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31

GUIDANCE NOTE

Fresh Produce Safety in Primary Production in Ireland

Guidance Note No. 31: Fresh Produce Safety in Primary Production in Ireland

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ABBREVIATIONS

Department of Agriculture, Food and the Marine (DAFM)

European Union (EU)

European Commission (EC)

European Food Safety Authority (EFSA)

Food Safety Authority of Ireland (FSAI)

Food and Agricultural Organization of the United Nations (FAO)

Good Agricultural Practices (GAP)

Good Hygiene Practices (GHP)

Good Manufacturing Practices (GMP)

Hazard Analysis Critical Control Point (HACCP)

Persistent Organic Pollutants (POPs)

Polychlorinated Biphenyls (PCBs)

Rapid Alert System for Food and Feed (RASFF)

Shiga-Toxin *Escherichia coli* (STEC)

World Health Organization (WHO)

1. SCOPE

This document covers the good hygiene practices (GHP) and good agricultural practices (GAP) involved in the production of fresh produce, i.e. fruit, vegetables, herbs etc., at the primary production level in Ireland. This document is applicable to the primary production of all fresh produce produced in Ireland. Issues relating to fresh produce quality are not covered under the scope of this document.

This document gives guidance on aspects of fresh produce production that are common to most types of fresh produce and includes specific guidance on mushrooms and sprouted seeds.

Fresh produce refers to fresh fruits, vegetables, mushrooms and edible flowers as well as sprouted seeds that have not been processed, i.e. raw, or altered in form, by peeling, slicing, chopping, shredding or other treatment, prior to being packed by the grower or another food business.

This document is applicable to fresh produce produced in the field, under protective structures using hydroponics or collected in the wild, such as mushrooms, berries etc.

This document will consider microbiological, chemical and physical hazards associated with fresh produce. Specific guidance relating to certain fresh produce identified by the European Food Safety Authority (EFSA) as being of particular risk is included in Appendices 2 and 3.

As the Irish fresh produce market continues to evolve, the scope of this document may need to be updated to address these changes.

2. INTRODUCTION

In 2000, the Food Safety Authority of Ireland (FSAI), together with an expert working group, produced and published a code of practice for food safety in the fresh produce supply chain in Ireland[1]. The code of practice has been an important reference source for Bord Bia in the development of various fresh produce quality assurance schemes which have been adopted by the Irish fresh produce industry.

Since the code of practice was published, there have been many developments and much research into fresh produce safety which requires an update of the code of practice. At the request of the industry, the FSAI convened a new expert working group to produce a guide to good practice in Ireland on *'Fresh Produce Safety in Primary Production'* [2].

This document addresses both GHP and GAP in the primary production of fresh produce that will help control, or reduce to a safe level, physical, chemical and microbiological hazards.

The popularity and consumption of fresh produce globally has increased over the last 20 years, particularly through increased consumer demands for convenience and the innovative use of new technologies by the food industry to meet consumer demand [3]. Fresh produce is an integral component of a healthy diet [4]. However, outbreaks of foodborne illness associated or implicated with fresh produce have also increased in recent times [5, 6].

A search of the European Rapid Alert System for Food and Feed (RASFF) between 1st January 2012 and 1st January 2014 revealed 25 alert notifications concerning microbiological contamination of fresh produce. This demonstrates the potential threat to human health and underlines the importance of food safety in the fresh produce sector.

EFSA also compared data on foodborne outbreaks in the EU between 2007 and 2011, 10% of outbreaks, 26% of cases, 35% of hospitalisations and 46% of deaths were associated with food of non-animal origin. However, these data are strongly influenced by a large outbreak of Shiga-Toxin *Escherichia coli* (STEC) O104:H4 in Europe during 2011 [7-8].

Much fresh produce is consumed raw and therefore, the presence of pathogens represents a serious risk to public health [3, 5] In 2008, a joint expert group working with the World Health Organization (WHO) and the Food and Agricultural Organization (FAO) of the United Nations, issued a report that looked at the risk ranking of fresh produce [9-10]. By way of summary, the microbiological hazards associated with fresh produce that are most relevant to Ireland are pathogenic bacteria (disease-causing bacteria) like *Salmonella* spp., *Shiga-Toxin Escherichia coli (STEC), Campylobacter* spp. *and Listeria monocytogenes*. Appendix 2 outlines EFSA's Risk Ranking of Fresh Produce.

These pathogens can originate in soil, either naturally or introduced through the addition of soil amendments like slurry, manure or biosolids. Pathogenic bacteria can also be waterborne or introduced via human handling of fresh produce, as well as from ingress of farmed, wild and domestic animals into fields. It is also possible for pathogenic bacteria to be present on seeds [7].

Viruses, parasites and protozoa of which norovirus, hepatitis A virus, *Giardia lamblia* and *Cryptosporidium* spp. are of greatest relevance in Ireland, are more likely to be introduced to fresh produce via water, human handling of fresh produce or via soil amendments [5, 11]. In 2013, hepatitis A virus in frozen berries caused 240 confirmed cases of illness but a further 1,075 cases were classed as probable cases across 11 European countries including Ireland [12].

In Europe during 2011, a rare strain of STEC (*E. coli* O104:H4) in fenugreek sprouted seeds caused approximately 3,800 cases of illness, 2,353 hospitalisations (with over 800 developed kidney failure) and 53 deaths [7-8]. Since that outbreak, EFSA has been assessing the public health risks posed by pathogens that may contaminate foods of non-animal origin such as fresh produce[13]. EFSA has identified what fresh produce poses the highest risks in the European Union (EU) and these include leafy greens, bulb and stem vegetables, tomatoes, melons, fresh pods, legumes or grains, sprouted seeds and berries [8, 14-18] (Appendices 2 and 3).

In the United States, it was reported that fresh produce outbreaks, as a proportion of all outbreaks, increased from less than 1% to 6% between the 1970s and 1990s [19]. Also in the United States, between 2012 and 2014, 12 outbreaks involving fruits and vegetables were recorded, sickening 1,321 people. These outbreaks were caused by a number of different bacteria, viruses and protozoa [20].

There are few reviews in the published literature regarding chemical hazards associated with fresh produce, however, the FSAI has identified some issues relevant to fresh produce of Irish origin. Heavy metals are a natural feature of soils and concentrations depend on the underlying geochemical conditions [129]. The heavy metals cadmium, lead, arsenic and zinc are of primary concern in Ireland. Heavy metals can also concentrate in soils locally as a result of industrial activity, especially from mining [129]. Persistent organic pollutants (POPs) like dioxins, polychlorinated biphenyls (PCBs) and flame retardants could also be hazards in soils and water courses resulting from uncontrolled incineration/back garden burning and fly-tipping of waste. Heavy metals and POPs may also result from the use of soil amendments, particularly biosolids produced from municipal and industrial sources [11, 21]. Banned persistent organochlorine pesticides such as DDT, aldrin and dieldrin may be present from previous use on horticultural land.

Pesticides and biocides used in primary production form another class of chemical hazards. Chemical residues from fertilisers, soil conditioners, e.g. gypsum, and pH adjustors, e.g. lime, should also be considered as hazards for fresh produce. Some fertiliser may also be a source of cadmium and other heavy metals [22].

EFSA has indicated that the major risk factors for fresh produce most commonly identified on farms are [8]:

- Field history and adjacent land use
- Animal control (domestic and wild)
- Water
- Manure and soil amendments
- Field management (including field sanitation and sanitary facilities)
- Production activities
- Harvest activities
- Worker health, hygiene and sanitary facilities
- Storage and distribution

All of these identified risk factors are discussed in following sections of this document.

3. GENERAL ASPECTS OF PRIMARY PRODUCTION

Under Regulation (EC) No 852/2004, the production of primary products, i.e. fresh produce, is restricted to practices/processes such as transport, storage and handling at the place of production, e.g. farm, provided that the nature of the primary product is not substantially altered. It also includes transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment [23-24].

Under European legislation, growers are considered to be food business operators and have a legal obligation to ensure that the primary products they produce are safe and protected against contamination. While food business operators are not legally obliged to have a Hazard Analysis Critical Control Plan [HACCP] plan in place [23], they must comply with any relevant European and national legislation and standards relating to the control of hazards in primary production and associated operations, i.e. control contamination arising from the air, soil, water, feed, fertilisers, plant protection products, storage, handling and disposal of waste etc.,[23-24]. Growers producing and/or harvesting plant products are legally required to take adequate measures to [23]:

- Keep clean and where necessary, after cleaning, disinfect in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels
- Ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of plant products
- Use potable or clean water whenever necessary, to prevent contamination
- Ensure that staff handling foodstuffs are in good health and undergo appropriate training
- Prevent, as far as possible, animals and pests from causing contamination
- Store and handle wastes and hazardous substances so as to prevent contamination
- Take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health
- Use plant protection products and biocides correctly, as required by the relevant legislation
- Take appropriate remedial action when informed of food safety and hygiene problems identified during official controls

Primary products such as fruits, herbs, vegetables, mushrooms etc., are grown and harvested in Ireland using various agricultural inputs and technologies, on farms of varying size and location. Biological, chemical and physical hazards may therefore, vary significantly from one farm to another. Anything which comes into contact with fresh produce has the potential to cause contamination. Once fresh produce has been contaminated, removal of the contaminant can be difficult. Prevention and minimisation of contamination through the use of GAP and GHP are the best options to reduce the risk of food safety hazards [9-10, 25-27].

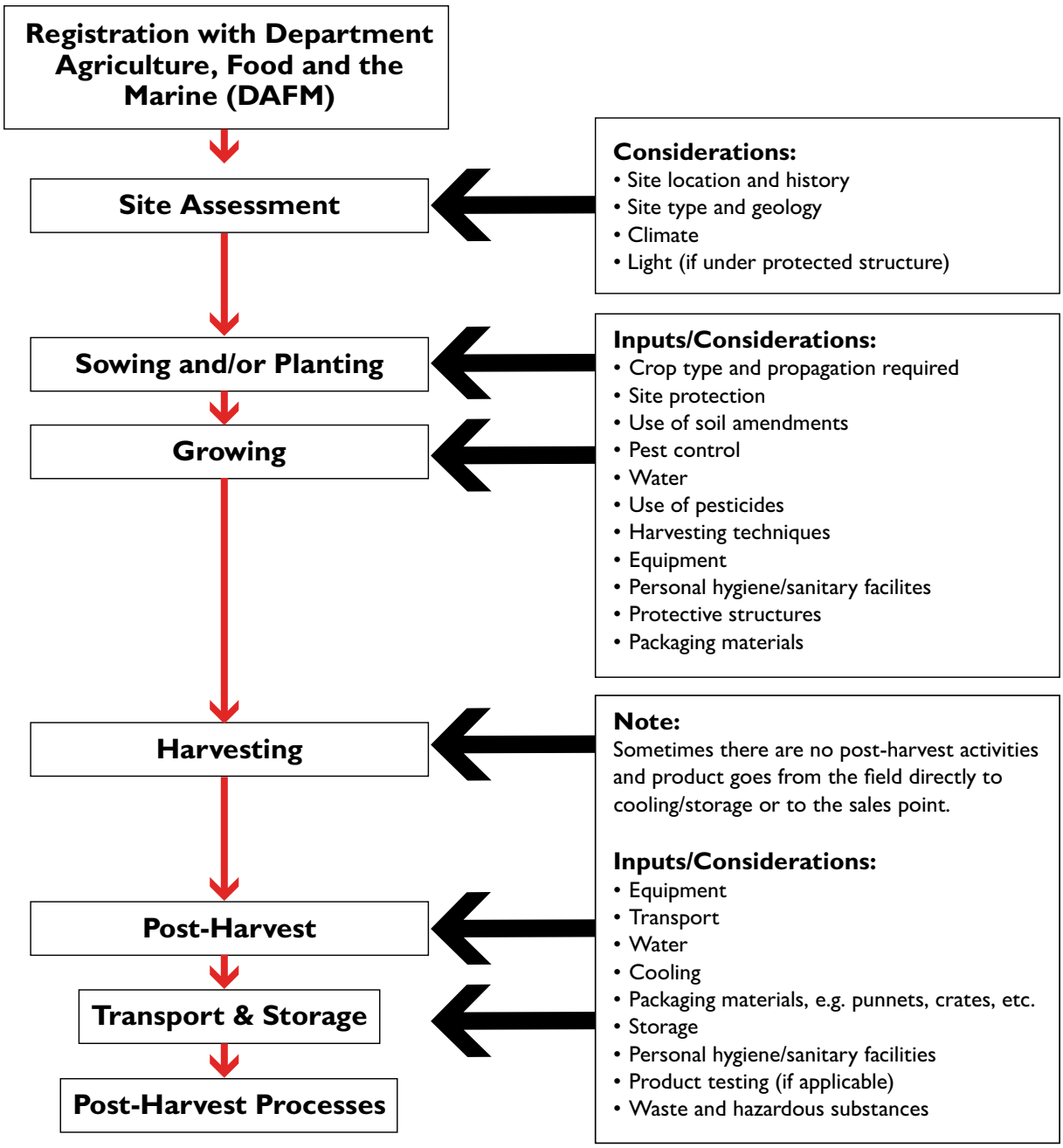
In primary production, contamination of fresh produce is typically the result of contact with contaminated soil amendments, water, infected workers and food handlers, contaminated equipment used in harvesting and/or contaminated packaging. Conditions during transport and storage such as dirty floors and walls of vehicles and containers can also contaminate fresh produce.

In the planting and growing of fresh produce, there are a number of agricultural inputs and considerations which growers should be aware of in order to manage the risk of fresh produce contamination. Due to Ireland's climate, protective structures such as glasshouses and tunnels are often used for growing specific fresh produce crops and raising transplant crops. The same considerations that influence the risk and control of hazards related to outdoor fresh produce will apply to produce grown under protective structures. Before planting and growing fresh produce crops, it is also important to consider any possible risks from the particular type of crop, e.g. presence of pathogens on seeds, and if a crop requires propagation prior to planting, which can also introduce risk.

As it is not possible to deal individually with all the types of fresh produce grown in Ireland, it is important that each grower look at their own farming practices and ensure that all steps are considered. Although production processes vary between commodities, there are common production activities which apply to most fresh produce produced in Ireland.

Figure 1 outlines the steps and inputs which are typically seen in the primary production of fresh produce in Ireland. This figure is not intended to be used as an exhaustive list of steps and/or inputs as there will be many primary production processes which have steps or inputs which are not outlined. Figure 1 is provided to help growers identify the steps in their primary production process, the possible hazards that can occur at each step and the good practices necessary to control each of those hazards and reduce food safety risk(s).

Figure 1. Typical Steps in Primary Production in Ireland



3.1 Registration of Primary Producers

Before beginning primary production of fresh produce, primary producers are required to register with the Department of Agriculture, Food and the Marine (DAFM). Appendix I outlines the DAFM registration process for primary production establishments.

3.2 Site Assessment

Growers should consider the suitability of the site, e.g. field, for growing the crop to produce safe fresh produce, e.g. proximity to poultry and livestock is a particularly high microbiological risk in the case of ready-to-eat crops. This will help reduce the risk of specific hazards occurring.

While not always practical, a site for growing fresh produce should (i) have no recent history, i.e. within three years, of use for poultry or livestock production, (ii) not be close to an existing poultry or livestock operation, and (iii) not be downstream or down slope from sites that house poultry or livestock. The presence of barns, poultry houses or farm animals a short distance from cultivation sites increases the risk of produce contamination[28]. Assessment of the location of animals and their facilities and evaluation of drainage systems and water currents flowing near these areas will help determine the potential for contamination of produce in the field. Site assessment should follow a basic risk assessment approach which broadly considers the following before any fresh produce crops are sown [11, 29–30]:

- Site history, e.g. previous land use, agricultural practices applied
- Site location, e.g. risk of flooding, public access, neighbouring agriculture and industry
- Soil type and geology of the site
- Climate, i.e. prevalent weather patterns

3.2.1 Site history and location

Previous use of the land, agricultural practices applied, i.e. within the last three years, and the location of the site relative to potential hazards can all affect the safety of fresh produce. While in some cases difficult to obtain, information on site history can help identify the risk of specific hazards.

Agricultural land that has been used for activities other than producing fresh produce can be contaminated with pathogenic organisms, chemicals or physical hazards such as plastics, glass, metals, oils and lubricants from machinery. Even in situations where the site was used solely for agricultural production, prior production practices should be known. For example, improperly used soil amendments such as farm manure or biosolids can result in the survival of pathogens in the soil for long periods and contaminate fresh produce [5,11]. Poor, prior use of pesticides can also increase the risk of chemical hazards for fresh produce.

Obtaining information on site history should also include knowing if the land is prone to flooding. Land that has been flooded may have been exposed to contaminants and pathogens. If the site's prior use is unknown, it would be prudent, as a minimum, to take soil samples.

The presence of grazing animals, industry and other farms in areas adjacent or close to the site location, i.e. field for growing the crop, should be considered [28]. In addition, the possibility of public access to areas growing fresh produce may also introduce risk and should be considered.

All of the above have the potential to contaminate fresh produce. For example, in locations situated close to grazing animals, there is potential for microbiological contamination of crops due to run off or aerosol formation, i.e. through the air, from the adjacent grazing areas [9, 11, 29, 31]. Likewise, if animals are grazing upstream from a fresh produce site, and river water is used for irrigation, there is potential for contamination of crops.

3.2.2 Soil type and geology

Most fresh produce in Ireland is grown in soil. Soil can be a source of various hazards either naturally present or introduced through previous agricultural practices and use of the site. Likewise, crops such as mushrooms which are grown on specially composted materials or those grown in liquid media, i.e. hydroponics, can also be contaminated.

Soil is a natural environment for a variety of foodborne pathogens including *Listeria monocytogenes* and *Clostridium botulinum* [3]. However, the type and number of pathogens that may be present can increase considerably when soil amendments such as animal manures are inappropriately used on soil [3, 32]. Soil types, characteristics and suitability vary across Ireland. Some soils and sub-soils are shallow, highly permeable or prone to flooding or run off. Given that soil amendments can contain pathogens and chemical contaminants, such soils or subsoils can render underlying ground waters vulnerable to contamination from surface activities such as land-spreading [11].

Soils and subsoils provide protection to groundwater by filtering out microorganisms, or retarding their multiplication. The degree of protection depends on the type and thickness of the soils/ subsoils, with greater protection being afforded by thick soils/subsoils with high clay content. Before soil amendments are land-spread, the suitability of the land for such treatment, in terms of the type and thickness of the soil/subsoil, should be determined so as to take account of the vulnerability of the groundwater in the vicinity.

As there is a relationship between the degree to which soils and subsoils protect groundwater, and the extent to which they promote surface overland flow, i.e. run off to watercourses, it is important that, when assessing the suitability of sites with regard to land-spreading, the risk to both groundwater and surface waters is considered and balanced [11].

The geological structure of the land on which fresh produce is grown in Ireland differs significantly around the country. Chemicals from soil can accumulate in certain types of fresh produce such as root crops and leafy crops. Root crops such as potatoes and carrots for example, are particularly susceptible to contamination from cadmium found naturally in some soils in Ireland [33-34]. However, these hazards can be minimised with prior knowledge of the soil type, e.g. the availability of cadmium to plants, is influenced by pH and other factors such as zinc concentration in the soil and soil type, and GAP can be adopted to minimise uptake of these contaminants to harmful levels by crops [34].

Limits for the maximum content of various chemical contaminants in certain fresh produce and other foods are laid down in Regulation (EC) No 1881/2006 [35]. Growers must ensure that their produce complies with these limits. Research into GAP is also ongoing in Ireland and growers should consult expert advice, e.g. Teagasc or technical advisor/consultant. Information on the general geochemical content of soils in all regions of Ireland is also available from the Soil Geochemical Atlas of Ireland, the Irish Soil Information System and the National Soils Database [33, 36].

3.2.3 Climate

Climate is defined as the average weather conditions over a period of time, normally measured in years. The incidence of foodborne illness can be correlated with climatic conditions and shows some seasonality patterns, e.g. cases of foodborne illness caused by *Salmonella* increase during warmer months, although the mechanisms underlying seasonality are likely to be a combination of factors which include climate [37]. In particular, growers should be aware of rainfall and the risk of surface water run off and localised flooding onto lands used to grow fresh produce [38]. Heavy rain has been shown to lead to contamination of fresh produce with pathogens due to splashing of soil amendments onto edible portions of the crop or spreading pathogens throughout a field during flooding events [39-42, 44-45].

4. WATER

Water is used for many activities in primary production, including irrigation, mixing and application of plant protection products, humidification of glasshouses, post-harvest cooling, and cleaning/ washing/rinsing operations. Water is also used by workers for hand-washing. Growers should use basic risk assessment techniques to help assess the risk of using water in the production of fresh produce in Ireland [9-10, 27].

4.1 Assessing the Vulnerability of Water to Contamination

In Ireland, water for use in primary production is abstracted from a wide range of sources. But regardless of the source, water can become contaminated. While contamination of all water sources is possible, in general, the risks of contamination are highest for surface water supplies and lowest for public mains supplies [46]. Growers should consider the following in Table 1 when assessing the vulnerability of their water source to contamination [3, 29, 37, 47-48]:

Table 1. Considerations in Assessing the Risk of Water Contamination [a]

1	**Type, prevalence and location of the following adjacent to the water source:** • Farming, e.g. run off from grazing livestock into waterways • Industry, e.g. effluent discharges into waterways • Urban wastewater treatment plants, e.g. effluent discharges into waterways • Private septic tanks, e.g. poorly constructed, sited or leaking septic tanks • Livestock, pets and wild animals e.g. access to the water source
2	**On farm practices:** • Poorly constructed storage of farm manure and slurry, e.g. leaking or overflowing slurry tanks or manure lagoons • Poorly managed application of soil amendments on land • Poorly managed storage, use and disposal of pesticides etc. • Poorly managed collection, storage and distribution of water, e.g. rainwater [b]
3	The construction, nature and location of private wells, e.g. shallow, damaged, poorly protected or constructed [c-d]
4	Local rainfall patterns and land topography, e.g. may increase run off from land into water source particularly during periods of high rainfall and flooding

[a] The water quality in Ireland's major rivers and tributaries is surveyed and assessed by the Environmental Protection Agency (EPA) and these results are available from its website. Local authorities also publish results of water quality monitoring.

[b] Any water which is collected, stored and distributed for use with fresh produce should be assessed to determine its suitability for use, e.g. in general rain water from rain harvesting systems should be considered non-potable water unless proven otherwise.

[c] The construction, nature and location of many private wells in Ireland means there is an increased risk of contamination.

[d] Please see the EPA website for detailed guidance on private well construction. It is recommended that growers use the services of a hydrogeologist before constructing any new well or borehole.

4.2 Assessing the Suitability of Water for Intended Use

To minimise contamination of fresh produce from water, potable water, i.e. drinking water, should be used. However, this may not be practical for many Irish growers.

Currently, clean water or potable water [a] can be used whenever necessary to prevent contamination of fresh produce during primary production [23]. Clean water can be used by a grower if it can be demonstrated that the water does not contain microorganisms, chemical contaminants or other harmful substances at levels that could affect the safety of the produce [23-24]. However, there is a lack of information available to growers clarifying when clean water can be used for specific agricultural practices [23-24, 46, 49].

The European Commission (EC) has recently developed guidance on the hygiene requirements for fresh fruit and vegetables at primary production. In relation to water, this European guidance assigns risk to both the source and the intended use of the water [50]. For the purposes of primary production of fresh produce in Ireland, this European guidance has been adapted in this document. In relation to water, risk is assigned into three categories of high, medium and low risk as set out in Table 2 [50]. As an indicator of faecal contamination in water, limits for levels of *Escherichia coli* are set which thereby determine the suitability of that water for an intended use (Table 2) [3, 23-24, 27, 29, 30, 37, 50-73].

Testing water for the presence of *E. coli* indicates the presence of faecal contamination and the possibility that pathogens are present. However, while the presence of *E. coli* in water indicates the potential for pathogens to be present, it does not consistently correlate with the presence of pathogens. Likewise, the absence (or low numbers) of *E. coli* in water does consistently correlate to the absence of pathogens.

Additionally, growers should be aware that *E. coli* is only one measure of water quality. The presence or absence of *E. coli* bears no relationship to the presence or absence of chemical contaminants. Chemical testing of water, e.g. pH, nitrite/nitrate, ammonium levels, pesticides etc., may also be required if a specific contaminant is suspected or identified through risk assessment. As with all laboratory tests, results can vary considerably and only reflect the water quality at the time of sampling [59, 62, 64-73].

Table 2 provides a simple risk assessment tool for growers to assess the potential contamination risk due to a combination of water source, intended use and potential contact with fresh produce. Risk is defined as high, medium. Suggestions for frequency of testing water for the presence of *E. coli* are given in the accompanying notes to Table 2. However, Table 2 may be modified and/or adapted by individual growers based on their own risk assessments.

[a] **Clean Water** is water that does not contain microorganisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food. **Potable Water** is water which meets the requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption and S.I. No. 122 of 2014.

Table 2. Potential Contamination Risk from Water Sources Depending on the Source and its Intended Use with Fresh Produce [A-E]

Source → / Intended Use ↓	**Untreated Surface Water** Risk related to nature of surface water, weather conditions, presence of industry and agriculture	**Untreated Well Water** Risk related to location and construction	**Untreated Rain Water** Risk related to collection and storage methods	**Treated, Controlled and Monitored Surface, Well and Rain Waters**	**Public Mains [F]**	**Recommended Limits for *E. coli* as an Indicator of Contamination[F]** [Colony Forming Units/100ml]
	Risk					
1. Irrigation/ Pesticides Crops likely to be eaten uncooked - Water in direct contact with edible portion *Includes water used for pesticide dilution, cleaning and sanitation with these crops*	**High**	**High**	**High**	**Medium**	**Low**	100
Crops likely to be eaten uncooked - Water not in direct contact with edible portion *Includes water used for pesticide dilution, cleaning and sanitation with these crops*	**Medium**	**Medium**	**Medium**	**Medium**	**Low**	1,000

Source → / Intended Use ↓	**Untreated Surface Water** Risk related to nature of surface water, weather conditions, presence of industry and agriculture	**Untreated Well Water** Risk related to location and construction	**Untreated Rain Water** Risk related to collection and storage methods	**Treated, Controlled and Monitored Surface, Well and Rain Waters**	**Public Mains** [F]	**Recommended Limits for *E. coli* as an Indicator of Contamination**[F] [Colony Forming Units/100ml]
	Risk					
Crops likely to be eaten cooked - Water in direct contact with edible portion *Includes water used for pesticide dilution, cleaning and sanitation with these crops*	**Medium**	**Medium**	**Medium**	**Medium**	**Low**	1,000
Crops likely to be eaten cooked - Water not in direct contact with edible portion *Includes water used for pesticide dilution, cleaning and sanitation with these crops*	**Low**	**Low**	**Low**	**Low**	**Low**	10,000

Source → / Intended Use ↓	Untreated Surface Water Risk related to nature of surface water, weather conditions, presence of industry and agriculture	Untreated Well Water Risk related to location and construction	Untreated Rain Water Risk related to collection and storage methods	Treated, Controlled and Monitored Surface, Well and Rain Waters	Public Mains [F]	Recommended Limits for *E. coli* as an Indicator of Contamination[F] [Colony Forming Units/100ml]
	Risk					
2. Hydroponics	**High**	**High**	**High**	**Low**	**Low**	100
3. Cooling (post-harvest)	**High**	**High**	**High**	**Low**	**Low**	100
4. Final Washing and Rinsing of Fresh Produce (post-harvest)	**High**	**High**	**High**	**Low**	**Low**	Potable Water Only
5. Staff Hygiene, Drinking, Ice, Cleaning and Sanitation (post-harvest)	**High**	**High**	**High**	**Low**	**Low**	

Notes on Table 2

A. For all fresh produce that is usually eaten raw/uncooked, water which is applied by irrigation or used to make-up pesticides and biocides within two weeks of harvest, should be of potable water quality [46, 50, 53, 74].

B. Water samples should be taken before and during the growing of each fresh produce crop to cover the entire period during which the water is used. The number of water samples to be taken by the grower to test for the presence of *E. coli* should be based on risk, but should always be greater on high-risk crops that are eaten uncooked. The following is a suggested water sampling regime:

- High-Risk Crops – at least ten water samples per crop
- Medium-Risk Crops – at least five water samples per crop
- Low-Risk Crops – at least three water samples per crop

C. Growers should also take into account when frequency of sampling should be increased, following an event such as heavy rainfall or flooding.

Notes on Table 2 continued

D. The timing of water sampling by the grower is not specified. However, water samples taken during high-use periods for irrigation, applying pesticides or washing fresh produce would be considered to be more representative.

E. It is recommended that growers focus on the adoption of GHP and GAP to minimise and control the risk of contaminated water. The testing of water for microorganisms and chemicals should not be used as the sole method of controlling waterborne hazards. Water testing should be used as a way to verify, i.e. show, that GHP and GAP are working and that the water is of a sufficient quality to be used for its intended purpose. It is recommended that growers consult with their local agricultural advisor, e.g. Teagasc or other technical advisor/consultant, competent authority, e.g. DAFM, or quality scheme, e.g. Bord Bia, when sourcing water for food production purposes [15, 51, 53].

F. Public water supplies in Ireland are subject to the provisions of the European Union (Drinking Water) Regulations, 2014. S.I. No. 122 of 2014 (as amended) [46]. As such, the recommended limits for *E. coli* as an indicator of contamination given in Table 2 do not apply to public water supplies.

4.3 Corrective Actions to Address Water Contamination

If test results exceed the limits or suggest a potential problem with the water, the grower should consider the following immediate and preventative corrective actions, or any others, to reduce the risk as outlined in Table 3 [14, 31, 45, 50, 57, 75-76]:

Table 3. Immediate and Preventative Corrective Actions to Address Contaminated Water

Immediate	
1	Place any affected produce on hold, pending laboratory testing of produce.
2	Confirm all laboratory results.
3	Investigate and try to identify the potential source of contamination.
4	Based on investigation, consider the following actions (non-exhaustive list): • Install back-flow valves to prevent contamination of water by back-flow from contaminated water in lines and tanks • Use an alternative water source • If the water supplier has been treating the water, check the performance of the water treatment equipment. Seek external expertise where necessary. Poorly maintained and malfunctioning water treatment equipment may allow contamination of the water. Consider developing written procedures to cover a preventive maintenance schedule for this equipment
5	Following corrective actions, re-test water to verify effectiveness of actions taken.
6	Document and record all corrective actions taken.
7	Review any preventative actions taken.
8	Review water risk assessment and if necessary, amend.

Table 3. Continued

Preventive (based on assessing the vulnerability of water to contamination and its suitability for use)	
1	Have a contingency plan which identifies an alternative water supply to be used in case of supply problems.
2	If using more than one water source, ensure all sources are clearly identified to prevent inappropriate use, e.g. provide separate systems for waste water, potable water supplies etc.
3	Ensure water sources are protected (as much as possible) from contamination by animals, e.g. fencing or netting.
4	If storing manure, slurry, composts and other soil amendments, ensure there are no leaks or spillage and they are positioned downhill from the water source, i.e. at least ten metres away, to minimise contamination.
5	If collecting rainwater, ensure the catchments and gutters of the harvesting system are regularly cleaned and maintained.
6	Ensure that all water storage tanks are covered, i.e. protected, to prevent contamination.
7	If using a private well, ensure it is located away from contamination sources, and constructed appropriately to prevent contamination, e.g. sealed on top.
8	Regularly check irrigation (suggest weekly), for damage or leaks and flush lines to remove accumulated organic debris. If there has been a period of wet weather, it is recommended to flush the system prior to use.

4.4 Irrigation

A summary of recommended GAP to minimise the risk of contaminating crops by irrigation is outlined in Table 4. These GAP should also be applied when using pesticides and hydroponics as outlined in Sections 4.5 and 4.6 [3, 10-11, 14, 16, 18, 27, 29, 37, 45, 57, 64, 74, 77-79].

Table 4. Recommended Good Agricultural Practices in Irrigation

1	Record the crop, date and time of irrigation, water source and any pesticides used.
2	Maintain and protect the source of the water used/stored and verify its quality.
3	Where possible, avoid the use of high-risk water sources such as poorly stored rainwater, untreated wastewaters and surface waters from rivers, lakes and ponds.
4	Growers should focus on the adoption of GAP to minimise and control the risk of contaminated water and not use testing as the sole method of controlling waterborne hazards.
5	The type of crop, i.e. ready-to-eat or requires cooking, timing, method of application, soil type and whether the irrigation water has direct contact with the edible portion of the plant should be considered by growers. If contaminated water is in contact with the edible portion of plants, the risk of contamination increases especially if close to harvesting.
6	Crops which have leaves and rough surfaces which can trap water or crops which are field-packed and receive little or no post-harvest washing are at an increased risk of contamination due to irrigation practices and the quality of water used.
7	Overhead irrigation presents the highest risk of contamination because it directly wets the edible portion of plants and its use should be avoided where possible. However, low volume sprays, drip, furrow or underground irrigation are all options that can be adopted to limit contamination.
8	Water spraying, i.e. misting, immediately prior to harvest presents an increased microbiological risk. If the soil is heavy and non-free draining, contaminated water can accumulate on the soil surface increasing the risk of crop contamination. It is recommended that water spraying immediately prior to harvest is avoided as it presents an increased microbiological risk.
9	Minimise soil splash from irrigation by choosing a system that delivers small water droplets. For low growing crops it may not be possible to minimise water contact in this way. It should also be noted that if soil has been contaminated by irrigation water, soil splash can transfer contamination to crops. The risk of contamination increases if large irrigation droplets are used or heavy rain occurs. It is recommended that growers try to minimise soil splash from irrigation by choosing a system that delivers small water droplets, i.e. < 3.6mm.

4.5 Pesticides (plant protection products and biocides)

Contaminated water which is used to reconstitute pesticides can be a source of contamination. Various studies have shown the ability of pathogens such as norovirus, *Salmonella, E. coli* O157:H7 and *L. monocytogenes* to survive and grow in commercial agricultural chemicals [3, 10, 14-15, 18, 27, 80-81]. Therefore, water used to make up plant protection products and biocides, and applied directly onto fresh produce should meet the limits suggested for *E. coli* in Table 2 [14-15]. However, in the case of fresh produce that may be eaten raw/uncooked, water which is used to make up plant protection products and biocides and applied within two weeks of harvest, should be of potable water quality [50].

4.6 Hydroponics

In the case of hydroponic production, water is used for both irrigation and as the growth medium and may therefore, present a high risk of microbiological surface and internal contamination [8, 82]. Plants grown in hydroponic systems absorb nutrients and water at varying rates, constantly changing the composition of the re-circulated nutrient solution. Therefore, water used in hydroponics should meet the limits suggested for *E. coli* in Table 2 and be changed frequently and treated to minimise microbial and chemical contamination. In addition, the water delivery systems should be maintained and cleaned, as appropriate, to prevent microbial contamination of water.

4.7 Washing and Rinsing (on farms)

The washing and rinsing of fresh produce on-site may follow harvesting, particularly if raw, fresh produce is sold directly as a ready-to-eat product. Washing and rinsing will help remove soil from the field, which in turn, will reduce the microbial load and contaminants on the produce [83]. However, using contaminated water and/or poor hygiene practices, and damaged or poor quality produce, can contaminate fresh produce [84-85]. The key GAP for growers related to washing and rinsing of fresh produce on farms are outlined in Table 5 [1, 10, 14-18, 27, 29, 86].

Table 5. Recommended Good Agricultural Practices for Washing and Rinsing on Farms

1	Only use potable water for the final washing and rinsing of all fresh produce.

2	Develop documented procedures for the washing and rinsing of fresh produce which includes:
	• Use vigorous washing to increase the chances of removing contamination if the fresh produce is not subject to bruising
	• Define a suitable frequency of water change for washing and rinsing to minimise risks of fresh produce contamination
	• Monitor water temperature during washing and rinsing
	  • Immersion of warm, whole or fresh-cut produce in cool water may induce water into the internal parts of the fresh produce
	  • Some fresh produce with high water contents, e.g. apples, celery, and tomatoes, are more susceptible to internalisation through openings in the peel such as stem-end vascular tissue, stomata or puncture wounds. If the temperature of the wash water is less than the temperature of the produce, the temperature differential can force water into the produce contaminating it on the inside
	  • It is recommended that in these cases, the temperature of the initial wash water is 10°C higher than the fresh produce, if possible
	• Where possible, use a de-watering step to remove excess water as dry produce is less likely to become re-contaminated. However, water should be removed gently to prevent damage to produce

3	Develop documented procedures for cleaning and sanitation of equipment used in washing and rinsing of fresh produce which includes: • All washing and rinsing equipment should be hygienically designed to help ensure adequate cleaning and sanitation • All equipment should be cleaned after use. Mud, soil and fresh produce debris should be removed from equipment, then it should be washed with a detergent and rinsed before a final wash with a chemical disinfectant and a thorough rinse with potable water • Ancillary equipment such as knives, blades, boots and protective clothing should be cleaned and disinfected at the end of each day
4	If treating water for use in washing and rinsing, seek professional advice before purchasing, installing and using any water treatment system, e.g. water chlorination system.

5. SOIL AMENDMENTS

In Ireland, various soil amendments such as farm manures and inorganic fertilisers are used to improve plant growth. They function in a number of different ways by supplying nutrients or changing soil characteristics such as pH and structure.

Research has shown that microorganisms in the soil can enter the root system of plants and become internalised whereupon they cannot easily be removed during processing [32, 79, 86-89]. Microorganisms in the soil may also contaminate plants indirectly through splashing during irrigation and rainfall leading to internalisation [45, 87]. As such, direct or indirect contact between soil amendments and fresh produce should always be minimised [29]. However, internalisation of fresh produce with foodborne pathogens can occur at a number of different infiltration sites, both pre-harvest and post-harvest [90-92].

The fate of viruses in soil amendments and pre-harvest contamination of fresh produce is largely unknown [37]. However, it is clear that viruses from human faeces such as hepatitis A virus can contaminate fresh produce [12, 43]. As the infectious dose of viruses can be very small, i.e. <100 particles, pre-harvest contamination of fresh produce presents a significant food safety concern [37]. In 2008, the FSAI assessed the hazards and associated risks involved with the use of soil amendments on agricultural land used for food production in Ireland, and these are outlined below [11].

5.1 Farm Manures

Farm manures which include both solid, e.g. farmyard manure, and liquid manures, e.g. slurry, dirty water and leachate from stored manures, are materials applied to agricultural land in Ireland to improve soil fertility. The majority of farm manures used on Irish farms come from cattle and pigs [11].

Poultry litter (including imported poultry litter) to a lesser extent is also spread on agricultural land in Ireland. DAFM has produced a good practice publication in relation to the spreading of poultry litter on land [11, 93]. In its publication, DAFM recommends that, where possible, poultry litter should only be spread on tillage land, e.g. land used for cereal production, and immediately ploughed in [93].

The principal hazards associated with the use of all farm manures are the presence of pathogens such as *Listeria monocytogenes, Campylobacter, Salmonella, Escherichia coli* O157:H7 etc., which can contaminate fresh produce and cause foodborne illness[11]. These pathogens can also be found in water which comes into contact with manures or leachate from manure[11].

Contamination of fresh produce from farm manures can occur through a range of different practices which include [11]:

- Land-spreading farm manure before a crop is sown
- Faeces/Faecal matter deposited on land by livestock, wild animals and pets before a crop is sown
- Applying farm manure to growing fresh produce crops
- Access by livestock, wild animals, domestic pets and the general public to a growing crop
- Contamination by aerosols generated in adjacent or nearby fields
- Use of contaminated equipment
- Use of contaminated irrigation water
- Water run off from nearby or adjacent fields following land-spreading
- Leachate or slurry from leaking or overflowing storage units

The treatment and management of farm manures will affect the survival and growth of pathogens [11]. Pathogens can persist in farm manure and soil for periods of days, weeks or months with the potential to contaminate fresh produce [11]. To minimise the risk of contaminating fresh produce with pathogens, it is better to destroy or reduce pathogens in the farm manure itself or the soil, before a crop is harvested.

The moisture content and temperature of soil have been identified as principal variables influencing pathogen survival [11]. Sandy soils are considered to be less favourable than clay soils to pathogen survival, because they are more susceptible to moisture loss. However, pathogen persistence and survival in soil is complex. Pathogens can adapt to soil environments and survive variations in soil and environmental conditions [11].

As people and animals may ingest soil on fresh produce, the time interval between land-spreading, i.e. application, of farm manures and other organic fertilisers to land and planting and harvesting of crops (particularly ready-to-eat crops) to allow pathogen die off, should always be maximised [14, 50, 94]. EFSA has indicated that pre-harvest intervals of 120 days are generally accepted in GAP guidance, although 60 days is considered the minimum duration [14, 94]. However, survival of *Salmonella* depends on the type of organic material that is land-spread. For instance, in soil amended with fresh poultry manure and in some EU Member States, a year between fresh slurries application and planting of leafy green fresh produce production may be required [14].

Further detail on pathogen persistence is given in Appendix 4.6 of the FSAI Land-Spreading Report [11].

Animal faeces/faecal matter deposited directly onto land by grazing livestock, wild animals and domestic pets may also contain pathogens [95]. In this regard, growers should take precautions to limit the access of livestock, wild animals and domestic pets to sites of fresh produce production. In particular, domestic animals should be excluded during the crop growing season. Where necessary, growers should check that fencing, hedges and gates surrounding cropped areas are appropriate to prevent entry.

The EU (Good Agricultural Practice for Protection of Waters) Regulations, 2014 includes requirements regarding farm manures. The Regulations aim to protect waters against pollution from agricultural sources, with the primary emphasis being on the better management of livestock manures and other fertilisers [96].

Farm manures which undergo adequate treatment to destroy or reduce pathogens can be used in primary production of fresh produce. However, incomplete or poor treatment can lead to survival of pathogens, contamination of produce in the field and foodborne illness in consumers who consume the produce [94]. As pathogens will die over time, storage of farm manures can be used as a treatment. Storage as a treatment relies on the passage of time, concentration of bacteria, dry matter content and aeration [30,] in conjunction with environmental factors such as temperature, pH, moisture and sunlight, to reduce pathogens.

The European Commission has indicated that the storage time for batch stored solid manures and slurry will vary according to region and climate etc [50]. It recommends that farm manures are stored as a batch for at least three months with no additions of fresh manure to the store during this period [50]. It also recommends batch storage of slurry for six months when no other treatment is applied, e.g. addition of quick or slacked lime to raise pH to 12 for at least two hours followed by storage for at least three months prior to use [50].

Composting is another common treatment in which solid farm manures are digested, aerobically or anaerobically, by microbial action [94]. When composting is carefully controlled and managed, and appropriate conditions are achieved, pathogens will be destroyed [29, 94, 97]. Composting, like storage, used as a treatment, should also be a batch operation. It should involve regular turning, i.e. at least twice within the first seven days, of the manure heap for the first 7-14 days to allow internal temperatures to rise to 55°C or greater for up to three days [30, 50]. This will help destroy most bacterial pathogens, but temperatures should be monitored with calibrated thermometers. If manure heaps are left static and not turned regularly, survival times of pathogens can be longer. Following this, the compost should be left for at least three months to mature before being used [29, 94, 97]. It is recommended that a front loader or purpose-built compost turner is used to turn compost heaps [50].

Other treatments for farm manures including pasteurisation, lime treatment, heat drying, anaerobic digestion, alkali stabilisation and aerobic digestion, are available [14, 30]. Teagasc and Cré (Irish Composting Association) can provide further information to growers on composting. A national standard on 'Quality Requirements for a Compost Manufactured From Source Segregated, Separately Collected, Biodegradable Materials', i.e. Irish Standard 441:2011, was published in 2011 by the National Standards Authority of Ireland.

Manure storage and treatment sites should be situated as far as is practical, from fresh produce production and handling areas. The minimum distance will depend on such factors as farm layout and slope of the land, what run off controls are in place, the likelihood of spread by wind or heavy rainfall and the quantity of manure and how it is contained. Where run off, leaching, or wind spread is a concern, barriers or physical containment should be considered. Storage on concrete slabs or in clay lined lagoons may reduce the potential for leachate to enter the groundwater. Covering manure heaps will protect them from rainfall that may result in leachate.

Recommended GAP for the use of farm manures are outlined in Table 6 below [11, 14, 29, 20, 30].

Table 6. Recommended Good Agricultural Practices for Use of Farm Manures

1	Growers who use farm manures and other soil amendments should take account of the source and/or storage/treatment these materials have undergone before use and be cognisant of any risks to food safety regarding their use with fresh produce.
2	Growers who purchase or take supply of farm manures from external suppliers should ensure that all materials supplied do not introduce additional physical, chemical or biological hazards.
3	Farm manures and slurry should be stored as a batch for a minimum of three and six months respectively with no additions of fresh manure or slurry during this time, before use on land.
4	If composting is used to treat farm manures, it should involve regular turning of the manure heap for the first 7-14 days to allow internal temperatures to rise to 55°C or greater, for up to three days. Following this, the compost should be left for at least three months to mature before being used on land.
5	Farm manures should be applied to soil prior to produce planting and harvesting.
6	The interval between application of farm manures, produce planting and harvesting should be maximised to reduce the level of pathogens and the risk of contaminating fresh produce.
7	No farm manure (including treated) should be applied to a growing fresh produce crop.
8	Record the source, type, date and time of application of farm manures used.

5.2 Biosolids

Biosolids, i.e. treated sewage sludge, are the organic by-products of urban waste water treatment, which once treated to an approved standard, may be used as a fertiliser/soil conditioner in agriculture. Current best practice for management and treatment of sewage sludge from urban waste water treatment for use in agriculture is in accordance with the Department of the Environment, Community and Local Government Codes of Good Practice [77].

Unlike farm manures, there is an increased risk that biosolids may contain contaminants such as heavy metals and organic micro-pollutants [21]. There remains significant data gaps in our knowledge and understanding regarding the effects these materials and others may have on food safety if land-spread on agricultural land used for food production [11]. **While biosolids are approved for use in agriculture, it is recommended that they are not used for growing fresh produce** [11, 77].

5.3 Inorganic Fertilisers

Inorganic fertilisers are generally manufactured using chemical processes. While these fertilisers are generally not a source of pathogens, growers should ensure that they follow manufacturer's instructions for use and prevent contamination of the fertiliser due to the use of contaminated water or equipment used to apply them.

As with other soil amendments, growers who purchase or take supply of inorganic fertilisers from external suppliers should ensure that all materials supplied do not introduce additional hazards, e.g. use reputable sources/suppliers to help ensure authenticity.

5.4 Application of Soil Amendments

The application or land-spreading of soil amendments such as farm manure should aim to control, reduce or if possible, eliminate the risk of contamination of water and fresh produce [9-10, 98]. The method, timing and rate of spreading farm manures can affect the survival of pathogens and increase the contamination of both surface and groundwater due to run off [11]. Land-spreading should only take place during specific times of year, in accordance with application rates, minimum distance from water sources and other restrictions as set out under the European Union (Good Agricultural Practice for Protection of Waters) Regulations, 2014 [96].

Land-spreading should be done in such a way as to minimise or eliminate the production of aerosols that may contaminate fresh produce [31]. Typically, the equipment used for land-spreading of slurry is a vacuum tanker fitted with a splash plate. This system can transport and surface-apply large volumes of slurry. However, control of application rates using the vacuum tanker can be poor and result in either under or over application of slurry to the land.

The splash plate spreader (particularly when upwardly directed) also generates an aerosol that may be contaminated and which can spread over a wide area. Low-trajectory injection, e.g. trailing shoe, and band spreading techniques can reduce the risk of aerosol generation and potential contamination by aerosol drift to adjacent crops, grazing land, livestock and waterways. To further minimise aerosol drift, avoid spreading on windy days, particularly if spreading is upwind of a fresh produce crop.

Solid manures are typically surface applied using the rear discharge spreader or side-flinger spreader which then requires a second tillage operation, e.g. ploughing for incorporation into the soil. Better control of solid manure can be achieved with rear discharge spreaders than with side-flinger machines [11].

Farm manures should be ploughed into soil and not left on the soil surface. This will reduce the chance of run off and contamination of water courses. However, manures applied in this way are likely to dry more slowly and be less exposed to sunlight, thereby increasing the potential for pathogen survival [11]. It is important that crops are not planted immediately after land-spreading. The risk of contaminating fresh produce can be reduced by maximising this interval between land-spreading of farm manures and produce harvesting [11].

6. PESTICIDES

Pesticides comprise plant protection products and biocides. They are products designed to kill or control harmful organisms, i.e. pest, disease or weed. Plant protection products, e.g. herbicides, insecticides, fungicides etc., are required to protect crops and plant produce from damage caused by insects, fungi, weeds and other pests. Plant protection products will contain at least one active substance and have one of the following functions:

- To protect plants/plant products against pests/diseases (pre/post-harvest)
- Influence the life processes of plants
- Preserve plant products
- Destroy or prevent growth of undesired plants or parts of plants

Pesticides are by their nature, substances which interfere in the normal development of selected life forms. Most modern pesticides are also highly selective and only have an effect on those pests or plants to which they are applied. Biocides are chemicals used to suppress organisms that are harmful to human or animal health, or that cause damage to natural or manufactured materials. These harmful organisms include pests and microorganisms such as moulds and bacteria. Examples of biocidal products include insect repellents, disinfectants, preservatives, pest control products, anti-foulants and other industrial chemicals.

In Ireland, the Pesticides Control Division of DAFM is responsible for implementing the regulatory system relating to the authorisation, marketing and use of pesticides to ensure that they are safe to humans, animals and the environment.

The Pesticides Control Division, in conjunction with the Pesticide Control Laboratory, is also responsible for controlling pesticide residues in food in Ireland. Produce may not contain pesticide residues above certain prescribed levels called Maximum Residue Levels (MRLs) which are designed to check whether the user has correctly followed label instructions and is consistent with GAP. MRLs for pesticides have been established for most fresh produce including fruit, vegetables and cereals [99]. Overall, the objective is to minimise the total amount of pesticide used, while maintaining the safety of fresh produce.

As part of a routine monitoring plan, fresh produce placed on the market in Ireland is sampled and analysed for pesticide residue content. A risk analysis is carried out on all produce found to contain residues in excess of their respective MRLs. Depending on the results of the analysis, produce may be destroyed at the owner's expense and without payment of compensation. In accordance with the relevant statutory provisions, offenders may be liable to a fixed penalty notice, prosecution or both.

Whilst the introduction of European and Irish legislation has greatly improved the safety and conditions of use of pesticides, when used incorrectly, they may pose a hazard to food safety, the operator and the environment. Growers must be trained in the correct use of pesticides and are legally bound to use them in compliance with the label recommendations (see Sections 6.1 and 6.2).

6.1 Registration as a Professional User

Since November 2015, only registered professional users, i.e. person using pesticides in the course of their professional activities, such as operators, technicians, employees and self-employed people, both in the farming and other sectors, may apply plant protection products authorised for professional use.

To register as a professional user requires the applicant to have undertaken a mandatory level of training. Additionally, by the **26th of November 2016**, all boom sprayers greater than 3m and all blast and orchard sprayers are required to be regularly tested every five years until 2020 and thereafter, every three years by a registered Inspector of Pesticide Application Equipment. A list of registered inspectors is available from the Pesticides Control Division of DAFM.

The GAP in relation to a plant protection product, e.g. crop it may be applied to, application rate, etc., can change on occasion. Growers should not assume that a product approved for use on a crop in previous years is still allowed in subsequent years. Information on product and crop approval status can be obtained from the Pesticides Control Division of DAFM.

6.2 Labelling and Directions for Use

Labelling of pesticides is designed to ensure that all risks associated with the use of the product are highlighted. The label provides precise directions as to:

- The method of use and application
- The crops for which use is approved
- Rate(s) of product application
- Precautions to be taken when applying the pesticide
- Restrictions of use
- Safety directions

It is a legal requirement that the pesticide is handled, applied and stored in accordance with the label instructions. Failure to comply with the instructions may lead to risks to the operator, bystanders, consumers, or damage to crops or the environment.

It is important that growers read the product label and record all use of plant protection products on the day of application including the relevant Pesticide Control Service number from the product container used rather that from an invoice or other document.

Safe handling, storage and use are promoted through the inclusion of warning symbols and risk and safety phrases on the label. In order to ensure that pesticides are used safely, it is essential that all the directions for use and recommendations as detailed on the label are followed precisely. The information on the label should include the following:

- Maximum individual dose: The maximum dose of the product that may be applied in any one application
- Maximum total dose: The maximum dose of a product that can be applied to a given crop or within a given period
- Maximum number of applications: The maximum number of applications of a product that can be applied to a particular crop/situation over a given period
- Time of application: Identifies the optimum time of application (weed development stage/ crop growth stage/pest development stage) of a plant protection product to ensure maximum effect on the target organism
- Pre-harvest interval is established to ensure the level of any potential residue in the produce is below the MRL at harvest. Observance of the pre-harvest interval period is critical in preventing a breach of an MRL(s)
- Recommendations to wear personal protective clothing such as gloves, eye and face protection, etc. are included on the label (or off-label) as a result of dedicated toxicology trials and should be adhered to
- Plant protection products should only be tank-mixed with other products/substances listed on the label as being compatible

Growers should note that any surplus of pesticides from mixing or leftovers from tank washing should be disposed of in a manner that does not pose a food safety risk or a risk of environmental contamination. Ideally, you should only mix the volume of product required to treat a given area. Growers should also note that pesticide storage areas should be suitably located to minimise cross-contamination between pesticides storage and crops and be built in a manner that complies with relevant legislation, and be secure with limited access to authorised staff only.

6.3 Pest Control

Appropriate steps to minimise and prevent pests, i.e. rodents, birds, insects etc., from contaminating fresh produce, should be taken by growers. This should involve the pest proofing of the growing area, storage buildings, keeping doors closed as much as possible and removing waste from the farm surroundings which can attract pests.

Where necessary, bait points and traps should be identified and monitored regularly to assess pest activity. However, only authorised biocidal products to control pests should be used. Recommended GAP for pest control are outlined below:

- Use a licenced/approved, external pest control contractor where possible and ensure the:
    - Contractor can demonstrate competence, e.g. evidence including membership of a national trade association, training records or a third-party audit
    - Scope of contracted service is clearly defined, e.g. contract agreed and on file, and should include the number of bait points, map indicating location of bait points, frequency of contractor visits and bait changes and provisions for additional treatments where required to eradicate pests, e.g. during summer months when pest activity can increase
- Where pest control is handled by the grower themselves:
    - Ensure those responsible have appropriate training with records of this training kept on file by the grower. Training should include legislative requirements for pest control, selection of appropriate chemicals and devices, proofing methods and limitations of pest control
    - Provide dedicated storage facilities for pest control chemicals, traps and other products and limit access to this facility
    - As with contracted services, define and document the scope of pest control activities including the number of bait points, map indicating location of bait points, frequency of inspection and bait changes and provisions for additional treatments where required to eradicate pests

6.4 Sustainable Use Directive

The Sustainable use of Pesticides Directive 2009/128/EC (SUD) is a European Directive that seeks to establish a framework to achieve the sustainable use of pesticides [100]. The Directive is aimed at reducing the risks and impacts of pesticide use on human health and the environment and to promote the use of Integrated Pest Management (IPM) and alternative approaches or techniques to chemical use [100]. It introduces new requirements surrounding the advice on sale, supply and the use of plant protection products [100].

In general, pesticides should only be used where necessary and used at all times in accordance with label recommendations to minimise their impact on the user, consumers, animals and the environment.

Since 2014, all professional users of plant protection products have been required to operate to the general principles of IPM, which are designed to help users of plant protection products reduce reliance on their use, thereby reducing the risks associated with such use, e.g. crop rotation, use of resistant/tolerant cultivars, balanced fertilisation, liming and irrigation practices etc.[100].

Records proving implementation of an IPM system must be maintained by all growers. If using a plant protection product, the reason for its use should be recorded in the Pesticide Application Record sheet. A 'tick box' worksheet has been designed by DAFM to enable growers demonstrate how they are adopting the general principles of IPM. General guidance on IPM is also available from DAFM.

7. HARVESTING AND POST-HARVEST PRACTICES ON FARMS

Harvesting and post-harvest practices involve significant contact between fresh produce and equipment, workers, water, the field environment and various cutting, picking, packing, transport and storage operations. All of these practices have the potential to contaminate fresh produce. Therefore, GHP in harvesting are important to prevent or minimise the risk of fresh produce contamination [3, 9-10, 23-24, 27, 29, 37, 101]. This is particularly important for fruit and salad crops that may not be washed, peeled or cooked by the consumer before consumption. While most contamination of fresh produce occurs in the field before and during harvesting, post-harvest practices can magnify and spread contamination [101-103]. Hygiene, health and facilities for agricultural workers are detailed in Section 8.

7.1 Mechanical Equipment

Mechanical harvesting of fresh produce is commonly used in Ireland [29, 104]. Tractors, trailers, spreaders, conveyors belts and other equipment can be a source of contamination. The key GAP for growers and all other food handlers are outlined below [9-10, 27, 104-105]:

- Consider developing written cleaning schedules for all equipment including frequency, cleaning practice and post-cleaning hygiene inspection
- Have daily start-up checks for cleanliness with documented records
- Fuel, oil and lubricant leaks from equipment should be considered physical hazards and included in daily start-up checks
- Ensure that someone on the farm has responsibility for ensuring that equipment is used correctly and cleaned appropriately
- Be aware of the farm layout and traffic flow that may allow a tractor or other equipment to contact a contamination source, e.g. manure, before entering a fresh produce site
- Vehicles such as tractors should not be driven through areas of farm manure or run off before entering fresh produce sites or between sites or storage areas
- Technical specifications from equipment manufacturers for usage and maintenance should be followed
- When purchasing new or previously used equipment ensure that its use is suitable for fresh produce and that it will not introduce unforeseen hazards
- Ensure that all equipment is designed to allow easy dismantling and cleaning, i.e. good sanitary design
- Harvesting equipment and machinery should be periodically cleaned and sanitised

- Spraying equipment should be serviced and calibrated at least annually. Sprayers should be calibrated at a pre-determined frequency, based on a risk assessment
- Dedicated scales and equipment used for pesticide mixing should be calibrated at a pre-determined frequency, based on a risk assessment

7.2 In-Field Harvesting

The key GAP for growers and all other food handlers related to in-field harvesting and packing is outlined below [3, 9-10, 27, 29-30, 37, 101]:

- Gross soil and mud should be removed from the produce before it leaves the field, e.g. when leafy produce is harvested it may be cut at the root or it may have roots intact. The amount of soil contamination is expected to be greater for the latter. However, it is acknowledged that this may not always be practical in wet conditions
- Containers, storage bins, crates and other storage equipment should not be placed directly onto soil in the field as this could transfer contamination to fresh produce during stacking
- Containers, storage bins, crates and other storage equipment coming into contact with fresh produce must be regularly cleaned and sanitised
- Containers, storage bins, crates and other storage equipment should not be used for carrying materials other than harvested fresh produce
- During use, containers, storage bins, crates should be re-cleaned and dried between loads, if possible
- When not in use, containers should be stored in a manner that minimises contamination and access by pests
- Containers that are damaged or unable to be cleaned should be discarded
- Tools use to cut, trim or core fresh produce in-field such as knives should be cleaned and disinfected after each use
- If possible, tools should be identifiable to a particular worker to facilitate verification of cleaning and disinfecting daily
- Tools, e.g. knives, used to cut, trim or core fresh produce should be regularly inspected for damage
- Potable water should be used in all cleaning and sanitation of storage containers and tools used for in-field harvesting

7.3 Waste Management

Poor waste management and handling of fresh produce can impact on both the safety and quality of fresh produce. The following GAP is recommended in relation to waste materials on site:

- Have documented procedures for the handling and management of all waste materials on site
- Minimise the accumulation of waste materials on site
- Ensure the regular collection and disposal of waste materials, e.g. pesticide containers, by approved waste hauliers
- Ensure records of collection/disposal and agreements with hauliers are kept on file
- Where the grower or competent authority deems fresh produce to be unfit for human consumption it should be clearly identified as waste and segregated from other fresh produce
- Fresh produce which cannot be made safe by further processing should be disposed of by approved waste hauliers to avoid contamination of other fresh produce or agricultural inputs. In some instances, where fresh produce is unsalable, e.g. damaged, it can be spread onto fields, ploughed into the soil or used for animal feed
- Packaging waste or other non-produce related waste should be removed from the harvesting area
- All waste water produced on site must be disposed of in a manner that does not cause pollution
- Where organic waste materials are composted on site, all measures must be taken to minimise the risk of contamination to the fresh produce

7.4 Transportation

The key GAP for growers and all other food handlers related to transportation of fresh produce are outlined below [9-10, 27, 29]:

- Ensure that vehicles used to transport fresh produce are not the same as those used for waste, rubbish, farm manure etc., and ensure that produce containers do not come into contact with such vehicles

- Vehicles and containers for transporting crops should be built to minimise damage to fresh produce and to avoid access by pests. They should be made of non-toxic materials that permit easy and thorough cleaning. They should be constructed in a manner to reduce the opportunity for potential contamination from physical objects such as glass, wood etc.
- Potable water should be used for all cleaning and sanitation of fresh produce containers and transportation vehicles
- Ensure that someone on the farm has responsibility for ensuring that vehicles and containers used for storage and transportation from the field are maintained, used correctly and cleaned appropriately

7.5 Cooling

For some products such as leafy greens, rapid cooling is carried out within two to three hours of harvesting to maintain quality. Many methods of cooling are available and their use depends on the type of fresh produce and its optimal storage temperature:

- Vacuum cooling, e.g. leafy greens such as lettuce
- Water (hydro) cooling by immersion or spraying, e.g. leafy greens, carrots etc.
- Forced air cooling, e.g. leafy greens, tomatoes, peppers etc.
- Static or room cooling, e.g. leafy greens, tomatoes, apples, berries etc.

Typically, the temperature of fresh produce will be similar to the air temperature, which depending on the time of year, can vary enormously in Ireland. Produce is best harvested early in the day, i.e. when night dew has lifted, to prevent the build-up of field heat that must then be removed by a cooling process [106].

Cooling of fresh produce can lead to cross contamination and/or internalisation of pathogens in fresh produce [107-111]. The key GAP for growers related to cooling is outlined below [9-10, 14-18, 27, 46, 107-108, 110]:

- Water and/or ice used for cooling should be of potable quality
- Water should only be used once and not recirculated unless suitably treated following use
- Low density fresh produce, e.g. lettuce, with open surfaces should be clean before cooling to prevent the internalisation of microorganisms
- Condensate and defrost water from cooling equipment should not drip onto fresh produce

- Air-cooling facilities must be clean and sanitary and the cool air must be free from microbiological contaminants
- The temperature of the cold storage for fresh produce should be controlled and monitored
- The inside of cooling systems should be maintained in a clean and sanitary condition

7.6 Facilities for Preparation, Storage and Packing

The key GAP for growers and all other food handlers related to facilities for the preparation, storage and packing of fresh produce are outlined below [9-10, 27, 29]:

- All facilities used for preparation, storage and packing of fresh produce should be constructed in a manner which prevents ingress of pests and be constructed of appropriate materials to facilitate maintenance, cleaning and disinfection:
    - The grounds and areas around facilities should be maintained to minimise sources of contamination
    - Floors should be constructed of durable, non-slip, water resistant materials and maintained in appropriate condition, i.e. no holes or cracks
    - Ceilings should be of sufficient height and facilitate easy cleaning and where necessary, sealed to avoid ingress of pests
    - Walls should be constructed of smooth, durable materials, be easily cleaned and impermeable to liquids
    - Appropriate drainage should be provided to avoid ingress of pests, e.g. open drains, and reduce risk of contamination of fresh produce
    - All pipes, pipe work, lagging and insulation, cables etc. must be clean, secure and properly constructed
    - Windows to the external environment should have sloping ledges, and if opening, be fitted with effective fly-screens
    - All windows, light bulbs, tubes, and any other glass or hard plastics, in facilities should be protected to avoid contamination of the fresh produce
    - Growers should implement procedures to deal with and minimise the contamination of product by broken glass or hard plastics, e.g. lighting should be permanently fixed and protected by shatterproof covering
- Where necessary, hygiene barriers should be put in place to limit access of staff and ingress of pests to facilities

- All staff should have access to appropriate hand-washing facilities adjacent or close to their work area, e.g. on entry to a packing facility
- All working surfaces, equipment and containers that come into contact with fresh produce should be made of materials which are appropriate, durable, easy to clean, disinfect and maintain [112-113]
- Harvest storage facilities should be cleaned before use and disinfected, if necessary.
- If pest activity is evident, measures should be taken to remove and exclude them
- All storage facilities [and anything that is going to come into contact with the food, such as packaging or crates] on farm must be designed and constructed in such a way as to minimise damage to fresh produce, to avoid access by pests, and to reduce the opportunity for potential contamination
- Potential contaminants, e.g. fuel, oil, waste materials etc., should be stored separately to prevent contamination of fresh produce

7.7 Packaging Materials

The extent of post-harvest packing will vary according to the type of fresh produce, as different fruit and vegetables may be handled and packed in different ways on the farm. Lettuce, for example, may be packed directly in the field immediately after harvest before going to distribution or transported to packing houses where it may be re-packaged. Alternatively, it may go for further processing where it is shredded, washed and bagged in a protective atmosphere [9-10]. However, regardless of what packaging materials are used and when, they must comply with the requirements of current legislation on food contact materials. Documents and specification relating to packaging materials used by growers should be kept on file [112-113]. Furthermore, all packaging materials should be stored appropriately to prevent damage and contamination.

7.8 Further Processing

Legally, at the level of primary production on the farm, primary products such as fresh produce may be transported, stored and handled, provided that these practices do not substantially alter the nature of the fresh produce. What this means for growers, is that limited practices are allowed on fresh produce if the status of the farm is to remain as a primary producer. These limited practices will include the following [23-24]:

- Normal harvesting techniques to remove the crop from the field and/or produce from the plant
- Packaging in the field without further treatment
- Sorting and grading of fresh produce
- Removal of leaves from fresh produce
- Topping and tailing of fresh produce
- Washing of fresh produce
- Packing without the application of packaging gases or the removal of gases
- Storage and transport of fresh produce

Other processes carried out at the farm that are likely to alter the nature of fresh produce and/or introduce new hazards are considered processes outside the scope of primary production. These will include the following processes [23-24]:

- Peeling
- Cutting, slicing, dicing and other size reduction methods
- Packing with the application of packaging gases or the removal of gases

If such further processing is carried out at the farm, additional requirements as outlined in Annex II of Regulation 852/2004, will apply [23].

8. HYGIENE, HEALTH AND FACILITIES FOR AGRICULTURAL WORKERS

All staff involved in directly handling fresh produce and also those workers indirectly involved, e.g. truck drivers, pest control personnel, buyers, equipment operators etc., must be aware of basic hygienic practices.

8.1 Hygiene and Health

Food handlers involved in harvesting can contaminate fresh produce as easily as those food handlers involved in further processing activities. This is especially important for crops such as fruit, scallions, leeks and lettuce that involve labour intensive harvesting and produce handling. For example, infected farm workers are considered the major source of viruses which cause foodborne illness through fresh produce [3]. The key GHP for growers in relation to staff hygiene and health are outlined below [9-10, 27, 114]:

- Before commencing employment, all new staff, including temporary staff, should complete a medical questionnaire or be passed as fit to work with food by a medical doctor
- Staff should receive basic training in personal hygiene to include toilet use, and techniques for hand washing and drying
- Staff should wear suitable protective clothing and footwear, as appropriate
- Staff suspected or known to be ill should not be allowed to handle fresh produce
- Staff should report any illness to employers and be excluded from work for an agreed period based on medical advice
- Growers should note that all visitors or sub-contractors should be made aware of the hygiene and health principles before entering the premises or commencing work

8.2 Facilities for Agricultural Workers

The key GHP for growers in relation to facilities for agricultural workers is outlined below [9-10, 27, 114]:

- Changing facilities should be provided to ensure that staff change their clothes, remove personal items, use toilet facilities and wash their hands before entering the harvesting area
- Prominently displayed signage to remind and encourage staff to hand wash should be provided in toilets, production entrances etc. and instructions provided in all appropriate languages
- Hand-washing facilities should include the provision of hot water, i.e. typically water at 38-40°C, preferably with hands-free operation, liquid soap, single-use towels or hand driers
- Staff facilities, e.g. washing hand units, canteen, lockers for personal belongings and mobile toilets, should be located within 500m, i.e. approximately a five minute walk, of the in-field work area
- Toilets and hand-washing facilities should be designed to allow removal of waste products without contamination of the site and/or fresh produce
- The use of portable toilets is not recommended. If portable toilets are used, they should not be emptied or cleaned on the fresh produce site, near irrigation water sources or equipment used in harvest. It should be noted that portable toilets and hand-washing units might not be supplied with 'hot' water
- Designated staff and areas for cleaning and storage of portable toilets should be identified by growers. A third party approved cleaning contractor should be considered for cleaning and servicing the toilets

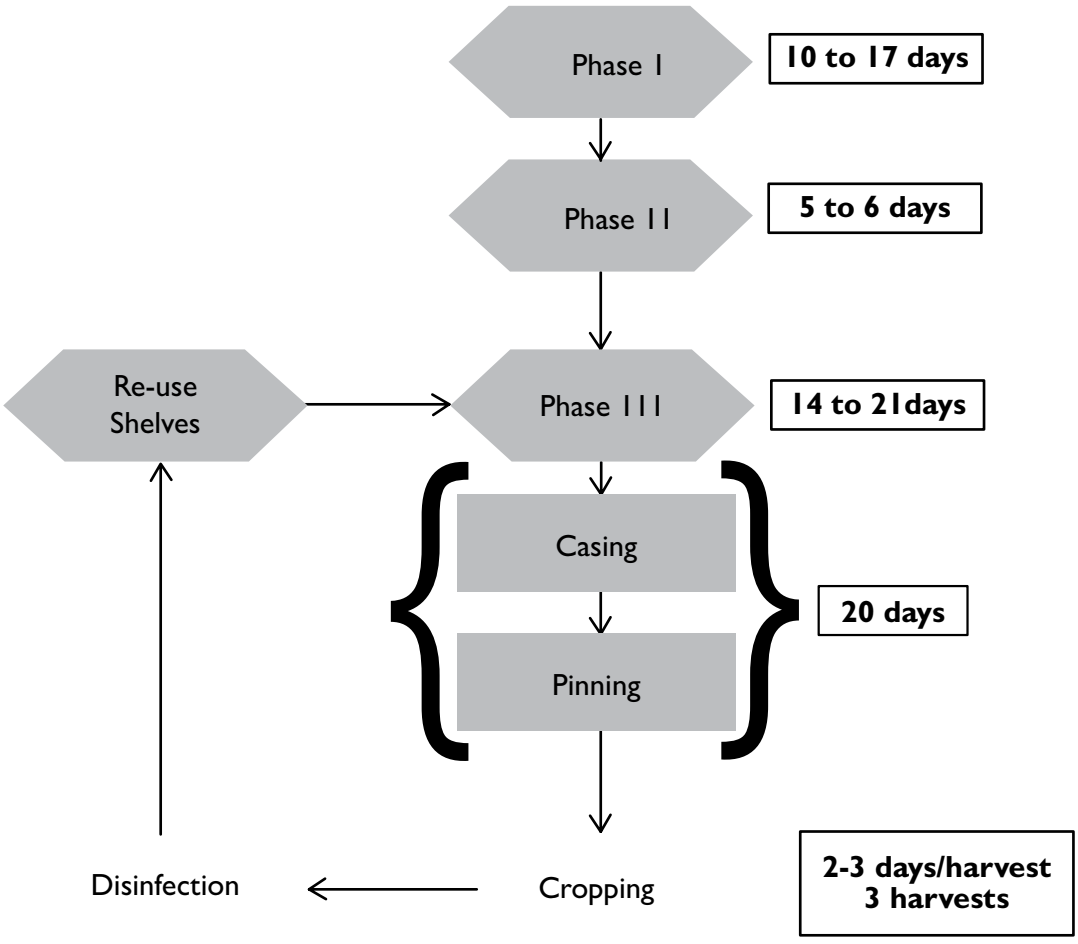
9. MUSHROOM PRODUCTION

The most commonly cultivated edible mushroom species in Ireland is *Agaricus bisporus*, though other species are also grown. This section outlines the primary production of the *Agaricus bisporus* species and specific issues related to GAP.

9.1 Commercial Production of *Agaricus bisporus*

The commercial production of *Agaricus bisporus* in Ireland typically follows six key steps as outlined in Figure 2:

Figure 2: Typical Steps in the Commercial Production of *Agaricus bisporus*



The six steps include Phase I mushroom substrate, Phase II mushroom substrate, Phase III mushroom colonisation of substrate, Casing, Pinning and Cropping (Figure 2). As *Agaricus bisporus* is a saprophytic fungus, i.e. a term used to describe fungus which obtains nutrients from dead organic matter, it is commercially grown in composted and pasteurised substrate, i.e. mushroom substrate, which provides nutrients for the mushrooms to grow. Typically, mushroom substrate preparation takes places in two phases, i.e. Phase I and Phase II.

Phase I: Mushroom Substrate Initiation

Mushroom substrate is a mixture of wheat straw and manure (either horse or chicken) which is moistened and mixed together with nitrogen supplements and gypsum, i.e. calcium sulphate dehydrate, as a conditioning agent if required. Following mixing, the composting process will begin with the growth and reproduction of microorganisms releasing heat, ammonia and carbon dioxide, i.e. aerobic fermentation process. Forced aeration is sometimes applied to improve the efficiency of this process.

The moisture, oxygen, nitrogen and carbohydrate content of the mushroom substrate are tailored to favour the growth of *Agaricus bisporus*. Every two to three days for approximately two weeks (depending on the nature of the material), the substrate is watered and turned to maximise the composting process. Typically, the Phase I process will be complete when the mushroom substrate has changed colour, has a soft pliable texture, a moisture content between 68% to 74% and a strong smell of ammonia.

Phase II: Pasteurisation and Conditioning

The purpose of the Phase II process is to eliminate any insects, nematodes, wild fungi species and remove any remaining ammonia. Phase II mushroom substrate consists of a controlled, temperature dependent process to allow certain microorganisms to grow and reproduce. These microorganisms will produce nutrients or serve as nutrients for the *Agaricus bisporus* mycelium, i.e. the vegetative part of the fungus, to develop, preventing other organisms from growing. At the end of Phase II, the nitrogen content will have built up by approximately 0.5%.

Phase III: Mycelia Colonisation of Substrate

Commercial mushroom spawn is grain which has been inoculated with propagated mycelium. This spawn is distributed and mixed thoroughly with the Phase II mushroom substrate. Under optimal temperature and moisture conditions, the spawn grows in all directions producing a network of white thread mycelium. The mycelium then colonises the mushroom substrate and the rate and distribution of colonisation depend on mushroom substrate quality, moisture and temperature. The complete spawn run is typically completed in 15 to 18 days.

9.2 Growing Rooms

Mushrooms should be grown in specially constructed growing rooms, i.e. tunnels or houses. However, while there are no standard specifications for growing rooms, it is important to consider the following:

- Use sealed cement floors with appropriate drainage for cleaning and disinfection
- Avoid flat roofs to eliminate condensation dripping onto the growing beds
- Use filtered air control to prevent entry of insects and airborne spores
- Clean and/or replace all filters regularly
- Do not recycle unfiltered air between different growing rooms
- Carefully control and monitor temperature, carbon dioxide and humidity
- Ensure the growing room is pest proof
- Control and limit access of staff to growing rooms

9.3 Growing Containers

The most commonly used containers for growing mushrooms in Ireland are shelves typically constructed out of galvanised metal to avoid rusting and to facilitate cleaning and disinfection.

9.4 Hygienic Procedures

Mushrooms have been associated with *Salmonella* and *Listeria monocytogenes* contamination and producers should consider these organisms a risk. In addition to the good agricultural and hygiene practices outlined in Sections 3 to 8, the following are some key points which can be used to reduce food safety risks in mushroom production:

- Growing areas should be sealed at all but one entrance, with foot baths supplied at the entrance
- Ensure that fully documented, scheduled, effective cleaning and disinfection procedures are in place and that staff carrying out this work are adequately trained and supervised
- Pickers and equipment should have allocated growing rooms and be restricted to these areas only
- Pickers should have pre-assigned equipment, e.g. knives, trays, scales etc.
- All equipment should be cleaned and sanitised using potable water
- Thoroughly disinfect, i.e. cook-out, the last mushroom crop from each house after harvesting
- Spent mushroom substrate, i.e. at the end of the harvesting, should be removed and should not be reused for further mushroom cultivation unless it has been pre-treated

10. SPROUTED SEED PRODUCTION

Sprouted seeds are young seedlings obtained from the germination of seeds and comprise different types of products obtained from seeds, according to the part of the plant which is collected and consumed, and in particular, whether the seed is still present or is removed [115].

Under the current legislation, the term 'sprouted seeds' is not defined but rather 'sprouts' are defined as 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 [116]. However, for the purposes of this document, the generic term 'sprouted seeds' will be used and will include sprouts, i.e. beansprouts and other speciality sprouts, where the seed is consumed, shoots and cress [115].

10.1 Background and Hazard Identification

Sprouted seeds are produced in a different manner to other fresh produce in primary production and this difference makes them more susceptible to microbial contamination. The process involves soaking seeds in water and then placing the seeds in a warm humid environment for a number of days to allow germination and growth. However, if pathogens are present in or on the seed or in the water, these conditions are ideal for their growth. In comparison to other fresh produce, sprouted seeds pose a high risk because of the potential for pathogens to grow during the production process [1].

Following a large food poisoning incident across Europe (but predominately France and Germany) in 2011, EFSA evaluated the public health risk of pathogenic bacteria that may contaminate seeds intended for sprouting [115]. Recognising that sprouts are generally consumed or minimally processed, EFSA concluded that sprouted seeds are ready-to-eat foods with specific food safety concerns because certain pathogenic bacteria can contaminate seeds and grow during sprouting [b]. EFSA indicated that preventing the initial contamination of seeds during production, storage and distribution was critical to food safety as there are currently no methods to eliminate pathogens in all types of seeds used for sprouting [115].

In 2013, the European Union enacted four new pieces of legislation in relation to sprouts and seeds intended for the production of sprouted seeds [116-119]. The new regulations established stringent rules to minimise food safety risks including new traceability, microbiological testing, and approval/ registration requirements for operators and importers of seeds for sprouting from third countries. The new Regulations [116-119] also imposed new requirements on seed producers and suppliers in third countries, in line with the good hygiene practices laid out in Regulation 852/2004, i.e. products from outside of Europe must now be imported with a certificate attesting their hygienic production [23].

[b] Although EFSA considered sprouted seeds as ready-to-eat in its 2011 opinion[115], the FSAI has recognised that they can be non ready-to-eat, provided the food business has validated cooking instructions as per the decision tree for determining the ready-to-eat status of food in the FSAI's Guidance Note No. 27 [120]

10.2 Approval

The production of sprouted seeds, unlike other fresh produce produced at primary level, requires approval from DAFM [121-122]. The basic requirements for this approval are listed in the Annex to Regulation (EU) No 210/2013 [118]. However, producers should contact DAFM for further information before beginning production as approval may not apply in all cases (see Appendix 1).

10.3 Seed Supply and Delivery

In Ireland, only imported seed is used in the commercial production of sprouted seed. Seed which is supplied and used for food production in Ireland comes from a variety of countries including Italy and China. The seed is typically supplied in bulk bags of 25kg. The following good practices are recommended when ordering and taking delivery of seed for use in producing sprouted seeds [27, 115]:

- As seeds are the most likely source of contamination, it is important that they are always purchased from a reputable supplier
- Seeds should be packaged and delivered in non-recycled solid bags
- Examine bags for signs of physical damage, e.g. wet, torn, opening from pests, and contamination, e.g. water stains, faeces, urine, insects, rodents etc.
- Some producers use UV light to identify contamination such as urine on bags. If bags are damaged or contaminated they should not be used for sprouting
- Ensure that appropriate documentation (for traceability and recall purposes) accompanies all deliveries imported into the EU/Ireland
- Ensure that the individual bags are appropriately labelled to identify source, lot/batch etc.
- Seeds should be stored in a clean, dry environment under conditions that prevent mould and bacterial growth and contamination, e.g. off the floor and away from the walls to reduce rodent contamination
- Ensure seeds are stored separately from other agricultural seeds and food production areas
- Opened bags should be stored in closed containers
- Ensure that seeds meet a specification of absence of pathogens to ensure that sprouted seed will meet the legal criteria of Regulation (EC) 2073/2005 [47, 117, 121, 123]

10.4 Premises and Equipment

The production of sprouted seed is typically an indoor activity in Ireland. Premises are required for production. The following good practices are recommended [27, 115]:

- The equipment materials, internal design and layout of the production area should permit good food hygiene practices, including protection against cross-contamination between and during operations and cleaning and sanitation
- The use of disused lorry containers as growing rooms for sprouted seed should be avoided as they are difficult to clean and sanitise
- Adequate drainage and waste disposal systems and facilities should be provided and be designed and constructed so that the risk of contaminating fresh produce is avoided
- Storage, seed rinsing, disinfection, germination, washing and packaging areas should be physically separated from each other

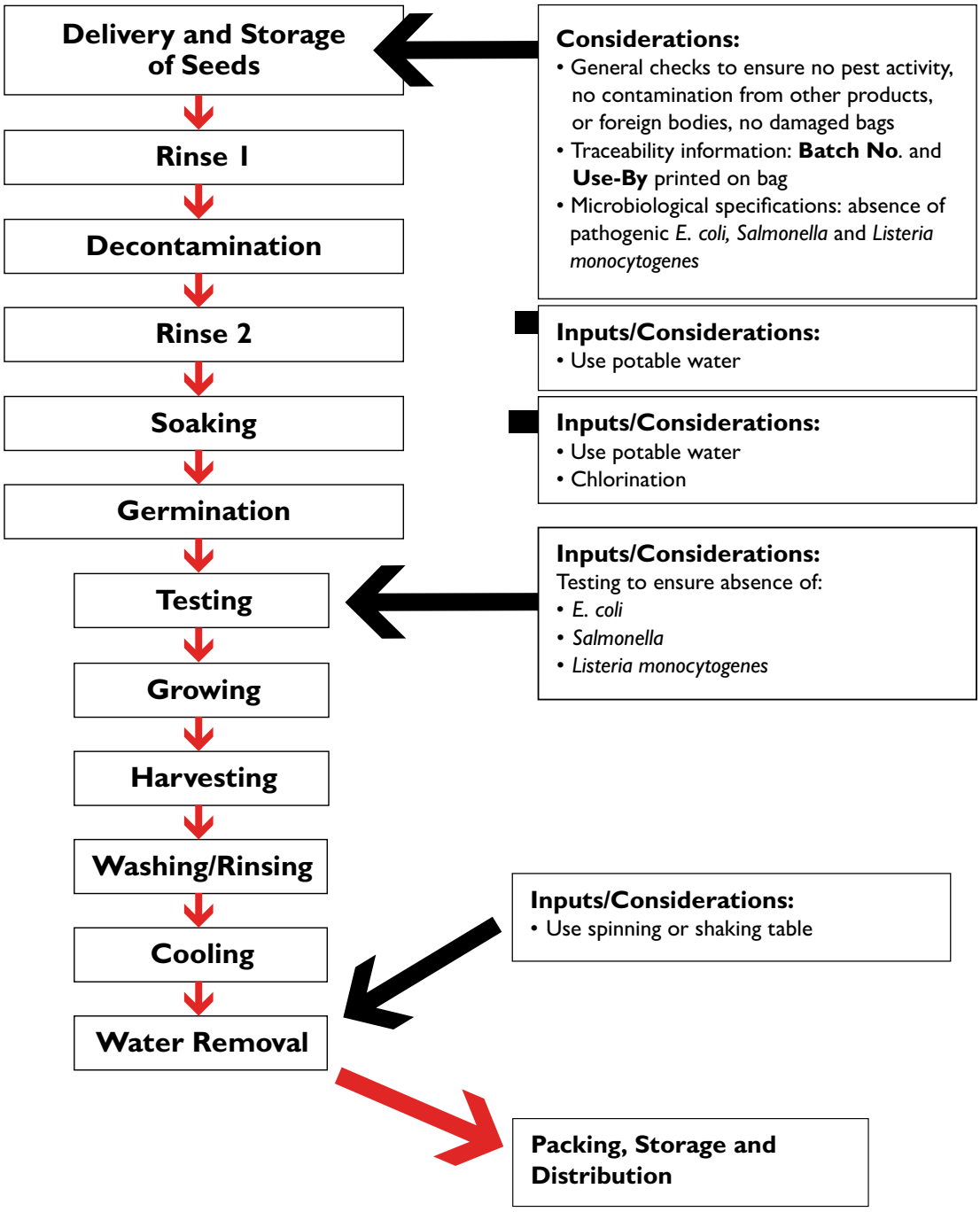
10.5 Water

Because of the specific microbiological hazards associated with sprouted seeds, only potable water which meets the requirements of the European Union Drinking Water Regulations should be used by producers [46]. An information leaflet on potable water quality for food businesses is available from the FSAI [53].

10.6 Control of Production Steps

A brief summary of the typical steps in sprouted seed production in Ireland is shown in Figure 3. However, sprouted seed production across the EU is diverse and a wide range of seeds are used to produce sprouted seeds, shoots or cress [115]. It is important to note that the hygienic design as well as the size of sprouted seed production facilities and the equipment used, varies. Some production facilities specialise in a few types of seeds, whereas others produce a wide range of sprouted seeds [115].

Figure 3. Typical Steps in Sprouted Seed Production in Ireland



Rinse 1

The following good practices should be followed to clean and remove organic/foreign matter from the seeds before use [27, 115, 124]:

- Use only potable water
- Rinsing should be carried out in an area separate to germination and packaging areas to avoid contamination of seed by non-decontaminated seeds and/or chemicals used in the process
- Seeds should be rinsed by agitation in large volumes of potable water (ratio of water to seeds 5:1 or greater) to maximise surface contact with the seeds and facilitate removal of as much foreign and organic matter as possible
- Repeat rinsing a number of times with fresh potable water until as much foreign and organic matter as possible is removed and the rinse water appears clear

Microbiological Decontamination

Despite considerable research, no chemical method of decontamination has been shown to ensure pathogen-free seeds for use in sprouted seed production. There are very few treatments that will achieve a substantial reduction in pathogen numbers, i.e. greater than 5 logs. Good agricultural and hygiene practices (including during the growing of seeds) remain the best way to minimise the risk of hazards occurring [115].

Not withstanding this, decontamination treatments do provide reduction of pathogen numbers, i.e. 1 to 3 logs, on seeds, thereby reducing risk, and their use is recommended. In Ireland, the most commonly used chemical method of decontamination is the use of chlorine. The following good practices should be followed to when decontaminating seeds using chlorine [27, 115, 124]:

- Use only potable water
- Carry out decontamination in an area separate to germination and packaging
- Only use approved chlorine products (biocidal products like chlorine can only be distributed and used in Ireland if they have been notified to or authorised by DAFM) and follow manufacturers' instructions for use
- Use freshly chlorinated water for each batch/lot of seed
- Clean and disinfect containers used in microbiological decontamination before/after use
- Agitate the seeds in large volumes of chlorinated water (ratio of chlorinated water to seeds 5:1 or greater) to maximise surface contact with the seeds

- Measure and record the duration of treatment and the concentration of chlorinated water used

Rinse 2

Following decontamination, seeds should be rinsed again by agitation in large volumes of potable water (ratio of water to seeds 5:1 or greater) to maximise surface contact with the seeds and facilitate removal of the chlorine residues. If necessary, repeat the rinsing a number of times with fresh potable water to remove as much chlorine as possible.

Soaking (pre-germination)

Soaking is often necessary to improve germination. When soaking, the following good practices are recommended [27, 115, 125]:

- Use only potable water
- Seeds should be soaked in the potable water, or where possible, running potable water, for the shortest possible time to minimise microbial growth (typically at ambient temperature for three to a maximum of ten hours)
- After soaking, seeds should be rinsed thoroughly with cold potable water
- All containers used for soaking should be food grade and cleaned and disinfected prior to use

Germination

During germination, it is very important to keep the environment and equipment clean and disinfected to avoid contamination. Germination is typically carried out at high temperatures (28-30°C) for four to six days. However, some producers may use lower temperatures and extend the duration of sprouting. Germination and growth conditions depend on the type of sprouted seeds [115]. When germinating, the following good practices are recommended [27, 115]:

- Use only potable water
- The germination area should be physically separated from other production areas
- All equipment and containers should be cleaned and disinfected before use
- Where necessary, and when used, soils should be treated, e.g. pasteurised, to reduce microbial contamination

Harvesting

All equipment should be clean and disinfected before each new batch. Harvesting should be done with clean and disinfected tools dedicated for this use [27].

Final Rinse and Cooling

A final rinse is required following germination in order to remove the seed coat (hull), reduce the microbial load and cool the sprouted seed. During the final rinse, the following good practices are recommended [27, 115]:

- Rinse in cold (≤ 5°C) potable water to lower the sprouted seed temperature and reduce microbial growth. A rapid cooling of two to five minutes to reduce temperature to ≤ 5°C is recommended
- Ensure ice used in the process is made from potable water
- Water should be monitored and changed as needed between batches to limit cross-contamination
- Sprouted seed should be drained to remove excess water using appropriate clean and disinfected equipment, e.g. shaking table, centrifugal dryer, etc.

Packaging, Storage and Distribution

In packaging, storage and distribution, the following good practices are recommended [27, 115]:

- All packaging used must comply with the requirements of current legislation on food contact materials
- Pack the finished product in a separate area from that used for growing, washing etc.
- All finished product must comply with the requirements of current legislation on labelling and the label should facilitate traceability [126]
- Store finished product at ≤ 5°C to minimise microbial growth during the intended shelf-life of the product
- Transport vehicles should be refrigerated and cleaned and disinfected frequently
- Transport vehicles should protect the finished product from contamination during transportation
- Ensure regular monitoring of cleaning/disinfection and temperature of storage areas and transport vehicles

10.7 Traceability

The general provisions for traceability are outlined in Article 18 of Regulation (EC) No 178/2002 and provide for a one step backward/one step forward traceability system in all types of food business [127]. This means that a food business must have in place, a system which enables them to identify their immediate supplier(s) and their immediate customer(s), except when they are final consumers.

All food businesses must establish a traceability and recall system that can effectively identify and remove unsafe food from the market in the event of a food safety incident occurring [127]. The precise nature of the traceability and recall system is not defined in legislation but it should be accessible to other businesses, customers and the competent authorities [127]. However, whatever system is used, it should reflect both the scale and sophistication of the producers operations and be documented.

There are additional requirements for traceability under Regulation (EU) No 208/2013 for the production, processing and distribution of sprouted seed and seeds intended for the production of sprouted seeds [116]. Producers must keep and pass to the next food business, the following information [116]:

- Accurate description of seeds including the taxonomic name, i.e. Greek/Latin name
- The volume or quantity supplied
- The name and address of the food business from which they were dispatched
- The name and address of the owner, if different from the food business from which they were dispatched
- The name and address of the food business to which they were dispatched
- The name and address of the owner, if different from the food business to which they were dispatched
- A reference identifying the batch
- The date of dispatch

Note: *The above information should be passed to the next food business on the day of delivery in any form as long as it is easily retrievable.*

If a delivery comes from outside the European Union, a certificate must also accompany the consignment. The certificate must indicate that the consignment:

- Was produced under conditions which comply with the general hygiene provisions for primary production and associated operations set out in Part A of Annex I to Regulation (EC) No 852/2004 [23]
- Was produced under conditions which comply with the traceability requirements laid down in Regulation (EU) No 208/2013 [116]
- Was produced in establishments approved in accordance with the requirements laid down in Article 2 of Commission Regulation (EU) No 210/2013 [118]
- Meets a specification for absence of pathogens (pathogenic *E. coli*, *Salmonella* and *Listeria monocytogenes*) so that the sprouted seeds will be in compliance with the microbiological criteria laid down in Annex I to Regulation (EC) No 2073/2005 [123]

The aforementioned certificate must be similar to the model certificate set out in the Annex to Regulation (EU) 211/2013 [119]. Additionally, records of all the above traceability information, including the aforementioned certificates, should be kept up-to-date and be easily retrievable. It is strongly recommended that producers familiarise themselves with the FSAI's Guidance Note No. 10 on Product Recall and Traceability (Revision 3) [128].

10.8 Records

All producers should keep written records relating to the products produced and the operational controls used during their production [23]. The following good practices are recommended for keeping records [124]:

- All records should be available to competent authorities on demand and without delay and should be legible, complete, accurate, up-to-date and signed-off
- Records should include written procedures, controls, limits, product testing results, monitoring results, follow-up documentation, raw material suppliers, water analysis results (microbiological and chemical), cleaning and disinfection checks, pest control details, production volumes, traceability and recall systems and checks, storage/transportation temperature monitoring, packing details, customers, product distribution, consumer complaints, shelf-life testing etc.

10.9 Sampling and Testing

Regulation (EU) 209/2013 has introduced new microbiological sampling and testing requirements for establishments producing sprouted seeds which are summarised in Table 7 [117, 121, 123].

Table 7. Food Safety Microbiological Criteria [a]

Food Category	Microorganisms	Sampling Plan		Limits	Analytical Reference Method	Stage Where Criterion Applies
		N	C			
1.2 Ready-to-eat foods able to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes	*Listeria monocytogenes*	5	0	100 cfu/g [d]	EN/ISO 11290-2 [e]	Products placed on the market during their shelf-life
		5	0	Absence in 25g [f]	EN/ISO 11290-1	Before the food has left the immediate control of the food business operator who produced it
1.3 Ready-to-eat foods unable to support the growth of *L. monocytogenes*, other than those intended for infants and for special medical purposes [b-c]	*Listeria monocytogenes*	5	0	100 cfu/g	EN/ISO 11290-2 [e]	Products placed on the market during their shelf-life
1.18 Ready-to-eat sprouted seeds [g]	*Salmonella*	5	0	Absence in 25g	EN/ISO 6579	Products placed on the market during their shelf-life
1.29 Sprouts [g]	Shiga Toxin producing *E. coli* (STEC) O157, O26, O111, O103,O145 and O104:H4	5	0	Absence in 25g	CEN/ISO TS 13136 [h]	Products placed on the market during their shelf-life

Notes to Table 7

a Extract adapted from Regulation (EC) 2073/2005 as amended [123].

b Products with pH ≤ 4.4 or Aw ≤ 0.92, products with pH ≤ 5.0 and Aw ≤ 0.94, products with a shelf-life of less than five days shall be automatically considered to belong to this category. Other categories of products can also belong to this category, subject to scientific justification.

[c] Regular testing not required for certain ready-to-eat foods but excludes sprouted seeds

[d] This criterion shall apply if the manufacturer is able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit 100 cfu/g throughout the shelf-life. The operator may fix intermediate limits during the process that must be low enough to guarantee that the limit of 100 cfu/g is not exceeded at the end of shelf-life.

[e] 1ml of inoculum is plated on a 140mm wide Petri dish or on three Petri dishes of 90mm diameter.

[f] This criterion shall apply to products before they have left the immediate control of the producing food business operator, when he is not able to demonstrate, to the satisfaction of the competent authority, that the product will not exceed the limit of 100 cfu/g throughout the shelf-life.

[g] Excluding sprouts that have received a treatment effective to eliminate *Salmonella* spp. and STEC.

[h] Taking into account, the most recent adaptation by the European Union reference laboratory for *Escherichia coli*, including *Verotoxigenic E. coli* (VTEC), for the detection of STEC O104:H4[115].

Preliminary Testing of Seed

Unless exempted from preliminary testing, producers of sprouted seed must carry out preliminary testing on a representative sample of each new batch [c] of seeds when used for the first time. Representative samples of seeds can be [117, 121, 123]:

- 0.5% of the batch weight taken in 50g sub samples across the whole batch

or

- selected based on a structured, statistically equivalent sampling strategy, verified by the competent authority

For the purposes of performing the above preliminary testing, the producer of sprouted seed must sprout the seeds in the representative sample under the same conditions as the rest of the batch of seeds to be sprouted and test as per Regulation 2073/2005 which is outlined in (Table 7) [123].

[c] Under Regulation (EU) No 208/2013, a batch is defined as: quantity of sprouts or seeds intended for the production of sprouts, 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 [116].

Exemption from Preliminary Testing

When justified on the basis of the conditions outlined below, and authorised by the relevant competent authority, the sprouted seed producer may be exempt from preliminary testing of seed if [117, 121, 123]:

(a) The competent authority is satisfied that the sprouted seed producer implements a food safety management system in the establishment, which includes steps in the production process, which reduces the microbiological risk

and

(b) Historical data confirm that during at least six consecutive months prior to granting the authorisation, all batches of the different types of sprouts produced by the sprouted seed producer comply with the food safety criteria set out categories 1.18 and 1.29 of Table 7

When a sprouted seed producer is exempted from preliminary testing of seed, this exemption will only apply to batches of seed coming from existing suppliers. If a new supplier is used, preliminary testing of seed will be required. Sprouted seed producers should ensure that their seed supplier keeps them informed of any changes to the supply of seed.

Testing of Sprouted Seed and Spent Irrigation Water

Producers of sprouts shall take samples for microbiological testing at the stage where the probability of finding Shiga toxin producing *E. coli* (STEC) and *Salmonella* spp. is the highest, in any case, not before 48 hours after the start of the sprouting process.

Samples of sprouts shall be analysed and must comply with the food safety criteria set out in Categories 1.18 and 1.29 of Table 7. However, if a sprout producer has a sampling plan, including sampling procedures and sampling points of the spent irrigation water, they may replace the sampling requirement set out in Categories 1.18 and 1.29 of Table 7 with the analysis of five samples of 200 ml of the water that was used for the irrigation of the sprouts. In this case, the requirements set out for Categories 1.18 and 1.29 in Table 7 shall apply to the analysis of the water that was used for the irrigation of the sprouts, with the limit of absence in 200 ml.

When testing a batch of seeds, or their spent irrigation water, for the first time, sprout producers may only place sprouts on the market if the results of either microbiological analysis comply with the food safety criteria set out in Categories 1.18 and 1.29 of Table 7. As sprouted seeds are considered ready-to-eat, they must also comply with the food safety criteria set out in Category 1.2 and the process hygiene criteria 2.5.1 of Regulation (EC) 2073/2005 [123].

In all cases where samples are being tested, i.e. seed, sprouted seeds, sprouts, water etc. sprout producers should choose a laboratory that uses the correct ISO method (Table 7) and is accredited to ISO17025 standards.

Process Hygiene Criteria

Sprouted seeds are considered to be ready-to-eat foods and as such, producers should include the sampling of processing areas and equipment for *L. monocytogenes* as part of their sampling and testing scheme [117].

Sampling Frequency

Producers of sprouts shall take samples for microbiological analysis at least once a month at the stage where the probability of finding Shiga toxin producing *E. coli* (STEC) and *Salmonella* spp. is the highest, in any case, not before 48 hours after the start of the sprouting process.

10.10 Actions to be Taken in the Event of Positive Results

Seed contamination is thought to be sporadic, at low levels or unequally distributed throughout seed lots. Therefore, a negative result does not guarantee the absence of pathogens. However, a positive result allows a producer to avoid using contaminated seed lots. It should be remembered that even low levels of pathogens are a concern, given the ideal conditions during sprouting for these pathogens to multiply. If any of the analytical samples are positive for pathogens, the following actions should be taken by the sprout producer:

1. Suspend production
2. Place contaminated seed batch/lot on hold
3. Notify the competent authority
4. Notify the seed supplier
5. Notify customers (as applicable)
6. Investigate the source of the contamination
7. Consult with the competent authority
8. Do not recommence production until given permission by the competent authority

11. RECALL AND TRACEABILITY

All growers must establish a food recall and traceability system that can effectively identify and remove unsafe food from the market in the event of a food safety incident occurring [127].

The precise nature of the food recall and traceability system is not defined in legislation [127]. However, whatever system is used, it should reflect both the scale and sophistication of the growers operations. Excluding sprouts which have specific traceability requirements, the following is required for a grower's recall and traceability system:

- There must be documented traceability procedure(s) in place, and accessible to other businesses, customers and the competent authorities
- The scope of the traceability system must include all raw materials and services, e.g. seed, packaging, water, chemicals, etc., to be traced back to the suppliers and forward to customers, i.e. if supplying fresh produce to another business. Information which must be maintained to facilitate traceability will include, but is not restricted to, the following:
  - ✔ Names and addresses of suppliers
  - ✔ Nature of raw materials and services supplied
  - ✔ Dates of the transaction/deliveries
  - ✔ Supplier batch codes/lot numbers
  - ✔ Size of the delivery
  - ✔ Delivery records, e.g. invoices, delivery dockets etc.
  - ✔ Pesticide application records
- The traceability system must distinguish between and include fresh produce from other growers if supplied, e.g. growers may supplement their output to ensure continuity of supply throughout the season or supply other fresh produce items which they don't grow themselves
- There must be a documented recall/withdrawal procedure in place, on file and accessible to other businesses, customers and the competent authorities
- The recall procedure should be tested on a regular basis (at least annually) to ensure it operates correctly
- It is strongly recommended that food businesses refer to the FSAI's Guidance Note. 10 on Food Recall and Traceability (Rev 3) for further information [128]. Additional information and frequently asked questions are also available on the FSAI website

12. RECORD KEEPING

From a legal perspective, growers must keep and retain records relating to measures put in place to control hazards, i.e. GAP and GHP, in an appropriate manner and for an appropriate period, relevant to the nature and size of their operation. Growers must make relevant information contained in their records available to the competent authority and customers on request [23]. Growers producing or harvesting plant products must keep records on [23]:

- Any use (pre- and post-harvest) of pesticides (plant protection products and biocides), to include product name, Pesticide Control Service no., location, crop, area, rate of application, date of application, justification for application, and evidence of implementation of IPM
- Any occurrence of pests or diseases that may affect the safety of products of plant origin
- The results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health, e.g. microbiological or chemical tests on soil, water, work surfaces, staff, produce etc.

Growers can be assisted by other persons, such as agronomists and farm technicians, with the keeping of records [23-24]. In addition, records related to the following should also be kept by growers (as applicable):

- List of all suppliers and customers
- Records proving implementation of an integrated pest management system
- Harvesting records, e.g. information on produce harvested, date harvested, seed type/ variety including a batch code or other identifier, field location and/or growing structure, and yield or quantity harvested
- Source, date and time of water used for irrigation
- Source, type, date and time of application of soil amendments used

- Calibration of measurement equipment, i.e. this equipment should be calibrated and traceable to a national or international standard and records of calibration kept on file
- Traceability and recall records should be retained in a format that allows access in a timely manner by both the grower and the competent authority. Maintaining records of production and associated operations such as packaging and transport will help to identify sources of contamination in the food chain and facilitate product recall
- Records to demonstrate temperature control for fresh produce during storage and transport
- Records and results of laboratory testing including swabs, water, soil, fresh produce and pesticide residue analysis (as appropriate)
- Records of cleaning and sanitation operations for facilities and equipment
- Records/details of staff training and experience
- Records of officially approved waste hauliers used for waste collection and records of collection agreements

It is recommended that growers sign and date all records and hold on file for three years unless an alternative period is required by legislation or the relevant competent authority.

13. GLOSSARY

All definitions as laid down in Directive 98/83/EC, Regulation (EC) No 178/2002, Regulation (EC) No 852/2004, Regulation (EC) No 369/2005 [99], Regulation (EC) No 2073/2005, Regulation (EC) No 1881/2006, Directive 2009/128/EC and Regulation (EC) No 528/2012 will apply. For the purpose of this document, the following terms are defined below:

Active substance is any chemical, plant extract, pheromone or microorganism (including viruses), that has action against pests or on plants, parts of plants or plant products

Biocides are chemicals used to suppress organisms that are harmful to human or animal health, or that cause damage to natural or manufactured materials

Biosolids are an organic by-product of urban waste water treatment which, when treated to an approved standard are used as a fertiliser/soil conditioner in agriculture

Grower is a farmer or producer of fresh produce.

Good Agricultural Practices (GAP) are knowledge and practices applied to the production of safe fresh produce.

Good Hygiene Practices (GHP) relate to general, basic conditions for hygienic production of a fresh produce, including requirements for hygienic design, construction and operation of the plant, hygienic construction and use of equipment, scheduled maintenance and cleaning, and personnel training and hygiene.

Farm manures include both solid, e.g. farmyard manure, and liquid manures, e.g. slurry, dirty water and leachate from stored manures, and are applied to agricultural land in Ireland to improve soil fertility. The majority of farm manures used on Irish farms come from cattle and pigs [11]

Fresh produce refers to fresh fruits, vegetables, mushrooms, edible flowers as well as sprouts that have not been processed, i.e. raw, and altered in form, by peeling, slicing, chopping, shredding, or other treatment, prior to being packed for use by the consumer or a retail establishment. It includes washed and unwashed product

Pre-harvest incorporates all activities that occur before fresh produce is harvested

Post-harvest incorporates all activities that occur after fresh produce is harvested including cooling, cleaning, sorting and packing

Primary production is the production and growing of fresh produce. The following operations are associated with primary production therefore, the term 'primary production' in this guidance document, should be understood as primary production including these associated operations [23-24]:

- The transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature
- In the case of products of plant origin, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment
- The harvesting of wild mushrooms and berries and their transport to an establishment

Risk is a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s)

Risk assessment is a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation

Ready-to-eat food is food intended by the producer or the manufacturer for direct human consumption, without the need for cooking or other processing effects, to eliminate or reduce to an acceptable level, microorganisms of concern

Sprouts 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 seeds include sprouts, i.e. beansprouts and other speciality sprouts, where the seed is consumed, shoots and cress

Soil amendments are anything mixed into or onto soil to promote plant growth and health including farm manures, biosolids and inorganic fertilisers

Water *(clean)* is water that does not contain microorganisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food

Water *(potable or drinking)* is water which meets the requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption and S.I. No. 122 of 2014

Water *(non-potable)* is water which does not meet the requirements laid down in Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption and S.I. No. 122 of 2014

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APPENDIX 1. REGISTRATION AND APPROVAL OF PRIMARY PRODUCTION ESTABLISHMENTS

Registration

All food business operators are required to register with the competent authority under the EU Food Hygiene legislation, i.e. Regulation (EC) No 852/2004 of the European Parliament and of the Council on the Hygiene of Foodstuffs [23]. Food business operators who undertake primary production are required to register with DAFM. This registration is achieved when the food business operator completes a client application registration form which includes general information that is used to determine the risk posed by the food. A copy of the registration form and a list of frequently asked questions can be found on the DAFM website.

On receipt of the completed form, the details are recorded on the DAFM Register and the next unique primary food producer business role identifier is allocated. This unique client business role identifier has the format HFR followed by four numeric characters. The process is completed when a registration letter is issued as confirmation of registration. All registered food business operators are subject to regular unannounced inspections by DAFM to verify compliance with S.I. No. 432/2009 European Communities (Food and Food Hygiene Regulations). The register is maintained by the Crop Policy, Production and Safety Division of DAFM. The FSAI also has access to it.

Approval

In addition to registration all sprout producers, i.e. sprouts' 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, must also be approved by DAFM.

Approval is subject to food business operators meeting the requirements set out in Annex I of Regulation (EC) No 852/2004 and the requirements in the Annex to Commission Regulation (EU) No 210/2013 [23, 118]. Approval is achieved when the food business operator, following a pre-approval inspection, meets the conditions set out in the above legislation, but in particular, the following:

1. The design and layout of establishments to permit good food hygiene practices. 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 for 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 for washing food, where necessary. 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

Compliance with Commission Implementing Regulation No. 208/2013, Commission Regulation No 209/2013 and Commission Regulation No. 211/2013 is also required [116-117, 119] (see Section 10.2 for further information).

APPENDIX 2. RISK RANKING OF FRESH PRODUCE, BASED ON MICROBIOLOGICAL RISK

EFSA has indicated that the five top ranking groups of food/pathogen combinations in the following decreasing order of priority are [8]:

- *Salmonella* spp. and leafy greens eaten raw as salads
- *Salmonella* spp. and bulb and stem vegetables; *Salmonella* spp. and tomatoes; *Salmonella* spp. and melons; and pathogenic *Escherichia coli* and fresh pods, legumes or grain
- Norovirus and leafy greens eaten raw as salads; *Salmonella* spp. and sprouted seeds; and *Shigella* spp. and fresh pods, legumes or grain
- *Bacillus* spp. and spices and dry powdered herbs; norovirus and bulb and stem vegetables; norovirus and raspberries; *Salmonella* spp. and raspberries; *Salmonella* spp. and spices and dry powdered herbs, *Salmonella* spp. and leafy greens mixed with other fresh food of non-animal origin; *Shigella* spp. and fresh herbs, pathogenic *Escherichia coli* and sprouted seeds; and *Yersinia* spp. and carrots
- Norovirus and tomatoes; norovirus and carrots; *Salmonella* spp. and nuts and nut products and *Shigella* spp. and carrots

The following is reproduced based on the WHO/FAO report on microbiological hazards in fresh fruits and vegetables [9-10]:

Level I Priorities (Highest Risk)

Leafy green vegetables, e.g. spinach, cabbage, raw watercress, lettuce and salad leaves (all varieties), fresh herbs (coriander, basil, parsley), chicory etc., were accorded the highest priority based on the ranking criteria. The available data varied in completeness but the meeting concluded that there was sufficient information to indicate that, from a global perspective, leafy green vegetables currently presented the greatest concern in terms of microbiological hazards. Leafy greens are grown and exported in large volumes, have been associated with multiple outbreaks with high numbers of illnesses in at least three regions of the world, and are grown and processed in diverse and complex ways, ranging from in-field packing to pre-cut and bagged product. Such post-harvest activities contribute to the possibility of amplification of foodborne pathogens.

Level 2 Priorities

Berries (including frozen berries), green onions, melons and tomatoes were considered the second highest priority based on the ranking criteria. Given the available knowledge, berries, green onions and tomatoes were considered to be similarly problematic and it was not possible to rank them from a global perspective. However, it was clear that regional differences exist and therefore, it would be easier to rank these commodities in order of priority from a regional perspective.

Level 3 Priorities (lowest risk)

This is the largest group and includes carrots, cucumbers, baby corn, onions (excluding green onions), garlic and celery. These were considered to be the lowest priority of the identified commodities of concern. While all these commodities have been implicated in cases or outbreaks of foodborne illness, the public health impact was considered to be low, based on information available. Also, there are limited data available for most of these commodities and in several cases, the associated problems have been recognised only recently. However, these may be emerging problems and it is recommended that problems linked to these commodities are noted and the commodities are monitored for further problems. As more information becomes available, the ranking of these commodities will need to be re-evaluated.

APPENDIX 3. SUMMARY OF EFSA MITIGATION OPTIONS FOR VARIOUS FRESH PRODUCE CROPS

	Leafy Greens [14]	Berries[16]	Tomatoes[18]	Bulb, Stem Vegetables and Carrots [15]
1	Ensure compliance with any existing prerequisite programmes which includes GAP, GHP, GMP and recommended Codes of Practices and guidance such as the relevant Codex guidelines.			
2	Implement a Food Safety Management System based on the principles of HACCP.			
3	Prevent direct contact with animal faeces and human sewage as well as indirect contact through slurries, sewage, sewage sludge, and contaminated soil, water, equipment or food contact surfaces as well as food handlers. Ensure appropriate production, treatment, storage, management and use of soil amendments such as animal manure.			
4	Evaluate production areas for hazards that may compromise hygiene and food safety, particularly potential sources of faecal contamination. If its concludes that contamination in a specific area is at levels that may compromise crop safety, e.g. heavy rainfall and flooding, intervention strategies should be applied to restrict growers from using this land until the hazards have been addressed			
5	Each production environment (including open field, enclosed or greenhouse production, and wild areas) should be evaluated independently for hazards as each represents a unique combination of characteristics that can influence occurrence and persistence of pathogens in or near fields for growing crops.			
6	Among the potential interventions, both water treatment and efficient drainage systems that take up excess overflows are needed to prevent the additional dissemination of contaminated water. Risks posed by water should be minimised by assessing the microbial quality of the sources of water used on the farm for the presence of pathogens. Since *Escherichia coli* is an indicator microorganism for faecal contamination in irrigation water, growers should arrange for periodic testing to be carried out to inform preventive measures.			
7	All persons involved in the handling of crops [including those involved in cutting, grating, dicing, etc. of bulb and stem vegetables as well as carrots for buffets in catering and restaurants] should receive hygiene training appropriate to their tasks and receive periodic assessment while performing their duties to ensure tasks are being completed with due regard to good hygiene and hygienic practices			
8	**Leafy Greens and Berries:** Compliance with hygiene requirements, in particular hand hygiene, is an absolute necessity for food handlers at all stages of the production and supply chain to reduce the risks of both *Salmonella* and Norovirus contamination **Tomatoes:** The risk of Norovirus contamination can be reduced by scrupulous adherence to hand hygiene by food handlers at all stages of the supply chain. **Bulb, Stem Vegetables and Carrots:** The main mitigation options for reducing the risk of pathogen contamination is scrupulous adherence to hand hygiene by food handlers at all stages of the supply chain			

	Leafy Greens [14]	Berries[16]	Tomatoes[18]	Bulb, Stem Vegetables and Carrots [15]
9	Employees with symptoms of gastroenteritis including vomiting should be excluded from working in food production, i.e. including harvesting and minimal processing, until their symptoms have subsided.			
10	Equipment should be cleaned and disinfected on a regular basis according to written procedures to ensure that the potential for cross-contamination is minimised.			
11	Attention should be paid to the selection of the water sources for irrigation, agricultural chemical application, e.g. fungicides, pesticides, and in particular to the avoidance of the use or the ingress of contaminated water at all stages of the supply chain. **Leafy Greens:** Mitigation strategies aiming to reduce risks of microbial contamination for all water used during processing and only potable quality water should be used. This should include wash-water where used, as well as that used for other purposes (including ice). **Berries:** The only reservoir for Norovirus is humans; therefore avoiding the use of sewage-contaminated water at all stages of the supply chain is an important mitigation option for reducing the risk of Norovirus contamination on berry fruits. **Bulb, Stem Vegetables and Carrots:** It is recommended that water used during minimal processing be monitored to assess its microbial quality. When disinfectants are used in wash water, the concentration should be monitored to verify that they are applied effectively to reduce the potential risk of cross-contamination while avoiding the accumulation of disinfection by-products.			
12	Clear information (including labelling) should be provided to consumers on appropriate handling of berries which includes specific directions for product storage, preparation, intended use, and shelf life indicators. Consumers should be advised on how to avoid cross-contamination with foodborne pathogens from various sources, e.g. hands, sinks, cutting boards, utensils, raw meats. **Bulb, Stem Vegetables and Carrots:** Consumers should be informed if bulb and stem vegetables as well as carrots are intended to be consumed as ready-to-eat, and, to scrub whole or peeled products using potable running water when appropriate.			
13	**Berries:** A high proportion of berries consumed in the EU are imported from non EU countries, mostly as frozen berries. Although *Salmonella* declines during freezing of whole berries and berry products, it is not possible to use freezing as a critical control point to ensure the absence of this pathogen.			

NOTES

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