

Sprouts and seeds intended for sprouting: Q&A guidance on the package of EU regulations for food business operators and local authorities

Questions and answers about the requirements for sprouts and seeds intended for sprouting. This guidance, which is for relevant food business operators and local authorities, will be updated when new information or new issues are raised.

The guidance is grouped by the four areas of legislation that were introduced in 2013, following the outbreak of *E.coli* O104:H4 in Germany and France in 2011:

- microbiological criteria
- imports
- approval of establishments
- traceability

Imported fenugreek seeds used for sprouting were identified as the most likely source of contamination that caused the outbreak.

Part one: Microbiological Criteria and Sampling Rules for Sprouts

What are the sampling and testing requirements that have been introduced for sprouts and seeds used for the production of sprouts?

Regulation (EU) 209/2013 amending Regulation (EC) No 2073/2005 as regards microbiological criteria for sprouts has introduced microbiological sampling and testing requirements for establishments producing sprouts. These include a new criterion for Shiga-toxin producing *E. coli* (STEC) stated at point 1 (c) of the Annex. The Annex sets down 'sampling rules for sprouts' at point 2 (b) including requirements for testing batches of seeds used for the first time, see the Decision Trees at Annexes A and B of this Q&A document for further information.

How frequently must testing be carried out?

Samples of sprouts or spent irrigation water must be taken at least once a month and analysed to show absence of spp. and STECs O157, O26, O111, O103, O145 and O104:H4 in 25g. Food Business Operators (FBOs) will also need to carry out preliminary tests on a representative sample of each batch of seeds used. Local Authorities may exempt FBOs from the requirements for preliminary testing of each batch of seeds, when an FBO has implemented a suitable food safety management plan in the establishment and can demonstrate at least 6 months compliant historical testing data (the 6 months must be that period of 6 months immediately prior to the exemption). When a derogation has been authorised FBOs must carry out at least 1 test for *Salmonella* spp. and STEC per month on sprouts or spent irrigation water sampled during routine production.

When must preliminary testing be carried out on batches of seeds?

Unless exempted from the requirement to carry out preliminary testing, an FBO must carry out preliminary testing on a representative sample of each new batch of seeds when used for the first time. When exempted from this requirement an FBO is no longer required to carry out preliminary testing of seeds unless batches of seeds from a new supplier or supply chain with no established history of compliance are obtained. As far as possible FBOs should make arrangements with their seed supplier to ensure they are notified of any changes to an established seed supply chain and review their food safety management controls to determine whether changes are required.

What is meant by a representative sample?

Regulation 2073/2005 requires a representative sample of seeds to either be at least 0.5% of the batch weight taken in 50g sub samples across the whole batch or, as an alternative, it provides flexibility for an FBO to use a structured statistically equivalent sampling strategy providing it has been verified by the local authority.

Can an FBO continue to use an established seed sampling plan?

Yes, providing an FBO can demonstrate their established sampling plan is appropriately structured and statistically equivalent to testing 0.5% of the weight of the batch of seeds in 50g sub-samples to the satisfaction of the local authority.

How much of the batch should be tested?

FBOs must conduct preliminary tests as stated in the Annex to Regulation 2073/2005 unless exempted from the requirement to carry out preliminary testing of seeds. This requires that FBOs conduct preliminary tests using a representative sample of at least 0.5% of the weight of the batch of seeds in sub samples of 50g. Alternatively a representative sample may be selected based on a structured statistically equivalent sampling strategy which has been verified by the competent authority. Following preliminary testing, or when a derogation exempting the FBO from this requirement has been authorised by the local authority, samples of sprouts or spent irrigation water may be taken from routine production at least once per month.

When should an FBO test for *Salmonella* and STEC?

The regulations require that each batch of seeds used should be germinated and the resulting sprouts tested for STEC and *Salmonella* spp. prior to, or as part of, the first production run according to the requirements for preliminary testing prescribed in Regulation 2073/2005, unless exempted from those particular requirements. The minimum frequency for testing is one test per month. When granted a derogation from the requirements of preliminary testing of all batches of seeds FBOs can carry

out sampling during routine production. See the Decision Trees in Annexes A-C of this Q&A document.

Is it appropriate to sanitise seeds prior to carrying out the preliminary testing?

Yes, if the process includes a sanitising step, then this can be used for preliminary testing. The legislation requires that FBOs sprout a representative sample of seeds under the same conditions as the rest of the batch is to be sprouted, according to the routine sprouting process. When testing a batch of seeds for the first time, FBOs may only place sprouts on the market if the results of the microbiological analysis of those sprouts comply with sections 1.18 and 1.29 of Chapter 1 of [Regulation \(EC\) No 2073/2005](#).

Are FBOs required to have their microbiological testing carried out by accredited laboratories?

FBOs are not obliged to use accredited labs for testing. However, FBOs must be able to provide evidence that the laboratory is competent and results of sampling and testing are robust and laboratory accreditation would contribute to that evidence. Testing data must be robust if FBOs are to properly validate and verify their food safety management procedures. Any laboratories used should be able to demonstrate competence satisfactorily and accreditation would therefore be an advantage.

Can laboratories carrying out testing for FBOs use alternative analytical methods?

Regulation (EC) 2073/2005, Article 5 (5) paragraph 3 allows laboratories to use alternative methods to the reference method (see Annex B) as long as they have been validated against the reference method and, if a kit, certified appropriately. Under Article 5 (5) paragraph 4 FBOs can also use other methods that have not been validated or certified in this way if the Competent Authority, has approved their use.

Are there any commercial labs in the UK capable of carrying out STEC testing?

As far we are aware, there are several commercial labs currently offering STEC testing. We understand some may be working towards accreditation for the reference method, i.e. CEN/ISO TS 13136 taking into account the most recent adaptation by the European Reference Laboratory for *E. coli* (VTEC) for the detection of STEC O104:H4.

What are the requirements for laboratories carrying out official controls?

Regulation 882/2004 on official controls for food and feed requires that official laboratories are accredited for the methods used when testing for official control purposes.

Sampling and analysis methods used in official controls must comply with EU rules or, in the absence of such rules, internationally recognised rules such as CEN/ISO. In the case of sprouts and seeds intended for the production of sprouts, the relevant international standards are CEN/ISO TS 13136 (STEC), CEN/ISO 6579 (*Salmonella* spp.) and EN/ISO 11290-1 or EN/ISO 11290-2 (*Listeria monocytogenes*- see Annex A) respectively.

Will washing seeds and sprouts remove microbiological contamination?

Thorough washing will remove much of the bacteria that may be present on the surface of the seed or sprout, although it will not remove everything, particularly where bacteria are protected in cracks or crevices in the seed coat or internalised within the seed itself. Producers have a responsibility to ensure that sprouts are safe to eat and monitoring of the sprouts and irrigation water for evidence of any contamination with pathogens is important.

Can I guarantee food safety by microbiological testing?

No. Food safety is achieved through a preventative approach, based on risk assessment and consistent implementation of good agricultural practices and good hygiene practices and good manufacturing practice to minimise opportunities for microbial contamination at each stage of the food chain. The frequency and levels of *Salmonella* and STEC contamination of seeds are likely to be very low and sporadic in occurrence and such contamination is difficult to detect through sampling a large batch of seeds. Negative test results provide no guarantee that the whole of the batch is free from these pathogens due to the limitations associated with sampling.

Although microbiological testing is not a control by itself, it has an important role in verifying the effectiveness of control measures applied during production, handling, distribution and supply of seeds and sprouts.

Part Two: Import certification

Have competent authorities in third countries been informed of the EU requirement for the provision of signed export certificates for sprouts and seeds intended for sprouting, as required under Regulation 211/2013?

The Commission has confirmed that the relevant authorities in exporting countries have been informed about the requirements. Initially, there were issues with the capability for some third countries to provide the health attestation that the seeds were produced in accordance with the hygiene requirement set out in Regulation (EC) No 852/2004. This resulted in a time-bound derogation which allows the seeds to undergo testing prior to export. This derogation ended on 1 July 2015, and the Commission are content that third countries can now provide the attestation so it is not intended that the derogation be extended.

An example of a model certificate for the import of sprouts or seeds intended for the production of sprouts is available in the Annex to [Regulation \(EU\) No 211/2013](#)

What position should UK enforcement authorities take in respect of Regulation 211/2013 if a consignment is not accompanied by a required certificate?

The certificate is a legal requirement. There is no requirement in Regulation (EU) No 211/2013 for checks to be carried out at the border. This does not prevent Port Health Officers initiating routine checks on consignments of seeds if they have concerns about particular consignments or as part of their routine inspection programme. Checks at ports of entry can be implemented under the Official Feed and Food Control (OFFC) Regulations 2009. Regulation 29 (checks on products) places an obligation on the FBOs to, where required permit documentary checks as provided for in Article 16 (types of checks on feed and food of non-animal origin) of Regulation (EC) No 882/2004. Where documentary checks are carried out, the document should be stamped and signed by the Port Health Officer.

If the documentary checks find that all the necessary information or certification is not present then the Port Health Officer should place the consignment under official detention and require the importer to provide the missing information. Where this is not provided the basic provisions of the legislation are not being met and it may be appropriate to reject the consignment.

Environmental Health Officers will need to ensure that any consignments at establishments have been imported with the correct documentation. Article 41 (1)(1A) of the sets out the provisions that any person importing or places on the market sprouts or seeds which do not comply with the certification requirements are committing an offence.

If I blend seeds from different countries which are dispatched to a number of different retailers over a period of time, do I have to attach a copy of each import certificate to every batch? Could I send a single copy to the retail technical manager along with the relevant start and end dates of the production lots?

Regulation (EU) No 211/2013, Articles 2 (definitions) and 3 (certification requirements) states that the original certificate should accompany the consignment until it reaches its destination as indicated on the certificate (and if that consignment is split a copy of the certificate should accompany each part of the consignment).

Once the producer has packaged the seeds or sprouts for sale at retail, then the requirement for the import certificate to accompany the product no longer applies. The FBO who imports and germinates the seeds would need to retain the relevant import certificates and have systems in place to be able to demonstrate traceability.

Part Three: Approval

What are the approval requirements for businesses producing sprouted seeds?

The majority of the requirements for approval relate to the actual premises and Regulation (EU) No 210/2013 sets out provisions which would permit good hygiene practices. These include provisions on:-

- The design and layout;
- Cleaning of equipment and surfaces;
- Supply of hot and cold water including a supply of potable water;
- Procedures to ensure establishments, equipment is clean and kept in good repair.

Are there any exemptions for producers from approval such as restaurants growing small quantities of sprouted seeds on their premises for direct sale to the final consumer as an ingredient in a prepared meal?

Yes, the European Commission interpretation is that restaurants growing a small quantity of sprouts from seeds for use as an ingredient or as a garnish for dishes served to customers are exempt from Regulation (EC) No 853/2004 (Article 1, (2) (c)) and Regulation (EU) No 210/2013 as they are supplying small quantities of primary products to the final consumers.

Do businesses producing, packaging and selling dry seeds have to be approved under 210/2013?

No, the approval requirement is solely for businesses producing sprouts. However, such businesses would be required to meet the traceability requirements set out in 208/2013 and the certification requirements provided for in 211/2013 if they are importing seeds for sprouting from a third country.

Is the approval a 'one off process'?

Yes, the actual approval of a business by the local authority (either by the environmental health officer or the trading standards officer depending on the local decision on the most appropriate official to carry out the approval) will only need to be undertaken once, unless there is a later change to the business. There will be a requirement for inspections to ensure that the business remains compliant with the requirements of approval. The frequency of such inspections will be established on the same risk basis as that applied to other food businesses.

Is approval of the business dependent on the business complying with all of the measures contained in the sprouted seeds package (e.g. traceability, import certification and microbiological criteria)?

No, the actual approval of a business should be straightforward as the majority of the requirements needed in order to be approved are very similar to the existing requirements for a registered food business under Regulation 852/2004. However, the enforcement officer should check that there is compliance with the requirements contained in the rest of the package (Regulations EU Nos 208/2013, 209/2013, 210/2013 and 211/2013) if they are applicable.

Part Four: Traceability

What is the difference between the traceability requirements contained in 208/2013 and the existing requirements contained in Regulation (EC) 178/2002?

Article 18 of Regulation (EC) No 178/2002 makes the general provisions for traceability on a one step backwards and a one step forward basis which means that a FBOs must be able to identify where foodstuffs were sourced from and who they have sold on to (up to the point of supplying the final consumer). There are additional requirements contained in Regulation (EU) No 208/2013 for FBOs at all stages of production, processing and distribution of seeds intended for the production of sprouts or for batches of sprouts. These are similar to those which are in place for products of animal origin. These require that to enhance the one step back and one step forward provisions in Regulation (EC) No 178/2002, FBOs must keep and pass on to the next FBOs the following information:

- An accurate description of the seeds or sprouts, this should also include the taxonomic (the scientific) name of the plant;
- The volume or quantity of the seeds or sprouts which are being supplied;
- In cases where the seeds or sprouts have been sent from another FBOs, the name and address of the FBOs from whom the seeds or sprouts have been dispatched, and the consigner (owner) if this is different from the FBOs from whom the seeds or sprouts have been dispatched;
- The name and address of the FBOs who has been sent the seeds;
- The name and address of the consignee (owner) if this is not the person to whom the seeds have been sent;
- A batch number or a reference which can identify the batch;
- The date of dispatch.

Does the traceability information have to accompany the any seeds or sprouts which are sold onto another business?

There is no requirement that the traceability information has to physically accompany seeds or sprouts which are sold to another business, but the information should be transmitted in any format to them on that day. So it could be in paper or electronic format as long as the information can be matched to the consignment.

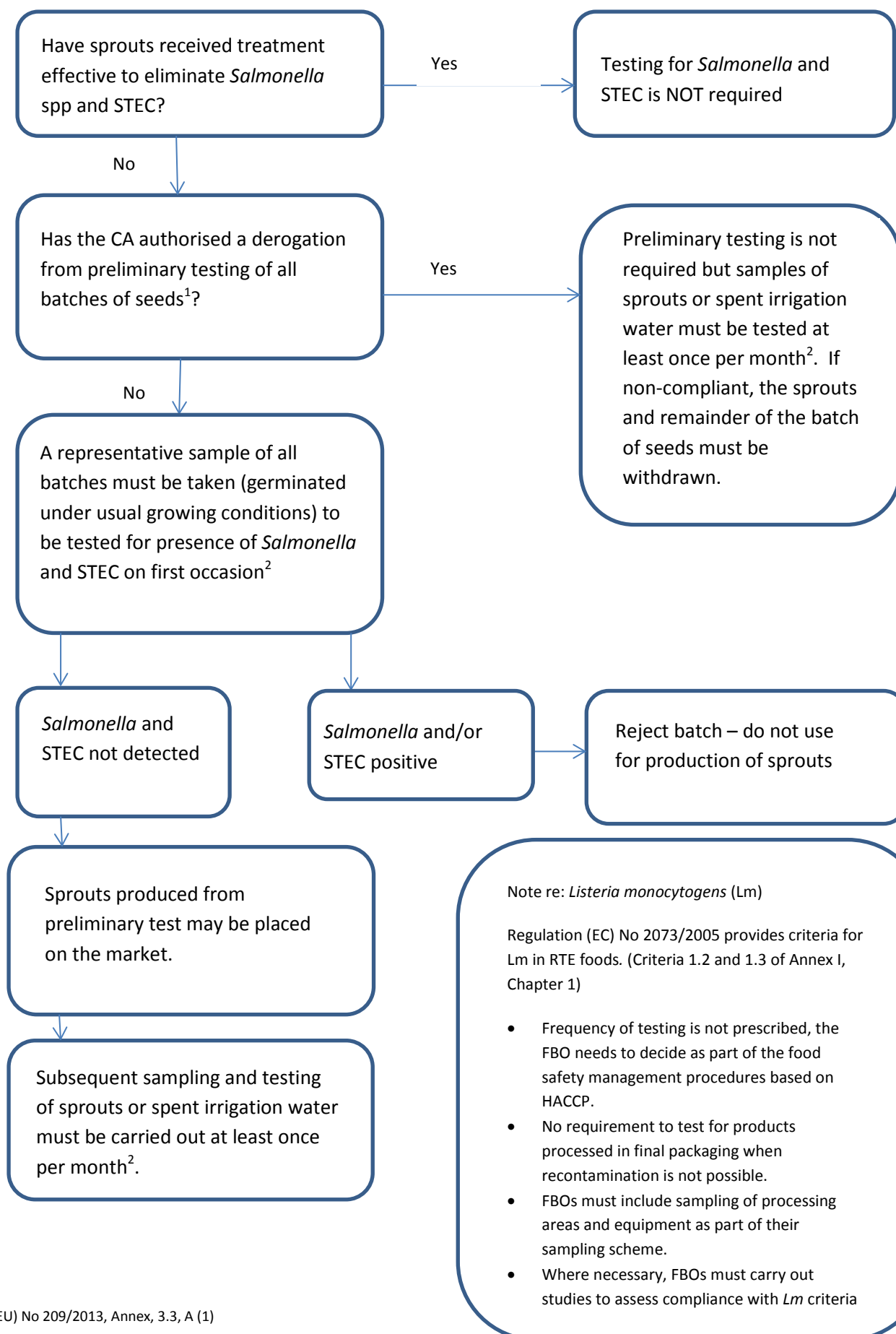
Is there any set format that the information must be kept?

No, there is no set format but the FBO has to be able to produce it for the competent authority on demand, so businesses will need to have systems in place to allow for this.

How long does a business have to keep this information for?

Again, there is no set time period for retention of traceability information except that it should be kept until at least such time that you can realistically expect that the seeds/sprouts have been consumed.

Sprout Production – Requirements for Microbiological Sampling and Analyses – *Salmonella* and STEC

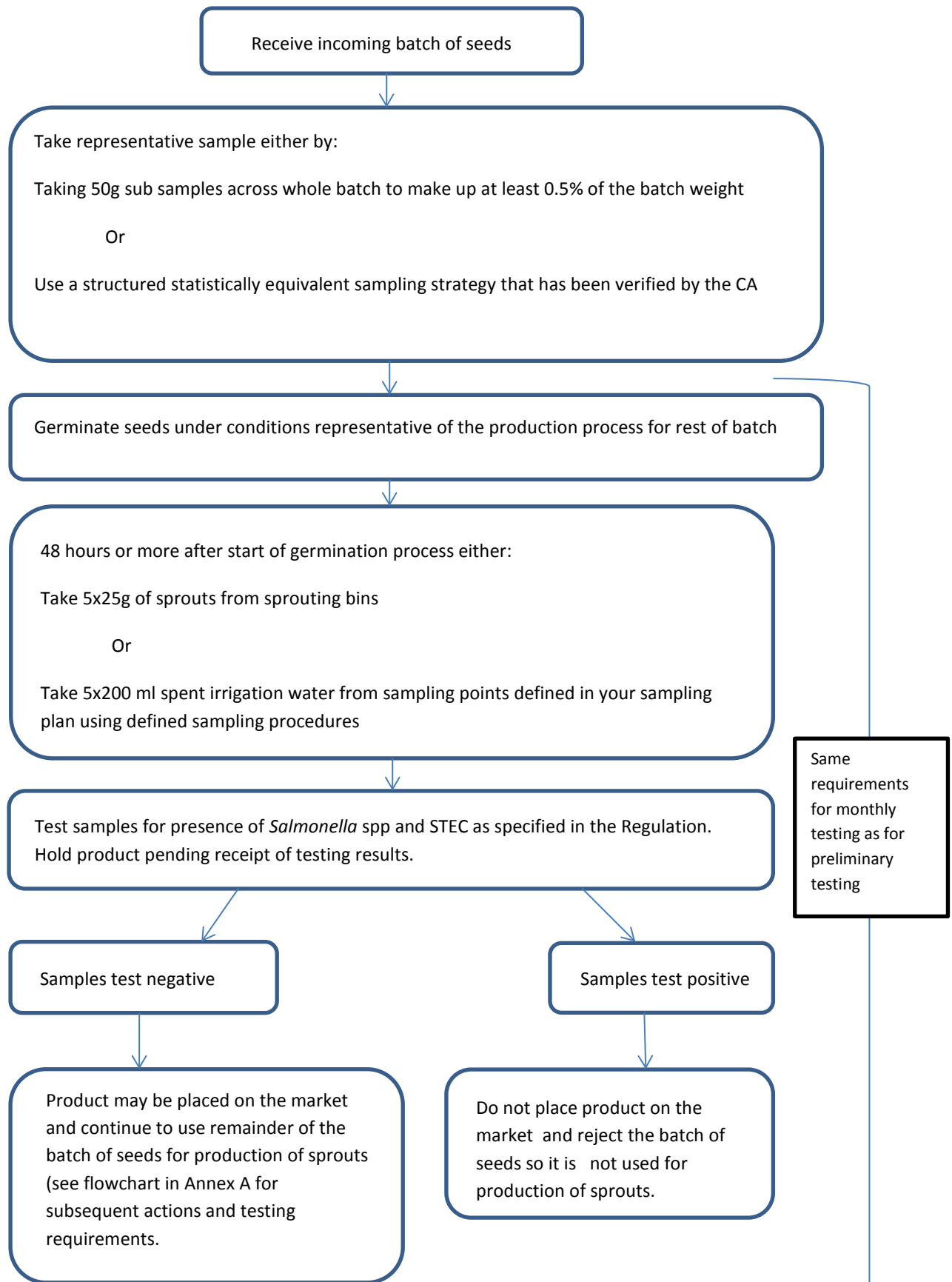


¹ Regulation (EU) No 209/2013, Annex, 3.3, A (1)

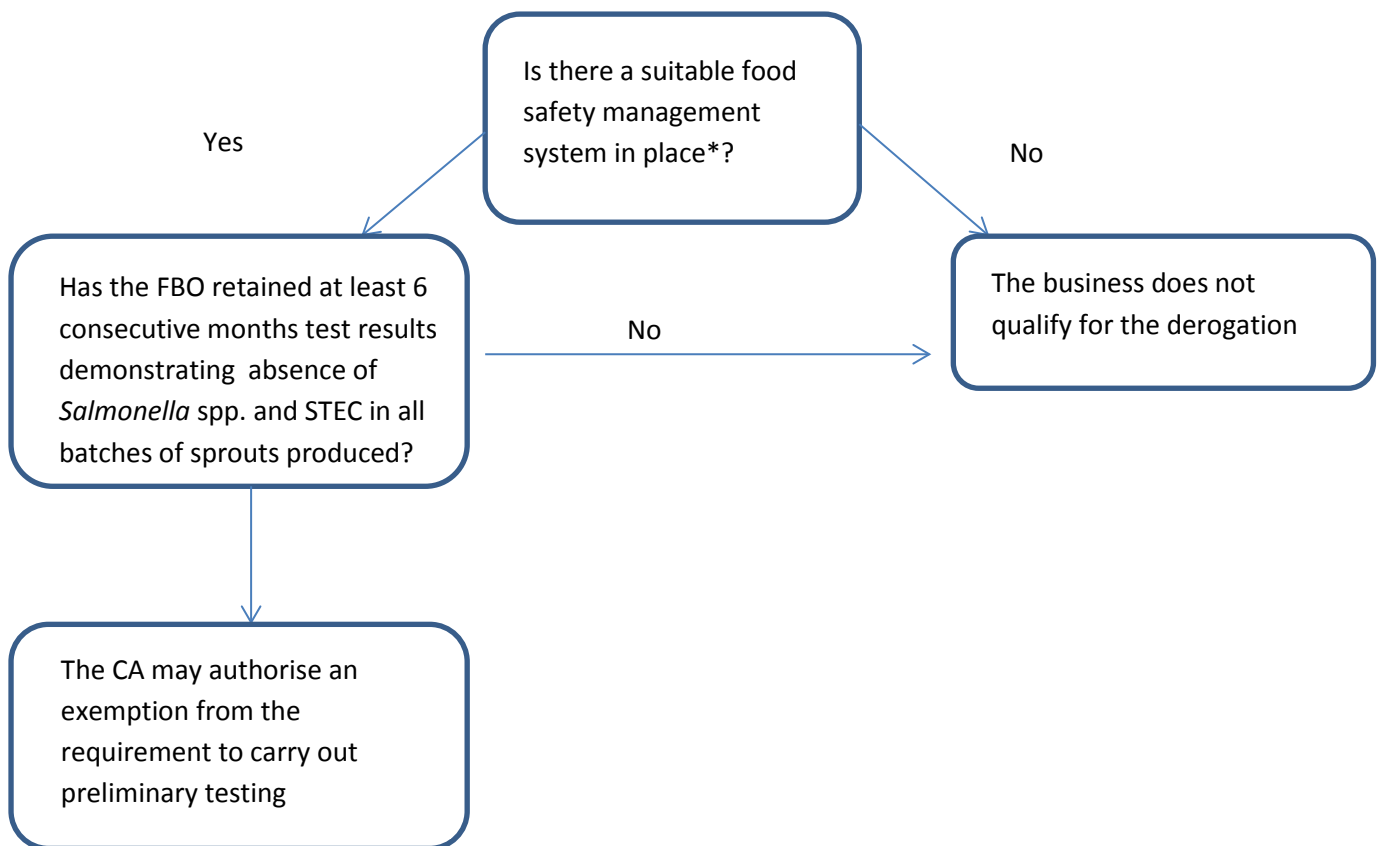
² Regulation (EU) No 209/2013, Annex, 3.3, A (2) requiring compliance with rows 1.18 and 1.29 of Annex I, Regulation (EC) No 2073/2005

How to undertake Preliminary Testing

Applies to all batches of seed tested for the first time¹:



¹When the derogation under section 3.3 Part C has not been authorised by the CA.

How do I obtain derogation from preliminary testing of all batches?

* This system can include steps which reduce the microbiological risk but this is not mandatory.