



European **Sprouted Seeds Association**

ESSA hygiene guideline for the production of sprouts and seeds for sprouting

European Sprouted Seeds Association

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Abstract

The EU sprouted seeds market is a highly specialised niche segment of the fresh produce market with approximately 120 professional production establishments throughout the EU. After the EHEC crisis in 2011 and EFSA's "Scientific Opinion on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds", new EU legislation entered into force to enhance the safety of this product segment across Europe. Different national guidelines were created to help in the implementation of these specific rules. The purpose of this European guideline, written by the European Sprouted Seeds Association (ESSA), is to give comprehensive instructions on the hygienic practices for the safe production of sprouts and seeds for sprouting, and make this information available to sprout producers in European countries and beyond.

This guideline may be used to create checklists and schemes in order to facilitate the application of the guideline.

Scope of this guide

This guideline refers to the commercial production of sprouts and seeds for sprouting in accordance with applicable legislation of the European Union. The germination of seeds - moistening seeds to increase the water content in them and bring them out of dormancy, until a new plant starts growing upward - is primary production in the EU. This hygiene guideline covers activities that are part of primary production. Activities outside the scope of primary production are not covered, but alternative guidance may be available and listed in the references below. This guideline does not cover the production of other sprouted seeds, like microgreens, shoots, cress and products that are cultivated in growing media or soil in greenhouses. Sprouted seeds commodities excluded from the scope of this guidance are covered by Commission Recommendation – Guidance document on addressing microbiological risks in fresh fruit and vegetables at primary production through good hygiene¹.

Applicable EU legislation for the production of sprouts and seeds for sprouting

The general food safety requirements including the obligation to only place safe food on the market are laid down in regulation (EU) No 178/2002. The hygienic production of foodstuffs in the EU is covered by Regulation (EC) No 853/2004 and in particular by Annex 1 Part A of this regulation. It obliges primary producers to make sure that primary products are protected against contamination, for example by putting measures in place that prevent contamination from the air, soil, water, fertilisers, plant protection products and biocides and the storage, handling and disposal of waste. The present guidelines give practical examples to supplement these general provisions.

More specific requirements for the production of sprouts are laid down in several additional EU regulations: Commission Implementing Regulation (EU) No 208/2013 on traceability requirements for sprouts and seeds intended for the production of sprouts, Commission Regulation (EU) No 209/2013 (amending Regulation (EC) No 2073/2005) on microbiological criterion for sprouts, Commission Regulation (EU) No 210/2013 on the approval of establishments producing sprouts and Commission Regulation (EU) No 211/2013 (amended by Commission Regulation (EU) No

¹ European Commission, DG Health and Food Safety. Food hygiene. [Guidance](#)

704/2014) on certification requirements for imports of sprouts and seeds for sprouting into the EU. The requirements of these regulations are included in this guideline.

All pieces of EU legislation mentioned throughout this guide are referenced in Annex I of this guide. Annex II provides references to other relevant sources of information related to the production of sprouts.

This guideline covers the minimum requirements for production of sprouts in the EU. Some EU member states may have more stringent requirements for the sprout producers established in these member states. It is generally recommended that sprout producers keep in contact with their competent authority to keep informed about the applicable rules in their relative member state.

Additional documents going beyond the present guidelines

Additional guidance is available through relevant publications of the Codex Alimentarius, general good agricultural practices (GAP) and hygiene practices (GHP) developed by different national authorities as well as guidelines from different private stakeholders and certification schemes. Information concerning guidance documents known to the European Sprouted Seeds Association (ESSA) has been included into the references and annexes of this guideline.

DISCLAIMER

This present guideline is a recommendation without legally binding value. It has been established for information purposes only. The European Sprouted Seeds Association (ESSA) does not guarantee the accuracy of the information provided, nor does it accept responsibility for any use made thereof. Users should therefore take all necessary precautions before using this information, which they use entirely at their own risk. The duty to enforce European food safety legislation lays with the European Commission and the competent authorities of the EU member states. Sprout producers are asked to contact their competent authority to obtain full information about the legal requirements in their member state of establishment.

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List of abbreviations

CCP: critical control point

EC: European Community

EFSA: European Food Safety Authority

ESSA: European Sprouted Seeds Association

EU: European Union

GAP: Good Agricultural Practices

GHP: Good Hygiene Practices

HACCP: Hazard Analysis and Critical Control Points

STEC: Shiga toxin-producing *E.coli* O157, O26, O111, O103, O145 and O104:H4

WHO: World Health Organisation

Definitions

Batch²: a quantity of sprouts or seeds for sprouting with the same taxonomic name, which is dispatched from the same establishment to the same destination on the same day. One or more batches can make up a consignment. However, seeds with a different taxonomic name, which are mixed in the same packaging and intended to be germinated together and sprouts thereof are also considered as one batch.

Clean water³: means clean seawater and fresh water of a similar quality.

Competent authority⁴: the central authority of a member state competent for the organisation of official controls or any other authority to which that competence has been conferred; this can also, where appropriate, refer to the corresponding authority of a third country.

Consignment⁵: a quantity of sprouts or seeds intended for the production of sprouts and which is: (i) originating from the same third country; (ii) covered by the same certificate(s); (iii) conveyed by the same means of transport.

Contamination⁶: means the presence or introduction of a hazard.

Cress⁷: sprouted seeds obtained from the germination and development of true seeds in soil or in hydroponic substrate, to produce a green shoot with very young leaves and/or cotyledons. Cress is sold as the entire plants in its substrate or soil.

Critical control point (CCP)⁸: a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Establishment⁹: means any unit of a food business.

Good agricultural practices (GAP)¹⁰: practices that address environmental, economic and social sustainability for on-farm processes, and result in safe and quality food and non-food agricultural products.

Good Hygiene Practices (GHP)¹¹: general, basic conditions for hygienic production of a foodstuff, including requirements for hygienic design, construction and operation of the establishment, hygienic construction and use of equipment, scheduled maintenance and cleaning, and personnel training and hygiene. A developed and implemented GHP programme is a pre-requisite for HACCP system.

Food¹²: means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

Food business operator¹³: means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

Food hygiene¹⁴: hereinafter called "hygiene", means the measures and conditions necessary to control hazards and to ensure fitness for human consumption of a foodstuff taking into account its intended use.

² Definition as set by the European Commission in [Commission Implementing Regulation \(EU\) No 208/2013](#)

³ Definition set by the European Commission in [Regulation \(EU\) No 852/2004](#)

⁴ Idem note 3

⁵ Definition as set by the European Commission in [Commission Regulation \(EU\) No 211/2013](#)

⁶ Idem note 3

⁷ [EFSA "Scientific Opinion](#) on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds"

⁸ Definition set by Codex Alimentarius Commission. [Hazard Analysis and Critical Control Point \(HACCP\) System and Guidelines for its Application](#)

⁹ Idem note 3

¹⁰ Definition as set by the European Commission in [Regulation \(EC\) No 396/2005](#)

¹¹ ESSA definition based on [Commission in Regulation \(EC\) No 2073/2005](#)

¹² Definition set by the European Commission in [Regulation \(EC\) No 178/2002](#)

¹³ Idem note 12

¹⁴ Idem note 3

Food law¹⁵: means the laws, regulations and administrative provisions governing food in general, and food safety in particular, whether at Community or national level; it covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food-producing animals.

Hazard¹⁶: means a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.

Hazard analysis¹⁷: the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Hazard analysis and critical control points (HACCP)¹⁸: a system which identifies, evaluates, and controls hazards which are significant for food safety.

Labelling¹⁹: means any word, particulars, trademarks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food.

Microbiological criterion²⁰: means a criterion defining the acceptability of a product, a batch of foodstuffs or a process, based on the absence, presence or number of micro-organisms, and/or on the quantity of their toxins/metabolites, per unit(s) of mass, volume, area or batch.

Monitor²¹: the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP (critical control point) is under control.

Official controls²²: means any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules.

Packaging²³: means the placing of one or more wrapped food-stuff in a second container, and the latter container itself.

Primary production²⁴: production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.

Primary products²⁵: products of primary production including products of the soil, of stock farming, of hunting and fishing.

Potable water²⁶: water meeting the minimum requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.

Ready-to-eat-food²⁷: means food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing effective to eliminate or reduce to an acceptable level micro-organisms of concern.

Representative sample²⁸: means a sample in which the characteristics of the batch from which it is drawn are maintained. This is in particular the case of a simple random sample where each of the items or increments of the batch has been given the same probability of entering the sample.

¹⁵ Idem note 12

¹⁶ Idem note 12

¹⁷ Idem note 8

¹⁸ Definition set by Codex Alimentarius Commission. [Recommended international code of practice general principles of food hygiene](#)

¹⁹ Definition set by the European Commission in [Regulation \(EU\) No 1169/2011](#)

²⁰ Idem note 11

²¹ Idem note 8

²² Idem note 3

²³ Idem note 3

²⁴ Idem note 3

²⁵ Idem note 3

²⁶ Idem note 3

²⁷ Idem note 11

²⁸ Idem note 11

Risk²⁹: means a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard.

Risk analysis³⁰: means a process consisting of three interconnected components: risk assessment, risk management and risk communication.

Sample³¹: means a set composed of one or several units or a portion of matter selected by different means in a population or in an important quantity of matter, which is intended to provide information on a given characteristic of the studied population or matter and to provide a basis for a decision concerning the population or matter in question or concerning the process which has produced it.

Seeds for sprouting³²: seeds intended for the production of sprouts.

Seed producer³³: any person responsible for the management of activities associated with the primary production of seeds including post-harvest practices.

Seed distributor³⁴: any person responsible for the distribution of seeds (handling, storage and transportation) to sprout producers. Seed distributors may deal with single or multiple seed producers and can be producers themselves.

Shoots³⁵: sprouted seeds obtained from the germination and the development of seeds to produce a green shoot with very young leaves and/or cotyledons. The shoots and the leaves are harvested at the end of the production process and the final product does not include the seed integuments and the roots.

Spent sprout irrigation water³⁶: water that has been in contact with sprouts during the sprouting process.

Sprouts³⁷: means the product obtained from the germination of seeds and their development in water or another medium, harvested before the development of true leaves and which is intended to be eaten whole, including the seed.

Sprouted seed³⁸: include the following categories: sprouts, cresses and shoots.

Sprout producer³⁹: any person responsible for the management of the activities associated with the production of sprouted seeds.

Sprouted seeds distributor⁴⁰: any person responsible for the distribution of sprouted seeds (handling, storage and transportation) to the buyer/customer. Sprouted seed distributors may deal with single or multiple sprouted seeds producers and can be producers themselves.

Substances⁴¹: means chemical elements and their compounds, as they occur naturally or by manufacture, including any impurity resulting from the manufacturing process.

Traceability⁴²: means the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food and feed, through all stages of production, processing and distribution.

²⁹ Idem note 12

³⁰ Idem note 12

³¹ Idem note 11

³² ESSA definition based on [EFSA "Scientific Opinion](#) on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds"

³³ Definition set by Codex Alimentarius Commission. [Code of hygienic practice for fresh fruit and vegetables](#)

³⁴ Idem note 7

³⁵ Idem note 7

³⁶ Idem note 7

³⁷ Idem note 2

³⁸ ESSA definition based on [EFSA "Scientific Opinion](#) on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds"

³⁹ Idem note 33

⁴⁰ ESSA definition based on the definition of "seeds distributor"

⁴¹ Definition set by the European Commission in [Regulation \(EC\) No 1107/2009](#)

⁴² Idem note 12

1. SPROUTS PRODUCTION

1.A. Establishment

1.A.1. Approval of establishments producing sprouts

Before starting production of sprouts, producers must register with the national authorities. It is a legal requirement in the EU under Regulation (EC) No 852/2004, art. 6 that all food business operators are registered by the national competent authorities. In addition, establishments located in an EU member country producing sprouts must be approved by their competent authority in accordance with Commission Regulation (EU) No 210/2013. In order to approve a sprout producer, the competent authority must verify that the operator complies with Annex I of Regulation (EC) No 852/2004 on the hygiene of foodstuffs and with the Annex of Commission Regulation (EU) No 210/2013. Sprout producers must ensure the sprouts that they produce are protected against contamination.

Sprout producers also must take measures to control contamination arising from the air, soil, water, fertilisers, plant protection products and biocides and the storage, handling and disposal of waste.

In practice, competent authorities may refer to this present guideline or the list of national guidelines to check whether sprout producers fulfil the provisions contained in Annex I of Regulation (EC) No 852/2004 on general rules on the hygiene of foodstuffs.

1.A.2. Design and layout of facilities

The legal requirements for the approval of establishments producing sprouts are listed in the annex of Commission Regulation (EU) No 210/2013. Requirements listed in Commission Regulation (EU) No 210/2013 are as follows:

1. The design and layout of establishments shall permit good food hygiene practices, including protection against contamination between and during operations. In particular, surfaces (including surfaces of equipment) in areas where foods are handled and those in contact with food shall be maintained in a sound condition and be easy to clean and, where necessary, to disinfect.
2. Adequate facilities shall be provided for the cleaning, disinfecting and storage of working utensils and equipment. These facilities shall be easy to clean and have an adequate supply of hot and cold water.
3. Adequate provision shall be made, where necessary, for washing food. Every sink or other such facility provided for the washing of food shall have an adequate supply of potable water and be kept clean and, where necessary, disinfected.
4. All equipment with which seeds and sprouts come into contact shall be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination, and to enable it to be kept clean and, where necessary, to be disinfected.
5. Appropriate procedures shall be in place to ensure that:
 - a. the establishment producing sprouts is kept clean and, where necessary, disinfected;
 - b. all equipment with which seeds and sprouts come into contact is effectively cleaned and, where necessary, disinfected. The cleaning and disinfection of such equipment shall take place at a frequency sufficient to avoid any risk of contamination.

In addition, the following requirements should also be followed:

- sprout production should take place indoors in fully-closed buildings;
- facilities should be designed in such a way that seeds and sprouts are kept at a distance from objects and substances that could pose a threat of contamination. The production process and other related processes (waste management, worker sanitation etc.) should be designed in such a way that any danger of cross-contamination is minimised. Where possible, there should be physical separation between the areas where seeds are received and stored, the areas where seeds are prepared and rinsed, the areas where germination takes place and the areas

where sprouts are cooled and packaged. Where possible, seeds and sprouts should not return into a room in which they have already been. Where appropriate, the flow of the production process could be indicated to staff through signs or labels. Facilities should be easy to clean and to maintain;

- sanitary facilities should be equipped with running clean hot water, soap dispensers and hand drying equipment (e.g. disposable towels). Preferably automatic sensor taps should be installed. Wherever possible, they should be constructed in such a way that they do not provide direct access to the area in which the production process takes place. Sanitary facilities should be equipped to ensure hygienic removal of waste and undergo regular cleaning and maintenance as appropriate;
- a cloakroom or equivalent should be available for workers (see point 1.A.7.);
- to prevent contamination from air, due care should be taken that food products are not directly exposed to air from origins that may be contaminated (e.g. mould, moisture etc.). Air conditioning should not blow directly onto food products. Where appropriate and feasible, instruments to de-oil, dehydrate and filter the air should be used. Where necessary, these instruments should undergo regular maintenance.

Some EU member states may have more stringent requirements for the design and layout of facilities.

1.A.3. Sanitation

Where appropriate, sanitation work should be done by cleaning and disinfection of surfaces and equipment. Sprouting facilities should have a written cleaning plan (indicating methods and schedule of personnel) to ensure that all relevant areas of the facility will be regularly cleaned. The cleaning plan should mention the frequency at which cleaning takes place. This plan should identify areas where moisture, mould, dirt, animals, insects or bacteria are likely to establish themselves, and describes how to prevent this from happening.

All equipment that comes into contact with seeds or sprouts should be regularly cleaned and disinfected followed by final rinsing with water in accordance with the instructions of the cleaning products if required. Only approved cleaning products should be used and only potable water or water of a trusted source can be used for cleaning and disinfection. Where possible, equipment should be easy to clean or disinfect.

Cleaning and disinfection should be carried out in a way that makes it impossible for food products to be contaminated with cleaning products (e.g. by cleaning at times when no seeds are sprouted). If biocidal products are used then these biocides must meet requirements listed in European regulation on biocides (Delegated Regulation (EU) No 1062/2014) and provisions set by national authorities.

Sufficient time should be given in accordance with the instructions of the cleaning product before cleaned/disinfected surfaces come into contact with food products again.

Sprouting companies should keep records of the dates of cleaning and disinfection and the areas and pieces of equipment that have been cleaned and chemical used.

Any danger of contamination from glass or metal shards, debris, chemical substances, cleaning and disinfection products or other dangerous objects should be minimised by keeping these objects separate from the production process. Cleaning and disinfection products should be stored in a dedicated location or closet that is kept locked and carries appropriate signs or labels.

1.A.4 Maintenance

Where maintenance work is conducted, this should be done in such a way that contamination of food products is impossible (e.g. by conducting repair work outside of the production area or at times when no production is taking place). Where appropriate, maintenance work should be followed by cleaning or disinfection of surfaces and equipment that will come into contact with food products.

Records of the maintenance work including dates and identification of the objects that are covered should be kept.

1.A.5. Worker health status

Staff members known or suspected to have a disease or illness that can be transmitted to the sprouts should not be allowed into areas where they may come into direct or indirect contact with seeds or sprouts.

Staff injuries that could present a danger of contamination should be adequately treated with waterproof detectable covers before the worker can come into contact with seeds or sprouts. Where possible, wounded workers should avoid direct contact with seeds or sprouts for human consumption.

1.A.6. Pest control

The production facility should be kept in a general good condition that makes it difficult for pests or animals to access the facility or establish themselves inside.

Access of pests and animals should be prevented by keeping windows and other entry paths closed and by protecting windows with mesh wire or other materials where appropriate. Other outlets that could allow the access of pests or animals should be kept sealed. Infrastructure related to the production process (e.g. pipes or air ducts) should be constructed or fitted in a way to prevent access of pests or contaminating substances.

For prevention reasons, in order to prevent any possible establishment of pests in the facilities, the operators should set a pest control plan and provide pest traps. A contract with pest control firm should be set up.

1.A.7. Personal hygiene and suitable clothing

In a general manner, staff members should keep a high degree of personal hygiene.

Everyone who works in a food preparation area must practice good personal hygiene. All workers should be aware of the principles of hygiene and health, and should be informed about all the dangers that could contaminate the product. They should receive hygiene training appropriate to their tasks and be periodically assessed. Such training should be delivered in a language and manner to ensure understanding of the required hygienic practices.

Staff and visitors should wear clean clothing and wear head covering while they are in the production facility.

Overall, the entering of visitors into processing or storage areas should be forbidden unless they have been informed about hygiene requirements. Visitors who enter these areas should be provided with a suitable uniform and their names should be recorded. Records should be kept for an appropriate amount of time.

Staff working in food handling areas must practice good hygiene:

- have clean hands or wear gloves if they are handling seeds and sprouts;
- not smoke or spit in the food handling area;
- avoid contamination of sprouts through sneezing and coughing over them;
- ensure that hair does not pose a risk of contamination;
- cover cuts, wounds, healing skin or other skin conditions likely to cause contamination of foods (on hands or other exposed parts of the body) with waterproof dressings;
- not wear jewellery or beauty products that may present a risk of contamination;
- staff should keep their fingernails short and clean.

Hands should be washed:

- before handling ready-to-eat food;
- after a break;
- after going to the toilet;

- after cleaning;
- after removing waste.

Although there may be slight variations on hand washing techniques all include the following steps:

- wetting of hands before applying soap;
- thorough hand rubbing, to remove contamination from all parts of the hands;
- rinsing of hands with potable water or water from a trusted source;
- hygienic drying.

Staff hygiene rules should be printed and attached to the walls either in written form or in form of signs or labels.

1.A.8. Waste treatment

Waste should be removed promptly from the vicinity of food products.

If appropriate waste bins in the production area should be covered and kept at a distance from food products and emptied on a daily basis. Large amounts of waste should be immediately removed from the production area.

Where larger waste containers are necessary, these should be kept outside the production area, where possible in an area that is inaccessible to rodents, animals, insects and other pests.

Waste bins and containers should be regularly cleaned and regularly disinfected.

1.B. Training

All staff coming into direct or indirect contact with seeds or sprouts must receive training in order to obtain a proper understanding of:

- implementation and supervision of a food safety management system;
- food safety procedures;
- food allergen management;
- food hazards and the risks associated with them;
- risks linked to cross contamination;
- importance of high standards of cleanliness in the production, handling and packaging areas;
- techniques involved in controlling and monitoring food safety;
- personal hygiene and suitable clothing (see point 1.A.7.).

All personnel involved in sanitation should receive training to understand the cleaning and disinfection plan, the handling of chemical substances and the separation of cleaning products from the production process.

Sprout producers should keep records of the dates of training, the topics that have been covered and the participating employees.

1.C. Control of incoming seeds

Food producers are under obligation of the EU's general food law regulation (Regulation (EC) No 178/2002) to only put safe products on the market. This means that sprout producers will be held responsible for any contamination that may have occurred in earlier stages of the supply chain before the arrival of the seed batches in the sprouting facility. For this reason, sprout producers should only purchase seeds from trusted suppliers that have procedures in place to assure good hygienic production of the seeds and traceability of the batches.

Sprout producers should only purchase seed that has been grown in such a way that the risk of contamination with pathogens is minimised (seeds should be fit for purpose).

This chapter and the provisions on seed production contained in the second chapter of this guideline provides help to meet this requirement.

1.C.1. Import certificate

If the seeds for the purpose of sprouting are originating from non-EU countries, it is obligatory that each consignment of seeds is accompanied by an import certificate during all stages of trade as required by Commission Regulation (EU) No 704/2014 (amendment of Commission Regulation (EU) No 211/2013). A copy of this certificate must be made available to the sprout producer and kept on record by the sprout producer for a sufficient time after the sprouts can be assumed to have been consumed. The certificate must be issued in the official language or languages of the issuing country and the language or languages of the country of reception. Where this is not possible, the certificate can also be accompanied by a certified translation into the language of the country of reception. Where seeds arrive in one EU member state and are then sent to another EU member state, the competent authority of the receiving country may request certified translations of the certificate into its own language. A specimen of the import certificate can be found in Commission Regulation (EU) No 211/2013.

If sprout producers sell batches of seeds to a different sprout producer with the intention to be sprouted in that establishment, every batch of seeds must be accompanied by a copy of the corresponding import certificate and a document with the traceability information given above, including the name and address of the seed supplier and the sprout producer who initially received the seeds. If information on the supplier of seeds for sprouting for commercial reasons is hidden in the copy of import certificate, such information should be disclosed to the buyer and competent authorities in case of contamination of seeds. If traders are involved in the supply chain of seeds for sprouting, these must also follow the same traceability requirements.

If a batch of seeds originating from a non-EU country is not accompanied by this certificate, it must not be used to produce sprouts for human consumption.

The import certificate needs to be issued by the competent authority of the exporting country (normally the health or food safety authority or Agriculture ministry). By signing the certificate, the competent authority certifies that the seeds were grown in compliance with the requirements in Annex 1 Part A of Regulation (EU) No 852/2004 (i.e. good hygiene practices). The second part of this guideline (see Chapter 2. Production of seeds) contains practical examples that supplement the general requirements in Regulation (EU) No 852/2004. Chapter 2 of this guideline can therefore give valuable support to authorities in third countries and also within the EU to determine whether the general requirements in Annex 1 Part A of Regulation (EU) No 852/2004 for seed production are fulfilled or not.

Where a batch of seeds for sprouting is packaged and sold to retail with the intention to be sprouted by the final consumer, the batch must also be accompanied by a copy of the import certificate. The copies of the certificate shall be provided to business operators to which the seeds are dispatched until they are packed for sale at retail.

1.C.2. Traceability requirements related to incoming seeds

Sprout producers must obtain a document with the following information from their seed suppliers – regardless whether EU or non-EU supplier – for each batch of seeds (a consignment can consist of several batches):

- name of the product including the Latin name (taxonomic name);
- identification number or equivalent batch reference;
- name of the supplier;
- name and address of the recipient (if a forwarder or agent is used: name and address of the agent or forwarder);
- date of shipping;
- quantity supplied.

The seed suppliers should keep a copy of this document on record.

Seed suppliers and earlier stages in the supply chain are required to keep additional information on record as stipulated in Commission Implementing Regulation (EU) No 208/2013.

The seed suppliers and the sprout producers must keep a copy of this document on record for a sufficient time after the sprouts can be assumed to have been consumed.

If seeds have been procured from a supplier outside of the European Union, the batch of seeds must be accompanied by an import certificate and record of the certificate should be kept. Rules with regards to import certificate are listed in point 1.C.1.

Sprout producers should put in place a system to ensure traceability of the batches from the moment of arrival of the seeds until the moment of dispatch of the sprouts. Records should be kept for a sufficient time after the sprouts can be assumed to have been consumed. Traceability requirements of the final product – sprouts are listed in point 1.K.

1.C.3. Visual inspection

Bags/containers and seeds should be visually checked (e.g. for physical contamination with human or animal waste, unpatched holes in bags which obviously do not come from sampling probes, stains, foreign matter etc.) after arrival or prior to sprouting. Documents should be available attesting that the visual inspection has taken place.

1.D. Seeds storage

Seeds should be stored in new sound bags without holes (except patched holes or equivalent that come from sampling probes or other procedural elements), and not in used or second hand bags to avoid chemical or microbiological contamination. Bags should be kept dry. Where possible, bags should not be stored on the floor and not immediately against walls but on pallets and with clean cardboard sheets between the bags and the pallet. Producers should also consider whether it is necessary to cover the tops of storage piles with suitable material to protect the goods.

Storage areas and equipment should be cleaned and kept dry. Measures should be in place to prevent ingress and contamination from weather, animals and pests (see point 1.A.2).

Where sprout producers handle seeds intended for the production of sprouts as well as seeds not destined for sprout production, these should be kept clearly separated, and where appropriate, clearly labelled to avoid any mixing. Due care should be taken to ensure that stored batches correspond to the records and that these batches will be traced throughout the production process.

1.E. Hazard analysis and critical control points

The sprouting of seeds involves minimal processing of the original product and can therefore be considered primary production. The application of hazard analysis and critical control points (HACCP) principles to primary production is currently not legally required by European legislation (Regulation (EC) No 852/2004), but is considered essential by ESSA.

“Commission Notice on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses”⁴³ provides guidance on how to implement good hygiene practices and HACCP-based procedures.

1.F. Water use

During all steps of the production process, water that comes into contact with seeds or sprouts should be water meeting the microbiological requirements of potable water listed in Council Directive 98/83/EC, part A.

⁴³ [Commission Notice](#) on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses

If clean water (which meets microbiological requirements listed in Council Directive 98/83/EC, Part A) is used, then the chemical properties of the water from that source should be analysed based on the risk assessment, but at least once a year.

Water delivery systems should be appropriately maintained and cleaned (see point 1.A.3. and point 1.A.4.) to avoid contamination of the water from corrosion or external sources. Records of the maintenance should be kept.

A water recycling system may only be used during germination, growth and irrigation processes. If water is recycled, it is recommended to reuse the water within the same batch of seeds/sprouts and not spread over multiple batches in order to prevent the contamination of the whole ongoing production, instead of production in one batch.

Any water, including recycled water should be monitored and analysed regularly based upon a risk analysis (according to Council Directive 98/83/EC, part A).

Measures should be taken to prevent the access of insects, animals, soil, waste and other sources of contamination to the water source.

If water is treated with biocidal products in order to meet microbiological parameters set in Council Directive 98/83/EC, part A, then these treatments must meet requirements listed in European regulation on biocides (Delegated Regulation (EU) No 1062/2014) and provisions set by national authorities.

1.G. Sprouting process

1.G.1. Initial rinse of the seeds

Depending on the results of the visual inspection, seeds should be rinsed thoroughly before sprouting to remove dirt. Agitating seeds thoroughly in the washing container can improve the removal of dirt.

Potable water or clean water which meets microbiological requirements listed in Council Directive 98/83/EC, Part A, must be used for the rinsing of seeds. The water used for the washing of seeds should not be reused.

1.G.2. Microbiological decontamination of seeds

There is no harmonization within the European Union in terms of using microbiological decontamination treatments on seeds. However, only treatments authorised by national competent authorities are allowed for microbiological decontamination of seeds.

According to EFSA-report "Scientific Opinion on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds"⁴⁴ there is limited information on the efficacy of decontamination treatments of sprouts derived from seeds. Despite considerable efforts, to date, no chemical, physical or biological methods of disinfection have been able to ensure the seed to be pathogen free. Decontamination treatments should not kill seed or reduce the germination rate.

If microbiological decontamination is used, there should be measures in place to ensure that re-contamination cannot take place once the seeds have been decontaminated. Due care should be taken that containers and equipment used for decontamination have been disinfected. Following decontamination, seeds should be rinsed with potable water once again to eliminate chemical agents.

1.G.3. Pre-germination soak

Where sprout producers make use of pre-germination soaking, this should be done in potable water or clean water, which meets microbiological requirements listed in Council Directive 98/83/EC, Part A. Equipment and containers used for soaking should be thoroughly cleaned,

⁴⁴ Idem note 7

disinfected and rinsed before use and should be suitable for food production. The water used for soaking should not be directly reused.

1.G.4. Germination, growth and irrigation

The germination chamber should be kept in good hygienic conditions. The chamber itself and equipment used during the germination process should be cleaned and disinfected before sprouting a new batch of seeds.

It is strictly required to use potable water or clean water which meets microbiological requirements listed in Council Directive 98/83/EC, Part A, as initial source of irrigation water during the sprouting process to prevent contamination and potential outgrowth of pathogens during the sprouting process.

If recycled water is used, it should meet requirements listed in point 1.F. on water use.

1.G.5. Harvesting

Only equipment suitable for food production should be used for harvesting of sprouts. All equipment used should be cleaned and disinfected at least on a daily basis. Workers should take due care that they and their uniform or clothes are in good hygienic conditions before entering the germination chamber.

1.H. Processing, packaging, storage and transport

1.H.1. Final rinse, removal of hulls and cooling

Equipment used for rinsing of sprouts and removal of hulls should be cleaned and disinfected at least on a daily basis.

For the final rinse, removal of hulls and cooling only potable water or clean water that meets microbiological requirements listed in Council Directive 98/83/EC, Part A, should be used. After rinsing and removal of hulls, sprouts should be immediately refrigerated at the temperature between 2-8°C. In following, the cold chain should be upheld until the product reaches the final consumer. For the entire period of the cold chain (cold room, truck, etc.), the temperature of the cold chain should be monitored. Different national cold chain requirements may apply.

1.H.2. Microbiological decontamination of sprouts

There is no harmonization within the European Union in terms of using microbiological decontamination treatments on sprouts. However, only treatments authorised by competent authorities are allowed for microbiological decontamination of sprouts.

The same conditions as listed in point 1.G.2. on microbiological decontamination of seeds apply.

1.H.3. Materials and articles intended to come into contact with sprouts

During production process, various materials come into contact with sprouts. Any materials and articles intended to come into contact with food which is placed on the market should comply with the requirements of the Regulation (EC) No 1935/2004.

Due care should be taken that packaging material is clean and stored in a way that makes contamination with dust, dirt or foreign matter impossible.

Packing should take place indoors in closed and dry areas that prevent the ingress of dust, dirt or other sources of contamination.

Equipment used for packing should be regularly cleaned and disinfected (see point 1.A.3).

1.H.4. Storage of sprouts

Care should be taken that sprouts are stored in closed and protected environments that prevent the access of dust, dirt or other sources of contamination. Storage areas should be equipped in such a way that the cold chain for sprouts can be upheld (see point 1.H.1.).

1.H.5. Product information and consumer awareness

The customer or next person in the supply chain should be supplied with all the information relevant to them to handle, store, process, prepare and display the product safely and correctly. Where appropriate and useful, this information can be included into the packaging label.

Products should be correctly labelled to facilitate traceability and recall where necessary (see points 1.J. and 1.K.). Identification or batch numbers as well as name and address of the producer on the packaging label may facilitate traceability and recall.

All legal labelling requirements set in Regulation (EU) No 1169/2011 should be fulfilled and all mandatory information which is required in this regulation should be provided on the label.

Labelling, advertising, consumer information material and packaging should not mislead the consumer.

1.H.6. Transportation

Facilities, equipment, containers, crates, vehicles and vessels used to transport sprouts and seeds should be kept clean and where possible disinfected in order to prevent from microbiological contamination during transport.

Transport time is a part of the total shelf life of the sprouts and must therefore be seen as an integrated part of the cold chain (see point 1.H.1.).

1.I. Microbiological testing of seeds and sprouts

According to Commission Regulation (EC) No 2073/2005, amended by Commission Regulation (EU) No 209/2013, sprout producers must carry out a preliminary testing of a representative sample of each batch of seeds. This testing is obligatory for Shiga toxin producing *E.coli* (STEC) O157, O26, O111, O103, O145 and O104:H4 and *Salmonella* spp. with the objective of this test is to use only positive released batches of seeds (see point 1.I.1.).

Sprout producers should carry out testing of the sprouts for Shiga toxin producing *E.coli* (STEC) O157, O26, O111, O103, O145 and O104:H4 and *Salmonella* spp. at the stage where the probability of finding these pathogens is the highest, in any case not before 48 hours after the start of sprouting process at least once a month. There is no obligation to test each batch of the sprouted seeds as the objective is to verify the currently implemented good practices and food safety management system (see point 1.I.2.).

Commission Regulation (EC) 2073/2005 also obliges producers to test sprouts on food safety criteria when products are placed on the market during the shelf-life period. Tested sprouts should meet limits set in category 1.18 for *Salmonella* spp. and in category 1.29 for STEC. Moreover, ready-to-eat products like sprouts also are required to be tested for *Listeria monocytogenes*. These tests do not need to be done for every batch, but it should be done at regular intervals and it is also used as a verification of good practices. The frequency of testing for STEC, *Salmonella* spp. and *L. monocytogenes* should be fixed by the operator – if possible after consultation with the competent authority – and be risk based. To analyse sprouts for *L. monocytogenes*, criterion 1.3 of Annex I of Commission Regulation (EC) No 2073/2005 must be applied.

Sprout producers are also recommended to sample the processing areas and equipment for *Listeria* spp. as part of their sampling scheme.

1.I.1. Guidance for sampling of seeds

These samples should be treated according to Chapter 3.3 in Commission Regulation (EC) No 2073/2005 and analysed according to the requirements in rows 1.18 and 1.29 of Chapter 1 of the same regulation. For each batch of seeds to be sprouted a preliminary testing should be performed. For the purpose of performing the preliminary testing, the food business operator must sprout the seeds in the representative sample under the same conditions as the rest of the batch of seeds to be sprouted. A representative sample shall include at least 0.5% of the weight of the

batch of seeds in sub samples of 50g. The representative sample can also be selected based on a structured statistically equivalent sampling strategy, if this has been verified by the competent authority. In principle, each bag in the batch should be sampled and the number of sub samples per bag is decided according to the following calculation:

- the total weight of the sample = the total weight of the batch * 0.5% (= 0.005)
- the total number of sub samples = the total weight of the sample/50g
- the number of bags in the batch = the total weight of the batch/the weight of each bag
- the number of 50g sub samples per bag = the total number of sub samples/the number of bags in the batch

For example, to sample a batch of 100 tons, packed in 25kg bags:

- the total weight of the sample = 100,000kg * 0.5% = 500kg
- the total number of sub samples = 500kg/50g = 10,000 sub samples
- the number of bags in the batch = 100,000kg/25kg per bag = 4000 bags
- the number of 50 g sub samples per bag = 10,000 sub samples/4000 bags = 2.5 sub samples/bag

Due care should be taken that this is carried out in hygienic conditions and with equipment that is in good hygienic condition. Appropriate records of the sampling process should be kept to prove correct sampling vis-à-vis the competent authority.

The sampling should be carried out by food business operators producing sprouts and can be done manually or mechanically by sprouts grower or by an accredited third party. Some companies will use mechanical sampling devices that extract representative quantities of seeds e.g. while refilling bulk deliveries into smaller bags, subject to confirmation by the competent authorities. Other companies will pierce and reseal bags or equivalent to extract the representative quantity of seeds.

It is the responsibility of sprout producer to make sure that the sample is representative and the testing is done according to the rules set in Commission Regulation (EU) No 209/2013.

As long as the sampling requirements are fulfilled, it should be possible for sprout producers to ask seed suppliers to conduct sampling at origin at the moment of packing the bags, and to send the sample to the sprout producer along with the batch, in (a) separate and clearly labelled bag(s) (labelled "sample for microbiological testing" or equivalent).

In case sampling of seeds is done by third party, then mechanical sampling devices at origin should be preferably an integral part in the process of packing the bags. In case the sprout grower does not carry out the sampling of seeds himself, he should verify that sampling is carried out according to Commission Regulation (EU) No 209/2013

The sprouting process for the other seeds in the representative test sample may continue as usual. However, both the sprouts growing out of the remaining culture after sampling as well as the remaining dry seeds from which the sample was taken should not be used unless satisfactory results for all of the samples have been reported by the laboratory. This is the principle of positive batch release.

1.I.2. Sampling and testing frequency of the sprouts at least 48 hours after the start of the sprouting process

Five samples should be taken at the stage where the probability of finding Shiga toxin producing *E.coli* (STEC) O157, O26, O111, O103, O145 and O104:H4 and *Salmonella* spp. is the highest, in any case not before 48 hours after the start of the sprouting process, at least once a month to verify the good practices and food safety management. No systematic sampling of batches is required.

The five samples should be kept separate from each other and be sent to a laboratory accredited (ISO 17025) for the testing of STEC and *Salmonella* spp.

These samples should be treated according to Chapter 3.3 in Commission Regulation (EC) No 2073/2005 and analysed according to the requirements in rows 1.18 and 1.29 of Chapter 1 of the same regulation.

Or, if the sprout producer has a sampling plan, including sampling procedures and sampling points of the spent sprout irrigation water, the competent authority may authorise them to replace the sampling requirement of the sprout with minimal age of 48 hours under the sampling plans set out in rows 1.18 and 1.29 of Chapter 1 in Commission Regulation (EC) No 2073/2005 with the analysis of 5 samples of 200ml of the water that was used for the irrigation of the sprouts. This method provides more representative sample of the seeds to be tested. This is the reason that ESSA strongly recommends to analyse the spent irrigation water that has been in contact with 100% of the sprouts of the test batch. The testing method when five samples of 25 grams of sprouts from the batch are analysed is much less reliable and accurate.

1.I.3. Sampling of end product

In addition, sprouts, being the packed end product, should also be sampled (with n=5) and analysed for STEC and *Salmonella* spp. according to row 1.18 and 1.29 of Commission Regulation (EC) No 2073/2005 (see point 1.I.2.). The analysis should be carried out after the packing of product. The sampling frequency should be defined on a basis of risk.

A challenge test should point out how to analyse *L. monocytogenes*, i.e. according to row 1.2 or 1.3 in Chapter 1 of Annex 1 Commission Regulation (EC) No 2073/2005 (see also 1.I.). Analysis should be carried out according to the result of this evaluation.

1.I.4. Test results

None of the five samples (representative samples or samples of end product) may show positive findings for STEC or *Salmonella* spp. If the absence of microbiological contamination has been proven by the laboratory, sprouts produced from the analysed batch may be placed on the market.

Actions in case of contamination of seeds or food/sprouts are listed in point 1.J.1.

In case of sprouts are contaminated with *L. monocytogenes*, these sprouts may be submitted for further processing, however a treatment eliminating the hazard should be applied. This can also be applied for STEC or *Salmonella* spp. as long as the treatment eliminates the risk and is approved by the competent authority. This treatment may only be carried out by food business operators other than those at retail level (Commission Regulation (EC) 2073/2005).

1.I.5. Derogation from the preliminary testing of all batches of seeds set out in 1.I.1.

Under Chapter 3, section 3.3.B. of Annex I of Commission Regulation (EC) No 2073/2005 (as amended by Commission Regulation (EU) No 209/2013) competent authorities can exempt sprout producers from the obligation to test every single batch of seeds, if the sprouting facility implements a food safety management system with steps that reduce the microbiological risk. However, this exemption can only be granted under certain conditions determined by the competent authority and if historical data is available to confirm that all batches of the six consecutive months before authorisation did not result in any findings of STEC and *Salmonella* spp. In this case, sprout producers must keep all their testing results on record for more than six months.

The European Sprouted Seeds Association (ESSA) cautions sprout producers to carefully weigh the balance between the high cost of analysis and the potentially disastrous consequences of a food safety problem which may result from only one single contaminated batch of seeds. Where seeds are sourced from new origins, it is therefore highly recommended to conduct testing even if a derogation has been granted to the sprout producer and even if the seeds are delivered by the same trader or supplier. Where sprout producers have reason to doubt the integrity of the product, it is also highly recommended to conduct an analysis as a precautionary measure. As a conclusion,

ESSA is not an advocate of this derogation because of the fact that different years of harvest of seeds most probably will result in different contamination risks of the seeds.

The exemption in Chapter 3 Section 3.3.B. of Annex I of Commission Regulation (EC) No 2073/2005 does not relieve sprout producers from the duty to sample the sprouts or the sprout irrigation water at the stage of the final product at least once every month. It is however provided in footnote 23 in Annex I of Commission Regulation (EC) No 2073/2005 that sprouts which have received a treatment effective to eliminate *Salmonella* spp. and STEC (if approved by the competent authority) do not need to undergo the monthly testing obligation.

1.I.6. Alternative testing by seed supplier

It is within the discretion of the sprout producer to ask their seed supplier for preliminary testing of the batch. However, this does not exempt the sprout producer from the testing obligations detailed in this chapter.

1.J. Action in case of contamination

1.J.1. Detection of contamination before food has left the control of the sprout producer

The contaminated batch of sprouts or seeds should immediately be isolated from all others. The entire batch should be considered unsafe to eat/sprouting. If there is a danger that other batches may be contaminated, the production process should be interrupted until a point where the contamination has been eliminated and the production line is in a clean and hygienic state.

Sprouts or seeds from the contaminated batch or batches should not be placed on the market for human consumption in their current state. However, contaminated sprouts may be submitted to further processing by a treatment eliminating the hazard in question. This treatment may only be carried out by food business operators other than those at retail level.

As an example, if mung beans are contaminated, it is possible to manufacture to split mung beans, which will not germinate and will not produce any sprout. With the appropriate precautions, that product could be sold for "cooking" (including for human consumption).

More generally, the sprout producer may also use the batch for purposes other than those for which it was originally intended, provided that this use does not pose a risk for public or animal health and provided that this use has been decided within the procedures based on HACCP principles and good hygiene practice and authorised by the competent authority.

It is recommended that sprout producers lay down written procedures to follow in cases where contamination occurs. These rules should be easily accessible for all employees and covered in training programmes for staff members.

The seed supplier should be contacted so that he/she can follow up possible shipments of the same seed batch seeds to other sprout producers. In this case, recall of the seeds may be necessary.

Sprout producers should take measures and increase monitoring to find the cause of the contamination (the water, the environment, the staff, etc.). Sprout producers should keep the testing results on record for sufficient time after the sprouts can be assumed to have been consumed. It is recommended to keep all testing results on record for sufficient time so that they can be shown to competent authorities during official controls.

1.J.2. Detection of contamination after food left the control of the sprout producer - withdrawal and recall

Articles 18 and 19 of Regulation (EU) No 178/2002 require all food business operators to have traceability and recall systems in place. Due care should be taken to ensure that recording and traceability obligations are upheld throughout the entire production process and records are kept for a sufficient time after the sprouts can be assumed to have been consumed. Traceability codes or numbers printed on the packaging material may facilitate recalls in the event that food contamination occurs.

If one or several batches are known or assumed to be contaminated and these batches are no longer under the control of the sprout producer, the sprout producer must immediately take the initiative to contact the buyers to whom the products have been supplied. Batches known or assumed to be contaminated must be immediately withdrawn from the supply chain. The sprout producer must also notify the competent authority.

Where sprouts have already been distributed to consumers, sprout producers must inform these consumers that unsafe food may have been distributed to them. Sprout producers must inform consumers of the reason for the recall and where necessary, physically recall the food from the final consumers. However, depending on the case at hand, it is not always necessary that products are physically recalled from final consumers if other measures are sufficient to protect public health.

When managing a food recall situation, sprout producers must collaborate with the competent authorities on actions taken to avoid or reduce risks posed by the supply of the sprouts.

It is recommended that sprout producers lay down written recall procedures to follow in cases where contamination occurs. These rules should be easily accessible for all employees and covered in training programmes for staff members. Where no written recall rules exist, one staff member with knowledge of recall procedures must be available at all times.

The seed supplier should be contacted so that he/she can follow up possible shipments of the same seed batch seeds to other sprout producers. In this case, recall of the seeds may be necessary. Also, sprout producers should take measures and increase monitoring to find the cause of the contamination (the water, the environment, the staff, etc.). Sprout producers should keep the testing results on record for sufficient time after the sprouts can be assumed to have been consumed. It is recommended to keep all testing results on record for sufficient time so that they can be shown to competent authorities during official controls.

1.K. Traceability and record keeping

Commission Implementing Regulation (EU) No 208/2013 establishes specific traceability requirements for seeds for sprouting and sprouts. If sprouts are exempted from the requirements listed under this regulation, then still the Regulation (EC) No 178/2002 applies (more in detail in point 1.K.3.).

The traceability rules are designed to increase food safety because they allow tracing of food products through all stages of production, processing and distribution and make it possible to react rapidly in case of outbreaks of food-borne disease.

1.K.1. Process traceability in the sprouting establishment

Sprout producers should put in place a system to ensure traceability of the batches from the moment of arrival of the seeds until the moment of dispatch of the sprouts. It should be possible at any moment during the physical flow of the production process to know which batch of sprouts originates from which immediate supplier. This can be achieved by assigning codes or numbers to the batches of seeds received, or by defining smaller batches to which codes or numbers are assigned. These codes should then be maintained until the sprouts have been packaged and dispatched. If batches are re-organised or consolidated, due care should be taken to ensure that the link between the original batch of seeds and the re-organised or consolidated batches is upheld. Appropriate records should be kept for a sufficient time after the sprouts can be assumed to have been consumed.

1.K.2. Traceability requirements of final product - sprouts

Point 1.C.2. lists traceability requirements regarding controls of incoming seeds.

The food business operator producing the seed for sprouting has to transmit information to the food business operator producing the sprouts. The food business operator sprouting the seeds needs to keep records of origin of seeds and transmit this information to the next food business operator. Records should be kept at all stages.

The final product, sprouts, must comply with the legal traceability requirements set in the Regulation (EC) No 178/2002.

The sprout producer has to ensure that all information required in Commission Implementing Regulation (EU) No 208/2013, article 3(1) is transmitted to the food business operator to whom the sprouts are supplied. The following elements should be indicated:

- name of the product including the Latin name (taxonomic name);
- identification number or equivalent batch reference;
- name of the supplier;
- name and address of the recipient;
- if a forwarder or agent is used: name and address of the agent or forwarder;
- date of shipping;
- quantity supplied.

Sprout producers should keep a copy of this document on record for a sufficient time after the sprouts can be assumed to have been consumed. A copy of the document should be provided to the buyer.

National legislation in some member states may impose additional traceability requirements that are not mentioned in this guideline. In case of uncertainty, it is recommended that sprout producers contact their competent authority to obtain more information about the national requirements.

All records mentioned in this chapter must be updated every day to take account of the latest incoming and outgoing shipments. Records can be kept in any appropriate form as long as they are easily retrievable and understandable for competent authorities in cases it is required. Where authorities require information, this must be provided without delay.

Alternative systems may also be feasible to ensure appropriate traceability. Some private electronic traceability schemes have been developed in the recent past, including Trace, IRIS, EPCIS, Fosstrak (Open Source) and some systems based on SAP (system application and product for data processing).

1.K.3. Exemption from the requirements in this chapter

As stated in Article 1 of Commission Implementing Regulation (EC) No 208/2013, sprouts that have undergone a treatment which eliminates microbiological hazards, compatible with European legislation, do not need to comply with this regulation (more about microbiological decontamination of seeds in point 1.G.2.). However, sprout producers are still under obligation by the General Food Law (Regulation (EC) No 178/2002, Article 18(3)) to have systems and procedures in place to identify businesses to which their products have been supplied – even for those products that have undergone a microbiological treatment.

1.L. Summary: Recording obligation

Throughout the production process, producers are asked to record and have available the following information (in any appropriate form as long as it is easily retrievable and understandable for competent authorities):

1. Establishment and maintenance of the sprouting facility:
 - a. Confirmation of approval of the facility by the competent authority;
 - b. Written cleaning and disinfection plan;
 - c. Dates of cleaning and cleaned areas;
 - d. Dates of maintenance and maintained objects/areas;
 - e. Dates, topics and participating employees in hygiene training;
 - f. Dates, topics and participating employees in cleaning training;
 - g. Where feasible, staff hygiene rules in written form or in form of signs or labels, to be attached to the walls;
 - h. Names of visitors and dates of visit (recommended – only to be kept for a certain amount of time);

- i. Where water sources other than municipal water system are used: risk based microbiological testing of the water source for microbiological requirements according of Council Directive 98/83/EC, part A;
 - j. Where municipal water system is used: statement from the municipal water supplier and at least once a year own analysis at the point from where the water is taken.
2. Incoming seeds (to be kept for sufficient time until the final product can be assumed to have been consumed):
 - a. If seeds are imported from non-EU country, import certificate as required by Commission Regulation (EU) No 211/2013 for each batch of imported seeds ;
 - b. Document indicating name of seeds, identification number or equivalent batch reference, name of supplier, name and address of recipient, name and address of forwarding agent if such agent is used, date of shipping, quantity supplied ;
 - c. Document to prove that visual inspections of incoming seeds have taken place (recommended).
3. Microbiological testing (to be kept for sufficient time until the final product can be assumed to have been consumed):
 - a. Certificates confirming microbiological testing for STEC and *Salmonella* spp. (to be kept on record for more than six months if producer wants to ask competent authority for exemption from the obligation to conduct preliminary testing of all batches of seeds for STEC and *Salmonella* spp.).
4. Process traceability (to be kept for sufficient time until the final product can be assumed to have been consumed):
 - a. Appropriate documents in written or electronic form to identify batches of seeds throughout the production process (highly recommended).
5. Outgoing sprouts (to be kept for sufficient time until the final product can be assumed to have been consumed):
 - a. Document indicating name of sprouts, identification number or equivalent batch reference, name of supplier, name and address of recipient, name and address of forwarding agent if such an agent is used, date of shipping, quantity supplied(one copy to be given to buyer).
6. Withdrawal and recall:
 - a. Written procedures for staff members which must be followed in the case of food contamination both inside the establishment and with regard to external distributors and consumers (highly recommended).

2. PRODUCTION OF SEEDS

Context

The pursuit of a high level of protection of human life and health is one of the fundamental objectives of Regulation (EC) No 853/2004. That Regulation constitutes a common basis for the hygienic production of all food.

2.A. General

All equipment should be cleaned regularly to prevent potential contamination from dust, insects and animals (with particular regard to faeces). Where possible, a diary should be maintained of the maintenance of all equipment.

Different methods:

Seeding:

Mechanical or hand drilling

Broadcast of seeds by hand

Harvesting:

Combined harvest

By hand pulling ripe pods from plants

Undercut of plants

2.B. Soil/land treatments

Grazing or potential ingress by wild and domestic animals should be avoided, and preventive measures such as fences or nets should be put in place by producers.

Fertilizers should only be applied in sufficient amounts to meet the needs of growth of plants for seeds. Organic fertilizers are widely and beneficially applied to meet seeds' nutrient requirements and improve soil fertility, but their incorrect use can be a source of both microbiological and chemical contamination. Pathogens may be present in manure and other natural fertilizers and may persist for weeks or even months, particularly if treatment of these materials is inadequate.

Physical, chemical or biological treatment methods (e.g. composting, pasteurization, heat drying, UV irradiation, alkali digestion, sun drying or combinations of these) may be used to reduce the risk of potential human pathogen survival in manure, sewage sludge and other organic fertilizers.

Organic fertilisers should not therefore contain microbial, physical or chemical contaminants at levels that may adversely affect the safety of fresh fruit and vegetables and their use must comply with the relevant EU regulations and take account of WHO guidelines⁴⁵ on the safe use of wastewater and excreta in agriculture, as appropriate.

Producers should use plant protection products in compliance with the label instructions of the individual products. Only authorised plant protection products should be used.

A diary should be maintained of the treatments used. Products and advice how to treat soil/land should be sourced from qualified professionals.

2.C. Worker hygiene

All workers should be aware of the basic principles of hygiene and health, and should be informed about all the dangers that could contaminate the seeds.

Staff should maintain good personal hygiene conditions at all stages of harvest and processing. Staff members known or suspected to have a disease or illness that can be transmitted to the seeds should not be allowed into areas where they may come into direct or indirect contact with seeds or sprouts. Staff members should immediately inform the management if they believe that they

⁴⁵ [WHO Guidelines](#) for the safe use of waste water, excreta and greywater

might have a relevant illness or have recovered from a relevant infectious disease but continuing to shed the microorganisms.

Staff injuries that could present a danger of contamination should be adequately treated with waterproof detectable covers before the worker can come into contact with seeds. Where possible, wounded workers should avoid direct contact with seeds or sprouts for human consumption.

Workers should have and use adequate sanitary facilities (incl. hand-washing facilities) available where feasible and necessary, e.g. when seeds are not in pods and workers are in direct contact with them. Where viable, workers should have clean uniforms. They must wash hands when starting, when needed during the day and at least each time the toilet was visited.

2.D. Irrigation

Several parameters may influence the risk of microbiological contamination of seeds: source of water, type of irrigation, the method of application of a water treatment by the grower, the timing of irrigation in relation to harvesting, possible access of animals to the source of water or production area.

Where the risk exists that irrigation water will get in a contact with pods, special care should be taken to make sure that the quality of water is at least of clean water.

All animal access to water sources and pumping areas should be controlled.

2.E. Seeds

Producers must use seed for sowing from a recognized source, with a proven track record. Due regard should be made for seeds with good germination, which are free of disease, physical damages or other affects that are potentially adverse to a successful harvest of healthy beans. Where feasible and affordable producers should conduct analyses and pre-treatments to ensure seeds are of suitable quality.

2.F. Drying of plants/pods

There are different practices applied among producing countries. In some countries, it is necessary to dry the pods before threshing. In this case a clean tarpaulin should be used between the drying pods and the earth. Due care should be taken to prevent potential contamination whilst the pods are vulnerable and such drying should be made in a designated area that prevents the access of wild animals and birds. In other countries plants are harvested and threshed mechanically, and so there are different methods used.

2.G. Threshing

It should be made mechanically on suitably maintained and cleaned equipment. Machines should be cleaned promptly after the end of the season, and also prior to the beginning of the next season, and where viable between each batch. Equipment should be stored in a covered area to protect the integrity of the equipment. During or immediately after threshing the seeds should be packed.

2.H. Storage after harvesting

Goods should be stored where viable – practically and economically – in new sound bags, and not in used or second hand bags. Also producers should consider whether it is necessary to cover the tops of storage piles with plastic sheets to protect the goods.

Storage areas and equipment should be cleaned and well maintained to prevent ingress and contamination from weather, animals and pests.

If stored in bulk, then clean tarpaulins should be used both under and on top of the goods and between goods and the wall, if applicable.

2.I. Processing

Goods should be processed at professional seed processing facilities with suitable equipment, which should include:

- size grading, Gravity/Densimetric tables, destoners, magnets or metal detectors, and preferably colour sorters;
- all equipment should be regularly cleaned to prevent cross contamination of other products, and due attention should be paid to hygiene;
- staff should have adequate toilet & hand washing facilities (incl. soap) available, and where viable clean uniforms;
- local area should be maintained to prevent dust & dirt, insects, animals and birds;
- where viable, processors should have plans and keep records of contamination preventions. Mixing of batches should be as limited as is possible, and where viable restricted to similar growing regions;
- processors should have records available of where incoming seeds originated from.
- a quality regime implemented by trained staff to HACCP standard is recommended. Finished goods should be analysed according to buyers' requirements prior to shipment.

Annex I – general legislation and specific legislation on sprouts

General legislation

These documents are available in all European Union languages:

- [Regulation \(EC\) No 178/2002](#) of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (General Food Law).
- [Regulation \(EC\) No 852/2004](#) of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
- [Regulation \(EC\) No 882/2004](#) of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
- [Council Directive 98/83/EC](#) of 3 November 1998 on the quality of water intended for human consumption.
- [Commission Regulation \(EC\) No 2073/2005](#) of 15 November 2005 on microbiological criteria for foodstuffs.
- [Regulation \(EU\) No 1169/2011](#) of the European Parliament and of the Council of 25 October 2011 on the provision of information to consumers.
- [Delegated Regulation \(EU\) No 1062/2014](#) on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.
- [Regulation \(EC\) No 1935/2004](#) on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

Specific legislation on sprouts

These documents are available in all European Union languages:

- [Commission Implementing Regulation \(EU\) No 208/2013](#) of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts.
- [Commission Regulation \(EU\) No 209/2013](#) of 11 March 2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts and the sampling rules for poultry carcasses and fresh poultry meat.
- [Commission Regulation \(EU\) No 210/2013](#) of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council.
- [Commission Regulation \(EU\) No 211/2013](#) of 11 March 2013 on certification requirements for imports into the Union of sprouts and seeds intended for the production of sprouts, amended by [Commission Regulation \(EU\) No 704/2014](#) on certification requirements for import into the Union of sprouts and seeds intended for the production of sprouts.

Annex II – references to other relevant sources of information

- [European Commission Guidance document](#) on the implementation of procedures based on the HACCP principles, and on the facilitation of the implementation of the HACCP principles in certain food businesses.
- [Commission Notice](#) on the implementation of food safety management systems covering prerequisite programs (PRPs) and procedures based on the HACCP principles, including the facilitation/flexibility of the implementation in certain food businesses (2016/C 278/01).
- [Codex general principles of food hygiene](#). This document includes a section on the application of the HACCP principles.
- [Code of Hygienic Practice for Fresh Fruits and Vegetables](#). Annex II for sprout production.
- [International Standards Organisation \(ISO\). ISO 22000](#) - Food safety management. International guidance with requirements for a food safety management system.
- [International Featured Standards \(IFS\)](#)
- [European Commission Guidance Document](#) (Commission staff working document) on *Listeria monocytogenes* shelf-life studies for ready- to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. This is an informational document directed at food business operators in the EU.
- [EFSA Scientific Opinion](#) on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds.
- [WHO Guidelines](#) for drinking water quality.
- [WHO Guidelines](#) for the safe use of wastewater, excreta and greywater.