

# FSSC 22000 Version 5 FSMA PCHF REPORT ADDENDUM

**COMPANY: WORLÉE NATURPRODUKTE GMBH**

**Prepared by: dr. Ildikó Csapó**  
**Date: 11/11/2021**

<b>Registered legal name</b>	Worlée NaturProdukte GmbH
<b>Street address, city, country</b>	Grusonstrasse 22, 22113 Hamburg, GERMANY
<b>Project number</b>	PRJC-187949-2009-MSC-DEU
<b>Scope</b>	Production and refinement of all kinds of dried plant products. Filling in bulk: packing in PP-big bags, paper bags, paper bags with PE-inliner, cartons and PE-bags. Category CIV.
<b>Auditor Name</b>	dr. Ildikó Csapó
<b>Audit start date</b>	08/11/2021
<b>Audit end date</b>	10/11/2021

### 1. Auditor Competency and qualification - (CFR Title 21 part 117)

The auditor is trained to a level that meets FSMA qualified auditor requirements and has sufficient knowledge to effectively examine the implementation of the FSMA rule Preventive Controls for Human Food

Yes X / No ☐

### 2. Trained PCQI (or equivalent)

The facility has a trained PCQI (or equivalent) to create and oversee implementation of the Food Safety Plan(s)

Yes X / No ☐

Summary:

The QM Marcus v. Busse is qualified as PCQI by AIB International in online training on 22.04.2020.

### 3. PCHF Rule

The facility is accountable for compliance with the FSMA Rule Preventive Controls for Human Food and the CB auditor has verified that the identified gaps included in this Addendum has been addressed

Yes X / No ☐

Summary: Based on the conducted audit the auditor verifies compliance with the FSMA Rule Preventive Controls for Human Food.

### 4. Food Safety Plan – PCHF: § 117.126

The facility has prepared and implemented a written food safety plan

Yes x /No ☐\*

Summary (List the written Food Safety Plans that have been reviewed to confirm that they meet the FSMA Preventive Controls for Human Food regulation requirements in 21 CFR Part 117):

- HBQMW-0292 „HACCP Manual”/29.09.2021

- There are hazard analyses per each raw material and each flow chart. Seen example of 11012 “Plant raw materials”/02-12-2020: High risk due to microbiological contamination of Salmonella: need of heat treatment; high risk of metal foreign bodies controller by metal detector and magnet.

### Preventative Controls - PCHF: § 117.135

(a)(1) The facility must identify and implement preventive controls to provide assurances that any hazards requiring a preventive control will be significantly minimized or prevented and the food manufactured, processed, packed, or held by your facility will not be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act.

- (2) Preventive controls required by paragraph (a)(1) of this section include:  
 (i) Controls at critical control points (CCPs), if there are any CCPs; and  
 (ii) Controls, other than those at CCPs, that are also appropriate for food safety."

Yes X / No ☐\*

Summary:

List below all hazards requiring a preventive Control (HRPC) that were determined by the facility's hazard analysis – and the preventive controls employed:

<b>Hazards Addressed (HRPC) (Including Micro Species)</b>	<b>Preventive Controls Employed</b>	<b>Type of Preventative Control (process, allergen, sanitation or supply chain)</b>
Physical	Magnets	Strength (4,5 – 12,6 kGauss) is defined in xls document/29.09.2020. Monitoring during cleaning at start, at change, at end. Some magnets are self-cleaning. Strength is checked in every 2 years with own device. In case of decrease of the strength the magnet is replaced.
Physical	Metal detection	Critical limits: Fe 0,8 mm, NonFe 1,0 mm, SS 1,2 mm. The test of the sensitivity of the metal detectors (test of the main function) takes place by trained production employees at start of shift and end of production order, after unplanned downtime (e.g. device repair), if irregularities are suspected. In addition, an extended visual and functional check is carried out by the department every week and annually maintenance of the devices including software. If the test fails, the product is blocked since the last successful test and re-detected.
Microbiological (Salmonella)	Germ reduction with steam	Critical limits: min. temperature and time combinations for each product for batch process according to "Program list"/05.08.2021, and for continuous process in "C processing line"27.10.2021. Seen examples during site tours: batch program 26 for organic basil (115C, 2 minutes), batch program 25 for raspberry leaves (105C, 2 minutes), continuous program for peppermint =110C, 3 minutes). Traceability sample pumpkin seeds has critical limits 105C 6 minutes. Monitoring: Supervision of temperature-time logs for each batch by foreman, Doc.: Annex to product order 2. CA: blocking the batch, reprocessing; maintenance of the control instruments and thermometer/timing devices Doc.: Protocols technology.

The auditor confirms that the above PCs have appropriate validation, monitoring, verification (e.g. environmental monitoring) and corrective action procedures.

Yes X / No ☐\*

If no, please comment: .....

The auditor confirms that the above PCs are being appropriately implemented and documented.

Yes X / No ☐\*

If no, please comment: .....

The Auditor has verified that preventive controls are effectively implemented through following methods: (by records review and/or direct observation and/or employee interview and/or other-describe).

Yes X / No ☐\*

**Circumstances in which the owner, operator, or agent in charge of a manufacturing/ processing facility is not required to implement a preventive control: § 117.136**

(4) The organization rely on their customer to provide assurance that the food will be processed to control the identified hazard by an entity in the distribution chain subsequent to the customer and the organization:

(i) Discloses in documents accompanying the food, in accordance with the practice of the trade, that the food is "not processed to control [identified hazard]"; and:

(5) have established, documented, and implemented a system that ensures control, at a subsequent distribution step, of the hazards in the food product the organization distribute and document the implementation of that system.  
Yes ☐ / No ☐\* / N/As X

(b) Documented Records of any circumstance, specified in paragraph (a) of this section, that applies, including:

(1) A determination, in accordance with paragraph (a) of this section, that the type of food could not be consumed without application of an appropriate control;

Yes ☐ / No ☐\* / N/As X

(5) The system, in accordance with paragraph (a)(5) of this section, that ensures control, at a subsequent distribution step, of the hazards in the food product distributed.

Yes ☐ / No ☐\* / N/As X

**Summary:**

Although the company produces products for further processing by the food and feed industry, it is fully responsible for safety of the products and implemented a thorough preventive control plan.

\* § 117.136: If the hazard analysis determined there were no HRPCs, state that here:

NA

**Verification of implementation and effectiveness: § 117.165**

(3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready- to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples;  
and"

(4) Review of the following records within the specified timeframes, by (or under the oversight of) a preventive controls qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

(i) Records of monitoring and corrective action records within 7 working days after the records are created or within a reasonable timeframe, provided that the preventive controls qualified individual prepares (or oversees the preparation of) a written justification for a timeframe that exceeds 7 working days; and"

Yes X / No ☐

"(2) Product testing as required by paragraph (a)(2) of this section.

Procedures for product testing must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s) or other analyte(s);

(iii) Specify the procedures for identifying samples, including their relationship to specific lots of product;

(iv) Include the procedures for sampling, including the number of samples and the sampling frequency;

(v) Identify the test(s) conducted, including the analytical method(s) used;

(vi) Identify the laboratory conducting the testing;

Yes X / No ☐

"(3) Environmental monitoring as required by paragraph (a)(3) of this section. Procedures for environmental monitoring must:

(i) Be scientifically valid;

(ii) Identify the test microorganism(s);

(iii) Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites must be adequate to determine whether preventive controls are effective;

(iv) Identify the timing and -frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective;

(v) Identify the test(s) conducted, including the analytical method(s) used;  
(vi) Identify the laboratory conducting the testing;  
Yes X / No ☐

**Summary:**

Sampling is comprehensive, 50-60 samples are taken by an appointed the quality person per day. Product sampling plans are based on raw material hazard analysis, e.g. of fruits on 08.10.2018. Organoleptic, physical and chemical tests are done by the local lab, microb. by external lab GBA (accr. DAKKS D-PL-14170-01-00). Sampling procedure described in the instruction manual VAQMW-0081/10.06.2020.

The next parameters are tested from finished products: of the traced product pumpkin seeds heat treated on 21.10.2021: Moisture, ash, SO<sub>2</sub>, sieve analysis, water activity from each 4<sup>th</sup> lot, pesticides from each lot. If powder: each lot, if from Flex supplier: 4/year.

Further tests are done from products for customer request, e.g. bio spice mix lot 29931801 by GBA lab for pesticides, glyphosate, AMPA, glyphosate on 24.11.2020.

Microbiological sampling plan of products is included in "Documentation of hygiene during the production"/ 23.11.2020 for TVC, Coliforms, E. coli, St. aureus, sulphite reducing Clostridia, yeasts, moulds, B. cereus, Enterobacteriaceae, Salmonella. Tests are done by external lab.

Pathogen environmental monitoring is described in "Procedural instruction - Hygiene tours, hygiene status and microbiological line and environmental controls in production"/v2/02.11.2021. The canteen is also part of it. German Federation Institute guidance was taken into consideration to increase limit of Enterobacteriaceae from 5000 to 10000 cfu/g. The State Food Safety Authority checked and approved the previous plan against the EU regulation on 26.10.2020.

Appointed persons take the samples. Laboratory GBA (accr. DAKKS D-PL-14170-01-00) makes the analyses with accredited methods. 1-3 samples are taken monthly from defined hygiene points from 20x20 cm surface for Salmonella and Enterobacteriaceae. Limit of Salmonella is 0/25 g (according to EU regulation. Guide and limit values of Enterobacteriaceae are defined: guide < 1000 cfu/g and limit < 10000 cfu/g in each zone.

Seen examples in the direct online system, e.g. from Zone 3 floor, Zone 4 dosing part, Zone 3 floor, Zone 4 inside of the pipe, Zone 4 floor, Zone cleaned and unclean side of heat treating area, Zone 5 canteen.

Hand control with swab test is implemented twice/year for Coliform, E. coli, Enterobacteriaceae.

Air sample was taken as test of sampling device for customer requirement.

Cleaning after each production run with allergens is verified with rapid tests (mustard, sesame, nuts). Seen example: Lindoblender used for vegetables on 04.11.2021: after celery containing mix visual check; after next production run allergen test must be done in external lab. Similar case on 21.01.2021 no allergen was found (10 years ago they stopped cutting celery). In smoothie gluten and hazelnut was on 21.10.2021, swab was taken from Linder-blender, visually cleaning was no OK, rapid test was positive, after 2nd cleaning both were OK; next product has to be checked for gluten in external lab.

Trend analysis is regular and based on it the sampling program can be changed, e.g. in case of PAHs on cocoa powder: 12.11.2020 for the advice of GMA.

In case of NC result, corrective action is made, e.g. in August 2021 Enterobacteriaceae was higher (150000) in the culinary kitchen floor (zone 3), therefore samples were taken from the product and found conforming.

**Requirements applicable to a preventive controls qualified individual and a qualified auditor: § 117.180**

(8) Determination that re-analysis can be completed, and additional preventive controls validated, as appropriate to the nature of the preventive control and its role in the facility's food safety system, in a timeframe that exceeds the first 90 calendar days of production of the applicable food.

Yes ☐ / No X

**Summary:**

Re-analysis and additional preventive controls are not considered necessary.

**Additional requirements applying to the food safety plan: § 117.310**

The owner, operator, or agent in charge of the facility must sign and date the food safety plan:

(a) Upon initial completion; and

(b) Upon any modification.

Yes X / No ☐

**Summary:**

The HACCP plan was signed by the Quality Manager on 11.11.2021.

#### 5. Requirements for record retention: § 117.315

(2) Records that a facility relies on during the 3- year period preceding the applicable calendar year to support its status as a qualified facility must be retained at the facility as long as necessary to support the status of a facility as a qualified facility during the applicable calendar year.

Yes X / No ☐

Summary:

The company keeps FSFS records for 10 years.

#### 6. General requirements applicable to a Supply-Chain Program: § 117.410

(2) Considering supplier performance can be limited to the supplier's compliance history as required by paragraph (d)(1)(iii)(B) of this section, if the supplier is:

- (i) A qualified facility as defined by § 117.3;
- (ii) A farm that grows produce and is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5; or
- (iii) A shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens."

(b) For the purposes of this subpart, a receiving facility may not accept any of the following as a supplier verification activity:

- (1) A determination by its supplier of the appropriate supplier verification activities for that supplier;
- (2) An audit conducted by its supplier;
- (3) A review by its supplier of that supplier's own relevant food safety records; or
- (4) The conduct by its supplier of other appropriate supplier verification activities for that supplier within the meaning of §117.410(b)(4)."

(c) The requirements of this section do not prohibit a receiving facility from relying on an audit provided by its supplier when the audit of the supplier was conducted by a third-party qualified auditor in accordance with §§117.430(f) and 117.435.

Yes X / No ☐

Are third party audits used as part of supplier approval? If yes, then provide detail in the summary section below.

Summary:

Qualified supplier category does not apply.

The company does not accept solely own-verification of its suppliers.

The company purchases dry raw materials. QM-W-VA "Purchasing"/09.01.2019 includes criteria of approval and evaluation of suppliers. Suppliers are approved based on purchase specification, questionnaire, and evaluated by the Quality dept. (record issued on 13.03.2020), complete analysis of first delivery. Approved supplier list is dated on 21.10.2021. No new supplier since last audit.

Criteria of evaluation are quality, on-time delivery, flexibility, price, complaints, documents (certificate), cooperation are ranked with 1-6, the lower the better, and multiplied. E.g. supplier of the traced pumpkin seed is Estyria PL was evaluated on 21.10.2021 and achieved 50 rank point (acceptable).

Seen certificates:

- IFS certificate of Estyria supplying the traced pumpkin seeds peeled, valid till 22.11.2021.
- IFS certificate of El-Nenaiea Company supplying dried, sorted onion and leek, valid till 21.12.2021.
- IFS certificate of Telek paprika supplying culinary herbs, valid till 05.08.2021.

The most important suppliers are audited by the company once/3 year but not during Covid. E.g. supplier of traded product of chives in China was audited in Sept 2019. Photos were made about cultivation in the field, irrigation, green-house, processing area (washing, chopping, cooling freeze-drying, sieving, laser sorter, magnet, metal detection).

Outsourced process is cutting of garlic by a nearby company Krauterfabrik Dieckmann following a complete reception control Worlée. Cut product is checked and released for packing. This outsourced company is certified against GMP by State Service, and organic. Another outsourced process is sorting of raw materials in a Polish company Fan Fruits certified against IFS Food till 07.05.2022. Processes of the outsourced processors are considered as additional flow diagrams in the HACCP system.

Contingency plan for supply chain exists, sister company in Canada can take the job.

"Supplier Code of Conduct" was fully reviewed on 11.07.2021.

#### Conducting supplier verification activities for raw materials and other ingredients: § 117.430

(b)(1) Except as provided by paragraph (b)(2) of this section, when a hazard in a raw material or other ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans:

(i) The appropriate supplier verification activity is an onsite audit of the supplier;

Are any of the hazards controlled by the supplier classified as SAHCOHD hazards? If yes, specify below:

(c) If a supplier is a qualified facility as defined by § 117.3, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the supplier is a qualified facility as defined by § 117.3:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and"

(2) Obtains written assurance, at least every 2 years, that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

Yes X / No ☐ / N/A ☐

(e) If a supplier is a shell egg producer that is not subject to the requirements of part 118 of this chapter because it has less than 3,000 laying hens, the receiving facility does not need to comply with paragraphs (a) and (b) of this section if the receiving facility:

(1) Obtains written assurance that the shell eggs produced by the supplier are not subject to part 118 because the shell egg producer has less than 3,000 laying hens:

(i) Before first approving the supplier for an applicable calendar year; and

(ii) On an annual basis thereafter, by December 31 of each calendar year, for the following calendar year; and

(2) Obtains written assurance, at least every 2 years, that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States).

(f) There must not be any financial conflicts of interests that influence the results of the verification activities listed in § 117.410(b) and payment must not be related to the results of the activity.

Yes X / No ☐ / N/A ☐

#### Summary:

SAHCOHD hazards are contaminants (pesticides, heavy metals, mycotoxins) and pathogen microbes (E. coli, St. aureus, sulphite reducing Clostridia, B. cereus, Salmonella) above the legal/established limits. These hazards are controlled by the suppliers with the support of the auditee. Certificate of Analysis is required from the suppliers for each batch.

Sampling procedure is described in the instruction manual VAQMW-0081 "Sampling plan"/v1.1/ 10.06.2020.

Sampling is comprehensive, 50-60 samples are taken by an appointed quality persons per day. Organoleptic, physical and chemical tests are done by the local lab, microb. by external lab.

Sampling plans are based on raw material hazard analysis, e.g.

- of fruits on 18.12.2020 about quality parameters, micro., toxicology, allergens,

- of herbs on 05.11.2021 due to ethylene oxide: risk category chemical, probability + severity (2+4=6). Sulphite reducing Clostridia: high risk in Mediterranean and culinary herbs therefore all incoming batches are tested for Clostridium sp.

The sampling plan was updated by the working group on legislation on 08.10.2021 due to changes in pyrrolizidine alkaloids legislation, heavy metal limits, ethylene oxide issue (in sesame in India plus identified other materials e.g. curcuma, black pepper, ginger powder: testing ethylene oxide from each batch from India as well as 1st delivery from China and Turkey), new regulation on radioactivity: check radionuclides in materials from Balkan, Ukraine, Russia. Info is sent to purchase, quality. Comparisons with previous test results if exceeding of the limit is possible.

Seen plan of raw material tests (in the system):

- Organoleptic test of incoming goods takes place in 4 labs. From 1.5 packing units all are sampled, from 6-100 packing units 5 average samples are taken, from >100 packing units 10 samples are taken. Seen sensorial test of champion 2-6 mm, article code 107-7332, lot 50803607.

- Ethylene oxide testing plan in WIS sub-system of WAF: frequency, number of samples defined.

- Mushroom: moisture, ash, SO<sub>2</sub>, sieve analysis, water activity from each 4th lot, pesticides from each lot. If powder: each lot, if from Flex supplier: 4/year.



- Dried fruit, pesticide, aflatoxin, microb. – frequency is different. E.g. mango from new crop: moisture form each batch, aw once/year, SO2 form each batch, microb. from each batch, pesticides once/year, heavy metal and mycotoxins once/year.

Microbiological sampling plan is included in "Documentation of hygiene during the production"/23.11.2020 about raw materials for TVC, Coliforms, E. coli, St. aureus, sulphite reducing Clostridia, yeasts, moulds, B. cereus, Enterobacteriaceae, Salmonella. Tests are done by external lab. Seen example of shiitake raw material on 24.07.2020.

All raw materials are automatically blocked in the computer system until the sensory and analytical checks are completed. The Quality Assurance does the release. Seen example of the raw material of the traced product: arrived on 25.06.2020, 30.06.2020, released on 01.07.2020.

NC raw materials are managed according to VAQMW-0412 "Nonconforming product handling"/09.09.2019.

The company is informed about FDA regulations, e.g. seminar on 22.11.2020 by ASTA (American Spice Association).

Shell egg is not purchased.

There are no financial conflicts of interests. Payment is not related to the results of the activity.

#### **Supplier Approval - Onsite audit: § 117.435**

(2) For inspections conducted by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, the food that is the subject of the onsite audit must be within the scope of the official recognition or equivalence determination, and the foreign supplier must be in, and under the regulatory oversight of, such country.

(d) If the onsite audit is solely conducted to meet the requirements of this subpart by an audit agent of a certification body that is accredited in accordance with regulations in part 1, subpart M of this chapter, the audit is not subject to the requirements in those regulations.

Yes ☒ / No ☐ / N/A ☐

#### **Summary:**

The company is under regular supervision on of the local State Food Safety Authority. Confirmation of compliance was issued on 11.08.2020, last visit was for samples of ginger on 03.11.2021. Reference samples must be kept till end of the year.

FDA asked dates for audit, but it was postponed due to Covid-19.

#### **Supplier Approval - Records documenting the Supply- Chain Program: § 117.475**

(12) The following documentation of an alternative verification activity for a supplier that is a qualified facility (e.g. small business / income less than \$500,000).

(i) The written assurance that the supplier is a qualified facility as defined by § 117.3, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the supplier is producing the raw material or other ingredient in compliance with applicable FDA food safety regulations (or, when applicable, relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

A facility that meets the definition of a "qualified facility" in part 117 or part 507 is subject to modified requirements in 21 CFR 117.201 or in 21 CFR 507.7 respectively. These modified requirements include the requirement that the facility submit a form to FDA, attesting to its status as a qualified facility.

(13) The following documentation of an alternative verification activity for a supplier that is a farm that supplies a raw material or other ingredient and is not a covered farm under part 112 of this chapter:

(i) The written assurance that supplier is not a covered farm under part 112 of this chapter in accordance with § 112.4(a), or in accordance with §§ 112.4(b) and 112.5, before approving the supplier and on an annual basis thereafter; and

(ii) The written assurance that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose food safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);"

Yes ☐ / No ☐ / N/A ☒

(14) The following documentation of an alternative verification activity for a supplier that is a shell egg producer that is not subject to the requirements established in part 118 of this chapter because it has less than 3,000 laying hens:

(i) The written assurance that the shell eggs provided by the supplier are not subject to part 118 of this chapter because the supplier has less than 3,000 laying hens, before approving the supplier and on an annual basis thereafter; and



(ii) The written assurance that the shell egg producer acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Act (or, when applicable, that its food is subject to relevant laws and regulations of a country whose safety system FDA has officially recognized as comparable or has determined to be equivalent to that of the United States);

Yes ☐ / No ☐ / N/A ☒

(15) The written results of an appropriate inspection of the supplier for compliance with applicable FDA food safety regulations by FDA, by representatives of other Federal Agencies (such as the United States Department of Agriculture), or by representatives from State, local, tribal, or territorial agencies, or the food safety authority of another country when the results of such an inspection is substituted for an onsite audit;

Yes ☒ / No ☐ / N/A ☐

(18) When applicable, documentation of the receiving facility's review and assessment of:

(i) Applicable documentation from an entity other than the receiving facility that written procedures for receiving raw materials and other ingredients are being followed;

(ii) Applicable documentation, from an entity other than the receiving facility, of the determination of the appropriate supplier verification activities for raw materials and other ingredients;

(iii) Applicable documentation, from an entity other than the receiving facility, of conducting the appropriate supplier verification activities for raw materials and other ingredients;

"(iv) Applicable documentation, from its supplier, of:

(A) The results of sampling and testing conducted by the supplier; or

(B) The results of an audit conducted by a third- party qualified auditor in accordance with §§ 117.430(f) and 117.435; and

(v) Applicable documentation, from an entity other than the receiving facility, of verification activities when a supply-chain-applied control is applied by an entity other than the receiving facility's supplier."

Yes ☐ /No ☐ / N/A ☒

Summary:

Qualified supplier category does not apply.

Fresh produce is not purchased.

Shell egg is not purchased.

The State Food Safety Authority checked and approved the plan against the EU regulation on 26.10.2020.

Receiving facility is the company, all raw material tests are done onsite or ordered from accredited laboratory.

### Conclusion:

The requirements of the FSSC 22000 V5 FSMA PCHF Addendum have been considered and met.

Yes ☒

Yes, subject to closure of the significant deficiencies ☐

No ☐

If no, please provide detail:

### Significant deficiencies identified during the audit

Clause	Detail of the deficiency	Timeline for corrective action	Objective evidence supplied	Verified and closed by auditor

### Disclaimer

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*Annexes: Audit Plan (Agenda)*