Annex 11.2 Requirements for preparation processes

The annex 11.2 "**Requirements for Preparation Processes**" is obligatory for producers, who produce **soup greens/soup vegetables** or do **peeling processes** and would like to market the processed, if necessary packed products, as QS goods. Exceptions are activities in which the product is exclusively podded, hulled or cleaned (e.g.: the removal of roots and leaves, the removal of the heart in the case of cauliflower and cabbage, the removal of the root section in the case of kohlrabi, the shortening of leaves in the case of leek).

If more extensive preparation or processing processes are carried out, the guideline Preparation/Processing Fruit, Vegetables, Potatoes must be applied.

11.2 Good manufacturing and hygiene practice

11.2.1 Water quality

Drinking water must be provided in suitable quantities and may not pose any risk of contamination. A tapping point plan must be available within the company. Water, irrespective of origin or state, that is used for the manufacture and/or treatment of food as well as the cleaning of objects and facilities that come into contact with food must be sampled in accordance with a risk-based plan (at least once per year (approx. every 12 months)) to test for the following microbiological parameters:

- *Escherichia coli* (*E. coli*) 0 CFU/100 ml
- Enterococci 0 CFU/100 ml

The water sample must be taken directly at the tapping point without removing any attached devices and inserts, without prior disinfection and without draining water. Sampling must be carried out by a qualified sampler (this may also be a trained employee).

Only an accredited and officially approved laboratory may be commissioned to analyse the water samples.

If the above limits are exceeded, measures to prevent product contamination must be defined and documented immediately.

Process/washing water must be replaced and/or prepared at regular intervals based on a risk assessment. The risk of contamination must be kept as low as possible.

For the water used in the final wash cycle, the above-mentioned requirements for carrying out microbiological water analyses apply.

The requirement to perform water analyses is only necessary when handling products that are suitable for raw consumption.

Water quality control plan, tapping point plan

11.2.2 Handling of deviating products

The process for dealing with nonconforming goods, pieces of equipment and packaging materials in the company must be regulated and implemented in line with the defined stipulations. In particular, rules must be in place for dealing with fallen unpackaged products or products which do not meet specifications due to production defects. A responsible employee must decide on the subsequent use of the product (release, post-processing/secondary treatment, blocking, rejection/disposal).

Goods with expired best-before date/use-by date must be stored separately from the other goods. These goods must be handled in line with internal guidelines and, where necessary, disposed of in the proper manner.

Documentation regarding the handling of deviating products

11.2.3 [K.O.] Risk of contamination

Contamination must be avoided; this includes biological, chemical and physical hazards as well as nauseating influences. For this purpose, a risk-based management needs to be carried out, in which diverse sources of contamination like food waste or lubricants need to be taken into account.

The penetration of foreign matter into foods must also be avoided. The hazards and possible entry sources of foreign matter must be identified and assessed on the basis of a risk analysis. Appropriate

precautionary measures must be taken and procedures established to minimize this risk. All measures necessary to avoid contamination must be identified and documented.

The responsible employees must be aware of and observe the detection limits and application regulations for the equipment that is used. Regular internal checks must be performed to assess the success of detection. These checks must be documented.

Cross-contamination due to other products must be avoided. In particular, contamination of other products must be avoided in the preparation/processing of products that contain allergenic substances. To this end, appropriate stipulations and work instructions must be in place in the company. The responsible employees must be adequately trained.

Documentation of foreign substance management

11.3 Staff hygiene

11.3.1 Hygiene sluice

Hands and shoes must be cleaned and disinfected thoroughly before entering the preparation and processing area. On basis of a hazard analysis the cleaning and disinfection of footwear can be dispensed.

The effectiveness of cleaning and disinfection of hands is to be examined randomly risk-based with microbiological tests of the surfaces of employee's hands at least every year (approx. every 12 months).

11.4 General process requirements

11.4.1 Best-before date/use-by date

When assigning a best-before date (BBD)/use-by date, it must be guaranteed that the product possesses the properties that are typical for the product at the end of the best-before date/use-by date.

Validated microbiological data must be available for assignment of the declared best-before date/use-by date. Parallel to this, a sensory assessment of the products must be performed.

A process must be implemented that provides for regular inspection of the best-before date/use-by date.

Procedure for checking the best-before date/use-by date

Soup greens/Soup vegetables
Based on an appropriate risk analysis, the validated microbiological data for assignment of the declared best-before date/use-by date may be dispensed for soup greens/soup vegetables.

11.4.2 [K.O.] Microbiological testing in the operational facility

In order to guarantee an appropriate standard of hygiene, cleaning, and if necessary, disinfection measures must be carried out in the company.

- Requirements in case of an exclusive cleaning/flushing of the operational facility

  If an exclusive cleaning/flushing of the plant is carried out, an optical cleaning control must take place. The result must be documented.

- Requirements in case of a disinfection of the operational facility

  If a disinfection of the plant is carried out, microbiological testing on surfaces has to be carried out regularly in the preparation and processing rooms in order to monitor disinfection measures. If the results are unsatisfactory, measures have to be taken in order to reduce surface germ counts (e.g. training/instruction, testing of disinfectors and agents, maintenance of disinfectors, monitoring of the disinfection process). The responsible cleaning staff must be informed of striking tests as quickly as possible.

  Sampling has to take place at all relevant food contact points (e.g. equipment, systems, conveyor belts, knives, palms of hands) and on other surfaces (e.g. tables, door handles, switches, containers, boxes). These sampling points must be determined on the basis of a risk analysis and documented in a sampling plan. The defined sampling points are to be sampled individually on an alternating basis.

  The sampling plan must ensure that all defined spots in the company are sampled over a specified period. In order to check the effectiveness of disinfection activities, samples have to be taken during production months at least monthly.

In addition to these minimum requirements, the sampling frequency is to be chosen using a risk-based approach and adapted to (where applicable increased to take account of):

- Size of company
- Existing systems (places where washed products are handled)
- Microbiological sensitivity of the produced goods
- Results of previous tests

If required by the legislator, samples for the processing areas and the equipment have to be tested for *Listeria monocytogenes* within the sampling plan.

Sampling and analysing must be performed by qualified personnel using suitable methods.

If residual effects of disinfections are expected, drawing equipment (contact samples) with disinhibitory has to be used.

Sampling plans for the operational facility, evaluations, results, documentation of measures

11.4.3 [K.O.] Microbiological monitoring of the products

Sampling plans must be drawn up for the microbiological tests. In-house self-assessment processes must ensure compliance with the sampling plans and documentation of microbiological status. Proof of the microbiological quality of the products must be provided.

The microbiological analyses of the products have to be performed based on the risk analysis. At least, legal requirements regarding the microbiological criteria for foods have to be met according to **regulation (EC) No. 2073/2005**. The currently valid version of the standard applies.

In addition, it must be ensured that products comply with the microbiological criteria during their shelf life and that specific sensory characteristics are presented. With regard to the sampling for this analysis, one of the following alternatives is to be selected:

Alternative 1: the products (each component individually or each basic mixture based on the different mixing ratios) are to be tested for the parameters at least once a quarter during the production months.

Alternative 2: risk-based product groups must be formed. The product groups are to be tested for the parameters at least once a quarter during the production months.

The frequency of sampling of products is also to be decided on the basis of perceived risk and is to be adapted to (where applicable increased to take account of) the product group in question, sales volume and the results of previous tests.

Note: *risk-based monitoring of prepared/processed products for Norovirus, Hepatitis A virus, Campylobacter and Listeria is recommended if a contamination/risk for the consumer cannot be excluded.*

Microbiological testing of the products is to be performed by accredited laboratories (in line with EN ISO/IEC 17025 for the area of microbiology).

If the results are unsatisfactory, in case of exceedance of the action value (control plan preparation) and/or in the event of non-compliance with the food safety and process hygiene criteria, the production process must be analysed for causes and, if applicable, measures have to be taken to reduce the germ content:

- Corrective measures (e.g. in the area of production hygiene and in the choice of raw materials)
- Further measures to prevent renewed occurrence of non-acceptable microbiological contamination.

Additionally for obligate or facultative pathogenic microorganisms must be decided to what extend the sampled batch is a "safe food" in the sense of article 14 of the **Regulation (EC) No. 178/2002** and whether the marketability is guaranteed.

Preparation process

For ready-to-eat prepared fruit and vegetables, additionally the requirements of the "control plan microbiological monitoring for ready-to-eat prepared fruit and vegetables and products made from same" (table 1) have to be met.

Soup greens/Soup vegetables, products without BBD

In deviation from the control plan for ready-to-eat prepared fruit and vegetables (table 1), the microbiological tests for soup greens/soup vegetables are to be performed on the basis of perceived risk.

Sampling plans, plans for measures

Table 1: Control plan microbiological monitoring for ready-to-eat prepared fruit and vegetables [(a)] and products made from same

Food category	Parameter	No. of samples	Sampling frequency	Action value (CUF[(b)]/g)	Analytical reference method[(c)]	Test time (process stage)
Prepared fruit and vegetables	EHEC (VTEC, STEC)[(d)]	One sample	Every three months	Not detectable in 25 g	ISO/TS 13136	At the end of the best-before date
Prepared fruit (Exception near-earth fruit)	*Enterobacteriaceae*	One sample	Every three months	$1x10^4$	DIN EN ISO 21528-2	At the end of the best-before date
Prepared fruit and vegetables	Yeasts	One sample	Every three months	$1x10^5$	ISO 21527-1	At the end of the best-before date
Prepared fruit and vegetables	Coagulase-positive staphylococci[(d)]	One sample	Every three months	$1x10^2$	DIN EN ISO 6888-2	At the end of the best-before date

Legend Table 1:
(a) See QS definition of "Preparation"

(b) CFU: Colony-forming unit

(c) The currently valid version of the standard applies.

(d) Obligate or facultative pathogenic germs

11.4.4 [K.O.] Temperature recording and monitoring

If temperature treatment is carried out during preparation and processing, a procedure is to be implemented for temperature recording and monitoring. Corrective action is to be taken in the event of nonconformities.

Procedure for temperature recording and monitoring

11.5 Requirements for preparation processes

11.5.1 Ground clearance

A system must be implemented and enforced whereby prepared products and containers containing or intended to contain food must not be placed directly on the floor. The goods must be stored and transported in such a way that there is no risk of contamination.

Excluded are industrial containers (e.g. BIG boxes), that are designed to stand on runners or legs off the floor. If these containers are stacked, contamination of the food must be prevented via company regulations.

11.5.2 [K.O.] Compliance with temperature stipulations

The legal temperatures and any temperatures defined in specifications must be maintained during the production and transport of prepared products within the operational facility and can only be deviated from for short periods when this becomes necessary for practical reasons (e.g. when loading and unloading and during transport within the operating facility).

Temperature recorder, temperature monitoring, measuring records

11.6 Outgoing goods and returns management

11.6.1 [K.O.] Final product inspection

For the purpose of final product inspection, checking procedures must be defined that ensure flawless delivery of the products in question.

In the case of unpackaged goods, this includes:

- Where applicable temperature monitoring
- Damage/Soiling
- Correct labelling

Additional procedures for packaged goods:

- Where applicable seal tightness check
- Where applicable monitoring of filling weight
- Where applicable inert gas
- Where applicable best-before date/use-by date/storage notes

These checks must be performed and documented on a regular basis and must meet the legal requirements. In the case of monitoring of filling weight, quantity and contents (taking account of tolerances) must correspond to the details on the packaging or in the specification.

Documentation of final product inspection

11.6.2 [K.O.] Temperature recording and monitoring

Temperature specifications must be in place for all products subject to mandatory cooling requirements. Compliance with the cold chain must be monitored in the areas controlled by the company, and the temperatures must be documented. Measures to be taken in the event of temperatures above the permitted levels must be defined and known to the responsible employees.

Self-assessment records, checklists, documentation of temperature, documentation on measures in the event of nonconformities

11.7 Transport/logistics

11.7.1 [K.O.] Temperature control

Transport must be carried out in accordance with the product requirements. The transport of goods must be carried out with closed, heat-insulated vehicles or refrigerated vehicles, taking into account the type of goods, transport distance and outside temperatures. Goods transported in open containers on open transport vehicles shall be adequately covered. Loose goods are to be transported in such a way that no contamination can take place.

11.7.2 Ground clearance

A system must be implemented and enforced whereby prepared products and containers containing or intended to contain food must not be placed directly on the floor. The goods must be stored and transported in such a way that there is no risk of contamination.

Excluded are industrial containers (e.g. BIG boxes), that are designed to stand on runners or legs off the floor. If these containers are stacked, contamination of the food must be prevented via company regulations.