-faces of tubes, seals, joint sealing compounds, etc.

The choice of a vessel that is inert to the compounds to be analysed and that is adapted to the properties of the sample is of great importance.
Typical problems include
- Contamination with plastic additives, monomers and polymers (phthalates, POSH etc.) from sample bags.
- Contamination with anthraquinone or 2-phenylphenol from paper bags.
- Contamination of sampling bags/containers with biocides, as they may have been stored in places previously treated with biocides.
- Use of glass containers for pesticide analysis (some pesticides adhere strongly to glass surfaces).

3.3.9. Reduction of large samples and incorrect documentation

Large units such as pumpkins, watermelons or cabbages are difficult to sample and transport, especially considering that five units (directive 2002/63/EC) are required to prepare a laboratory sample. The idea of reducing samples and sending only parts to the laboratory is understandable. But the above-mentioned provision elaborates:
"Individual eggs, fresh fruit or vegetables must not be cut or broken to produce units." [83]
If units are mechanically manipulated by cutting or similar techniques, unfavourable processes can be triggered that alter the pesticide content, such as
- Degradation of sensitive analytes such as fungicides from the group of dithiocarbamates.
- Enzymatic degradation.
- Microbiological growth, which influences the pesticide content.
- Water loss, which leads to incorrect weight references and concentration ratios.

If important information is missing from the sampling protocol (description of the product, batch number, date, temperature (if required), etc.) or the informa-

83 Appendix, No. 3 "Definition, unit, note a)" of directive 2002/63/EC.

tion itself is incorrect (e.g. mixed-up lot numbers), the sample and the corresponding analytical results may become unusable.

3.3.10. Sample transport

Especially a suitable temperature control during transport and intermediate storage of the samples is important for the validity of the analysis results. As a bare minimum, cool boxes with cooling batteries of sufficient capacity should be available.
The samples must be stored under suitable conditions immediately after sampling (e.g. in the sampling staff's car), taking into account not only the aspect of contamination.
Temperature: As a rule, the samples taken must be stored and transported in a cool environment. In the case of longer transport times (several days, e.g. in the case of samples from overseas), freezing and transport using dry ice may also be appropriate. For microbiological analyses, samples should not be frozen, as this may affect certain microorganisms. In addition, the samples must be protected from light, especially from sunlight (UV radiation).
Sensitive samples such as berry products or rocket should be protected from pressure by containers such as plastic cans. Otherwise there is a risk that they may be crushed and arrive in the laboratory partly liquefied. The leaked cell water is able to break down active substances. In such cases, sample bags should not be used, but sample beakers or containers.

3.4. Practical implementation of sampling

A number of preparations must be made for the practical implementation of sampling. Depending on the problem that triggered the sampling and subsequent analysis, appropriate and target-oriented strategies have to be selected and provisions made for the sampling itself, for the preparation of the laboratory sample, for the selection of sampling equipment and sample containers as well as for documentation.

3.4.1. Sampling in the field and preparation of a lab sample

Sampling strategy
On the basis of field plans and documentation (e.g. geographical maps) as well as the crop to be sampled (orchards, cornfields, etc.), a meaningful sampling strategy should be determined in advance. Sometimes local conditions do not allow the original approach to be implemented. In such cases, the sampling strategy must be adapted spontaneously on site and the reasons for this must be documented.
Provided that no external critical influences can be identified (e.g. no conventionally chemically cultivated neighbouring fields, no direct emission sources, etc.) and no visual conspicuousness is detected in the area to be sampled, a mixed sample representative of the corresponding area should be taken.
Individual samples are taken at several points distributed over the entire area. The sampling points are determined schematically in advance on the basis of the field maps, e.g. by placing an X or W or a zigzag line over the area (see figure 14). The incremental samples shall then be taken at the end or turning or intersection points of the geometries thus placed on the surface, but at least five incremental samples shall be taken. In the case of correspondingly large surfaces, additional sampling points should also be considered on the longitudinal axes.
If, however, the documentation reveals obvious risk areas (e.g. conventionally chemically cultivated neighbouring fields, possibly even without protective strips; position of the field in the air flow area of the main wind direction of an emission source), or if visually noticeable anomalies are detected (e.g. discoloration or de-pigmentation of green plant parts, see figure 15), a different sampling strategy should be chosen. This could be, for example, separate sampling of border strips to neighbouring fields, with simultaneous individual sampling at locations that are unlikely to be exposed to the corresponding influence (e.g. in the centre of the field or on the opposite side without obvious influence). This may substantiate or refute a suspicion of

Figure 14: Possible shapes for sampling points in a variety of situations; upper figure: diagonal line, lower figure: zigzag pattern (X = notional equidistant sampling points: red X = actual sampling points). Source: https://www.bodenanalyse-zentrum.de/so-geht-s.

the use of unauthorised substances. As drift cannot be excluded within the organic inspection scheme, sampling should always be carried out – if possible due to local conditions – in such a way that areas untouched by neighbourly influence are sampled as an indicator for possible applications by the organic farmer.
These incremental samples may be taken in addition to a representative composite sample or alternatively. This must be decided individually on the basis of the respective local situation.
In addition to a possible risk-oriented sampling of edge rows, edge strips or other areas at risk of contamination or areas suspected of being contaminated in some other way, appropriate sampling points must always be determined depending on the problem. This can be e.g. a linear or diagonal sequence of sampling points in order to prove a possible direct contamination of neighbouring fields via a concentration gradient (= decrease of the measured pesticide contents with the distance from the potential source). In case of suspected unclear or diffuse inputs, a sampling strategy using zigzag patterns is more appropriate (see figure 14).

Figure 15: Carrot field with de-pigmented patches, caused by the application of clomazone. Source: Lach & Bruns Partnerschaft, Hamburg

Preparation of the test sample
After the incremental samples have been combined to form a bulk sample, the representative composite sample (= test sample) is to be prepared by mixing them well or by taking individual pieces from each incremental sample.
The aggregate sample must consist of sufficient material to form the laboratory sample(s) (if necessary, a laboratory sample consists of the complete aggregate sample). Directive 2002/63/EC provides guidance in this respect (see table 4).

Selection of sampled plants and reference samples
For a meaningful selection of plants or parts of plants to be sampled and analysed, it is also important to consider whether chemical substances or active ingredients accumulate in certain parts of a plant, while other parts of the plant may not show any accumulation behaviour.
In principle, it may be useful to take leaf samples in order to detect suspected applications, especially of fungicides (e.g. from the group of dithiocarbamates) or insecticides. Especially at an early stage of vegetation,

Accumulation of pesticides in plant parts
Carrots are a good example of the accumulation of pesticides in certain parts of the plant. Active ingredients (usually herbicides) absorbed from the soil are often transported via the roots into the leaves (carrot green) where they are enriched. The forerunner herbicide clomazone shows exactly this behaviour and also has the property of de-pigmenting leaf green. In a documented case on a southern European organic carrot field clomazone was found in low concentrations in the carrot green (approx. 0.01 mg/kg), whereas no evidence of clomazone could be found in the carrot roots or in the soil. Sampling and analysis with regard to a possible herbicide application were carried out, because during the inspection of the carrot field area punctual de-pigmentations of the carrot green were noticed (see figure 15). In the following interview with the producer it was turned out, that the field had actually been treated with clomazone before sowing the carrots.

when the actual fruits are still very small, this can be an appropriate procedure. Information from forecasting services (e.g. phytophtora/aphid warning services, advice emails on plant protection in conventional fruit, hop and vegetable cultivation) is helpful for the planning of samplings. In principle, leaf analyses are also important if there is a suspicion of drift from neighbouring fields or contamination as a result of long-range transport of pesticides (see chapter 1.1.).
In addition, in certain cases it may be useful to take a further sample from suitable areas that have not been directly treated. In this way a possible "background load" from atmospheric or long-range transport can be identified and distinguished from any signs of treatment. Depending on the region, such areas can be slopes, ditch edges, hedges, biotope strips or similar. Similarly, structured vegetation types should be selected for sampling, e.g. hedges or woody structures compared to orchards or other spatial cultures, or grassland vegetation compared to areas used for agriculture. Foliage of woody plants and growths of mown grassland reflect the respective vegetation period, whereas the bark of trees, as passive collectors, may reflect inter-annual stress situations and require a fundamentally different sampling methodology. Where available, floor spaces which are regularly managed without the use of pesticides (e.g. Miscanthus or clover-grass areas, flower mixtures) can also be sampled to quantify a local background load.

Summary of the Sampling Strategy in the Field

- Representative (within the scope of due diligence and without any visible critical influences on the area to be sampled).
- Risk-oriented considering the risk potential:
  - The area (geographical location, neighbouring fields, etc.).
  - The product.
  - The producer (farmer, gardener, production company, etc.).
  - The type of use prior to conversion to organic farming (e.g. application of persistent pollutants

Commodity classification	Examples	Nature of primary sample to be taken	Minimum size of each laboratory sample
Small sized fresh products units generally < 25 g	berries, peas, olives	Whole units, or packages, or units taken with a sampling device	1 kg
Medium sized fresh products, units generally 25 to 250 g	apples, or-anges	Whole units	1 kg (at least. 10 units)
Large sized fresh products, units generally > 250 g	cabbages, cucumbers, grapes (bunches)	Whole unit(s)	2 kg (at least 5 units)
Herbs	fresh parsley	Whole units	0.5 kg
	other fresh herbs		0.2 kg
Spices	dried	Whole units or units taken with a sampling device	0.1 kg
Pulses	beans, dried; peas, dried		1 kg
Cereal grains	rice, wheat		1 kg
Tree nuts	except coco-nuts		1 kg
	coconuts		5 units
Oilseeds	peanuts		0.5 kg
Seeds for beverages and sweets	coffee beans		0.5 kg

Table 4: Primary products – description of primary samples and minimum size of laboratory samples.

from previous cultivation, which can be highly enriched in certain organic products afterwards).

3.4.2. Sampling during processing or storage

At the collection points for primary agricultural products (cooperatives, producer groups, processors, exporters, etc.), individual deliveries (individual batches) are combined into collective lots. However, the producer deliveries can also consist of collective lots from the producer who, for example, has deliberately or accidentally mixed harvests from several fields or field plots.
The lots that have been newly combined at the collection points are then repacked at other intermediaries or exporters, if necessary, and new collective lots are created. At this point, it is crucial to ensure traceability to the producer and to the field or field plot in order to be able to investigate any suspected non-compliance with the requirements of the organic regulation 2018/848.
When combining consolidated lots, it is problematic that the products are usually not mixed carefully enough for a homogeneous lot. In a laboratory, on the other hand, a mixed batch (composite sample) is produced from delivered individual batches (single samples), which as such is homogeneous and representative. Inhomogeneities due to selective contamination or contaminated or non-compliant partial batches lead to contradictory analysis results if mixing is not carried out carefully, which makes a valid assessment of the contaminant or pesticide level difficult or even impossible.
For storage samples (whether in intermediate storage as bulk material or packed in warehouses), Directive 2002/63/EC defines the guidelines for the minimum number of individual samples (see table 5). They are combined to form a bulk sample from which the test sample is then generated.
The following influencing factors shall be considered when sampling during or after processing the products:

- Lot volume (may vary from a few kilograms to several tons).
- Processing conditions (technological processes, additives and adjuvants, packaging and equipment materials, tubes, connectors, conveyor belts, greases, plastic materials, etc. as possible sources of contamination).
- Spatial conditions (dust, emissions from fuels or waste gases, mixed operation organic/conventional, etc. also as possible sources of contamination).

In particular, sampling of dust in processing and storage facilities has in many cases proved to be an effective means in identifying and verifying the cause of contamination.

Commodity classification		**Minimum number of primary samples to be taken from the lot**
Products, packaged or in bulk, which can be assumed to be well mixed or homogeneous		1 (A lot may be mixed by grading or manufacturing processes, for example)
Products, packaged or in bulk, which may not be well mixed or homogeneous	**weight of lot/ number of cans or other containers in the lot**	
	<50 kg	3
	50 – 500 kg	5
	>500 kg	10
	1 – 25 units	1
	26 – 100 units	5
	>100 units	10
	For products comprised of large units, being primary food commodities of plant origin only, the minimum number of primary samples should comply with the minimum number of units required for the laboratory sample (see Table 4).	

Table 5: Minimum number of individual samples taken from a lot.

3.4.3. Sampling protocols and picture documentation

For *field sampling,* at least the following items should be documented in the protocol:

- Sampling number.
- Date and time of sampling.
- Size of the field.
- Lot size.
- Type of sampling (representative or risk-oriented, e.g. edge strip sampling).
- Address of the producer.
- Field/claims name.
- GPS data of the field.
- Climatic conditions (weather, temperature, wind, etc.).
- Sample matrix (e.g. “whole apples”).
- Sketch of the sampled field plot including adjacent field plots and their status as far as known or identifiable (organic or conventional farming, cultivated crop and its stage, fallow land, shrubs and hedges, water bodies, etc.).
- Name and signature of the sample taking person.

At least two digital photographs (panoramic and detailed) are taken of the sampled field, showing the situation and cultivation method. The photo will be stored electronically and transmitted if required.

In the case of *warehouse sampling,* at least the following points must be documented in the protocol:

- Sampling number.
- Sampled product (name).
- Date and time of sampling.
- Lot number.
- Container number.
- Lot size.
- Packaging/Units/Sorting of the sampled goods.

Figure 16: Sampling point sticker with basic information

- Address of the customer.
- Address and description of the sampling location.
- Comments.
- Name and signature of the sample taking person.
- Name and signature of the person responsible for the premises where the sampling is carried out.

The sampled lot shall be identified with a label at a sampling point. This sticker has a warning colour and contains basic information (see figure 16).

A digital photograph shall be taken of the place of sampling, showing this label and the corresponding labelling and packaging of the sampled lot. The photograph shall be stored electronically and transmitted if necessary.

3.4.4. Sampling devices

The material used for sampling that comes into contact with the product to be sampled should have been previously tested in a laboratory for possible contamination and approved for sampling purposes:

- safety knife,
- punch tube, shovel etc. (for sampling in the warehouse),
- alcohol (e.g. iso-propanol) for disinfection,
- paper towels,
- powder- and thiuram-free latex gloves (possible source of carbon disulphide),
- plastic bags (if possible without printings),
- adhesive tape,
- labels / stickers,
- ballpoint pen,
- waterproof pen,
- digital camera,
- sampling protocols,
- sealing labels,
- sticker in signal colour to identify the sampling location (for sampling in the warehouse),
- food-compatible closure labels (for sampling in storage),
- carton for sending to the laboratory.

All materials used in the course of sampling shall be visually inspected for cleanliness and possible damage. All equipment in contact with the food must be disinfected before use (e.g. with *iso-propanol*).

3.4.5. Sample containers and transport

The sample bags/cans etc. must be made of “residue-free” material, if possible tested and approved by the laboratory and marked with the following information:

- Client,
- sampling number,
- lab name.

The bags/cans etc. are to be closed with sealing labels (consecutive numbers).
All samples are sent or transported to the laboratory in closed boxes or containers. If necessary, the samples are sent in insulated boxes with cooling elements.

3.4.6. Counter samples/arbitration samples

If required by the customer or official procedures, counter samples must be taken. In this case, only the procedure described below is to be applied and no deviations from it are permitted:

- A sample for laboratory analysis.
- One control sample for counter-analysis – intended for the organic inspection body or authority.
- One sample for possible later arbitration analyses.
- Each sample is well packaged and shipped, for example, in a box that is firmly closed with adhesive tape/seal labels.

To ensure that the three representative samples are identical, three units are taken at each sampling point and filled into three different, clearly distinguishable bags. The units must be of comparable size and, in the case of field samples, origin from the same location and orientation of the plant.
The sample bags are handled as follows:

- The bag is tightly closed and sealed.
- The sampler labels a self-adhesive sealing label with the information listed below. The bag is closed with the inscribed sealing label in such a way that it is not possible to open the bag sub-sequently without damaging the seal.
- After attaching the sealing label, the sampling operator signs on the sealing label with a water-proof pen in such a way that part of the signature is also on the sampling bag.

The sealing label for counter and arbitration samples contains the following information:

- Customer
- Sample matrix
- Date of sampling
- Sampling number
- Name and signature of the sampling operator
- Note: “This sample is only valid if the label and seal are in perfect condition and the information on the bag corresponds to that on this label”.

As an alternative to the sealing label, a numbered disposable plastic seal can be used, which must be firmly tied below the knot. In this case, the seal number must be indicated under “Notes” on both the bag and the sampling protocol.

3.4.7. Sampling of soil, leaves (plant samples), dust and adjuvants

Soil samples

To detect residues and contaminants in the soil, it is useful to take the soil sample[84] from the surface. Especially when the possible cause of the contamination is presumably still at the surface, i.e. a possible application of e.g. plant protection products was not long ago and no tillage is expected in the meantime. Or, however, if plants are present which do not spread their roots deep into the soil but root directly on the surface.
The individual samples in soil sampling are taken according to the same scheme as already explained for food and feed field samples (see chapter 3.4.1.).
Taking a soil sample at only one location makes sense if a single location is to be specifically investigated. This is the case if a conspicuous differentiation of plant growth can be observed there (see figure 15) or a selective application of pesticides is suspected.
Sampling is usually carried out in the soil horizon from 0 cm (surface) to approx. 20 cm depth, in the case of certain deep-rooted crops possibly even deeper (e.g. if persistent contaminants such as Dieldrin or HCB are suspected, which are enriched by plants from the pumpkin family). If there is a suspicion of a recent application without tillage, sampling close to the surface in the range of 0 cm to 5 cm is useful.
Larger stones as well as parts of plants and animals are sorted out from the collective sample, which may be prepared. The aggregate sample is then mixed again thoroughly before the test sample is taken.

Leaves

Leaf samples serve as a valuable indicator of a possible application of plant protection products or to control a plot during the vegetation period.
In the first case it is recommended to collect the leaf samples at the suspected site in a plastic bag. The sample may be taken representatively during routine monitoring of the field. In this case the first leaf sample is picked in the middle of the field; in the case of adjoining conventionally cultivated areas, samples from the corresponding marginal areas are to be picked and stored in separate plastic bags.
The range of the contents of the active substances on the leaves may extend from trace concentrations (long ago application, drift etc.) to high concentrations in the mg/kg range (in case of an application shortly before). As information on the active substance content is not available at the time of sampling, the following procedure is recommended:

84 For choosing of a soil sample set see: https://www.bodenanalyse-zentrum.de/lexikon-bodenprobe-richtig-nehmen

- Samplers should wear powder- and Thiuram-free latex gloves.
- When moving from the centre of the field to the edges of the field, the gloves should be changed.
- Approx. 200 g leaf samples are taken at a time.
- The samples should be transported to the laboratory under refrigeration with cooling elements.

Other plant parts

If necessary, other parts of plants can also be sampled; this must be decided on a case-by-case basis and cannot always be planned sufficiently. Of particular importance here is a good decision-making ability of the sampling operator, who has to decide very quickly and under considerable stress during inspections of suspect plants, which sampling strategy has a chance of success in a specific suspect case.

Case studies for the sampling of plant parts

In one specific suspected case of the use of herbicides against couch grass (glyphosate), and in one case of land conversion which appeared to take place shortly before the verification visit, significant concentrations of AMPA (degradation product of glyphosate) were found in the couch grass rhizomes collected from the converted crumb, thus demonstrating the unauthorised use of glyphosate. In another case, herbicides were also detected in the remains of dead thistles and the surrounding spelt plants, thus also proving that glyphosate was being used.

In another case, the use of pesticide-encrusted seed pellets was detected by analysing the residual material of the original seed pellets left in the planting boxes and dumped at the edge of the field during the mechanical planting of young fennel plants, as well as on dug up and exposed seed pellets of the young plants in the stand.

In the case of growth anomalies in tomato cultures, the herbicide Aminopyralid was detected by analysis of the manure used for fertilisation (which was permitted to originate from conventional horse husbandry) and thus a carryover from the hay via the horse's digestive tract to the tomato.

Dust

Dust is a deposition of very fine particles, some of which are not visible to the eye. The dust particles float in the air and settle over time, but are repeatedly stirred up and mixed by air movements. They can be of organic or inorganic origin and are able to adsorb compounds of medium to low volatility (e.g. pesticides, mycotoxins etc.) on their surface. Due to this fact, the matrix "dust" is referred to as a passive collector of pollutants.

The collected dust sample is sieved in the laboratory if necessary, i.e. it is separated from stones, hair and other objects. The pollutants are then desorbed with the help of an extracting agent, from which the pollutants are then determined using instrumental analysis. The result of the analysis has the dimension [mg/kg] for each detected substance and allows a rough assessment of the residue situation and the resulting measures.

If dust accumulates over a long period of time in places that are difficult to access, it "tells the story" of the room or building in which it was collected. When converting from conventional to organic farming, it is imperative to sample the potato store, grain warehouse or greenhouse and check for contamination from conventional chemical cultivation or conventional processing.

The nitrofen scandal

In 2002, the "nitrofen scandal" caused unrest in the food industry: The organic grain sold nationwide by a feed manufacturer in Lower Saxony was contaminated with the banned herbicide nitrofen in a warehouse of a seed company in Mecklenburg-Vorpommern (a German state). The cause was found to be the storage of pesticides in the warehouse near the city of Neubrandenburg during GDR (German Democratic Republic) times. The precautionary measures mentioned in article 28 of the new organic regulation also result from this case.

The dust to be sampled should be an "old dust sample". It can be obtained by sweeping it together with a broom and dustpan at several places in the building or with the help of a vacuum cleaner equipped with a new dust bag. The sweeping sample is transferred into a brown glass bottle with a wide neck, the vacuum cleaner bag is completely packed in aluminium foil. Special transport conditions are not necessary.

Grinding or scraping samples of wood may also be used to estimate the surface of wood as a source of contamination (grain silos or floors/walls of older flat stores). For this purpose, scraping or grinding dust is removed as close to the surface as possible and packed like dust samples.

Wipe samples

If there is not enough material available for dust sampling, a wipe sample can be taken alternatively. For the wipe sample a wipe cloth is required, which is well moistened or even soaked with an organic solvent (e.g. cyclohexane or iso-propanol). The wet wipe is used to wipe the area under investigation and is then transferred to an amber glass bottle with a wide neck. The

wiping process can be repeated several times with a new cloth if necessary. It is imperative that the wiped area is recorded and documented using a template or a measuring stick. Only the reference to the surface can provide a meaningful statement about the residue situation in the end.
In another amber glass bottle with a wide neck, two to three clean cloths, soaked in the same solvent, are provided as blank samples for the laboratory and sent to the laboratory together with the sample. Special transport conditions are not necessary.
In the laboratory, as with the dust sample, the contaminants are desorbed with a suitable extraction agent. The result of the analysis has the dimension [µg/m²] for each detected substance and allows a rough assessment of the residue situation and resulting measures. The dimension [µg/m²] gives an idea, that the detected concentrations are significantly lower than in a dust sample. Therefore, the wipe sample requires a particularly careful and above all contamination-free sampling procedure:

a) The wipe should be residue-tested and approved by the laboratory in advance.
b) The solvent used should be residue-tested and approved by the laboratory in advance. In particular, the sampling procedure must be agreed with the laboratory in advance so that the op-timum solvent for the analyte is used (e.g. cyclohexane for pesticides, iso-propanol for quater-nary ammonium compounds, etc.).
c) Powder- and Thiuram-free latex gloves must be worn by the sampler.
d) The amber glass bottles are to be obtained from the laboratory in a highly cleaned condition or rinsed out beforehand with the solvent for the wipe sample.

Agricultural inputs

In recent years, the contamination of food by agricultural inputs has increasingly become the focus of food monitoring. Substances such as DDAC, ivermectin, matrine or phosphonic acid attracted increased attention. These components are effective but possibly undeclared ingredients of fertilisers and plant fortifiers. In order to provide the desired effect, these compounds must be added to the inputs in high concentrations.
Therefore, in the laboratory, the inputs are highly diluted before measurement, i.e. only a small amount of material is required for sampling. The dimension of the results is given in [g/kg] or [g/l].
The handling of such a primary source during sampling requires the utmost care with regard to contamination. The sampling of agricultural inputs must always take place at the end of the entire sampling process in case the above-mentioned sampling procedures are also applied:

e) Powder- and Thiuram-free latex gloves must be used by the sampler.
f) Approx. 10-50 ml (approx. 10-50 g) of the product is filled into a plastic tube which can be closed well. The tightness of the tube must be checked and guaranteed. Leaks during transport will contaminate samples in the package and make them unusable for analysis.
g) Ideally, these samples should be sent separately from other samples (food samples, leaf sam-ples, etc.).

The brochure of the Brandenburg State Office for Consumer Protection, Agriculture and Land Reclamation (LVLF)[85] provides detailed information on the sampling of fertilisers and commodities. Even if the purpose of the sampling is to determine the nutrient content of the farm inputs, the information given there is generally well suited for obtaining the bulk or composite samples and the subsequent reduction procedures for preparing the final samples (= test samples), and should also be followed when sampling for the purpose of analysis for pesticides or contaminants.
Sampling of agricultural inputs is particularly recommended if there are already findings in food or feed samples. It may include, for example, fertilisers, pesticides or plant fortification products. If necessary, it may also be advisable to take samples directly from sprayers, fertiliser spreaders, seed drills, irrigation ponds or systems, mixing systems of greenhouse irrigation systems, operating material stores etc. When sampling irrigation water in companies where the irrigation water is taken from near the surface or from receiving water bodies, a corresponding sample from the receiving water may be insightful, as these integrate the general drift of pesticides in intensively conventionally used agricultural landscapes. The same applies to precipitation water, which may flush the dust-like depositions in intensive agricultural or special crop regions into cisterns and collecting basins.
Depending on the suspected situation, the scope of analysis should be specifically defined in consultation with the analytical laboratory to be commissioned (for laboratory selection see chapter 3.1.).

Useful guidelines and references

- Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on

85 Cf. Ministerium für Ländliche Entwicklung, Umwelt und Verbraucherschutz des Landes Brandenburg (MLUV) (Hg.) (2009): "Hinweise zur Probenahme von Boden, Pflanzen und Düngemitteln". in: Schriftenreihe des Landesamtes für Verbraucherschutz, Landwirtschaft und Flurneuordnung Abteilung Landwirtschaft und Gartenbau, series on agriculture, Vol. 10 (2009) booklet XI, p. 30ff.

products of plant and animal origin and repealing Directive 79/700/EEC OJ L 187, 16.7.2002, p. 30–43
- Commission Regulation (EU) No 691/2013 of 19 July 2013 amending Regulation (EC) No 152/2009 (laying down the methods of sampling and analysis for the official control of feed) as regards methods of sampling and analysis
- Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs
- Directive 2011/91/EU of the European Parliament and of the Council of 13 December 2011 on indications or marks identifying the lot to which a foodstuff belongs
- relana® Position Paper No. 19-01 "Sources of contamination of samples for analysis" version 2019/04/12 http://www.relana-online.de/wp-content/uploads/2019/04/relana-pos.-paper-19-01-Sources-of-Contaminations-20190412-final.pdf.
- relana® Position Paper No. 19-02 "Influence of sampling" version 2019/06/21 http://www.relana-online.de/wp-content/uploads/2019/06/relana-pos.-paper-19-02-Influence-of-sampling-20190621-final-1.pdf.
- relana® Position Paper No. 19-03 "Differing results of competent laboratories" version 2019/06/25 http://www.relana-online.de/wp-content/uploads/2019/07/relana-pos.-paper-19-03-Differing-results-of-competent-laboratories-20190625-final.pdf.

3.5. Evaluation of analytical test results

An analysis provides measured values, i.e. numbers and their dimensions. This ratio is usually expressed in mass per unit, often in milligrams per kilogram (mg/kg). The same value can also be expressed in other dimensions, for example in micrograms per kilogram (µg/kg). Certain results refer to the dimensions litre (l) or millilitre (ml). At the same time, the measured value stands for a whole bundle of further information, conditions, and prerequisites – much of which we have described in the previous chapters. Without their consideration, a measured value cannot be assessed or can only be assessed to a very limited extent. If the regulations cited here impose the obligation to assess analyses on the operator on the one hand and the inspection bodies and authorities on the other hand, they must have or be able to access the highest possible level of competence. For this reason, central aspects that are helpful or necessary for a proper evaluation of analysis results are listed below. The findings from sampling and subsequent analysis can only be evaluated in connection with the conditions on site (field, storage, processing). The results of the analysis only can usually not be used to deduce or even substantiate a causal relationship regarding suspicion of possible violations of the requirements of the organic regulation.

The evaluation of analytical results for the organic products examined should be agreed upon in advance between the testing laboratory and the client (see chapter 3.1.). This prevents the laboratory from incorrectly evaluating findings with regard to the requirements of EU legislation on organic farming (e.g. suspect sample, monitoring sample, compliance sample, etc.). If the laboratory is not informed about the purpose of the sampling, it should not provide an assessment or interpretation of the results.

The laboratory can make an independent assessment of the test results on the basis of the information provided. However, the final assessment of the results with regard to the respective analytical objective is the responsibility of the commissioning body, i.e. the operator, the control body or the authority. The evaluation result should enable them to assess a measured value according to the following criteria (see articles 27 and 28 organic regulation; see also chapter 1.8.):

- Presence of unauthorised substances and products.
- Presence of contamination.
- Suspicion of the use of unauthorised substances.
- Reasoned suspicion.

External experts may also be consulted in order to perform an assessment in a proper way.

The agricultural raw materials for food and feed each have their own specific material properties and particularities with regard to growing, cultivation and

post-harvest treatment. For this reason, there can be no generally valid catalogue and no standardised evaluation procedure described, due to the obvious variety of products. Table 6 contains parameters which, if non-authorised substances are identified, can provide the necessary information for an individual case evaluation.

Parameter/aspect	Relevance / Questions	Sources
Sampling	• reason for sampling: suspected use, risk of use, visible damage in the culture, suspected mixing of processed products. • type of sampling: representative or risk sample, targeted sampling at risk site, pre-harvest sample, post-harvest sample, hotspot. • place of sampling: field, warehouse, silo, big bag, in process (define process stage). • possible errors during sampling, contamination during sampling. • identification/traceability of the batch.	sampling protocol, context of control, company statement
Active substances (pesticides, contaminants, other substances) indicated in the test report as having been detected and quantified	• proven quantities, validity of the analysis, range of variation. • chemical-physical properties of the active substances (vapour pressure, solubility, persistence, biological half-lives in plants, soil, distribution or accumulation in plants or plant parts, etc.). • volatility, transport due to application time/technology, application in indoor cultures. • usual contents of active substances in products of the same product group from a) organic and b) conventional cultivation (after active application). • application profiles of the active substances (in the case of pesticides) in the corresponding conventional product groups in terms of application rates per area, timing of applications, pre- or post-harvest treatments, etc. • applicability to the product concerned. • approval situation and regional distribution of the respective substances.	EU Pesticide database: (authorisation, maximum residue levels, EFSA dossiers, areas of application)[i] Pesticide Action Network (PAN)[ii] chemical and physical properties, toxicity, environmental hazards BVL Monitoring[iii] collection and evaluation of monitoring data Bio-Monitoring BW[iv] findings of residues in organic products, comparisons with conventional goods BNN residue database (organic products only)[v]
Nature of the product under investigation: • primary agricultural products (e.g. fruit, vegetables, etc.) • processed product • composite product (list of all ingredients)	• primary products: is the use of the pesticide(s) identified in the present product permitted or useful in conventional production? • processed products: is the application of one or more processing factors necessary to conclude on a possible application in the field? • standardised processing factors cannot reflect the variety of different processing processes and conditions. The processing factors derived from manufacturers in model studies for the authorisation of plant protection products are used, for example, in the EFSA and BfR data collections on processing factors for plant protection product residues. They should only be used with the utmost caution and only as a substitute. Whenever possible, unprocessed primary agricultural products should always be sampled and analysed if suspected. • for composite products: is there any indication of the source of the findings? Can the individual ingredients be identified and analysed individually? Can the mixture be separated manually to analyse the ingredients individually? If the source of the entry is identified, this ingredient is evaluated individually. If this is not possible, the evaluation can only evaluate this single mixture or sample.	BVL databases, registration of plant protection products in Germany[vi]

Leaf sample resp. soil samples	• leaf samples: characteristics of leaves as passive collectors, time of sampling. • soil samples: soil layer, typical contents in soils with conventional history, degradation rates, displacement, sorption	literature, own data base
Possible indications of contamination	Is there any evidence of contamination? • during cultivation (e.g. drift from neighbouring fields; known, locally occurring contamination)? • during transport and (on/off) storage (e.g. through contaminated boxes, conveyor belts or elevators, pest control measures with biocides)? • during processing (e.g. contaminated washing water or hydro-cooling water, brushes, etc.)? • contamination by long-range transport of pesticides (e.g. particle-bound active ingredients)? • contamination by "contaminated sites"?	landscape maps, literature, data on the history of the field or area, own observations and interviews during inspections/ audits
Applications in conventional cultivation	• is the use of the detected pesticide intended in conventional cultivation? • at what levels in the crop would such application typically result?	registration of pesticides (actives) in the EU (acc. reg. (EC) no. 1107/2009)[vii] registration of plant protection products (formulations) in Germany[viii] BVL and EU monitoring reports[ix]

Table 6: Basis for the evaluation of analytical test results

i Available online: https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN.

ii http://www.pesticideinfo.org/.

iii https://www.bvl.bund.de/DE/01_Lebensmittel/01_Aufgaben/02_AmtlicheLebensmittelueberwachung/04_Monitoring/lm_monitoring_node.html.

iv http://oekomonitoring.cvuas.de/start.html.

v Online at: https://www.bnn-monitoring.de/service/login.php.

vi Online at: https://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/01_Aufgaben/02_ZulassungPSM/01_ZugelPSM/01_OnlineDatenbank/psm_onlineDB_node.html.

vii Online at: https://eur-lex.europa.eu/homepage.html?locale=de.

viii Online at: https://apps2.bvl.bund.de/psm/jsp/index.jsp.

ix Online at: https://www.bvl.bund.de/DE/Arbeitsbereiche/01_Lebensmittel/01_Aufgaben/02_AmtlicheLebensmittelueberwachung/07_PSMRueckstaende/02_nb_psm_archiv/nbpsm_archiv_node.html.

Part 4: On the authors

Dr. Georg Eckert
Georg Eckert studied and did his PhD in agricultural science. He is operating manager of the organic control body ABCERT AG, deputy member of the "Expert group for technical advice on organic production" of the EU-Commission, president of the Association of European organic control bodies (EOCC) and member of various working groups in the field of organic law. Georg Eckert has many years of experience (since 1998) in control and certification as well as in the evaluation of residues in organic produce. He gives lectures at the University of Hohenheim and discusses topics in the field of organic agriculture at numerous expert and consumer conventions.

Dr. Günter Lach
For more than 30 years, the chemist Günter Lach is dealing with analysis and evaluation of residues and contaminants in food, materials and environmental samples. He has years-long experience in the development of strategies to attain and implement norms, directives and regulations both nationally and internationally. After about 15 years of leading and managing analytical service laboratories, he is now a partner of the Lach & Bruns Partnerschaft and working there as a consultant. His main areas of expertise are all aspects related to analytical quality and assessment competences of private laboratory service providers, as well as aspects regarding the integrity of organically farmed produce. Guenter Lach has been a member of the scientific advisory panel of the BNN e.V. since its beginning.

Albrecht Friedle *(Dipl.-Engineer (FH) Chemistry)*
Albrecht Friedle has studied analytical Chemistry and has been working with residues and contaminants in instrumental analytics for more than 35 years. In his early years, he worked for the official food control body in Baden-Wuerttemberg, 1990 he changed to the private sector. After building up a lab for environmental medicine as operating manager, and after leading an institute for environmental analysis, he became self-employed in 2003. Today Albrecht Friedle is owner of the Labor Friedle GmbH. The Labor Friedle GmbH deals with questions of food safety, residue analysis, indoor diagnostics and questions of environmental medicine. Albrecht Friedle is an active member of the working group on pesticides, in the scientific committee of the German Association of Organic Food Producers (AöL) and in the expert committee on quality assurance of the Professional Association of Building Biologist e.V. He works as a volunteer in expert bodies of several organic producer associations, is lecturer on residue topics and researches on anthropogenic insect death since 2017.

Martin Rombach

After finishing his studies in Karlsruhe, Martin Rombach worked as the head of a laboratory, as a quality assurance manager, in the management of both food businesses and pharmaceutical companies, as well as auditor in accordance with ISO 9001 and EMAS Regulation. Since 2001 he is operating manager and head of the control body Prüfgesellschaft ökologischer Landbau mbH (before Prüfverein Verarbeitung e. V.). His control body is responsible for controlling and certifying in accordance with the EU organic regulation, as well as many national and private standards for food, feed and cosmetics in both Germany and Luxembourg. Since 1994 he has been employed by businesses and associations regarding assessment of residues in organic produce. In 2006, he authored the Manual "Risk management of pesticide residues in food from organic agriculture" (editor: GfRS GmbH, research and development project 03OE461). Martin Rombach is member of the board of the "Bundesverband der Öko-Kontrollstellen e.V." (BVK), member of the scientific advisory panel of the BNN e.V., member in expert working groups of the Bundesverband ökologische Lebensmittelwirtschaft (BÖLW) and member of the certification panel for processing at Demeter e.V.

Sascha Schigulski

Sascha Schigulski (born 1975) studied law from 1995 to 2003 in Bonn (1st state exam 2003, 2nd state exam 2006). In the same year he was approved to be a lawyer. From 2007 to 2018 Sascha Schigulski worked at an office specialising in food law. Focus of his occupation was and is the advising of producers of animal-based foods, specifically raw and processed meats. Since 2018 he is founding partner of the lawyer's office "cibus Rechtsanwälte". Focus of this office is the representation and legal counselling of producers of animal-based foods, the defence of the both in criminal and civil cases in both food law and representation in administrative law matters. Sascha Schigulski also advises and represents companies in matters of EU-registration. His expertise includes further the counselling in acute product crises, meaning in cases where the recall of food products is on the table. Sascha Schigulski gives frequent lectures on current questions of food law.

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