

Article

# “Zero Residue” Concept—Implementation and Certification Challenges

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**Abstract:** This paper gives an overview of scientific challenges in implementing and certifying “Zero residue” approach. The rationale behind the concept is that final control of commodities during/immediately after harvesting should confirm that traces of all used plant protection products are less than or equal to 0.01 mg/kg. To evaluate the risks in applying this concept, FMEA (Failure Mode and Effect Analysis) as a tool has been used. Among the most common factors affecting the pesticide residue levels in fresh produce, the following three appeared to be the biggest challenges in the “Zero residue” concept implementation and certification process: the use of unregistered plant protection products, inadequate sampling plan, and inappropriate laboratory methods. The analysis showed that all three factors have strong influence on achieving “Zero residue” limits.

**Keywords:** primary production; zero residue; novel concept; FMEA

## 1. Introduction

Currently we are witnessing various initiatives in decreasing the use of pesticides and other chemical plant protection products as their extensive use raises risks and concerns in both food safety and environmental science. The need for reducing pesticide use became a major issue in public policies due to the myriad of negative impacts pesticides have on human health and the environment. Adverse effects on human and animal health have been scientifically proven and they include, among others, carcinogenic, reprotoxic, immunosuppressive and endocrine-disrupting effects both as standalone chemicals and as mixtures [1,2]. However, since most of the agri-food sector relies on pesticides, substantially reducing pesticide use is a complex and challenging issue [3].

An additional challenge in agricultural production is climate change, which is having a great impact on primary production [4]. Kovats et al. [5] identified the following climate change effects that will strike Europe in the approaching decades and affect all plant species: (i) great regional variability in main meteorological indicators such as temperature and rainfall along with occurrence of extreme climate effects; (ii) yield reduction of many crops, fruits and vegetables; (iii) intensified irrigation; and (iv) negative changes in the plant–pest–disease nexus. The main mitigation measures are implementation of integrated agricultural production systems to achieve healthy environment and soil biodiversity [6]. Within such practice, adapted actions in terms of optimizing chemical usage and improved irrigation patterns have the potential to minimize negative environmental effects [4].

Launched in December 2019, the European Green Deal sets the design to transform the European Union (EU) into the first climate-neutral continent by 2050. The European Commission has put forward a series of legislative proposals to make its policies fit for delivering the updated 2030 greenhouse gas emissions net reduction target of 55% below 1990 levels, as set out in the 2030 Climate Target Plan and written into the European Climate Law [7,8]. An integral and essential part of the European Green Deal is the Farm to Fork Strategy which aims to make EU food systems fair, healthy, and environmentally friendly. Even though the EU’s transition to sustainable food systems has started in many areas,



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food systems remain one of the key drivers of climate change and environmental degradation [9]. There is an urgent need to reduce dependency on pesticides and antimicrobials, reduce excess fertilization, increase organic farming, improve animal welfare, and reverse biodiversity loss [9].

In line with the EU Farm to Fork Strategy, the European Commission has adopted a proposal for a new Regulation on the Sustainable Use of Plant Protection Products [10] intended to replace the existing Sustainable Use of Pesticides Directive [11]. The main measures in this proposal include: (i) Legally binding targets at the EU level to reduce by 50% the use and the risk of chemical pesticides as well as to reduce the use of the more hazardous pesticides by 2030; (ii) Environmentally friendly pest control with new measures ensuring that all farmers and other professional pesticide users practice Integrated Pest Management (this implies an environmentally friendly system of pest control which focuses on pest prevention and prioritizes alternative pest control methods, with active pest control by using chemical pesticides utilized as a last resort); and (iii) a ban on all pesticides in sensitive areas such as urban green areas, including public parks or gardens, playgrounds, recreation or sports grounds, public paths as well as protected areas.

Additional strategies implemented by the EU are trying to increase the safety of EU consumers regarding the pesticide use. One of them is Regulation 1107/2009/EC [12] which sets the cut-off criteria when approving or reapproving certain active substances. These cut-off criteria are related to human health (regarding active substances classified as mutagens, carcinogens, reproductive and endocrine disruptors) and on the environment (regarding active substances classified as persistent organic pollutants and persistent, bioaccumulative and toxic substances). In parallel, there is a REFIT program under which the European Commission strives to make EU laws simpler, with less red tape, more targeted and easier to comply with [7].

The European Food Safety Authority (EFSA) annually reports on pesticide levels in food sold in the European Union (EU) market [13], providing information on potential health risks. Besides the regulatory side of the coin, various food safety standards targeting the reduction in using pesticides have been developed, such as pesticide-free certification standard [14] and zero/controlled pesticide residue [15].

Differing from organic production, where some active substances are permitted under specific conditions, the “Zero residue” concept has a requirement that the products at the time of reaching the market have highly limited residues of plant protection products i.e., in quantities not detectable by the analytical instruments of qualified and accredited testing laboratories [15]. For most of the plant protection products this limit is usually less than or equal to 0.01 mg/kg [14]. However, if/when the analytical method was providing possibility for increased analytical sensitivity, such value should be used as a limit for a “Zero residue” concept. In line with this, if producers decide to use a certification mark directly on the label, point-of-sale materials, or indirectly on websites or brochures, they have to indicate maximum limit of plant protection products and limitations of analytical methods used. This information must be written using fonts and sizes that are easily visible and clearly legible by the customer and consumer [16].

The “Zero residue” concept is foremost, but not exclusively, intended to be implemented by primary agricultural producers voluntarily and it is not intended to replace any regulatory requirements. Next to reduced environmental impact and the potential health risk to consumers, products certified under the “Zero residue” concept can be considered value-added products as the absence/reduced presence of pesticide residues in food products is one of the main requirements expected by the modern consumers. Therefore, the main objective of this conceptual paper was to analyze potentials of the “Zero residue” concept.

## 2. “Zero Residue” Certification Procedure

Typical third-party or certification food safety assessments are comprised of initial, surveillance, and re-certification audits, with the aim to demonstrate that specified require-

ments are fulfilled [17,18]. These specified requirements are developed or deployed from various regulations, standards and technical specifications. However, types of audits associated with food safety management systems vary as some have three year audit programs (certification plus two surveillance audits) as in the case of ISO 22000 [19] while others insist on verifying effectiveness of the entire food safety system every year, as in the case of BRC [20]. The “Zero residue” concept aligns to the latter case, due to the seasonality of primary production. The certification/re-certification process consists of both off-site and on-site activities. Off-site activities are focused on analyzing feasibility of plans related to the usage of plant protection products and control of the production process. On-site activities intend to verify implementation of all planned activities as well as to confirm that products sampled from the field satisfy defined “Zero residue” criteria. In general, the conformity assessment consists of testing the samples, verification of good agricultural practice and certification of the company, as outlined in the conformity assessment definition [18].

To summarize, the “Zero residue” certification procedure consists of the following steps:

- (1) Certification request—which implies that primary agricultural producers interested in the program (or other interested organizations) provide basic identification data as well as information on the production (type of farm, crops, production volume, etc.) including the possession of other types of certificates for fruits and vegetables (e.g., GlobalGAP [21]).
- (2) Verification of the producer’s plant protection plan—the producers applying for the certification must provide their plant-protection plans, i.e., their plans for pesticide and other plant-protection products usage, including type of plant-protection products, frequency of usage, estimated doses, etc.
- (3) Verification of the producer’s self-control plan—the producers applying for the certification must provide their self-control plans which include all types of audits, sampling, and laboratory analysis planning. This control plan has two main objectives: (i) to confirm that in all planned stages, the results are reliable and within defined limits; and (ii) to aid in planning the assessment.
- (4) Third party assessment of good agricultural practice in place, including onsite verification of implemented producer’s plant protection plan and self-control plan. The results of this assessment provide information about potential non-conformities that have an impact on the capability of the system to achieve intended requirements [17] outlined in “Zero residue” specific requirements, and aid in making final decision about the outcome of the assessment.
- (5) Sampling and laboratory analysis—products intended for certification shall be sampled and externally tested in line with EU regulations [22]. Selection and collection of products from the field should provide adequate level of assurance of conformity in relation to “Zero residue”-specified requirements. Testing shall be performed by a qualified laboratory according to the guidelines outlined in SANTE [23].
- (6) Declaration of conformity and appropriate use of the certification logo (“Zero residue” certificate, label and/or mark). Prior to ruling on the decision as to whether the company has or has not demonstrated fulfillment of “Zero residue”-specified requirement, suitability, adequacy and effectiveness of all previous activities and gathered objective evidence should be considered [18].

### 3. Materials and Methods

Risk assessment associated with implementing and certifying the “Zero residue” program was performed by the staff from the University of Belgrade with professional expertise in food safety and pesticide use covering science, scientific consulting and auditing as well as selected primary producers interested in implementing a “Zero residue” concept. In total, seven experts participated in the assessment.

In order to evaluate the risks, a Failure Mode and Effects Analysis (FMEA) tool has been used since it is a proven analytic method [24]. Procedures that have been followed

were in line with the international FMEA standard [25]. This method is capable of identifying potential failures as well as their (root) causes [26]. When using FMEA, some authors recommend use of a multidisciplinary team of experts [27]. The first step was to populate a list of potential failure modes, followed by risk evaluation [28]. For this research, authors jointly generated a list of potential challenges associated with implementing and certifying “Zero residue” concept in primary production in Serbia with the aim to identify internal/external issues in relation to the importance of the research study [29]. To calculate the risk (Equation (1)), a “risk priority number—RPN” has been determined using the following factors [26]:

$$\text{RPN} = \text{S} \times \text{O} \times \text{D} \quad (1)$$

where: (S) represents severity of the challenge; (O) indicates occurrence associated with the probability for a specific challenge; and (D) is linked with difficulties in detecting them. The populated list of failures was assessed by high values of severity and occurrence [29]. Table 1 depicts pre-defined weighting factors for the three factors (Table 1). As there are not many papers applying FMEA as a risk-based tool in food industry, authors combined values from several previous studies [30–32]. It is of note that there is no international consensus regarding RPN threshold limit [29] as it depends on many factors. In this research RPN values could range between 1 ( $1 \times 1 \times 1$ ) and 125 ( $5 \times 5 \times 5$ ). Delphi method has been employed when encouraging the team in calculating weighting factors and the final risk. This is a known method used when striving to achieve consensus, when eliciting experts’ knowledge [33]. Combination of Delphi and FMEA methods has the potential to validate this type of risk analysis in scientific non-regulated research apart from its proven applicability in manufacturing industries [29].

**Table 1.** Severity, Occurrence and Detection rating scale.

Severity Rank	Consequence	Description
1	None	No challenge(s)
2	Minor	Challenge(s) associated with Good Agricultural Practice documentation
3	Low	Challenge(s) associated with laboratory sampling
4	Major	Challenge(s) associated with laboratory results
5	Severe	Challenge(s) associated with the product
Occurrence Rank	Probability	Description
1	Very unlikely	Minimal probability of occurrence of challenge(s) as a result of <i>force majeure</i>
2	Unlikely	Occurrence of challenge(s) only as a result of misuse of plant protection products
3	Possible	Occurrence of challenge(s) only as a result of misuse of documentation
4	High probability	Occurrence of challenge(s) only for certain type of products
5	Certain	Occurrence of challenge(s) for the entire product portfolio
Detection Rank	Criteria	Description
1	Very high	Challenge(s) associated with implementation is easily detected
2	High	Challenge(s) associated with implementation is detected during consulting phase
3	Low	Challenge(s) associated with implementation is detected during self-control phase and/or testing
4	Remote	Challenge(s) associated with implementation is detected during certification phase
5	Never	No possibility of identifying challenge(s) associated with implementing the concept

Experts that participated in the session confirmed that all main challenges associated with implementation and certification were included. Prior to commencing, a short guide was distributed to the team giving them one hour to weight all challenges. There were no holdouts and a consensus for each challenge was reached in the second round with no opposed or confronting opinions for the final RPN score.

#### 4. Results and Discussion

Results of the FMEA analysis are depicted in Table 2. As it can be seen, main risks in the implementation phase (score 80) are associated with the use on unregistered pesticides, inadequate sampling plan and inappropriate laboratory methods employed.

**Table 2.** Failure Mode and Effect Analysis of implementation and certification.

No	Stage	Challenge	What Might Occur?	Potential Failure Effect?	Severity (S)	Occurrence (O)	Detection (D)	Risk
1	Implementation	Knowledge of consultants	Inadequate documentation	Food safety system not implemented	2	5	2	20
2	Implementation	Knowledge of consultants	Inadequate knowledge within the company	Food safety system not implemented	2	5	4	40
3	Implementation	Inadequate plant protection plan	Use of unregistered plant protection products	Plant protection product registered for different type of product	5	4	4	80
4	Implementation	Inadequate plant protection plan	Misuse of plant protection product(s)	Increase risk of exceeding zero limits	4	2	3	24
5	Implementation	Inadequate plant protection plan	Change of plant protection plan due to climate impact	Increase risk of exceeding zero limits	5	2	3	30
6	Implementation	Inadequate self-control plan	Inadequate sampling plan	Misleading laboratory results	5	4	4	80
7	Implementation	Exceeded “zero” limits	Laboratory results reveal exceeded limit	Breakdown of the food safety system	5	2	3	30
8	Implementation	Costs and Return of Investment	Yield decrease	Financial bankruptcy	5	5	2	40
9	Implementation	Costs and Return of Investment	Difficulty in increasing price of harvested products	Cash-flow difficulties	5	5	2	40
10	Implementation	Laboratory accreditation scope	Laboratory method not validated for specific analysis	Inadequate laboratory results	5	4	4	80
11	Certification	Competence of auditors	Inadequate calibration of third-party auditors	Third party verifier lacks integrity	2	5	5	50
12	Certification	Undeveloped scheme	Third party verifier has undeveloped/unaccredited scheme	Lack of trust from different stakeholders	5	5	2	50
13	Certification	Awareness of consumers	Consumers unaware of the concept and what “Zero residue” means	Inadequate promotion	5	4	1	20

Within the plant protection plan it is important to state an updated list of active substances and preparations used, clearly referred from the commercial products’ docu-

mentation. Legal requirements define how to register, control, import and use various plant protection products [34]. In practice for some crops, importers and producers of plant protection products register chemicals only for a limited number of crops (depending on their sales estimation), widening the “grey” zone for inadequate use of unregistered chemicals in spite of the fact that active substances may be applicable to the crops. This also leads to food fraud which is in many cases economically motivated [35] but can also be considered as a potential act that can increase food safety risks [36].

Regarding sampling, it is important to note that inappropriate sampling may cause inadequate conclusions, known as “consumer’s risk” and/or “producer’s risk” [37]. The good sampling practice outlined in General guidance on food sampling [38] highlights the following: what is to be controlled (type of crop and associated active compounds based on the plant protection plan), acceptable quality level, sample size (size of surface and/or production volume, number of production sites in line with self-control plan). Product historical data may be another factor in defining sampling size [21]. When conducting any type of monitoring for trace elements in foods (such as plant protection products), adequacy of sampling protocols is of utmost importance as contaminants may be heterogeneously distributed and vary even across the same field [39].

Finally, in line with the Global Food Safety Initiative (GFSI), where GlobalGAP is recognized as the most trustful standard for primary production [40], it is required that all external laboratory analyses used for various verification purposes are performed in accredited laboratories according to ISO 17025 [41]. Their scope of accreditation (and methods included) is usually based on the majority of analyses they perform. A potential challenge is mismatch in target active compounds outlined in legal requirements [42] and the ones outlined in plant production plans developed by the producer. This confirms the need for standardizing methods for detecting presence of pesticide residues, similar to complexity of various honey/pollen analyses [43].

A second group of risks in the implementation phase (score 40) are associated with the yield decrease, difficulties in obtaining adequate price and with the role of consultants and their knowledge. Financial issues are important when food companies are implementing some type of a food safety system. Costs associated with implementing food safety management systems are one of the most ranked difficulties in meat industry [44,45] or dairy industry [46]. Challenges in this case are costs associated with yield reduction that may occur due to limited use of plant protection products and difficulties in achieving higher prices for the “Zero residue” products. It is known that higher prices affect the consumer choices when they intend to purchase organic food [47]. Similar experience was seen in China where different food safety labeling systems exist, such as “Safe Food”, “Green Food” or “Organic Food” [48].

Food safety knowledge is a critical factor associated with regulatory agencies, food companies, consultants and scientists [49] where consultants should provide a bridge between knowledge sources and food technologists [50]. Their lack of knowledge may affect the final success when implementing a “Zero Residue” approach.

Finally, lowest risks (score  $\leq 30$ ) are related to the impact of climate on agricultural measures employed on the field, inadequate laboratory results and failure in achieving the limits below detection, misuse of plant protection products and inadequate documentation supporting the concept. Impact of climate on agricultural practices is overseen in adjusting irrigation and plant protection plans [21] as climate conditions may cause plant diseases and pest infestation. However, extensive use of plant protection products influences the climate through various impacts such as the emission of greenhouse gasses associated with global warming potential, as well as acidification and eutrophication potentials directly linked with the use of plant protection products [4,51].

When it comes to nonconforming/unsafe products, it is mandatory in all food safety systems to have an effective corrective actions system in place. However, some authors have revealed that control processes and handling nonconforming products in food safety systems are often inadequate, causing audit findings by external auditors [52,53].

Within the certification scheme, the main risks (score 50) are competences of auditors and scope of accreditation. Accreditation of certification bodies is outlined in ISO 17021 [17] where main pillars are competence (of auditors), consistency (in audit approach) and impartiality of bodies providing audit. Last, but not unimportant (score 20), is inadequate promotion of the concept which leads to partial benefits for retailers and producers holding new types of certificates. Different stakeholders may serve as business drivers in enforcing implementation of such concepts [52]. It is considered that the certificate guarantees implementation of an effective food safety system [53], although all audits are “snap-shots” limited by the audit frequency, competence of food safety auditors, the pre-defined audit scope that needs to be verified on-site, and food safety system audited [54]. Therefore, they have a “pass/fail” outcome where audited companies meet or fail to meet audit criteria [55]. As some authors emphasize that certification is a paper-driven process serving more as a marketing cue opposed to improving food safety performance [56], there is a trend of developing second-party audits as a more reliable supply chain tool [53].

### 5. Zero Residue Concept: Main Challenges and Practical Implication

Several agricultural practices and concepts co-exist regarding new trends in primary production. Landers et al. [57] in their concept paper discussed about various pros and cons regarding principles of conservation agriculture such as zero tillage, organic farming and regenerative agriculture. It is expected that these practices can pave the way for reduction of pesticide and fertilizer use. In spite of the fact that organic farming should provide benefits to consumers in reduced use of pesticides, European Food Safety Authority reported traces of synthetic chemicals in this type of food throughout Europe [58]. The main idea behind organic farming is absence of any type of synthetic agricultural inputs such as pesticides, growth regulators, and different types of fertilizers and supplements [59]. Schleiffer and Spencer [60] identified two main origins of this—food fraud and unintentional contamination coming from the environment, making it challenging for organic operators to achieve a ‘zero-tolerance’ approach associated with pesticide residues.

Findings from this study may serve as a guide for accelerated development of international guides and standards related to the “Zero Residue” concept. In parallel, it may inspire development of additional trainings related to use of plant protection products during primary production and mitigation measures in decreasing their use. Authors believe that this study can provide aid not only for primary producers and scholars, but also for certification bodies, auditors and consultants.

Finally, in line with the role of food systems in achieving sustainable development goals of the UN [61], “Zero residue” concept may be a brick in the wall of sustainable agricultural production as small farmers produce about 75% of food [62]. “Zero residue” may aid in efficient use of resources, mitigate climate change issues and upgrade global food security and farmers’ quality of life, targeting the following UN sustainable goals: SDGs 1, 2, 3, 6, 12, 13, 14, and 15 [63].

Limitation of the study is potential existence of additional challenges not included in the FMEA analysis.

### 6. Conclusions

This study has revealed four dimensions of challenges when implementing “Zero Residue” concept. The first dimension is the role of stakeholders. Consultants are very important as their (in)adequate knowledge and limited experience in this type of food safety concepts may lead to development of an ineffective paper-driven system. Certification bodies may have low interest in developing new schemes considering that new concepts (like “Zero Residue”) are still voluntary compared to GlobalGAP that is required by the GFSI scheme. Consumers and their low awareness of the benefits of commodities produced under “Zero residue” concept may be an implementation challenge. Finally, role of inspection bodies is also obscure in understanding the advantages for primary producers. The second dimension of challenges is related to type of plant protection products used,

the development of optimal plans for their usage, and adjustments to their use regarding potential climate impacts and misuse during the growing phase. The third dimension is associated with control, starting from sampling in control plans, use of competent external laboratories in terms of their scope of accreditation and handling of nonconforming/unsafe products. Finally, the financial dimension is also an important factor in terms of the profit companies and retailers could achieve from implementing this concept.

Future perspectives are twofold. First, there is a need of promoting the concept for the benefit of consumers but also other stakeholders in the fruit/vegetable chain continuum (primary producers, retailers, inspection services, policy makers). In parallel, there is a need for analyzing the life cycle of the concept in three dimensions *ex-ante* (before the implementation process), *ongoing* (during the implementation), and *ex-post* (upon successful certification).

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