

Guidelines for assessing the microbiological safety of ready-to-eat foods placed on the market

Interpretation of test results generated by UKHSA Food Water and Environmental Microbiology Services Laboratories 2024

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Where we are with the RTE guidelines 2024



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2024

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Prepared by members of the UKHSA Food, Water and Environmental Microbiology Service Strategic Management Group and in memory of Dr Jim McLauchlin.

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What's the point of these guidelines?

Intended use

- These guidelines are intended for use by Food Examiners within UKHSA as well as enforcement officers in local authorities and port health authorities in identifying situations requiring investigation for public health or food safety reasons. Samples can be collected under the following circumstances.
- FBOs have obligations to produce and serve safe food and ensure that
 microorganisms are eliminated or minimised to an acceptable level to the
 extent that they cannot cause harm to human health and that food is fit for
 human consumption.
- The FWEMS laboratories contribute towards the response to foodborne threats to health and work to provide authoritative and practical expert advice to a range of stakeholders.
- These guidelines do not take precedence over microbiological criteria within UK legislation

- They serve to be consistent with and complement legally enforceable standards (e.g. EC2073/2005 or EC178/2002), as well as providing an indication of the microbiological safety of foods where other standards currently do not exist or are not explicit.
- Recommends investigative and corrective actions that can be used to identify and rectify the cause for those
 foodstuffs not compliant with microbiological food safety criteria and/or where there is a perceived risk to public
 health.
- To safeguard public health, additional tests on RTE foods not covered by the regulations may be considered appropriate. Food samples prepared in a premises that are taken as part of inspections by enforcement officers we would expect satisfactory results for all parameters.
- Any deviation from satisfactory results should be investigated
- Urgency of response should be proportional to the extent and types of contamination

Significant changes to the guidelines

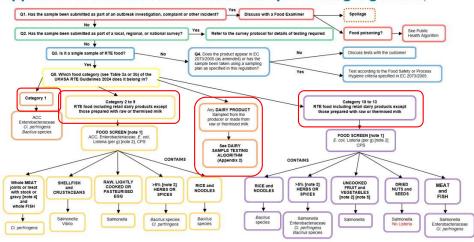
- Re-formatted to comply with government rules on accessibility
- Information has been updated and reorganised
- Information on current legislation and arrangements following EU Exit added
- Update to include the sample testing algorithms used by FWEMS to target resources at those foods more likely to pose a Public Health risk.
- Updated how we interpret low levels of Listeria monocytogenes in foods.
- We have updated information with respect to the detection and interpretation of Shiga toxin producing *E.coli*.
- We have added Yersinia spp to the pathogens with significance in RTE food
- More information on each food categories (1-13) has been provided in the revised guidelines and assessment of predominant flora in some food time may be require to fully interpret the results obtained.

Information updated and re-organised

- Sampling and transport —new section added recognising the critical importance of this
 in enabling interpretation of a sample result.
- Interpretation of results section added
 - PCR section added
 - Pathogens –represents a risk to health
 - Hygiene indicators faecal contamination, poor hygiene, inadequate practice, poor quality ingredients
 - ACC quality indicator
- Reporting of results section added
 - Formal samples section added
- Pathogen specific information has been brought together in a table format for ease of access and this is presented alongside a table of interpretation for that pathogen
- More information on food categories and ACC in foods

Testing algorithms used by FWEMS to target resources at those foods more likely to pose a Public Health risk –RTE food

Appendix 1. UKHSA FWEMS food sample testing algorithm



Notes

[Note 1] If the product is dried or frozen consider using the MPN method for E. coli.

[Note 2] If the product has been sampled as part of an outbreak investigation, has been sampled from the producer, has a shelf-life of >4 days or is for consumption by high risk groups perform detection in 25g.

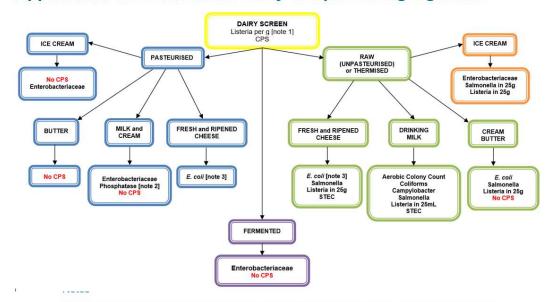
[Note 3] Test products with less than 5%, if herbs or spices are an unprocessed garnish or additive.

[Note 4] Test for Campylobacter if the sample is a poultry pâté or parfait.

[Note 5] RTE sprouted seeds should not be tested for *E. coli* or Coagulase positive staphylococci (CPS) but should otherwise be tested in accordance with the algorithm with inclusion of Shiga toxin producing *E. coli* (STEC) and Listeria in 25g.

Testing algorithms used by FWEMS to target resources at those foods more likely to pose a Public Health risk –RTE dairy

Appendix 2. UKHSA FWEMS dairy sample testing algorithm



[Note 1] Test 25g or 25ml if sample has a shelf-life of more than 4 days or if it is deemed able to support the growth of Listeria (pH >than 4.4, a_w>0.92 or >pH5.0 / a_w 0.94 in combination).

[Note 2] Phosphatase testing should not be carried out on whipped or clotted cream. There are no statutory limits for alkaline phosphatase in cream.

[Note 3] If the product is ripened consider using the MPN method for E. coli.

Bespoke Submittal forms

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7. Dressings, dips and pastes	□ Dri	ed nuts or seeds	☐ ILOG number:	
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Listeria monocytogenes and Listeria species

Table 1f.ii. Interpretation of results for detection and enumeration of *Listeria* monocytogenes from RTE foods placed on the market

Result (cfu/g)	Interpretation	Likely cause	Suggested actions (not exclusive)
>100 [note 1]	Unsatisfactory: potentially injurious to health and/or unfit for human consumption	Strong evidence for poor processing, environmental or cross-contamination during production or at point of sale, poor temperature control or inappropriate length of shelf-life.	Immediate investigation of: the food origin, production process and environment. Take investigative samples of food and environmental monitoring.
Detected [note 2] up to ≤100	Borderline	Likely evidence for poor processing and/or poor quality raw materials.	Risk will increase proportional to the levels detected and the likelihood of subsequent growth under storage conditions. When detected at \$100 cfu/g it is also necessary to know whether the manufacturer has evidence to show that >100 cfu/g is not likely to be exceeded throughout the shelf-life of the product. [note 1] Review quality of raw materials, food preparation environment (including cleaning), cooking, temperature and shelf-life controls. Consider taking investigative samples of food and environmental swabs. In refrigerated high-risk foods where there is a potential for growth during storage, and in foods likely to be served to vulnerable groups (such as that served in hospital) the presence of <i>L. monocytogenes</i> at any level may be of significance and should be investigated.
Not detected <10/20	Satisfactory	n/a	n/a

[Note 1] Regulation (EC) 2073/2005 (as amended) $(\underline{40})$ has a criterion for absence in 25g in RTE foods intended for infants and foods for special medical purposes placed on the market during their shelf life.

[Note 2] Includes where the organism has been detected by enrichment only in a 25g sample and at less than 10/20 cfu/g.

Table 2c. Interpretation of results for detection and enumeration of *Listeria* species. (not *L. monocytogenes*) from RTE foods placed on the market

Result (cfu/g)	Interpretation	Likely cause	Suggested actions (not exclusive)
>10²	Unsatisfactory	Strong evidence for poor processing, or poor temperature control including suboptimal operation of refrigerators, or over extension of shelf life.	Review factory hygiene (including cleaning) together with temperature and shelf-life controls. Take investigative samples of food and the food preparation environment, particularly plant and machinery.
Detected [note 1] up to ≤10 ²	Borderline	Possible evidence for poor processing or poor-quality raw materials. Indicate process has the potential to allow contamination by <i>L. monocytogenes</i> .	Review quality of raw materials, factory hygiene (including cleaning), temperature and shelf-life controls. Consider taking investigative samples of food and the food preparation environment, particularly plant and machinery. Consider sending isolates for reference tests. Action should be proportional to levels detected.
Not detected <20	Satisfactory	n/a	proposition and additional

[Note 1] Includes where the organism has been detected by enrichment only in a 25g sample and at <20 cfu/g.

STEC

Table 1e.i. Shiga-like toxin-producing Escherichia coli (STEC) of O157 and other Oserotypes in RTE foods placed on the market

Aetiological agent and incidence of infection	Members of a group of bacteria which are widespread in the enteric tracts of animals and containing shiga-toxin (stx) genes. The majority of STEC infections diagnosed in the UK are caused by serotype 0157 followed by 026. Detection methods are increasingly identifying more cases due to non-0157 STEC. All STEC should be considered as pathogenic for humans and capable of causing at least diarrhoea. Based on the analysis of the stx subtypes, certain STEC subtypes may be associated with severe illness, that is, haemolytic uraemic syndrome (HUS), bloody diarrhoea (BD) and/or hospitalisation. Although stx2a showed the highest rates of HUS, hospitalisation and BD, all other stx subtypes or combinations thereof, for which there was sufficient data, are also associated with at least one of these severe illness outcomes. There are around 800 cases diagnosed annually in England and Wales.
Symptoms and host risk factors [note 1]	Symptoms can range from asymptomatic to mild gastroenteritis through to severe BD. On rare occasions, STEC infections cause serious conditions: HUS; and thrombotic thrombocytopenic purpura (TTP). Cases of HUS and TTP usually require hospitalisation and can be fatal. Variable duration of illness. Gastrointestinal illness may last from a few days up to a week while more severe disease may last longer. Disease more likely to develop in children and the elderly. Asymptomatic carriage is rare.
Exposure and incubation period	1 to 6 day incubation period. Low dose exposures are likely to cause disease.
Transmission	Acquired through ingestion of viable organisms. Most cases are foodborne, transmission also by consumption of untreated water, direct contact with animals or natural environments and person-to person spread. Foods frequently associated with infection include undercooked red meats, for example, beefburgers; salads and other leafty greens; unpasteurised milk and dairy products; fermented meats. Linked to foods prepared outside the home, untreated water or milk (for example, associated with leisure activity, farm/caravan sites), children's nurseries and petting farms. Animal reservoirs include cattle, sheep, goats, pigs, horses, farmed deer, dogs, rabbits and geese.
Control measures	Killed by heat-treatment (equivalent to pasteurisation). May survive low pH (3.6 to 4.0), drying in food and fermentation processes, and for extended times in natural environments (for example, cow pats). Can grow in foods (7 to 46 °C) and survives well at chill temperatures. Hygiene controls during food preparation (for example, raw beef) are important to prevent cross contamination.
Additional information	Also known as Vero-cytotoxin producing <i>E. coli</i> (VTEC). There is a requirement in European food law (Regulation (EC) 209/2013) for sprouted seeds to be tested for the presence of STEC 0157, 026, 0111, 0103, 0145 and 0104.

[Note 1] Features other than those described may occur but are generally considered less common than those listed.

Table 1e.ii. Interpretation of results for detection of Escherichia coli O157 and other shigatoxin-producing E. coli (STEC) from RTE foods placed on the market

Result in 25g [note 1]	Interpretation	Likely cause	Suggested actions (not exclusive)
Detected [note 2]	Unsatisfactory: potentially injurious to health and/or unfit for human consumption	Inadequate processing and/or cross contamination Contamination of untreated raw products (for example, salads).	Immediate investigation of: the food origin, production process and environment; take investigative food samples and consider environmental monitoring
Not detected	Satisfactory	n/a	n/a

[Note 1] Testing of more or less food may be indicated during outbreak investigations or when sampling is based on Regulation (EC) 2073/2005 as amended (40). There can be occasions of presumptive detection of STEC which are not confirmed by the isolation of the bacterium. It is not possible to interpret presumptive detection by PCR in the absence of isolation of an STEC in pure culture. Detection by PCR alone could indicate that background bacteria have caused interference with the isolation of STEC by culture. Alternatively, stx genes may potentially be present in species of bacteria other than E. coli; or stx genes present in dead STEC organisms or free stx-containing phage may have been detected.

[Note 2] All STEC should be considered as pathogenic for humans and capable of causing at least diarrhoea and although stx2a showed the highest rates of HUS, hospitalisation and BD, all other stx subtypes or combinations thereof were also associated with at least one of these severe illness outcomes (58).

Yersinia species

Table 1j.i Yersinia enterocolitica and Y. pseudotuberculosis in RTE foods placed on the market

Aetiological agent and	Yersinia species are a diverse group of bacteria belonging to the
incidence of infection	Yersiniaceae family of bacteria. Yersiniosis, which is caused by the enteric bacterial pathogens Yersinia enterocolitica and Yersinia pseudotuberculosis is the third most commonly reported zoonotic
	infection in Europe (60). In the UK, diagnosis of yersiniosis is typically only attempted in patients with severe illness where yersiniosis is
	suspected or where immunological sequelae are evident following a gastrointestinal illness. In 2020 it was estimated that around 7,500 Y. enterocolitica infections go undiagnosed in England annually (60). The apparently low incidence of yersiniosis in England is probably due to
Symptoms	limited laboratory testing. Gastrointestinal symptoms that can last for 1 to 3 weeks. Following
and host risk factors [note 1]	Gastioniestinal symptonis taid call last for 1 to 3 weets. Perioding infection some patients go on to develop secondary immunological complications, including erythema nodosum, arthritis, Reiter's disease and glomerulonephritis. Y. entervocilitica and Y. pseudotuberculosis have also been associated with causing a number of other primary acute
	infections, including mesenteric lymphadenitis, terminal ileitis and pseudo-appendicitis.
Exposure and	The infectious dose is thought to be high at 108 to 109 cells, the
incubation period	incubation time is about 3 to 7 days but can be between 1 and 11 days.
Transmission	Transmission from animals to humans can occur via direct contact with animals or with their environment. Pigs are the animal most associated with transmission of pathogenic Y. enterocolitica although most human gastrointestinal infections are foodborne. Outbreaks of yersiniosis associated with the consumption of contaminated meat, dairy products, and salad vegetables have been reported.
Control measures	This organism will grow at refrigeration temperatures. The organisms are killed by adequate cooking. Food produced under good manufacturing practices pose only a negligible risk for transmission of Yersinia species. The presence of Yersinia species in RTE food may be seen as an indication of hygiene concerns such as cross-contamination, inadequate cooking and/or poor storage.
Additional information	Y. enterocolitica and Y. pseudotuberculosis are conventionally identified using biochemical tests to genus and species level. Y. pseudotuberculosis is a homogeneous species, whereas Y. enterocolitica
	is heterogeneous, comprising 6 biotypes. Historically, biotype 1A was regarded as being non-pathogenic in humans and biotype 1B was regarded as highly pathogenic. Pathogenicity can also be linked to particular serotypes of <i>Y. enterocolitica</i> , with O·3, O·8, O·9 and O·5,27 being the serotypes most commonly associated with human illness. Virulent strains carry virulence genes ystA, invA and ail. Currently there are no statutory microbiological criteria for <i>Yersinia</i> species

[Note 1] Features other than those described may occur but are generally considered less common than those listed.

Table 1j.ii Interpretation of results for detection of Yersinia enterocolitica or Yersinia pseudotuberculosis from RTE foods placed on the market

Result in 25g [note 1] [note 2]	Interpretation	Likely cause	Suggested actions (not exclusive)
Detected [note 3]	Unsatisfactory: potentially injurious to health and/or unfit for human consumption	Inadequate processing. Cross contamination. Poor temperature control.	Immediate investigation of the food origin, production process and environment; Consider the Enterobacteriaceae count obtained from the sample and virulence characteristics; take investigative food samples and consider environmental monitoring.
Not detected	Satisfactory	n/a	n/a

[Note 1] Testing of more or less food may be indicated during outbreak investigations.

[Note 2] Perform a risk assessment before any further action.

[Note 3] Levels of Yersinia that are likely to cause harm are not fully understood, but investigation should be undertaken where it is detected in RTE food.

Table 3 Aerobic Colony Counts

Microbiology guidelines for ready-to-eat foods placed on the market

Table 3. Guidance on the interpretation of results for aerobic colony count levels in category 1 to 13 RTE foods placed on the market

Foo	od category	Examples		Result (cf	u/g)
			Satisfactory [note 1]	Borderline [note 2]	Unsatisfactory [note 3]
1	Ambient stable canned, bottled, cartoned and pouched foods immediately after removal from container	Canned products such as tuna, salmon, corned beef, soups, stews, desserts, canned fruit, UHT products, jams, chutneys, sauces such as pasta sauce.	<10	n/a	Check pH and aw [note 4]
2	Foods cooked immediately prior to sale or consumption	Takeaway food without salad, burgers, kebabs, sausages, pizza, cook or chill and cook or freeze after regeneration.	<103	10 ³ to <10 ⁵	≥10⁵
3	Cooked foods chilled but with minimum handling prior to sale or consumption	Whole pies, sausage rolls, samosas, flans, quiches, chicken portions, canned ham, pasteurised foods including fruit juice, soups, sauces, desserts, rice.	<104	10 ⁴ to <10 ⁷	≥10 ⁷
4	Bakery and confectionery products without dairy cream; powdered foods	Cakes without dairy cream; soup powders, milk powder, powdered dairy products; other powdered foods that will be RTE after reconstitution or warming.	<104	10 ⁴ to <10 ⁶	≥108
5	Cooked foods chilled but with some handling prior to sale or consumption	Sliced meats, cut pies, pâté, sandwiches without salad, hot smoked fish (for example mackerel), molluscs, cooked crustaceans and other shellfish out of shell.	<10 ⁵	10 ⁵ to <10 ⁷	≥10 ⁷ determine predominant flora [note 5]
6	Non-fermented dairy products, butter, dairy desserts, cooked sauces [note 6]	Pasteurised milk, butter, cream, ice cream, fresh cheese (mascarpone, paneer), trifle with dairy cream, cakes with dairy cream, cooked chilled sauces and gravy	<10 ⁵	10 ⁵ to <10 ⁷	≥10 ⁷

Microbiology guidelines for ready-to-eat foods placed on the market

Foo	d category	Examples		Result (cf	u/g)	
			Satisfactory [note 1]	Borderline [note 2]	Unsatisfactory [note 3]	
7	Food mixed with dressings, dips, pastes	Coleslaw (mass produced only), dips, taramasalata, houmous, sandwich fillings containing mayonnaise.	<108	10 ⁸ to <10 ⁷	≥10 ⁷	
8	Extended shelf-life food products requiring refrigeration	MAP or vacuum packed products, for example, sliced meats, unsmoked fish.	<106	10 ⁶ to <10 ⁸	≥108 determine predominant flora [note 5]	
9	Raw RTE meat and fish, cold smoked fish	Sushi containing raw RTE fish, smoked salmon, gravadlax.	<10 ⁶	10 ⁶ to <10 ⁷	Indicative of spoilage if the predominant organism: [note 7]	
10	Preserved food products: pickled, marinated or salted	Pickled or salted fish, cooked shellfish in vinegar, vegetables in vinegar or oil, honey, jam and chutney out of open jars.	n/a		ACCs not usually performed. For	
11	Dried foods	Fruits, berries, vine fruits, nuts, sunflower seeds, herbs, spices, dried fish, biltong, jerky, insects.			spoilage investigation, consider	
12	Fresh fruit and vegetables, products containing raw vegetables.	Whole fruit, pre-prepared fruit salads, vegetable crudités, salads, sandwiches with salad, mixed commodity salads containing raw vegetables.			investigating the reasons for an elevated level if the	
13	Fermented, cured and dried meats, fermented vegetables, ripened cheeses	Continental sausages or salamis, sauerkraut, olives, bean curd, cheddar, stilton, brie, fermented milk drinks and butter, yoghurt and products containing the above.			predominant organism: [note 7]	

Notes

[Note 1] Satisfactory: no action required.

[Note 2] Borderline: consider the source of the food (for example, producer or retailer) and the stage of shelf life before determining action. If other samples from the same source are also of borderline quality, further investigation may be appropriate.

[Note 3] Unsatisfactory: consider investigating the reasons for this level.

[Note 4] Food category

- most products are sterile when sampled from the container but if they are consumed after subsequent further preparation then assess them
 as category 5.
- these products are 'Unsatisfactory' if spore forming anaerobes are present and the pH (>4.4) or a_w (>.0.92) of the food is unable to control
 potential growth of these bacteria.

[Note 5] Food categories 5 and 8. Determine the predominant micro-organism. 'Unsatisfactory' if the predominant organism is >10⁵ yeasts, >10⁷ Gram negative bacillus or *Bacillus* species, or >10⁸ lactic acid bacteria.

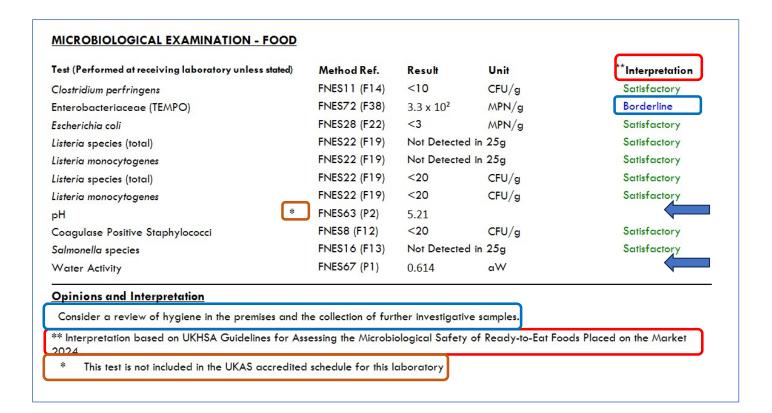
[Note 6] Food category 6. Separate standards exist for raw milk in the Food Safety and Hygiene (England) Regulations 2013 (<u>47</u>), requires that it must meet the standard of ≤20,000 <u>cfu</u> per ml.

[Note 7] is >108 yeasts, >107 Gram negative bacilli or Bacillus species, or >108 lactic acid bacteria unless added as a processing aid.

Interpretation

- Our StarLIMS system will be/has been updated to refer to the 2024 guideline in the opinions and interpretations section.
- The system has also been updated to automatically assign a borderline interpretation when Listeria is detected in 25g or in 25mL.
- When you receive a report with borderline Listeria particularly if it is L monocytogenes FWEMS recommends that this is followed up.
- Food Examiners and report approvers will be trained to interpret this

Reporting



Urgency of response

- Unsatisfactory Injurious to health- immediate action required.
- Unsatisfactory- Perform a review of hygiene or consider the reason for the high counts
- Borderline Consider extent and Consider a review of hygiene
- Satisfactory No action

Pathogens in food are to be notified to the FSA.

Summary

- The new RTE guidelines has now been published on 12th September.
- This is a significant revision overall but interpretation limits have really only been revised for *Listeria monocytogenes* and *Listeria* species where a borderline limit will now be used for single RTE foods on the market.
- Guideline has also been updated with respect to STEC including O157 STEC and non-O157 STEC and Yersinia species.
- These Guideline are the mainstay of how we interpreted test results and if used appropriate contribute to the protection of Public Health.