Food Safety
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GUIDANCE NOTE

Good Manufacturing Practices for the Production of Ready-to-eat Unpasteurised Fermented Plant-based Products

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Glossary

alcohol	the primary alcohol ethanol
ABV (%)	alcohol by volume expressed as a percentage
back sloping	the use of a natural/previously used wild starter culture in fermentation
brining	treating food with brine (salt and water), which preserves and seasons the food
fermentation	a process by which sugar is broken down into acid and other by-products by microorganisms (typically added as a starter culture), which will be present in the final product
Food contact material (FCM)	any material intended to come into contact with food, that is already in contact with food, or that can reasonably be expected to come into contact with food as defined in Regulation (EC) No 1935/2004
heterofermentative	fermentation resulting in several end products (lactic acid, propionic acid, ethanol, etc)
homofermentative	fermentation resulting wholly or principally in a single end product, typically lactic acid
kefir grains	a symbiotic culture of bacteria and yeast used in the production of kefir beverages
pH	a measure of a product's acidity or alkalinity on a scale of 0 to 14, (pH of 7 is neutral, <7 is acidic and >7 is alkaline)
redox potential (Eh)	a measure of the tendency of a chemical species to acquire electrons and thereby be reduced. The Eh of a food determines which type of microorganisms will grow in it, depending on whether they require oxygen for growth (aerobic) or not (anaerobic).
SCOBY	a symbiotic colony of bacteria and yeast commonly used in the production of kombucha
water activity (a_w)	the free or available water (0–0.999) within a food that is available to support microbial growth at a given temperature

Scope

This guidance is applicable to ready-to-eat (RTE) unpasteurised, fermented plant-based products.

The following products are within the scope of this guidance:

- Sauerkraut
- Kimchi
- Fermented carrots
- Tea kombucha
- Water kefir.

The following products are outside the scope of this guidance:

- Kombucha and water kefir made from concentrate
- Heat-treated/pasteurised products
- High-pressure processed products.

This guidance is intended for:

- Food business operators who produce ready-to-eat unpasteurised fermented vegetable products
- The Environmental Health Service (EHS) of the Health Service Executive (HSE) and the Food Safety Authority of Ireland (FSAI).

Introduction

The production of fermented food using plant material was common in most historical periods and is still practised in many parts of the world (Buckenhueskes, 2015). The earliest available records suggest that the fermentation of plant material for food production was first practised in China, from where it was introduced to Europe by the Mongols and Tatars (Barrau, 1983).

Historically, fermentation was a food production process used to extend the shelf life of perishable foods. However, more recently fermentation has also been used to produce foods with desirable flavour profiles.

Although Ireland does not have a significant tradition of producing fermented plant foods, there has been an increase in their production since the early 2000s mainly by artisan producers. The most common commercially available fermented plant-based foods found in Ireland include sauerkraut, kimchi, kombucha, and kefir, with a more extensive range available in other EU Member States (Table 1).

Table 1. Non-exhaustive list outlining the numerous fermented plant products available on the European market today

Artichoke	Green/waxy pepper	Red beets
Asparagus	Green beans	Red cabbage
Capers	Kimchi	Silver-skinned onions
Carrots	Kohlrabi	Swedes
Cauliflower	Lupinus beans	Turnips
Celery	Okra	White cabbage: whole heads and sauerkraut
Cucumbers	Olives	Kombucha[1]
Eggplants	Peas	Water and fruit kefir[2]

[1] Using a SCOBY.

[2] Using water kefir grains.

The production of fermented plant-based foods usually requires washing, shredding/slicing, salting (except for water kefir and kombucha) and mixing of the plant material before fermentation. Once the fermentation process is complete, the product is ready for direct consumption or packaging and refrigerated storage where applicable (Hutkins, 2008).

Food production in general should follow the basic principles of good manufacturing practices (GMPs) and good hygienic practices (GHPs) as well as application of the hazard analysis and critical control point (HACCP) as part of a food safety management system. Further information on food safety management systems can be found on the FSAI website (www.fsai.ie).

Safety aspects of fermenting vegetable foods

Fermented foods can pose the same safety and spoilage risks associated with other foods containing physical, chemical and biological hazards. Physical hazards include the inadvertent presence of foreign matter such as metal, glass or plastic. Chemical hazards can include, amongst other things, mycotoxins, pesticide residues, environmental contaminants, and chemical residues from cleaning agents (Medina et al., 2016). Biological hazards can be in the form of pathogenic microorganisms such as Clostridium botulinum, Listeria monocytogenes, Salmonella and Shiga toxin-producing E. coli [STEC] as well as viruses and parasites present in the unprocessed vegetables (Beuchat, 1996).

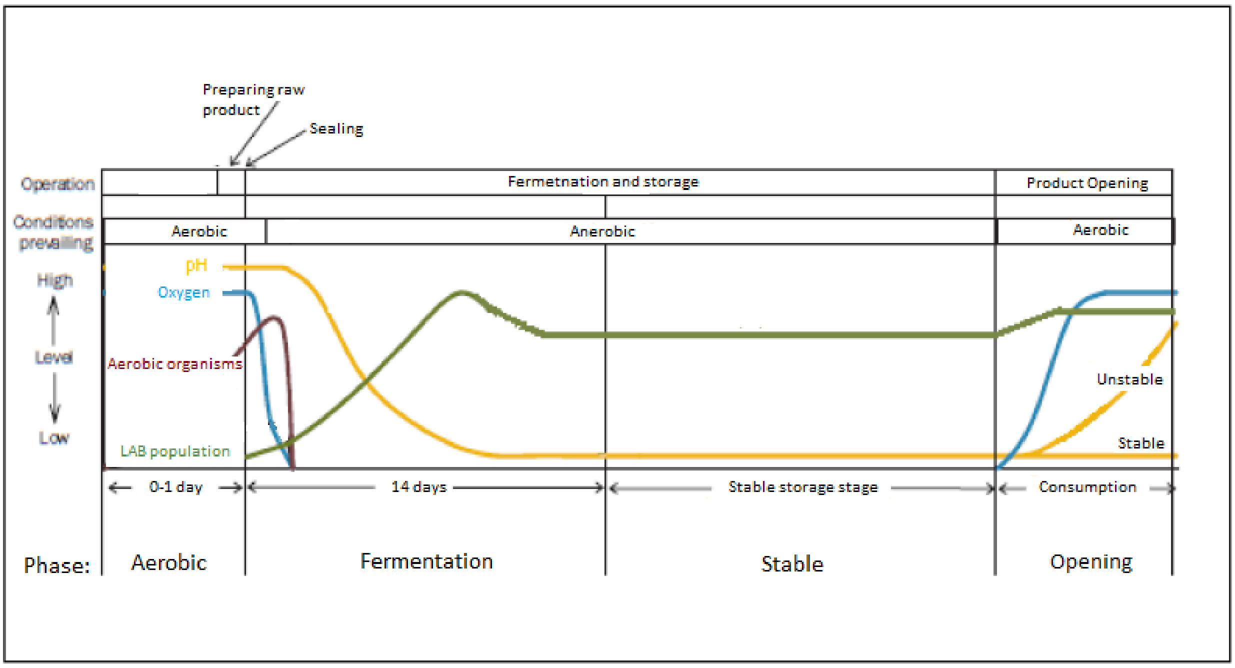
Many fermented plant-based foods are sold as ready-to-eat (RTE), i.e. consumed without further processing. Fermented plant products such as sauerkraut have a long history of microbiological safety. However, traditional fermentation undertaken by the indigenous microbiota is a relatively uncontrolled process, and may result in inconsistent final products and can contain pathogens (Medina et al., 2016). The safety of these products relies primarily on the good hygienic status of the starting plant material, appropriate storage and handling conditions, the experience of the food business operator and their understanding of the complex interactions that occur during and possibly after the fermentation process (Hutkins, 2008; Medina et al., 2016; Medina et al., 2017).

Fermented plant-based foods are generally stored and sold in sealed anaerobic containers, and therefore contamination with the anaerobic C. botulinum and the subsequent production of botulinum toxin is a potential risk if the food is not properly fermented and stored with the appropriate controls.

During the fermentation process, biogenic amines such as histamine may be produced due to the activity of the lactic acid bacteria. At low levels, biogenic amines do not pose a significant risk to a healthy consumer. However, high levels of biogenic amines in food can result in toxic effects such as hypertension, cardiac palpitations, headache, nausea, diarrhoea, flushing, and localised inflammation. In extreme cases, intoxication by biogenic amines may have a fatal outcome (Suzzi and Torriani, 2015). GMPs and careful selection of the starting culture have been shown to reduce the production of biogenic amines in fermented foods (Sarkadi, 2017).

The fermentation process

A successful fermentation process incorporates four separate phases: aerobic phase, fermentation phase, stable phase, and product opening phase. In order for the fermentation process to be a success, oxygen must be eliminated from the process to stop any aerobic microbial activity.



LAB: lactic acid-producing bacteria. Modified from Mcelhinney (2015)

Figure 1. Changes occurring during the various phases of a well-preserved fermented plant-based food

The process outlined in Figure 1 represents the fermentation of plant material (e.g. sauerkraut) using microorganisms naturally present in or on the plant material, rather than microorganisms added from an external source (e.g. starter culture).

Stage 1: Aerobic

The aerobic phase (with oxygen) is short-lived and ends soon after the fermentation vessel is sealed. During the aerobic phase, oxygen in and around the vegetables will be continually consumed for respiration by aerobic microorganisms and may generate a small amount of heat. Lactic acid bacteria, mainly belonging to the genera *Lactobacilli, Pediococcus, Streptococcus* and *Enterococcus* are naturally present on fresh vegetables, albeit in low numbers. Whereas the total population of other bacteria (e.g. *Pseudomonas, Flavobacterium, Escherichia and Bacillus*) may reach levels as high as 107 per gram, lactic acid bacteria are normally present at levels which are

1,000 times lower (Nout and Rombouts, 1992). The selection of key criteria, including the addition of salt, optimal temperature and removal of oxygen (anaerobiosis), favours the lactic acid bacteria allowing them to grow and produce acid.

Stage 2: Fermentation

The fermentation phase immediately follows the aerobic phase once oxygen-free conditions prevail. Depending on the composition of the plant material and the fermentation conditions (e.g. temperature, pH and sealing efficiency) this phase may last for days or weeks. During this phase, lactic acid-producing bacteria (LAB) convert sugars naturally present in the plant material to organic acids, alcohol and carbon dioxide (Medina et al., 2016).

During this phase, the pH can decrease from neutral (6.5–7.0) to acidic levels (3.8–5.0), which results in a decline in the growth and activity of acid-sensitive bacteria. A successful fermentation could see an increase in LAB numbers after fermentation from approximately 102–105 colony-forming forming units/g (CFU/g) on vegetables (e.g. cabbage) to 109–1010 CFU/g in sauerkraut (Buckenhueskes, 2015).

Stage 3: Stable

The stable phase can only be achieved in well-sealed fermentation vessels. Most of the microorganisms which were active before sealing now become inactive, except for acid-tolerant anaerobes such as certain lactic acid bacteria species. Some residual enzymatic activity of carbohydrases and proteases can continue, providing a slow supply of soluble carbohydrates and the breakdown of amino acids.

A complete fermentation dominated by lactic acid bacteria not only creates a preservative effect but may also enhance the sensory characteristics of the final product.

Once the fermentation is complete, the product is usually placed in refrigerated (<5º C) storage, where it can remain stable for some time. Although this guidance relates to unpasteurised fermented plant-based foods and derived products, a pasteurisation step may be included as an additional food safety control step.

Stage 4: Opening

Once the fermentation vessel is opened, the anaerobic environment that suppressed the proliferation of aerobic microorganisms ends. Over time, yeast and aerobic bacteria such as acetic acid bacteria can utilise lactic acid as a substrate, with a resultant increase in pH. However, an elevated pH creates a more suitable environment for the proliferation of spoilage organisms.

Legislation

Under European Union (EU) and Irish food law, all food businesses have a legal obligation to ensure that they do not place unsafe food on the market.

Regulation (EC) No 178/2002: The general principles and requirements of food law as amended. S.I. No. 747 of 2007

This regulation sets out a range of general principles and requirements that food business operators must adhere to.

Key points:

- The primary responsibility for producing safe food rests with the food business operator.
- Food businesses must ensure that the food they produce meets the requirements of all applicable food law.
- Unsafe food must not be placed on the market. Unsafe food includes food that is ‘injurious to health’ and/or ‘unfit for human consumption’.
- Food businesses must maintain a traceability system.
- Food businesses must have a system to withdraw or recall any unsafe food from the market. They must inform both consumers and the competent authority in such an event.

Regulation (EC) No 852/2004: Hygiene of foodstuffs

Food business operators must ensure that all stages of production, processing and distribution of food under their control comply with the relevant hygiene requirements.

Key points:

- Implement and maintain a food safety management system based on the HACCP principles.
- Ensure that food handlers have received food safety training to allow them to do their job safely.
- Comply with the general hygiene requirements as laid down in the Regulation.
- Ensure that the cold chain is maintained.

Directive (EC) No 98/83: The Drinking Water Directive S.I. No. 122 of 2014

This Directive sets out the quality requirements of water intended for human consumption, including through food consumption.

Directive (EC) No 2020/2184: The Drinking Water Directive (recast) was adopted by the European Parliament and of the Council of the EU on 16th of December 2020 and entered into force on 12 January 2021. Following this each EU member state has two years to transpose it into national legislation.

Key points:

- Essential quality standards at the EU level are laid out.
- Contains a list and specifications for microbiological and chemical indicators that must be monitored.

Regulation (EC) No 2073/2005: The microbiological criteria for foodstuffs

This regulation sets out the microbiological criteria used to assess the acceptability of food.

Key points:

- Outlines the parameters and criteria (food safety and process hygiene) for the microbiological assessment of food
- Identifies specific rules for testing and sampling of foods for microbiological assessment
- Forms an integral part of HACCP-based procedures or other hygiene control measures.

Regulation (EC) No 1169/2011: On the provision of food information to consumers

This regulation sets out a range of general principles and obligations in relation to food information that food business operators must adhere to.

Key points:

- Food business operators must ensure that information provided to the consumer is accurate, clear and easy to understand, and it must not be misleading.
- In Ireland, food information must be provided in English. Information may also be provided in other languages, including Irish.

Regulation (EC) No 1924/2006: Nutrition and health claims made on foods

This Regulation applies to all nutrition and health claims made in commercial communications. Further information on nutrition and health claims in foods can be found on the FSAI website.

Key points:

- Food businesses must ensure that any nutrition claims used are listed in the Annex to the Regulation and are in conformity with the relevant conditions of use.
- Food businesses must comply with the general principles, general and specific conditions of use for health claims in accordance with the Regulation.

Further information on nutrition and health claims:

A nutrition claim is any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

(a) the energy (calorific value) it

(i) provides

(ii) provides at a reduced or increased rate

(iii) does not provide

For example 'low in fat'

and/or

(b) the nutrients or other substances it

(i) contains

(ii) contains in reduced or increased proportions

(iii) does not contain

For example 'contains vitamin C'.

Nutrition claims are only permitted if they are listed in the Annex to Regulation (EC) No 1924/2006. For further information on nutrition claims see Information on Nutrition and Health Claims, which can be found on the FSAI website.

A health claim has been authorised concerning 'live yogurt cultures' and improved lactose digestion. For a product to bear this claim, it must contain at least 10^8 colony-forming units of live starter microorganisms (*Lactobacillus delbrueckii subsp. bulgaricus* and *Streptococcus thermophilus*) per gram.

Regulation (EC) No 1935/2004: Food contact materials (FCMs)

This regulation lays down general rules on the materials or articles intended to come into contact with food.

Key points:

- Ensure that any materials or articles intended to come into contact with food are sufficiently inert to preclude substances being transferred to food in quantities that could endanger human health, or bring about an unacceptable change in the composition of the food, or a deterioration in the organoleptic properties of the food, i.e. a taint in the food.
- Ensure that FCMs, particularly in food packaging, are:
  a) Clearly labelled
  b) Traceable back to the supplier
  c) Used in accordance with manufacturers' instructions
  d) Used in compliance with the legislation.

Manufacture

Ingredients

This section provides guidance on specific control measures which can be used by manufacturers of fermented plant-based foods to ensure GMP during all production steps.

Water quality

The quality of the water used by all food businesses must meet the basic standards governing the quality of drinking water intended for human consumption, i.e. potable water as set out in Council Directive 98/83/EC and implemented in Ireland under S.I. No. 122 of 2014 (European Commission, 1998; Government of Ireland, 2014).

As the definition of food under Regulation (EU) No 178/2002 includes water intentionally incorporated into food during its manufacture, preparation or treatment, food businesses have a responsibility for the quality of water used directly, e.g. as an ingredient in food production, or indirectly, e.g. in cleaning or processing during the manufacture of foods. (Government of Ireland, 1998; European Commission, 2002)

Where a food business uses an unconventional, unfixed water supply such as rainwater or a private water supply in the manufacture, preparation or treatment of food, the food business must take steps, e.g. treatment of the water to ensure that the quality of the water used meets the basic standards governing the quality of drinking water intended for human consumption outlined in the aforementioned legislation. The FSAI fact sheet on potable water can be found on the FSAI website.

Criteria for selecting suitable plant material

The fermentation process starts with sourcing and selecting the appropriate plant material and any other necessary ingredients. As part of the food safety management system, there should be controls in place to ensure that the ingredients used are of high quality and not a source of contamination by hazards including physical, chemical or spoilage/pathogenic microorganisms.

To produce high-quality and safe fermented foods, plant material must be undamaged and at the appropriate stage of maturity. Before fermentation, the plant material should be carefully inspected and if found to be damaged by machinery / equipment or withered, bruised, diseased, dirty, unripe or overripe, then it must not be used in the fermentation.

Raw materials that are selected for fermentation should be suitably size graded in order to achieve a homogenous fermentation. Further pre-treatment will be dependent on the type of plant material being fermented (e.g. peeling, piercing, or blanching).

Salting (sodium chloride)

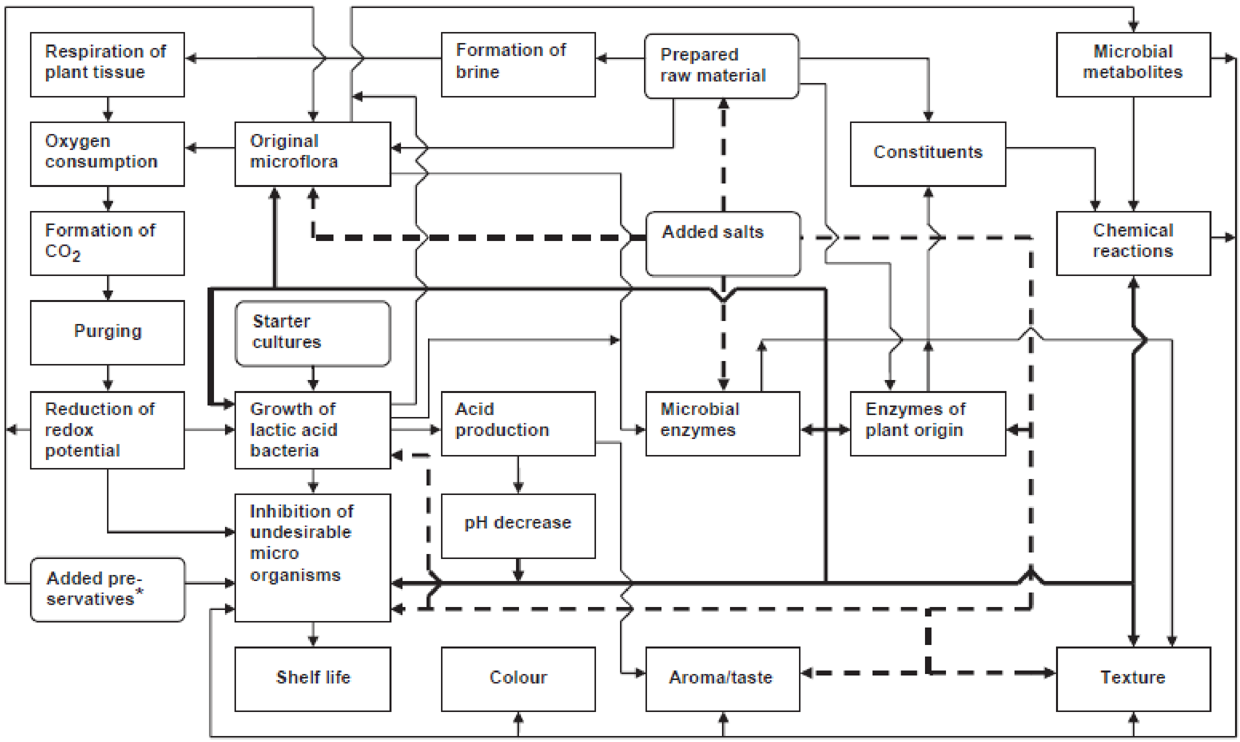
The addition of salt helps to promote the anaerobic environment in the fermentation vessel by increasing osmotic pressure and thereby accelerating the release of tissue fluids from the plant material. The salt draws out the plant juices containing fermentable carbohydrates and other nutrients, forming a brine. Salt dissolved in the brine provides selective conditions that discourage the growth of most of the microorganisms that would otherwise compete with the lactic acid bacteria. The salting step can also reduce pectinolytic and proteolytic activity during fermentation, ensuring that the food retains its texture and does not soften.

Unlike brining, the preservation of plant-based foods as a result of fermentation is achieved by lactic acid bacteria. However, the addition of salt is crucial for several technological functions (Figure 2) and to limit the progression of undesirable fermentation. The growth of undesirable bacteria and fungi is inhibited by increasing levels of salt, while at the same time it will selectively support the growth of lactic acid bacteria (Buckenhueskes, 2015).

Heterofermentative LAB, such as Leuconostoc species, favour low salt concentrations (≈1% w/v) in sauerkraut, whereas they are inhibited at 3%. LAB, such as Lactobacillus plantarum, are better adapted to higher amounts of salt, thus accelerating fermentation. On the other hand, salt concentrations below 0.8% frequently result in undesirable characteristics, including softening of the sauerkraut. Typically, for sauerkraut, between 2% and 2.5% (by weight) salt is added, although 2.25% is generally considered optimal (Hutkins, 2008).

Where salt is added, its distribution should be homogenous, in order to prevent spoilage hot spots. If the salt concentration is very high in localised areas, some yeast or lactobacilli may grow, leading to quality defects in the final product (ICMSF 1998).

For an example of calculation to determine how much salt should be added to the vegetables to be fermented, see Appendix III.



The bold broken lines indicate the reactions influenced by the addition of salt. The bold solid lines indicate the influence of lowering the pH caused through the microbial production of acids on the entire process.
Source: Buckenhueskes (2007)

Figure 2. Significant reactions and interactions that take place during the lactic acid fermentation of plant material

pH

The fermentation of plants can utilise microorganisms naturally present on the plant material or a starter culture of microorganisms that are added during the manufacturing process (e.g. tea kombucha). During the fermentation process, sugar in the plants is converted into acid, which lowers the pH value. The temperature during fermentation can have a major impact on production, which is generally controlled at room temperature, i.e. approximately 19 ºC.

A final pH of less than pH 4.2 is essential in order to limit the growth of harmful pathogens that can occur in fermented plant-based foods, including Listeria monocytogenes, Clostridium botulinum and Bacillus cereus. See FSAI Guidance Note 18: Validation of Product Shelf-life for further information on how pH and acidity affect the survival and growth of microorganisms in food.

If RTE fermented plant products have a pH ≤ 4.4 or aw ≤ 0.92, or have a pH ≤ 5.0 and aw ≤ 0.94, they fall into food category 1.3 of the microbiological criteria, Regulation (EC) No 2073/2005, because these foodstuffs are unable to support the growth of L. monocytogenes. For further information on the ability of foods to support the growth of L. monocytogenes, see the FSAI Guidance Note 27 on Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs, which can be found on the FSAI website.

The pH must be measured using calibrated equipment and as best practice according to the international standard of ISO 1842:1991: determination of pH in fruit and vegetable products. Recommendations for care and the use of pH meters can be found in Appendix I.

To reduce the risk of L. monocytogenes, the pH should be monitored throughout production (when possible) using a calibrated digital pH meter and recorded as part of the food safety management system. Contamination with acid-resistant pathogens such as Salmonella or Shiga toxin-producing E. coli (STEC) during production is a significant hazard when manufacturing fermented plant-based products.

An example record sheet for monitoring pH and pH meter calibrations can be found in Appendix I.

Wild fermentation

Wild fermentation is the process in which microorganisms naturally present on the plant and in the environment convert starch and sugar into lactic acid, in the absence of oxygen (Redzepi and Zilber, 2018). Three products that undergo wild fermentation and are currently produced in Ireland include sauerkraut, kimchi, and fermented carrots.

The production of these fermented plant products is a straightforward process. Variation in the final products will depend on the variability of many factors, including the (natural) yeast and bacteria flora, starting plant material, salt concentration, fermentation temperature and duration, the addition of flavouring agents, and storage.

Sauerkraut

Sauerkraut is a fermented cabbage utilising naturally occurring microorganisms. Salt (2–2.5% weight per weight (w/w)) is added evenly to finely sliced or shredded cabbage and this draws the liquid out of the cabbage. The cabbage and salt mixture may be further mixed by hand or pounded with a blunt implement, thus helping to further draw out the juices that contain fermentable sugars. Acid-producing bacteria which are naturally present on the cabbage leaves will, in the absence of oxygen, convert these sugars into acid. The acid will lower the pH of the natural brine and preserve the cabbage, as outlined in Figure 3.

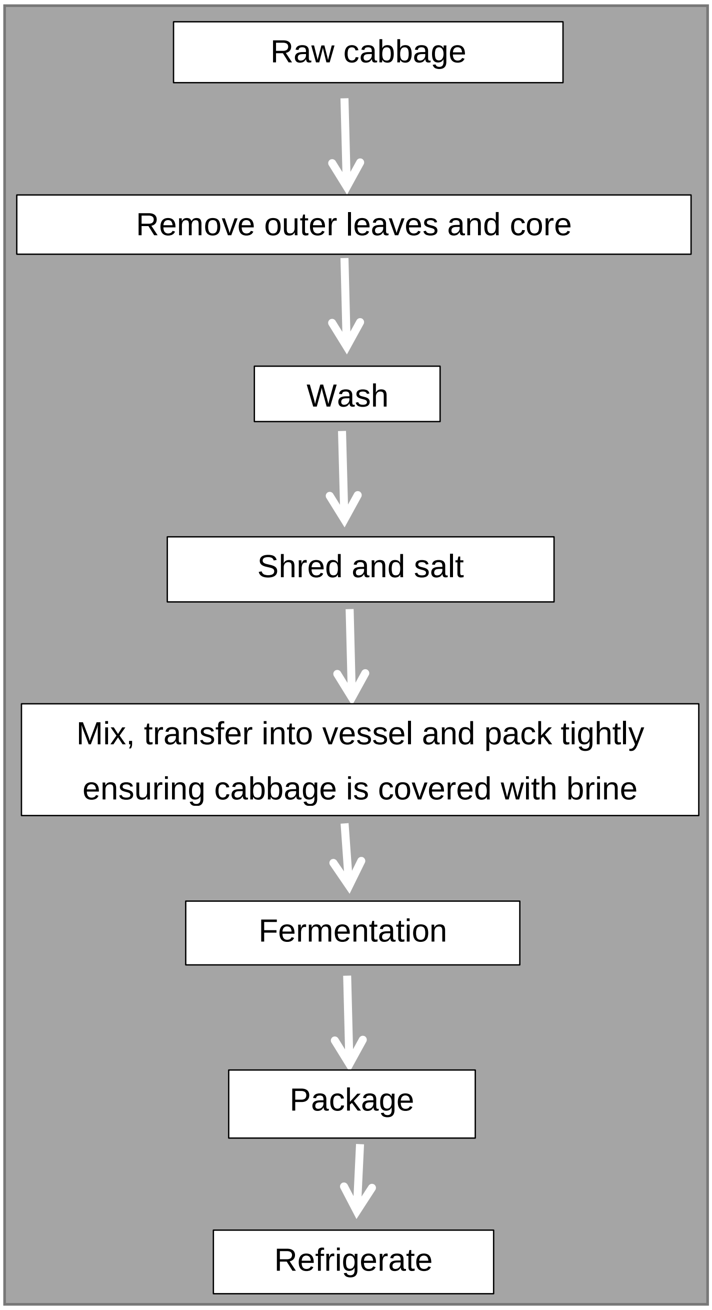


Figure 3. Manufacture of sauerkraut

Sauerkraut food safety controls

Several key controls can aid the efficient fermentation and safe production of sauerkraut.

Appendix IV outlines an example of HACCP considerations.

1. Selection of appropriate ingredients
   The cabbage used should be sourced from a reputable supplier and be undamaged. Food business operators must ensure that the cabbage leaves are free from physical hazards e.g. glass, plastic, stones, soil, insects and the leaves should be washed using potable water before chopping.

2. Chopping
   Chopping or shredding should be done using clean and sanatised utensils and a clean, sanatised chopping board.

3. Addition of salt
   The appropriate amount of salt should be added as per the recipe. The formula in Appendix III can be used to calculate the amount of salt required. The typical amount of salt that is added to the cabbage is 2–2.5% w/w (Hutkins, 2008). Salt levels below a concentration of 0.8% may result in the production of undesirable fermentation products. The salt must be well mixed throughout the chopped cabbage, ensuring an even distribution. The addition of salt combined with the low pH prevents the growth of harmful pathogens, including Clostridium botulinum.

4. Filling the fermentation vessel
   The salted cabbage is transferred to a sterile vessel that can withstand the reduced pH that is expected. Glass or plastic vessels are commonly used and must comply with FCMs legislation. The container must be free of chemical residue from cleaning products and other contaminants. When filling the fermentation vessel, salted cabbage should be packed tightly to promote the release of juice from the cabbage and eliminate air pockets. If a weight is being used to help compress the cabbage during fermentation, it must be clean, comply with FCMs legislation, and withstand the reduced pH range expected.

5. Fermentation

Fermentation is usually carried out using a sealed vessel with a one-way valve for the release of built-up gas that prevents the intake of air. Food business operators must understand that their fermentation process can be affected by many variables, including ingredients used, the temperature during fermentation, salt concentration, and the ingress of air. The time allocated for the fermentation of sauerkraut can vary. The food business operator should ensure that the fermentation has proceeded sufficiently to ensure a pH of <4.2.

6. pH

Under optimal sauerkraut production conditions, the pH of the cabbage should reduce from approximately pH 6.6 to less than pH 4.0 within 3–5 days. The food business operator should make sure that the fermentation has progressed enough to ensure that the pH is adequate to ensure food safety and inhibit food spoilage during the shelf life of the product. The optimal final pH for sauerkraut is pH 3.5 (Mheen and Kwon, 1984), but a range of between 3 and 4 is typical.

7. Shelf life

Food business operators shall estimate, validate and set the shelf life of their sauerkraut during product development using a shelf life study that considers the possible conditions of storage, distribution, and use. Additionally, food business operators should understand the effect of variable fermentation conditions (e.g. temperature and duration) on the shelf life of the product. For further guidance on shelf life, see FSAI Guidance Note 18: Validation of Product Shelf-life, which can be found on the FSAI website.

Kimchi

Kimchi, a staple in Korean cuisine, is a traditional side dish made from salted and fermented vegetables, napa cabbage and Korean radishes, with a variety of seasonings, including chilli powder, scallions, garlic and ginger. Kimchi is made by wild fermentation, the same process that creates sauerkraut. Microorganisms naturally present on the vegetables will, in the absence of oxygen, convert these sugars into acids. The acid will lower the pH of the natural brine and preserve the plant material, as outlined in Figure 4.

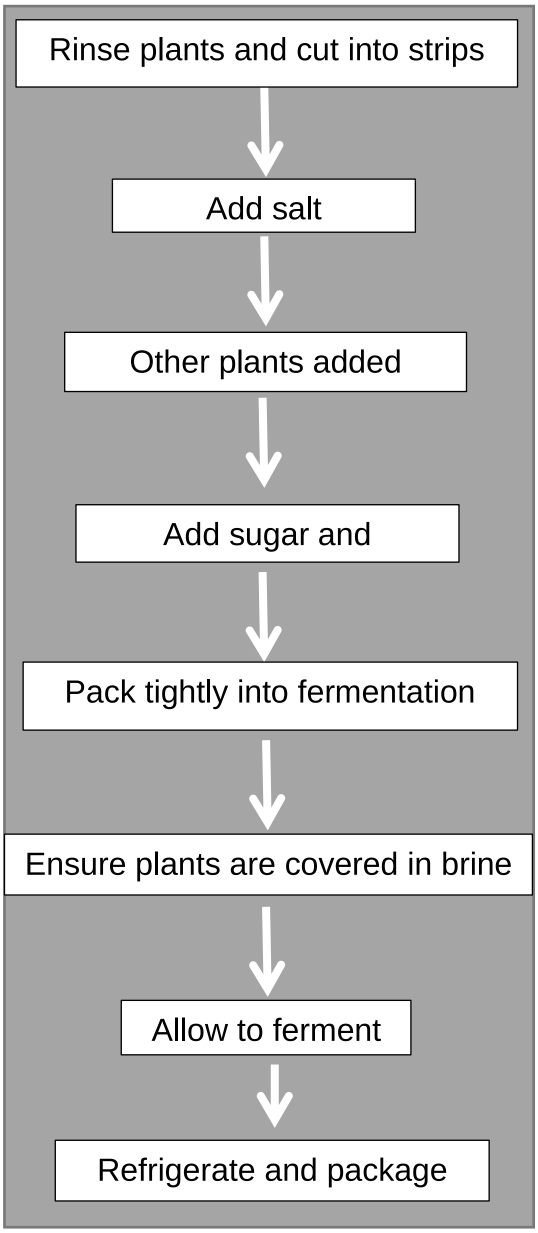


Figure 4. Manufacture of kimchi

Kimchi food safety controls

Several key controls can aid the efficient fermentation and safe production of kimchi.

1. Selection of appropriate ingredients
   Napa cabbage, garlic, ginger, sugar, radish, pepper, spices and other ingredients should be of good quality and sourced from a reputable supplier. Food business operators must ensure that the ingredients are free from physical hazards e.g. glass, plastic, stones, soil, insects.

2. Chopping
   Chopping or shredding should be done using clean and sanatised utensils and a clean, sanatised chopping board.

3. Addition of salt
   The appropriate amount of salt should be added as per the recipe. The formula in Appendix III can be used to calculate the amount of salt required. Salt concentrations in kimchi are typically between 2% and 3% w/v (Ahmadsah et al., 2015) and below optimal will result in quick acidification and softening of the kimchi (Mheen, 2010). The salt must be well mixed throughout the ingredients, ensuring an even distribution.

4. Filling the fermentation vessel
   The mixed ingredients are transferred to a sterile vessel that can withstand the expected reduction in pH. Glass or plastic vessels are commonly used and must comply with FCMs legislation. The container must be free of chemical residue from cleaning products and other contaminants. When filling the fermentation vessel, it should be packed tightly to promote the release of juice from the ingredients and to eliminate air pockets. If a weight is being used to help keep the plant material from floating, it must be clean, comply with FCMs legislation, and be able to withstand the pH reduction expected.

5. Fermentation

The fermentation is usually carried out in a sealed vessel, with a one-way valve allowing the release of gas and preventing the intake of air, thus keeping the contents in an anaerobic environment. The food business operator must understand that the fermentation process can be affected by many variables, including ingredients used, the temperature during fermentation, salt concentration, and the presence of air. The time allocated by a food business operator for the fermentation of kimchi is generally less than for sauerkraut, i.e. 2–3 days. The food business operator should make sure that the fermentation has progressed enough to ensure that the pH is sufficient to inhibit food spoilage and the growth of pathogens during the shelf life of the product. Kimchi is less acidic than sauerkraut and has an optimum pH of 4.2 (Mheen, 2010); however, it's generally in the range of pH 4.2 to pH 4.8.

6. pH

Under optimal kimchi production conditions, the pH of mixed ingredients should reduce from approximately pH 6.0 to between pH 4.2 and pH 4.8 within 3–5 days (Mheen and Kwon, 1984). The food business operator should understand the nature of their kimchi fermentation profile. To inhibit the growth of harmful anaerobic pathogens, including Clostridium botulinum, it is recommended that the minimum pH achieved for kimchi production is pH 4.6 or lower, and it should be maintained until the end of the shelf life of the product.

7. Shelf life

Food business operators shall estimate, validate and set the shelf life of their kimchi during product development using a shelf life study that considers the possible conditions of storage, distribution and use. Additionally, food business operators should understand the effect of variable fermentation conditions (e.g. temperature and duration) on the shelf life of the product.

Fermented carrots

Fermenting carrots is a simple process, with only a few steps. Microorganisms naturally present on the carrots will, in the absence of oxygen, convert sugars into acids. The acid will lower the pH of the brine and preserve the carrots. Figure 5 outlines the common steps involved.

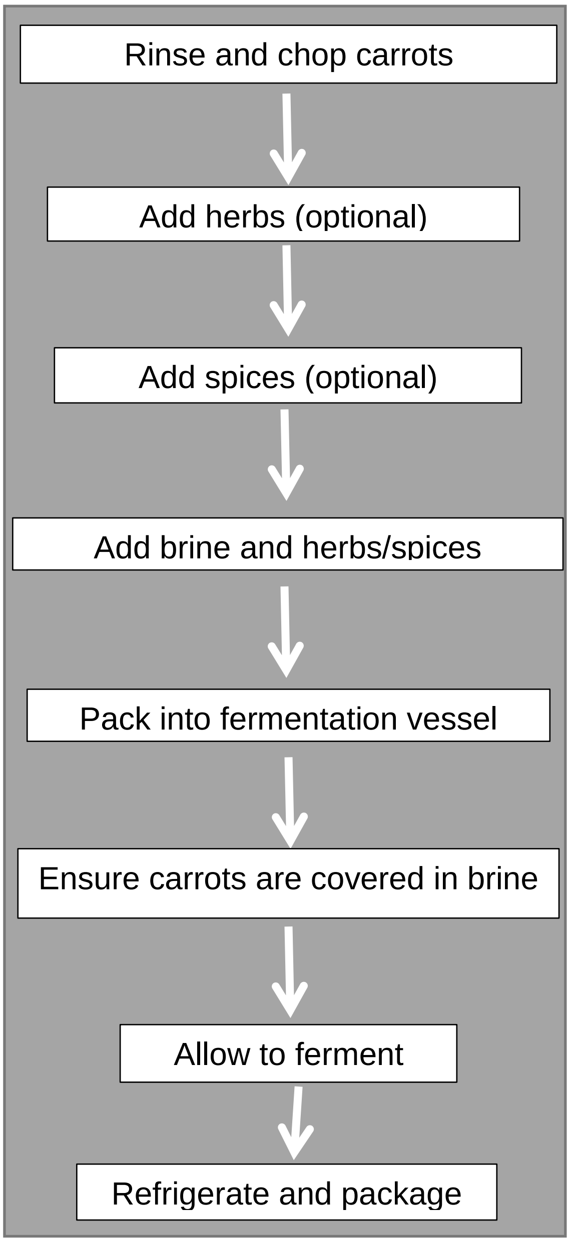


Figure 5. Manufacture of fermented carrots

Fermented carrots food safety controls

Several key controls aid an efficient and safe fermentation of carrots:

1. Selection of appropriate ingredients
   The carrots selected should be of good quality and sourced from a reputable supplier. Food business operators must ensure that the ingredients are free from physical hazards e.g. glass, plastic, stones, soil, insects. Herbs such as fennel are also sometimes used to flavour fermented carrots.

2. Peeling and chopping
   Carrots should be washed, peeled and trimmed using clean and sanatised utensils to remove contaminants (e.g. soil). Carrots can be fermented whole or sliced/chopped.

3. Addition of salt
   The appropriate amount of salt should be added to the water to form a brine. The formula in Appendix III can be used to calculate the amount of salt required. Brine concentrations used in fermented carrots are typically between 1.5% and 3.0% salt w/v (Niketic-Aleksic et al., 1973).

4. Filling the fermentation vessel
   Carrots are transferred into a sterile vessel that can withstand the expected pH. Glass or plastic vessels are commonly used and these must comply with FCMs legislation. The container must be free of chemical residue from cleaning products and other contaminants. Once the carrots are in place, the brine is poured into the fermentation vessel until it covers the carrots completely. If a weight is being used to help keep the carrots from floating it must be clean, comply with FCMs legislation, and be able to withstand the expected pH reduction.

5. Fermentation
   The fermentation is usually carried out using a sealed vessel, with a one-way valve allowing the release of gas but preventing the intake of air, thus keeping the contents in an anaerobic environment. Food business operators must understand that their fermentation process can be affected by many variables, including ingredients used, the temperature during fermentation, salt concentration and the presence of air. The time

allocated for the fermentation of carrots is generally a few days (e.g. 3–5 days); however, this depends on factors such as temperature and the desired organoleptic characteristics of the final product. The food business operator should ensure that the fermentation has progressed enough to ensure that the pH is adequate to inhibit food spoilage and the growth of pathogens during the shelf life of the product.

6. pH
The pH of fermented carrots (2.5% salt; 20 ºC) generally falls from pH 6.5 to less than pH 4.2 within 5 days (Niketic-Aleksic et al., 1973). However, the typical final pH can be in the range of 4.0 to 3.5. The food business operator should understand the nature of their fermentation profile, ensuring that a pH value of less than 4.4 is reached during fermentation and maintained until the end of the product shelf life. This will prevent the growth of Listeria monocytogenes and toxin formation by Clostridium botulinum.

7. Shelf life
Food business operators shall estimate, validate and set the shelf life of their fermented carrots during product development, using a shelf life study that considers the possible conditions of storage, distribution and use. Additionally, food business operators should understand the effect of variable fermentation conditions (e.g. temperature, brine concentration and duration) on the shelf life of the product.

Fermentation using a starter culture

Unlike the fermented plants previously discussed which naturally contain the microbial flora used in the fermentation process, the following two fermented products use an added starter culture otherwise known as a symbiotic combination of bacteria and yeasts (SCOBY). There are different SCOBYs available and these are generally made from a poorly defined consortium of yeasts and bacteria (Jarrell et al., 2000). SCOBYs can be purchased from a commercial supplier and generally continue to grow, reproducing new SCOBYs.

SCOBYs should be purchased from a reputable supplier who can guarantee that the live cultures in the SCOBY are safe for use and free from pathogens or spoilage microorganisms.

Kombucha

Kombucha is a fermented sweet tea that could contain alcohol, but the fermentation processes are highly variable (Jayabalan et al., 2014; Villarreal-Soto et al., 2018). Figure 6 outlines the common steps involved.

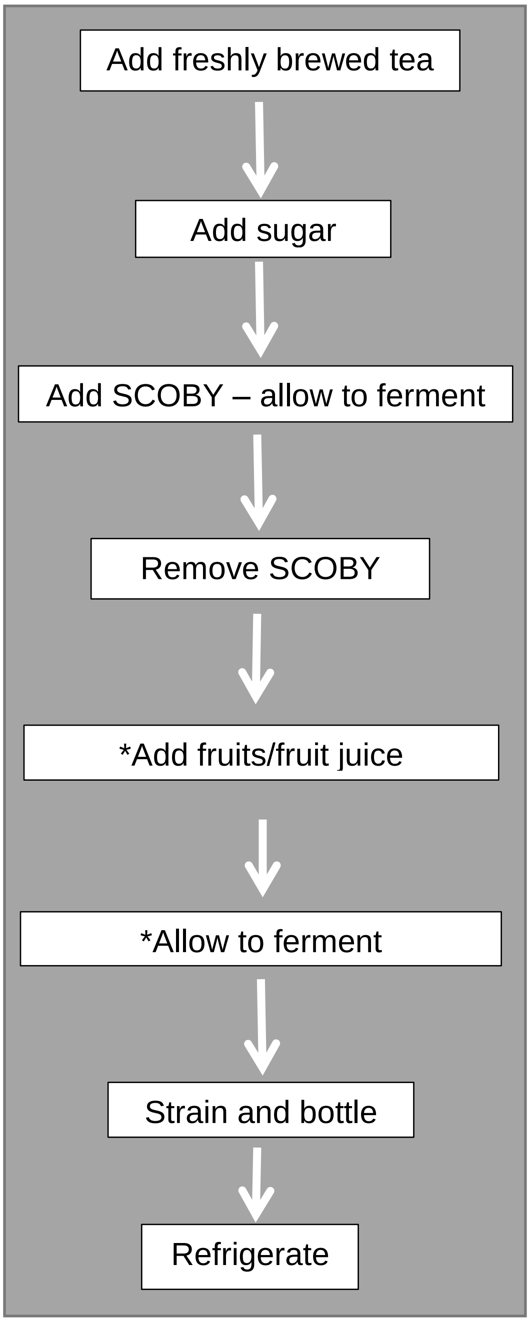


Figure 6. Manufacture of kombucha

*Optional secondary fermentation steps

When fermenting tea to make kombucha, the fermentation vessel is unsealed (the SCOBY needs air to thrive), but it is covered with a clean breathable cloth material to prevent external contamination. This cloth material must comply with FCMs legislation. The fermentation is generally conducted over 6–14 days under aerobic conditions and approximately at room temperature (i.e. 19 °C) (Lavefve et al., 2019). A secondary fermentation step is optional; in such cases, fruit, fruit juice or other sugary liquid can be added to the final container in order to obtain a stronger flavour and increased effervescence.

When making kombucha, a starter culture is used. The kombucha starter culture (Figure 7) (SCOBY) is held together by polysaccharides to form a cellulose biofilm. It resembles a mushroom cap (Figure 7), which is why the culture is also referred to as a mushroom, even though it is not a fungus.

Kombucha is the result of a semi-spontaneous fermentation of the tea by the SCOBY, the quality of which is crucial in obtaining a safe drink with the desired quality. Unlike wine, beer or fermented dairy products, pure starter cultures that could improve consistency in the plant-based fermentation process have not been identified.

Kombucha production is known to include a variety of yeast and bacteria (Table 2). As shown in Figure 7, the SCOBY may float, but in some cases it may sink below the surface of the liquid. During fermentation, a new ‘daughter’ SCOBY may form on top of the ‘mother’ SCOBY (Figure 7)

Table 2. Microorganisms involved in the production of kombucha

Bacteria involved (Phylum)	**Yeasts involved (Family)**
Actinobacteria	Saccharomycetaceae
Bacteroidetes	*Yeasts involved* (species)
Deinococcus–Thermus	*Zygosaccharomyces* spp.
Firmicutes	*Dekkera*/*Brettanomyces* spp.
Proteobacteria	
Bacteria involved (species)	
Lactic acid bacteria	
Acetic acid bacteria	

Source: Lavefve et al. (2019)

When kombucha is produced safely, the health risks are low. However, some isolated cases of adverse reaction (i.e. lactic acidosis) due to excessive consumption, or consumption of compromised kombucha, have also been reported (Sunghee Kole et al., 2009; Gedela et al., 2016).

Source: (Boochcraft, 2021; Brewers, 2021)

Figure 7. SCOBY being held in the palm of a hand (left) and the SCOBY floating on the surface of black tea during the production of kombucha (right).

The arrow highlights the split between 'mother' and 'daughter' SCOBYs.

Kombucha food safety controls

Several key controls can aid an efficient fermentation and safe production of kombucha. Appendix IV outlines an example of HACCP considerations for kombucha production.

1. Selection of appropriate ingredients
   The selected tea and other ingredients, i.e. fruits/herbs should be of good quality and sourced from a reputable supplier. Food business operators must ensure that the ingredients are free from free from physical hazards e.g. glass, plastic, stones, soil, insects.

2. Tea preparation
   Tea leaves are added to boiling water and allowed to infuse for a short time, e.g. 10–15 minutes, after which the leaves are removed. Boiling water will inactivate vegetative pathogens that may be present on the tea leaves. A sugar source (sucrose) at an optimal concentration of 5–10% weight per volume (w/v) is dissolved in the hot tea and left to cool (Jayabalan et al., 2014; Villarreal-Soto et al., 2018). The tea should be covered with clean breathable material, in order to reduce the risk of contamination, and it should be allowed to cool to room temperature. The cooled sweetened tea is then poured into a sterile fermentation vessel.

3. Addition of starter culture (SCOBY)
   The cooled sweetened tea is inoculated with a SCOBY, which generally floats on the surface of the liquid. In addition, some previously fermented kombucha is sometimes added to inoculate the cooled sweetened tea (i.e. back sloping).

4. Covering the fermentation vessel during the fermentation period
   Kombucha is generally fermented aerobically and the vessel is unsealed but covered with breathable material to prevent the entry of small insects, e.g. fruit flies that will be attracted to the sugary solution. Some producers prefer to use sealed vessels to enhance organoleptic properties. However, there are several risks associated with this practice, i.e. over-pressurised vessels that may explode, increased production of alcohol, and the inhibition of typical kombucha fermentation due to excess build-up of

carbon dioxide. The vessel, which is typically made of glass or some other material, must comply with FCMs legislation.

5. Fermentation

Fermentation is usually carried out in an unsealed sterile vessel to allow gas exchange; this is done using a clean breathable material that complies with FCMs legislation. Food business operators must understand that their fermentation process can be affected by many variables. The time allocated for the fermentation of kombucha is generally 6–14 days, but this will depend on fermentation factors, including temperature, the composition of the ferment, and the desired organoleptic properties.

6. pH

The pH of optimally fermented kombucha generally falls to less than pH 4.2 within 5 days (Niketic-Aleksic et al., 1973; Lončar et al., 2006); however, the typical final pH is in the range of 3.5 to 3.0 (Lončar et al., 2006). The food business operator should understand the nature of their fermentation, ensuring that a pH value of less than 4.4 is reached during fermentation, and maintained until the end of the product shelf life. This will prevent the growth of Listeria monocytogenes and toxin formation by Clostridium botulinum. If the pH does not reach 4.4 or less within 7 days, and then to an endpoint of around pH 3.5–3.0, it is an indication of a contaminated culture or an insufficient fermentation temperature (Nummer, 2013). The lowest acceptable pH should not be below pH 3.0, as this is the pH of the human digestive tract (Lončar et al., 2006).

7. Shelf life

Food business operators shall estimate, validate and set the shelf life of their kombucha during product development, using a shelf life study that considers the possible conditions of storage, distribution and use. Additionally, food business operators should understand the effect of variable fermentation conditions (e.g. temperature, brine concentration, sugar concentration, and duration) on the shelf life of the product.

8. Alcohol concentration

Many factors influence the organoleptic and nutritional properties of kombucha. These factors include temperature, pH, oxygen/carbon dioxide concentration, the nature and composition of the SCOBY, duration of fermentation, plant material, sugar concentration and type used (Marsh et al., 2014; Wolfe and Dutton, 2015). For further information on alcohol in fermented plant beverages, see the Alcohol content section of this Guidance Note.

Unless the kombucha is pasteurised, it is recommended that it is stored refrigerated throughout its shelf life, in order to prevent further fermentation and alcohol production.

Water kefir

Water kefir is a fermented beverage based on fermentation using water kefir grains, water and sugar solution, with the optional addition of dried and fresh fruits. Water kefir grains are made up of a variety of bacteria and yeast, which appear as small translucent grains (Table 3). In the traditional process of water kefir production, the kefir grains are put into water containing dried fruits (typically figs) and some slices of lemon. Fermentation over 1 or 2 days at room temperature results in a cloudy, lightly carbonated and straw-coloured drink, which is acidic, low in sugar and may contain low levels of alcohol (Gulitz et al., 2011). Figure 8 outlines the common steps involved.

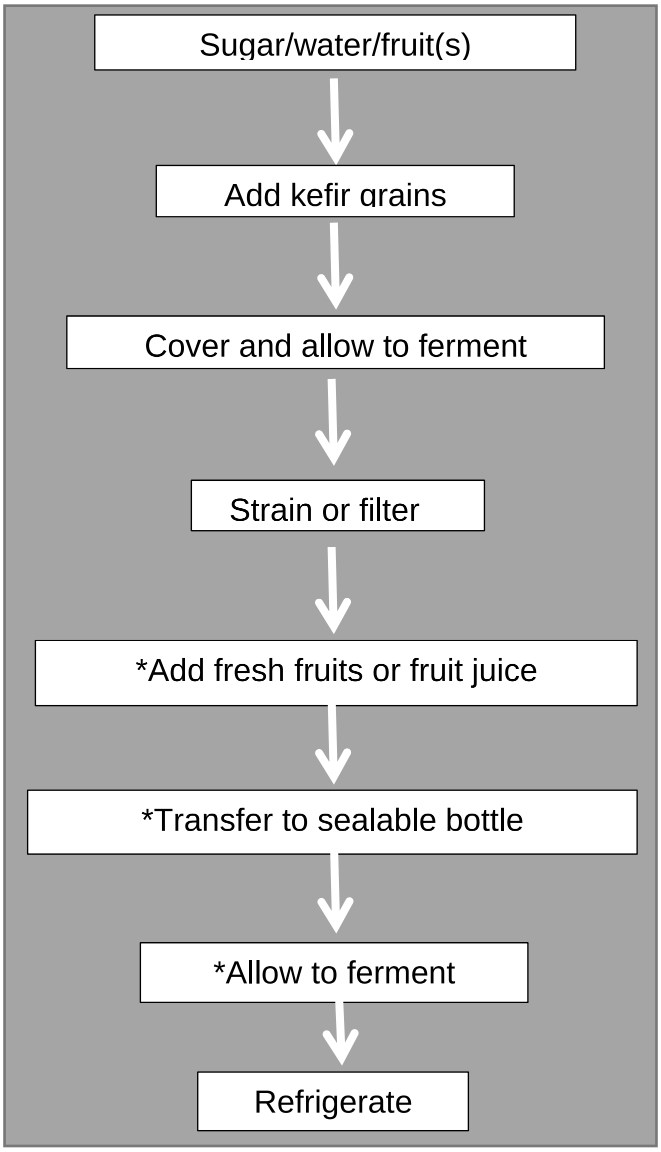


Figure 8. Manufacture of water kefir

* optional secondary fermentation step

Fermentation is carried out in an unsealed vessel, covered by a clean breathable cloth material to prevent contamination. The kefir will still ferment if the lid is sealed; however, the gases produced may cause the vessel to explode. The fermentation is generally conducted over 1–2 days under aerobic conditions and at room temperature (i.e. 19 ºC).

A secondary fermentation step (duration 12-24hours), designed to add flavour, is optional. In such cases, fruit, fruit juice or other sugary liquid can be added to the sealed container.

Source: (Openshaw, 2018; Cultured Food Life, 2021)

Figure 9. Photograph on left shows water kefir grains freshly strained from a batch of water kefir; photograph on right shows a kefir fermentation.

Water kefir grains are gelatinous structures of 5–20 mm in diameter. They have a dry matter content of 10–14% (w/w) and an irregular, cauliflower-like shape (Lynch et al., 2021)

Table 3. Microorganisms involved in the production of water kefir

Bacteria (species)	Yeasts (species)
Lactobacillus spp. and *Lacticaseibacillus* spp.	*Kluyveromyces* spp.
Lactococcus spp.	*Saccharomyces* spp.
Leuconostoc spp.	*Pichia* spp.
Streptococcus spp.	
Candida spp.	
Lactic acid bacteria	
Acetic acid bacteria	

Source: Lavefve et al. (2019)

Kefir food safety controls

Several key controls can aid in an efficient fermentation and safe production of kefir.

1. Selection of appropriate ingredients
   The kefir grains, sugar source and other ingredients, i.e. fruits/herbs selected should be of good quality and sourced from a reputable supplier. Food business operators must ensure that the ingredients are free from physical hazards e.g. glass, plastic, stones, soil, insects.

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2. Sugar solution preparation
   A sugar source (sucrose) at an optimal concentration of 8% w/v is dissolved in boiling water. The solution should be covered with clean breathable material to reduce the risk of contamination and it should be allowed to cool to room temperature. The cooled sweetened water is then poured into a sterile fermentation vessel.

3. Addition of kefir grains
   Kefir grains are added to the sweetened water and these generally fall to the bottom of the fermentation vessel. In addition, some previously fermented kefir water is sometimes added to inoculate the cooled sweetened water (back sloping). Fruits including figs or freshly sliced lemon are sometimes added at this point.

4. Covering the fermentation vessel during the fermentation period
   Kefir is generally fermented aerobically and the sterile vessel is unsealed but covered with a clean breathable material to prevent the entry of insects, e.g., fruit flies that will be attracted to the sugar water. Some producers prefer to use sealed vessels to enhance organoleptic properties. However, there are several risks associated with this practice, e.g. over-pressurised vessels that may explode, increased production of alcohol, and the inhibition of typical kefir fermentation due to excess build-up of carbon dioxide. The vessel is typically made of glass or other material and must comply with FCMs legislation.

5. Fermentation

The fermentation is usually carried out using an unsealed vessel. Food business operators must understand that their fermentation process can be affected by many variables. The time allocated for the fermentation of kefir is generally 1–3 days, but this will depend on other factors, including ambient temperature, the composition of the ferment and desired organoleptic properties.

6. pH

The pH of optimally fermented kefir is generally less than pH 3.4 within 5 days (Gulitz et al., 2011; Laureys and De Vuyst, 2014); however, the typical final pH is in the range of pH 3.0 to 3.5 (Laureys and De Vuyst, 2014). The food business operator should understand the nature of their fermentation, ensuring that a pH value of less than 4.4 is reached during fermentation and maintained until the end of the shelf life of the product. This will prevent the growth of Listeria monocytogenes and toxin formation by Clostridium botulinum. The lowest acceptable pH should not be below pH 3.0, which is the pH of the human digestive tract (Lončar et al., 2006).

7. Shelf life

Food business operators shall estimate, validate and set the shelf life of their kefir during product development using a shelf life study that considers the possible conditions of storage, distribution and use. Additionally, food business operators should understand the effect of variable fermentation conditions (e.g. temperature, brine concentration and fermentation duration) on the product shelf life.

8. Alcohol concentration

Many factors influence the organoleptic and nutritional properties of kefir. These factors include temperature, pH, oxygen/carbon dioxide concentration, the nature and composition of the kefir grains, duration of fermentation, fruits and sugar concentration, and type used (Sarkar, 2008; Laureys and De Vuyst, 2014). For further information on alcohol in fermented plant beverages, see the Alcohol content section of this Guidance Note.

Unless steps such as dealcoholisation or pasteurisation have been taken to ensure that the alcohol concentration remains below 1.2% alcohol by volume (ABV), it is recommended that kefir is stored refrigerated during its shelf life.

Labelling of prepacked fermented foods

For prepacked foods, the following mandatory information must appear directly on the package or on an attached label.

1. The name of the food
2. The list of ingredients
3. Any ingredient or processing aid listed in Annex II to Regulation (EU) No 1169/2011 or derived from a substance or product listed in Annex II causing allergies or intolerances used in the manufacture or preparation of food and still present in the finished product, even if in an altered form
4. The quantity of certain ingredients or categories of ingredients
5. The net quantity of the food
6. The date of minimum durability or the 'use by' date
7. Any special storage conditions and/or conditions of use
8. The name or business name and address of the food business operator
9. The country of origin or place of provenance where its absence may mislead the consumer as to the true origin or provenance of the food, or where the country of origin is specifically required under legislation
10. Instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
11. With respect to beverages containing more than 1.2% alcohol by volume (ABV), the actual alcoholic strength by volume. (For further information, see the Alcohol section in this document.)
12. A nutrition declaration (some exemptions are permitted as per Regulation (EU) 2016/559).

For further information and examples of labels from prepacked foods, please refer to FSAI guidance documents on food information to the consumer; these can be found on the FSAI website (www.fsai.ie).

Alcohol content

Fermented beverages produced using a starter culture of bacteria and yeast may contain alcohol (ethanol) produced during the fermentation process. Sometimes, after bottling and in the absence of oxygen, the yeast can continue to degrade residual sugars, which increases carbonation and produces alcohol levels greater than the labelling threshold of 1.2% (Dufresne and Farnworth, 2000). In a sealed container the build-up of carbon dioxide inhibits the conversion of alcohol to acetic acid (Nummer, 2013).

Fermented beverages such as kombucha and kefir can contain varying levels of alcohol. In accordance with Article 9.1 (k) of Regulation (EU) No 1169/2011, beverages containing more than 1.2% alcohol by volume (ABV) must indicate the actual alcoholic strength by volume (% v/v). Annex XII to Regulation (EU) No 1169/2011 also specifies that the volume of alcohol must be indicated by a figure to not more than one decimal place, followed by the symbol '% vol' and may be preceded by the word 'alcohol' or 'alc'.

Under Article 7(a) of Regulation (EU) No 1169/2011 on the provision of food information to consumers, the labelling must not be misleading. Therefore, declaring kombucha and kefir as 'Alcohol-free' or 'Non-alcoholic' may carry a risk of misleading the consumer where alcohol production continues after the fermentation process, and while the kombucha and kefir products are in storage.

The food business operator should ensure that a fermented food or drink which exceeds the alcohol content of 1.2% ABV conforms with the labelling requirements of Regulation (EU) No 1169/2011. Necessary steps to prevent the excess production of alcohol during shelf life should be clearly illustrated where appropriate. For example, the storage instructions for an unpasteurised product should indicate that it is to be stored in a chilled environment (e.g. 5 °C) to prevent additional fermentation during the specified shelf life.

Control of factors, including temperature, pH, sugar content, and the proportion of yeast and bacteria, aid in limiting anaerobic alcohol production after packaging. Kombucha and kefir can also be pasteurised, for example, at 70 °C for 2 minutes to prevent the production of alcohol during storage. Approved preservatives may also be used to inhibit further fermentation.

Measuring alcohol content in beverages

Direct measurement of alcohol is possible using several methods, including a pycnometer, density meter, and near-infrared and gas chromatography. Indirect measurement of alcohol is possible using several methods, including a hydrometer and a refractometer.

The method of analysis selected for the determination of alcohol in fermented products must be validated against an accredited method within a tolerance of 0.3% ABV as per Annex XII to Regulation (EU) No 1169/2011. See Appendix II for an example of validation data required for an alcohol testing method.

Packaging

During the fermentation of plant material using the natural microbial population or with a starting culture, there may be variations in the amount of gas produced. During production and packaging, the pressure produced by the fermentation process may be released using valves or a fermentation airlock valve. The final product should be packaged using food-grade packaging and it should be stored in such a way as to minimise the risk of post-production fermentation. Specifically, glass containers that develop excessive pressure as a result of the fermentation process may unexpectedly explode and pose a potential physical risk from shattered glass.

Shelf life stability of raw fermented vegetable products

Manufacturers of fermented food are responsible for setting and validating the shelf life. The fermented food should be stored as per instructions from the manufacturer.

There is no generic approach for determining the shelf life of fermented food, as this will be influenced by many factors, e.g. microbiological quality of the raw ingredients, the fermentation process, use of a starter culture, etc. The food business operator will need to choose a suitable approach to setting and validating shelf life based on the fermented food they are producing, in order to fulfil their obligation to produce food that is safe for the consumer.

Further information on good practice to estimate, set and verify the safety of food over its shelf life can be found in the FSAI's Guidance Note 18: Validation of Product Shelf-life.

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Appendix I pH

Recommendations for the appropriate use of pH meters and probes

1. The operating specification of the meter and probe should span the range of the expected use and storage environmental conditions.
2. The pH meter and calibrants should be accurate and reliable.
3. Calibrant solutions used during calibration should span the range expected to be measured.
4. Calibrant solutions should be at a similar temperature as the matrix being tested. For example, if the food product is fermenting at 19 ºC, the calibrants should be stored at a similar temperature.
5. Calibration should be undertaken at a similar temperature as the product being tested.
6. The pH probe should be appropriate for the product that is being tested. Discussion with equipment suppliers is advised, in order to source the most appropriate pH probe type for specific applications.
7. The life of a pH probe has a limit, usually defined by the manufacturer, and this limit should be observed as best practice.
8. pH probes should be stored in pH probe storage solution, not in water or deionised water and never allow the pH bulb to dry out.
9. Never reuse calibrant solutions – always use a fresh calibration solution for each calibration.
10. Keep a calibration log for the pH recording system.
11. It is best practice to have the pH measuring system calibrated by an external certified testing service periodically (e.g. annually).

Table 4. pH calibration template

Date	Calibration ID (year/number)	pH meter ID	pH probe ID	Calibrant 1 pH*/ actual**	Calibrant 2 pH*/ actual**	Calibrant 3 pH*/ actual**	Temp (ºC) of calibrants	Signature
1 January 2020	2020/2021	001	001	**1.67**/1.65	**4.01**/3.99	**7.01**/7.05	19.5 ºC	A Jones

Note: Record date of calibration, meter and probe ID, and calibrate the system as per the manufacturer's calibration instructions. Multiple calibration points are more accurate than a single calibration point (e.g. 7.01) and the calibrants should span the range of expected pH values (e.g. pH 7.01, pH 4.01 and pH 1.67) *Certified calibrant pH value. ** The actual pH value of the pH calibrant when tested after the calibration. Where the actual pH tested deviates +/- 0.2 pH units from the certified calibrant pH value, the system should be recalibrated.

Table 1. Batch pH record template

Fermented product name ________________________________

Batch ID	Date/pH	Date/pH	Date/pH	Date/pH	Date/pH	Critical control point	Comments	Signature
001	1 January 2020/pH 6.45	3 January 2020/pH 4.35	6 January 2020/pH 3.55	9 January 2020/pH 3.35	12 January 2020/pH 3.32	<4.2	Satisfactory	A Jones
002	1 January 2020/pH 6.45	3 January 2020/pH 6.35	6 January 2020/pH 6.25	9 January 2020/pH 6.25	12 January 2020/pH 6.22	<4.2	Unsatisfactory, discard	A Jones

Appendix II Alcohol

Table 2. Example of validation data for alcohol testing method

Date	Batch #/ Replicate	Result A Alcohol v/v determined by ebulliometer* (%)	Result B Alcohol v/v determined by INAB-accredited laboratory ¥ (%)	Variance difference between Result A and B (%)	Is the variance greater than 0.3%? Yes/No **	Result	Signature
1 January 2020	123/1	0.3	0.3	0.0	No		A Jones
1 January 2020	123/2	0.2	0.4	0.2	No	**Satisfactory**	A Jones
1 January 2020	123/3	0.4	0.2	0.2	No		A Jones
3 January 2020	124/1	0.6	1.0	0.4	Yes		A Jones
3 January 2020	124/2	0.7	1.0	0.3	No	**Unsatisfactory: Revalidation required.**	A Jones
3 January 2020	124/3	0.6	1.0	0.4	Yes		A Jones

Note: Record the date of the validation process. Sampling (in triplicate per batch) should span typical production and represent the expected shelf life of the products. *Or determined by another suitable method, e.g. gas chromatography, distillation followed by gravimetric determination of the distillate, near-infrared spectrometry or another suitable analytical method. **Acceptable tolerance value 0.3% derived

from the method of analysis used to determine the alcoholic strength as per Regulation (EU) No 1169/2011 Annex XII. Revalidate the test method if the 0.3% v/v deviation is exceeded. ¥INAB accredited test for quantification of ethyl alcohol (ethanol) which is measured at 20 ºC.

Table 3 Alcohol concentration data sheet template

Table 7 is an example of a data sheet record to monitor the alcohol content of fermented beverages where alcohol concentration may exceed 1.2% v/v.

Date	Batch #/ Replicate	Alcohol ABV (%)	Alcohol ABV (%) Greater than 1.2% ABV?	Corrective action	Comments	Signature
1 January 2020	123/1	0.9	No	N/A	Satisfactory	A Jones
1 January 2020	123/2	1.5	Yes	Discard	Unsatisfactory. Review process and discard product.	A Jones

Note: Record date, time, alcohol content and initials of the operator. Alcohol measuring device should be cross-validated with an external INAB-validated method (see Appendix II) and must not exceed 0.3% v/v tolerance deviation.

Appendix III Calculating the correct amount of salt for fermented vegetables

How to calculate the correct amount of salt for fermented vegetables

Fermented vegetables, such as sauerkraut or kimchi, need between 1% and 3% salt in order to provide adequate food safety during fermentation.

To calculate what percentage salt you are currently using, the following calculation can be used:

Divide the amount (grams) of salt by the amount (grams) of vegetables (and water (grams) if using a brine) and multiply it by 100.

$$(\textbf{Salt} \div \textbf{vegetables}) \times \textbf{100}$$

Note: both vegetables and salt must use the same unit of measurement, such as grams.

For example, the calculation below is for when you are using 2 kg of cabbage and 40 g of salt.

$$\textbf{(40 g (salt)} \div \textbf{2000 g (vegetables))} \times \textbf{100 = 2\%}$$

Therefore, the recipe uses 2% salt.

To calculate a 2% salt dosage, for example, use the following calculation:

$$\textbf{(Vegetables (g)} \times \textbf{2\% = salt required (g))}$$

If you do not know how much salt to use in your formulation, use the following calculation:

$$\textbf{(2000 g} \times \textbf{2\%) = 40 g salt required.}$$

Appendix IV: HACCP considerations for kombucha and sauerkraut

Table 8. Example of HACCP considerations for kombucha

Kombucha				
Step	What can go wrong here? (hazards)	What can I do about it? (control/critical limits (CLs))	How can I check? (monitoring/verification)	What if it is not right? (corrective actions)
Steeping of tea	Survival of vegetative pathogens in loose tea	Use boiling water to steep the tea.	Check visually that the water has reached a rolling boil before use.	Continue to boil the water until a rolling boil is reached.
Cooling	Biological cross-contamination	Cover the container with a suitable material (e.g. cheesecloth) to protect the food.	Visual check	Staff training
Preparation	Contamination of the culture with undesirable moulds, etc.	Use a commercially purchased culture on first use. Reuse only culture that shows no signs of mould/contamination.	Visually check for mould growth.	Discard the culture if necessary.
Fermentation at room temperature	1. Growth of pathogens in tea 2. Over-fermentation	1. Ferment aerobically to ensure that acetic acid production reaches a	1. pH monitoring using a calibrated pH meter	Dilute high-acidity tea with freshly brewed tea, in order

	3. Chemical leaching from fermentation containers	point where pH </=4.2 and >3.0. Use a container with a pressure release. 2. Control fermentation temperature. 3. Proper storage 4. Ferment in a non-metallic food-grade container.	2. Typical fermentation temperatures range 18–22 °C 3. Store away from sunlight and preferably in dark-coloured containers 4. Visually check that the food-grade container is non-metallic and in sound condition.	to reach correct acidity (pH </=4.2 and >3.0).
Storage	Over-fermentation of the tea	1. Store refrigerated at 5 °C in a covered container with a tight-fitting lid, in order to slow fermentation. This will cause the headspace in the container to fill with carbon dioxide.	1. Temperature checks on the fridge with a thermometer 2. Determination of shelf life and shelf-life testing 3. Using a calibrated hydrometer, check that the percentage of	Discard the product.

		2. Production of excessive alcohol in stored product	alcohol remains below 1.2%.	
Steeping of tea	Survival of vegetative pathogens in loose tea	Use boiling water to steep the tea.	Check visually that the water has reached a rolling boil before use.	Continue to boil the water until a rolling boil is reached.
Bottling	The outgrowth of undesirable pathogens/alcohol fermentation	1. Employ pasteurisation technique. 2. Hot fill containers and invert for 15 seconds.	Ensure that the pasteurisation temperature (82 °C) is reached. After 30 seconds, invert bottle and hold for another 30 seconds. Allow bottles to cool.	Discard the product.
Labelling/product information.	Overconsumption above recommended daily intake (RDI)	Provide product information to consumers, as appropriate, and on labels, as appropriate.	1. Ensure that no more than 110 ml served to consumers per day (US Centers for Disease Control and Prevention (CDC) guidelines) 2. Product shelf life	

Table 4 Example of HACCP considerations for sauerkraut

Sauerkraut				
Step	**What can go wrong here? (hazards)**	**What can I do about it? (control/critical limits (CLs))**	**How can I check? (monitoring/verification)**	**What if it is not right? (corrective actions)**
Supplier control	High biological loading on the cabbage as an ingredient	Use reputable suppliers.	1. Carry out visual checks on goods delivery. 2. Seek supplier quality credentials (registered food business operator, quality system, etc.)	Reject delivery.
Salting	Uneven distribution of the salt Cross-contamination	1. Thoroughly mix the salt into the slaw at a rate of 2–3% per weight. 2. Use sanitised equipment.	1. Visually check that the salt is evenly dispersed. 2. Follow the prerequisite programme.	Continue mixing.

Fermentation	Growth of pathogens in sauerkraut	1. Cover the container with a suitable, clean and food-grade material (e.g. cheesecloth), in order to protect the food. 2. Ferment aerobically with cabbage mixture covered completely with brine, in order to ensure that lactic acid production reaches pH </= 3.8 and >3.5.	pH monitoring using a calibrated pH meter	Discard.
Filling	An outgrowth of undesirable pathogens in the final product	1. Sterilisation of jars/containers 2. Hermetic seal on containers	1. Ensure that boiling water is used to sterilise jars. 2. Ensure that jars are sealed.	Staff training
Storage		Store refrigerated at <5 °C in a covered container with a tight-fitting lid in order to slow decomposition and maintain pH stability.	1. Temperature checks on the fridge with a thermometer 2. Determination of shelf life and shelf-life testing	Discard the product.

Labelling/product information	pH changes in product during shelf life	Provide product information to consumers on storage conditions (<5 °C).	Ensure that product labels contain correct information.

Consultation Process

During the creation of this guidance document widespread consultation was sought from many internal and external stakeholders. They included FSAI staff, the artisan forum, the Health Service Executive, food business operators, and Teagasc.

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