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Supporting document 4

Labelling - Application A1269

Cultured quail as a novel food

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application to permit the use of cultured quail as a novel food ingredient in food products marketed to caterers for use in high end restaurants.

Novel foods are regulated under Standard 1.5.1 (Novel Foods) and Schedule 25 (Permitted novel foods) in the Australia New Zealand Food Standards Code (the Code). Where specific labelling requirements are mandated for the sale of novel foods, these requirements are listed as conditions of use for the permitted novel food in section S25—2 of Schedule 25. Generic labelling requirements in Part 1.2 (Labelling and other information requirements) also apply to novel foods unless specific labelling requirements prevail.

As part of the assessment of the applicant’s cultured quail cells, FSANZ has reviewed generic labelling requirements to determine how they apply to the applicant’s cultured quail cells, and whether additional labelling measures would be warranted.

To inform the proposed approach, FSANZ has also had regard to a labelling risk management framework (comprising the priority objectives in section 18 of the FSANZ Act (1991), relevant Ministerial Policy Guidelines, international and overseas regulations, a systematic review of available scientific literature on cell-based food terminologies published by the Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO), industry perspectives on nomenclature, the hazard and risk assessment (Supporting Document 1 (SD1)) and consumer evidence (SD2).

For food for sale that contains the applicant’s cultured quail cells as a novel food ingredient, FSANZ’s proposed approach is to:

- require the following labelling elements:
 - require the statement ‘cell-cultured’ in labelling for food identification purposes
 - if the food for sale is not represented as a quail food product—apply the existing food name requirements
 - if the food for sale is represented as a quail food product—in addition to existing food name requirements, require the statement ‘cell-cultured’ to be included in the name of the food

- apply existing ingredient naming requirements to packaged food products, except:
 - require the statement ‘cell-cultured’ to be used in conjunction with the name of the novel food ingredient in the statement of ingredients, and
 - the generic ingredient name ‘poultry meat’ would not apply
- apply existing nutrition information requirements to packaged food products, except for the exemption for poultry that comprises a single ingredient or a category of ingredients from the requirement for a NIP, which would not apply
- apply characterising ingredient declaration requirements, except for the exemptions for prepared filled rolls, sandwiches, bagels or similar products and for a food for sale that is sold at a fund raising event, which would not apply
- for food for sale that is not required to bear a label:
 - if the food is not represented as a quail food product—require the statement ‘cell-cultured’ in conjunction with the ingredient name
 - if the food is represented as a quail food product—require the statement ‘cell-cultured’ to be included in the name of the food
 - the statement ‘cell-cultured’ is information that would be required to be stated in labelling that accompanies the food or is displayed in connection with the display of the food.
- apply existing requirements for the following labelling elements:
 - declaration requirements for certain foods (allergens)
 - date marking requirements to packaged food products
 - directions for use and storage
 - nutrition content and health claim requirements
 - information relating to a food sold to a caterer, and for other food sales.

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1. Introduction

As noted in section 1.2 of the 1st call for submissions (CFS), the applicant's cultured quail cells are being assessed as a novel food. Cell-cultured foods are not currently permitted for sale in Australia and New Zealand. FSANZ has considered, in this supporting document, how existing generic labelling requirements would apply to cultured quail cells as a novel food ingredient and whether additional labelling measures are warranted.

Generic labelling requirements in Part 1.2 (Requirements to have labels or otherwise provide information) of the Code include:

- the name of the food
- ingredient names
- mandatory declarations for certain foods
- date marking
- directions for use and storage
- nutrition information
- nutrition content and health claims, and
- characterising ingredients.

FSANZ has also considered information requirements for food for sale that is not required to bear a label and for food sold to a caterer or other sales of food (e.g. from an ingredient supplier to a manufacturer).

In considering food identification requirements for cultured quail cells, FSANZ has had regard to relevant Ministerial Policy Guidelines, overseas regulations, a Food and Agriculture Organization of the United Nations (FAO) and World Health Organization (WHO) systematic review of available scientific literature on cell-based food terminologies, and published industry perspectives on nomenclature for cell-cultured food.

FSANZ's proposed approach for the 1st CFS has been informed by:

- a hazard and risk assessment for harvested cultured quail cells (Supporting Document 1 (SD1)) and
- the findings of a rapid systematic review on consumer understanding, preferences and acceptance of different cell-cultured meat terminologies, and perceptions of cell-cultured meat relative to conventional meat (SD2).

FSANZ has also commissioned the University of Adelaide to conduct a full systematic literature review examining consumers' levels of awareness, understanding, perceived risks and benefits, and prospective behaviour regarding alternative proteins, including cell-cultured meats. The findings of this literature review will inform the 2nd CFS.

The proposed approach is underpinned by a labelling risk management framework, comprising of FSANZ's priority order objectives as the risk management principles.

1.1 Background

1.1.1 Food Standards Code requirements

Currently, the Code does not include specific labelling requirements for a cell-cultured food.

Standard 1.5.1 Novel foods sets specific requirements for the sale of novel foods. Section 1.5.1—3 states that ‘despite paragraphs 1.1.1—10(5)(b) and (6)(f), a food offered for retail sale may consist of, or have as an ingredient, a novel food: if (a) the novel food is listed in the table to section S25—2 of Schedule 25; and (b) any conditions of use specified in the corresponding row of that table are complied with’. Paragraphs 1.1.1—10(5)(b) and (6)(f) specify that food for sale must not be a novel food (or have a novel food as an ingredient) unless expressly permitted. These requirements prevail over generic provisions in sections 1.2.1—8 and 9 of Division 2 (Retail sales) of Standard 1.2.1 (Requirements to have labels or otherwise provide information).

The application of generic labelling requirements set out in Part 1.2 (Labelling and other information requirements) of the Code to the novel food ingredient is considered separately below in sections 3.2, 3.3 and 4. These include requirements for: name of the food, statement of ingredients, mandatory declarations for certain foods, date marking, directions for use and storage, nutrition information, nutrition content and health claims and characterising ingredients.

Generic provisions in Division 3 (Sales of food to caterers) in Standard 1.2.1 apply to novel foods and novel food ingredients. Section 1.2.1—17 states the caterer must be provided with any information: (a) requested by the caterer; or (b) required by the relevant authority to be provided, that is necessary to enable the caterer to comply with any compositional, labelling or declaration requirement of the Code in the sale of the food or of another food using it as an ingredient.

Similarly, the generic provision in Division 4 Other sales in Standard 1.2.1 would apply. This Division regulates other food sales, such as the sale of an ingredient by an ingredient supplier to a manufacturer of a food. Section 1.2.1—21 is consistent with section 1.2.1—17 mentioned above, except that it requires the information is provided in writing if requested by the purchaser or required by the relevant authority.

1.1.2 Ministerial Policy Guidelines

The *Ministerial Policy Guideline on Novel Foods* (2003)¹ specifies a high order principle is to ensure that consumers have access to sufficient information to enable informed and healthy food choices. This Policy Guideline also refers to ensuring consumers are not misled by novel foods or food ingredients, which appear similar to existing foods but may differ in terms of nutrition or function, as a specific principle.

The scope of the *Ministerial Policy Guideline on the Labelling of foods produced or processed using new technologies* (2014)² provides guidance on the expectations for a case-by-case consideration of labelling of foods produced or processed using a new technology following a pre-market safety assessment. It recognises that labelling on these foods can be an issue of consumer interest and that labelling following a pre-market safety assessment is not a public health and safety issue. Instead, labelling refers to the provision of information on a package or display of the food, identifying that the food has been produced or processed using a new technology.

¹ Food Regulation <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/food-policies>.

² Food Regulation <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/food-policies>.

1.1.3 International and overseas regulations

Codex Alimentarius has no international standard that is specifically relevant to cell-cultured food.

To date, Singapore is the only country to establish labelling requirements for cell-cultured food. Section 9.5 of the regulations specifies that ‘Companies selling pre-packed alternative proteins (including cultured meat) are required to label the product packaging with suitable qualifying terms such as “cultured” or “cell-based” to indicate their true nature. Similarly, food establishments selling non-prepacked foods are required to clearly communicate to their customers on the true nature of their food sold. For example, misrepresenting cultured meat as conventionally produced meat will not be allowed’ (SFA 2022).

The United States Food and Drug Administration (US FDA) and United States Department of Agriculture Food Safety and Inspection Service (USDA FSIS) have signalled their intent to develop joint principles for labelling of cell-cultured food. In the interim, food companies can provide their proposed label to the USDA FSIS for pre-approval (US FDA 2019). In its final submitted dossier for approval, Good Meat proposed its products be labelled as ‘cultured chicken’ (US FDA 2023a). Upside Foods made no explicit reference to proposed labelling in its dossier, however it referred to ‘cultured poultry meat (CPM) products’ in relation to standards of identity (US FDA 2023b). Both companies received approval to label their cell-cultured chicken products as ‘cell-cultivated’ (Good Meat 2023, UPSIDE Foods 2023).

1.1.4 Senate Inquiry

FSANZ notes the final report from the Senate Inquiry on the ‘Definitions of Meat and Other Animal Products,’ led by the Senate Standing Committee on Rural and Regional Affairs and Transport (the Committee), was released in February 2022. In the report, the Committee noted the potential for increased consumer confusion arising from cultured meat entering the Australian market and the likelihood of existing labelling and marketing practices appropriating meat category branding for such foods. The Committee recommended a mandatory regulatory framework for the labelling of plant-based products (Recommendation 1) and that this framework is applicable to cultured meat products (Recommendation 3). The Government response to the Senate Inquiry report has yet to be published.

2. Labelling risk management framework

FSANZ has assessed whether the application of existing food identification labelling requirements (that is, the name of the food and ingredient name) to cultured quail cells would satisfy FSANZ’s priority objectives in Section 18 of the FSANZ Act (1991), specifically the priority objectives for:

- the protection of public health and safety (paragraph 18(1)(a))
- the provision of adequate information relating to food to enable consumers to make informed choices (paragraph 18(1)(b))
- the prevention of misleading or deceptive conduct (paragraph 18(1)(c)).

These priority objectives form the principles for our assessment. The principles are also consistent with Ministerial policy guidelines as noted in section 1.1.2 of this report. the Ministerial Policy Guideline on the Labelling of foods produced or processed using new technologies (2014) and the Ministerial Policy Guideline on Novel Foods (2003).

The extent to which certain terminology may support consumer acceptance of foods produced using cell-culturing techniques is not part of FSANZ’s consideration of food identification labelling requirements.

3. Food identification

3.1 Terminology

3.1.1 Consumer evidence

The available consumer literature was assessed to determine the effect of different terminology on consumer understanding, preferences, and acceptance of cell-cultured meat terminologies, and perceptions of cell-cultured meat relative to conventional meat. The evidence indicates that terms incorporating the word 'cell' (e.g. 'cell-cultured', 'cell-cultivated' and 'cell-based') perform the best for consumers to correctly identify the true nature of the product. These terms were viewed as being the most descriptive based on objective and perceived levels of understanding and enabled consumers to best differentiate the product from conventional meat and plant-based meat alternatives. Consumer acceptance of these terms was lower than for terms 'cultured' and 'cultivated'.

In contrast, the terms 'cultured' and 'cultivated' were rated the highest in relation to consumer preference and/or acceptance (e.g. perceived appeal). However, these terms produce low levels of understanding of the true nature of the product. The reasons differed depending on the term (e.g. some consumers believe 'cultured' or 'cultivated' chicken and beef to be sourced from farm-raised animals). Despite this finding, consumers still perceive 'cultured' and 'cultivated' to enable them to differentiate cell-cultured meat products to a moderate extent.

Consumer understanding of allergenicity of cell-cultured meat/seafood is not high, even for the best performing terms for accurate product identification ('cell-cultured', 'cell-cultivated'), as only up to 66% of consumers correctly identified that the product was not safe to consume for those with an allergy to the traditional counterpart. The term 'cell-based' produced low levels of perceived allergenicity for beef products in particular (only 38% of consumers). Regardless, the overall findings suggest that terminology alone cannot sufficiently convey allergen information to consumers.

Terms such as 'lab-grown meat', 'artificial', 'clean meat', 'slaughter free meat' and 'in vitro meat' were also examined but did not consistently perform well in relation to accurate product identification, differentiation, preferences and/or acceptance. For example, 'lab-grown meat' has a high level of accurate product identification, but it has lower levels of perceived safety compared with other terms. The evidence indicates descriptive phrases (e.g. 'grown from [animal] cells, not farmed [or fished]', and 'cultivated from the cells of') can assist consumers to correctly identify products (as with single terms that incorporate the word 'cell'). However, these phrases were less appealing than the terms 'cultivated' and 'cultured'.

Across four studies that used comparable methodologies in four different countries, consumers consistently perceived cell-cultured meat (or equivalent terminology) as less healthy and/or nutritious than conventional meat when provided with a neutral description of cell-cultured meat. Similarly, another study that provided participants with a neutral description of cell-cultured meat and asked them whether they perceived it to be "molecularly the same as real meat" found that consumers on average disagreed.

However, there is a high level of variance in consumer perceptions across the other reported studies. This is likely due to the differing terminologies used, question wording/response options, descriptions provided (neutral vs. biased descriptions), and the types of conventional meat products compared with their cell-cultured equivalents (e.g. chicken vs. chicken nuggets). This may indicate that consumer perceptions of the healthfulness/nutritional value of cell-cultured meats are highly malleable based on the type of information received and

product categories compared.

Qualitative findings suggest that levels of trust in scientists, experts and/or cell-cultured meat companies may impact consumer perceptions of the healthfulness and/or nutritional equivalence of cell-cultured meat. That is, those participants who had confidence in those involved in the production process had confidence that they would make it equivalent to conventional meat on these measures, and vice versa.

See SD2 for the rapid systematic review report.

3.1.2 FAO and WHO Food safety aspects of cell-based food – terminologies

The FAO and WHO recently published a systematic review of available scientific literature on cell-based food terminologies, including non-scientific reports and public communications (FAO & WHO 2023). The review included:

- a list of modifier terms (e.g. 'cell-based', 'cultivated', 'cultured', 'lab-grown') used by authorities, industry, academics, and media (professional sectors) to describe cell-based food
- a discussion on the impact of the use of modifier terms in relation to public perception and acceptance, language barriers and translation issues, and whether they are fit for purpose, and
- a summary of studies that examined the impact of terminology on the perception of cell-based food by consumers.

Based on the available evidence, the FAO and WHO recommended the modifier terms 'cell-based', 'cultivated' or 'cultured' noting the specific use might be further determined by the target audience or language-specific associations of these terms. The discussion also noted the modifier term 'cell-based' may be useful when not referring to specific commodities (e.g. cell-based food products, cell-based food production), while 'cultivated' and 'cultured' most likely need to be followed by a commodity name, such as meat, chicken, fish and so forth.

The studies included in the FAO and WHO systematic review, as they relate to consumer understanding, preferences, and acceptance of different cell-cultured meat terminologies, have been incorporated in FSANZ's consumer literature review (see SD2).

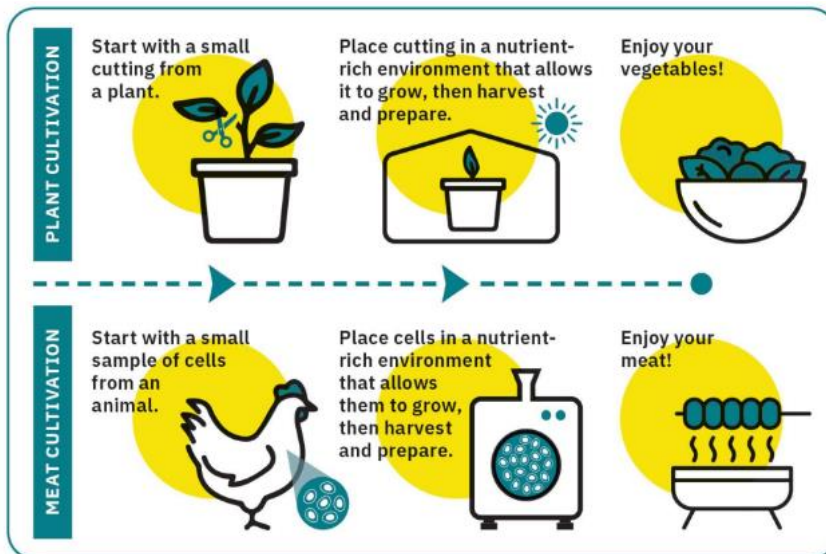
3.1.3 Industry perspectives on nomenclature

FSANZ notes the Alternative Proteins Council (APC) recently published guidance for Australian and New Zealand industry for the labelling of meat alternative products. This guidance does not recommend a preferred term for cell-cultured meat; however it states the APC may consider releasing additional guidance once a regulatory framework for other Meat Alternative Products such as cell-based products has been developed (APC 2023).

The FAO/WHO systematic review indicated that, globally, the food industry prefers the modifier term 'cultivated' because it can be used to differentiate from other products, appeal to consumers and be amenable to consumer education. The use of cultivation-related language, such as 'cultivator', for the reaction vessel in which cells are grown, enables industry to build a narrative around the new technology.

In October 2022, 36 Asia-Pacific stakeholders representing cellular agriculture groups and leading start-ups signed a memorandum of understanding (MoU) to use the common term 'cultivated' for meat and other food products grown from animal cells. The MoU included the infographic in Figure 1 below as an example 'to build public trust through industry transparency, clear and consistent nomenclature, and a shared understanding of story telling narratives that consumer audiences find compelling'.

Figure 1. Example narrative targeted to consumers



The MoU stated the signatories considered this term to be the ‘most effective in fostering consistently positive responses from consumers’, which FSANZ understands is referring to consumer appeal, understanding and performance in relation to differentiation from conventional and plant-based meat alternatives. ‘Cultivated’ was also viewed as ‘a scientifically accurate term that clearly distinguishes foods that are cultivated from animal cells from other existing products in the marketplace’. The MoU was facilitated by the Good Food Institute Asia Pacific (GFI APAC) and the APAC Society for Cellular Agriculture (APAC-SCA) (GFI-APAC & APAC-SCA 2022). The GFI has published further information on its website about why it uses the term ‘cultivated meat’ (GFI 2023).

3.1.4 Terminologies used in academic research

The recent systematic review undertaken by the FAO and WHO (FAO & WHO 2023) included an examination of 144 scientific articles published between 2013 and 2022 on the topic of cell-cultured food. The most used terms were ‘cultured’ and ‘cell-based’, followed by ‘in vitro’, ‘artificial’ and ‘cellular’. The terms ‘cultivated’ and ‘cell-cultured’ were less commonly used, i.e., each term featured in less than seven percent of the scientific articles examined. No studies were reported that had investigated preferred terms.

3.1.5 Discussion

3.1.5.1 Regulatory versus non-regulatory approach

FSANZ notes that overseas regulators are considering labelling measures to inform consumers of the nature of cell-cultured food. To date, two countries (Singapore and United States of America) that have already approved the sale of cell-cultured food have chosen to set specific labelling measures (see section 1.1.3 in this report).

An alternative would be to employ a non-regulatory approach and rely on generic labelling requirements (e.g. name of the food, ingredient name requirements) set out in sections 3.2 and 3.3 below. While this approach would provide flexibility for industry, it could lead to labelling inconsistencies among products or non-compliance if the name does not clearly indicate the ingredient is not a conventional quail ingredient (i.e. not a name that describes the true nature of the food or ingredient). Both scenarios may result in consumer confusion and a resulting lack of trust in the new technology.

Given the principles FSANZ has set out in the labelling risk management framework, and relevant policy guidance (sections 2 and 1.1.2 of this report, respectively), FSANZ considers it is important to ensure products made with cultured quail cells are adequately labelled so consumers can understand and distinguish them from conventional quail products or plant-based alternative products.

3.1.5.2 Specific statement versus generic requirement for a descriptor

FSANZ has considered whether to require a specific statement or to mandate the use of a descriptor or statement without specifying the term or words. To date, there is no consistency in the regulatory approaches adopted by Singapore and the United States of America (USA). Singapore only provides guidance on the qualifying descriptors, whereas in the USA, the specific term 'cell-cultivated' was approved for two companies' cell-cultured chicken products (refer to section 1.1.2 of this report).

FSANZ considers mandating a specific statement would ensure labelling consistency across products and promote consumer understanding and familiarity over time. This approach would also enable consumers to make informed choices and reduce their risk of being misled when comparing products containing cultured quail cells with conventional quail products.

While industry would have less flexibility with this approach, it would provide regulatory clarity for both industry and enforcement agencies. Mandating a specific statement is unlikely to significantly impact international trade of cell-cultured foods because there is no established trade due to the newness of the technology and because few overseas regulators have considered cell-cultured foods for approval.

3.1.5.3 Assessment of options for specific term or statement

FSANZ's literature review (see section 3.1.1 of this report and SD2) indicates consumers find the terms 'cell-cultivated', 'cell-cultured' or 'cell-based' to be the most descriptive for accurately identifying cell-cultured food products. Terms that include the word 'cell' perform best in relation to consumers' objective understanding, and therefore satisfy the labelling risk management principles of providing adequate information for informed choice and prevention of misleading or deceptive conduct.

The term 'cell-based' has been ruled out because consumer evidence indicates it produces low levels of perceived allergenicity compared with the terms 'cell-cultured' and 'cell-cultivated' and therefore it does not meet the labelling risk management principle for the protection of public health and safety (sections 2 and 3.1.1 of this report). Further, the FAO and WHO recommended the term 'cell-based' to be more appropriate as a non-commodity specific term e.g. cell-based food, cell-based food products or cell-based food production (FAO & WHO 2023).

The consumer evidence also indicates that consumers were able to use the descriptive statement 'grown from [animal] cells, not farmed [or fished]' to correctly identify products, including those products that are food allergens. However, this descriptive statement performed similarly to the terms 'cell-cultured' and 'cell-cultivated' in relation to accurate identification. FSANZ considers a shorter statement would be more appropriate because it would be linked to the ingredient in the statement of ingredients. A longer descriptive statement would lengthen the statement of ingredients (which may have label space constraints), thus making the statement of ingredients more complex. Alternatively, the descriptive statement may be missed by consumers if it is located as a separate statement elsewhere on the label. FSANZ has discarded this option because a requirement for a descriptive statement would not meet the labelling risk management principles in section 2 of this report and would likely impose a greater regulatory obligation on food industry.

FSANZ notes the terms 'cultured' and 'cultivated' feature prominently in the FAO and WHO Systematic Literature Review and in industry publications. Singapore regulations and guidance also refer to them as suitable qualifying terms (see sections 3.1.2 and 1.1.3 of this report).

As noted in section 3.1.2 of this report, the FAO and WHO recommend 'cultivated' or 'cultured' as modifier terms for use in association with the commodity name (e.g. 'cultivated meat', 'cultured chicken'). A caveat was that the specific use may need to be determined by the target audience or language-specific associations of the terms (FAO & WHO 2023). The WHO and FAO review report also referred to evidence that consumers may misinterpret 'cultivated' or 'cultured' seafood as being from conventional aquafarming, i.e. 'farmed seafood'. FSANZ's consumer literature review also noted this finding (see SD2). Further, United States' federal agencies use the term 'cultivated' to identify farmed shellfish (FAO & WHO 2023). FSANZ considers the possibility that the terms 'cultivated' and 'cultured' may be misinterpreted is inconsistent with the labelling risk management principles in section 2 of this report.

Further, FSANZ notes that industry considers the term 'cultivated' as having greater consumer appeal and higher levels of acceptance (see section 3.1.3 of this report). FSANZ's consumer literature review provided similar findings, where the evidence indicates the terms 'cultivated' or 'cultured' have greater appeal than the terms 'cell-cultured' and 'cell-cultivated'. While consumer appeal is important for promoting awareness in and acceptance of food produced using a new technology, it is less important from a regulatory perspective and is not a consideration under the labelling risk management principles (section 2 of this report).

Based on the evidence and this assessment, FSANZ concludes that a specific statement would be appropriate to identify a cell-cultured food and the best options for consideration are 'cell-cultured' and 'cell-cultivated'.

In relation to the terms 'cell-cultured' versus 'cell-cultivated', FSANZ's consumer literature review found no evidence to indicate consumers preferred one term over the other (see SD2).

The FAO and WHO systematic literature review noted the modifier term 'cell-cultured' (amongst other terms that did not include the word 'cell') is used as a common synonym for animal cell-based products by different professional sectors. The term 'cell-cultivated' was not identified as a synonym (FAO & WHO 2023). In contrast, two companies in the United States of America were granted regulatory recent approval to market their cell-cultured chicken products using the term 'cell-cultivated' (see section 1.1.3 of this report).

FSANZ considers the term 'cell-cultured' more accurately describes the production process. For example, 'cultured' or 'culturing' means growing cells outside their natural environment under controlled conditions and involves the use of culture media. 'Cultivated' is less specific, as it can relate to a 'cultivator' (bioreactor) or relate to its use in agriculture to describe crops.

The term 'cell-cultured' also accurately describes the end product for Application A1269 (that is, FSANZ is assessing the safety and considering the approval of harvested cultured quail cells). Further, 'cell-cultured' is an established term in scientific literature, whereas the FAO & WHO did not report 'cell-cultivated' was used (FAO & WHO 2023).

FSANZ also notes the technology is expected to evolve beyond the production of a cell biomass made up from a single cell type, such as fibroblasts in Application A1269. In the future, different cell types (e.g. muscle and fat cells) may be mixed together for organoleptic properties. Cell mixing may occur post-harvest or as part of the cell production process to form meats intended to mimic the taste and appearance of conventional meats (Fish et al 2020, Kang et al 2021). FSANZ considers the term 'cell-cultured' would remain relevant for these scenarios (including post-harvest when cells are mixed outside the bioreactor). Cell mixing could involve the formation of structured meats, for example, a 3D printed whole cut meat-like tissue, or the cells could be grown onto a 3D printed biodegradable scaffold. In these examples, the tissue or cells (either from a single cell type or different cell types) would still be cultured (kept alive in a culture dish with media) but not cultivated in the industry-description sense, because a bioreactor is not involved in the assembly of the final product.

Based on this assessment, FSANZ is proposing to require the statement 'cell-cultured' to identify foods that are produced using this new technology.

3.1.5.4 Allergen declarations

Cell-cultured food products can have the same level of risks for allergic reactions as conventional counterparts (Hallman & Hallman 2020, cited in WHO & FAO 2023).

Quail is not a listed food in the Code to which allergen declaration requirements apply. Further, the hazard and risk assessment concluded the expression of egg allergens in the embryonic fibroblasts is highly unlikely and the applicant's harvested cells are unlikely to pose a food allergenicity concern (see sections 2.2.3.4 and 2.3 of SD1).

However, FSANZ acknowledges the use of a specific statement would be relevant for future approvals of cell-cultured foods that are listed food allergens in the Code (for example, crustacea and fish; see table to S9—3 of Schedule 9). FSANZ has therefore considered the available evidence for consumer understanding of allergenicity of cell-cultured food. The studies examined whether different naming conditions affected their ability to signal allergenicity.

In an article about a joint meeting of the US FDA and USDA on the future of cell-based meat, the author reported a developer of cell-cultured seafood stated that 'If one is allergic to animal-based seafood, that person has a high probability that they'll be allergic to the seafood made with our technology'. The author of the article said that if cultured salmon was identified as 'cell-based artificial salmon product', consumers with an allergy to salmon might not realise the cell-cultured product posed the same threat (Lamb 2018, also cited in FAO & WHO 2023). In its systematic review, the FAO & WHO stated it is important that the modifier terms do not conceal the animal species (FAO & WHO 2023).

FSANZ considers that one term to indicate the food product is cell-cultured would be clearer for individuals with food allergy. FSANZ previously investigated the evidence for consumer understanding of allergen information in Proposal P1044 Plain English allergen labelling. That evidence indicates consumers consider the use of clear and consistent terms allow for efficient identification and comprehension of allergen information required for informed and safe food choices (FSANZ 2020).

Based on consumer evidence reviewed for this report, the proposed term 'cell-cultured' produced a higher level of consumer understanding of allergenicity compared to the term 'cell-based'. Although other terms such as 'cultured' and 'cultivated' produced higher levels of consumer understanding of allergenicity, this is because consumers were unable to distinguish 'cultivated' and 'cultured' products from conventional meat. FSANZ considers the term 'cell-cultured' best meets the labelling risk management principle for the protection of public health and safety (see section 2 of this report). However, it should be noted the intent of a mandated term for cell-cultured food is to complement rather than prevail over existing allergen declaration requirements.

3.1.6 Proposed approach

FSANZ's proposed approach is to require the statement 'cell-cultured' in labelling for food identification purposes.

3.2 Name of the food

Paragraph 1.2.2—2(1)(a) of Standard 1.2.2 (Information requirements – food identification) requires packaged food to be labelled with a prescribed name if one is prescribed. Food names are prescribed for public health and safety reasons relating to the food for sale, for example the names 'Infant formula' and 'Follow-on formula' are prescribed to ensure caregivers can identify the appropriate formula for their infant.

In the case of cultured quail cells, they would be added as a novel food ingredient to a mixed-food product such as, but not limited to, logs, rolls and patties. As noted in section 1 of SD1, the harvested cells would be mixed with other ingredients such as food additives, oils or fats, and textured vegetable protein. It is not appropriate to prescribe a name for a mixed food product given the amount of cultured quail cells added as a novel food ingredient could vary, and the food for sale may not be represented as a product containing cultured quail cells. However, FSANZ notes that ingredient declaration requirements would still apply for these foods (see section 3.3 of this report).

If the name of a food has not been prescribed, the food is required to have a name or description sufficient to indicate the true nature of the food (subparagraph 1.2.2—2(1)(b)(i)) and include any additional words the Code requires to be included in the name of the food (subparagraph 1.2.2—2(1)(b)(ii)).

FSANZ considers these requirements are appropriate for foods for sale containing the novel food ingredient and are represented as a quail product. The requirement in subparagraph 1.2.2—2(1)(b)(ii) to include the additional words 'cell-cultured' (as proposed in section 3.1 of this report) in the name of the food would apply. Therefore, if a food for sale is represented as quail food product (e.g. quail patties), the statement 'cell-cultured' would need to be included in the name of the food (for example, 'cell-cultured quail patties' or 'patties made from cell-cultured quail').

The proposed approach would meet the labelling risk management principles as it would ensure consumers are able to distinguish between foods represented as quail food products that contain cultured quail cells and those which are made using conventional quail meat. These food name requirements also ensure consumers can make informed choices.

In relation to the animal source of the cell-cultured ingredient, FSANZ considers mandating the species name as part of the name of the ingredient is unnecessary and considers existing requirements in subparagraphs 1.2.4—4(b)(i) and (ii) are sufficient.

3.2.1 Proposed approach

FSANZ is proposing food name requirements for the applicants' cultured quail cells as a novel food ingredient as follows:

- if the food for sale is not represented as a quail food product—apply the existing food name requirements (subparagraph 1.2.2—2(1)(b)(i)).
- if the food for sale is represented as a quail food product—in addition to generic food name requirements, require the statement 'cell-cultured' to be included in the name of the food (subparagraphs 1.2.2—2(1)(b)(i) and (ii)).

3.3 Name of ingredient

Standard 1.2.4 (Information requirements – statement of ingredients) in the Code requires ingredients to be identified in a statement of ingredients on food labels using any of the following:

- a name by which they are commonly known; or (subparagraph 1.2.4—4(b)(i))
- a name that describes its true nature; or (subparagraph 1.2.4—4(b)(ii))
- a generic ingredient name if one is specified in Schedule 10 – Generic names of ingredients and conditions for their use (subparagraph 1.2.4—4(b)(iii)).

FSANZ considers it is appropriate to apply existing requirements in subparagraphs 1.2.4—4(b)(i) and (ii) and require the statement 'cell-cultured' to be used in conjunction with the name of the novel food ingredient in the statement of ingredients. The requirement would apply to all packaged products containing cultured quail cells.

Information that the quail ingredient is 'cell-cultured' will assist consumers to distinguish between food products containing the novel food ingredient or conventional quail. This requirement meets the labelling risk management principles for provision of information to enable informed choice and the prevention of misleading or deceptive conduct.

As noted above, Standard 1.2.4 permits the use of a generic ingredient name if one is specified and any conditions for their use are met (subparagraph 1.2.4—4(b)(iii)). Section S10—2 of Schedule 10 in the Code includes the generic name 'poultry meat' without any conditions for its use. Generic names may be used in place of a more specific name or names (for example, to allow for ingredient substitutions or several types of that food to be used together without the need for declaration).

FSANZ considers the generic name 'poultry meat' by itself is not appropriate for cultured quail cells as an ingredient because consumers would not be informed of the true nature of the novel food ingredient. Further, there is potential for consumers to be misled if this generic name is used in conjunction with the statement 'cell-cultured' as proposed. For example, 'cell-cultured poultry meat' may mislead consumers that other poultry species are produced using cell-culturing techniques. FSANZ also considers that, given the nature of the novel food ingredient, another generic name would not be appropriate. FSANZ is therefore proposing to prohibit the use of the generic name 'poultry meat' for cultured quail cells as a novel food ingredient.

3.3.1 Proposed approach

FSANZ is proposing existing ingredient naming requirements would apply to the applicant's cultured quail cells as a novel food ingredient when it is used in a packaged food for sale.

FSANZ is also proposing to require the statement 'cell-cultured' to be used in conjunction with the name of the novel food ingredient in the statement of ingredients.

The generic ingredient name 'poultry meat' would not apply to cultured quail cells.

3.4 Use of the term 'meat'

FSANZ has stated cultured quail cells is not 'meat' as defined in subsection 1.1.2—3(2) of the Code (see section 1.3.4 of the 1st CFS). Therefore, the term 'meat' cannot be used in isolation to describe a food containing cultured quail cells (e.g. 'quail meat patties'), or as the ingredient (e.g. 'quail meat').

Manufacturers may, however, wish to refer to the novel food ingredient as 'meat' on the label of the food, either in the name of the food or as part of the ingredient name.

As noted in sections 3.2 and 3.3 above, FSANZ is proposing to require the statement 'cell-cultured' to be included in the name of the food (if the food is represented as a quail food product), and in conjunction with the name of the novel food ingredient (i.e. 'cell-cultured quail').

The question then becomes whether consumers would find the use of the term 'meat' as part of generic food name and ingredient name requirements, and together with the proposed required statement 'cell-cultured', to be misleading (e.g. 'cell-cultured quail meat'). Some consumer studies reported consumers found the use of 'cell'-type terminologies with the term 'meat' (e.g. 'cell-based meat', 'cell-cultivated meat' and 'cell-cultured meat') to be 'moderately to very descriptive' and 'moderately to very differentiating' from conventional meat or plant-based meat alternatives (see SD2).

The evidence suggests the term 'meat', when used as part of generic food name and ingredient name requirements, and together with the proposed required statement 'cell-cultured' is unlikely to be misleading for the majority of consumers.

As noted in section 3.1.1 of this report, consumer evidence indicates the term 'cell-cultured' is one of the best performing terms for accurate product identification. FSANZ notes the proposed label requirement, when combined with the term 'meat' and/or the species name (e.g. 'cell-cultured quail meat'), should be considered as part of a suite of measures to ensure consumers can make informed product choices. Other measures such as consumer education about cell-culturing techniques would also be necessary to assist consumer awareness and understanding of this new technology.

4. Other generic labelling provisions

4.1 Mandatory declarations of certain foods

Division 3 of Standard 1.2.3 (Information requirements – warning statements, advisory statements and declarations) in the Code requires declarations of certain foods (e.g. allergens and ingredients that cause immune reactions such as in coeliac disease) on the label of food for sale.

Section 3.1.3 of SD1 states the applicant uses barley seed to manufacture recombinant growth factors that support the growth of the quail cells. The applicant has provided data to demonstrate that gluten levels are below the limit of detection in the harvested cells. If gluten is present in the food for sale that contains the cultured quail cells as an ingredient, it must be declared in a summary statement. Further, the presence of gluten from barley would trigger the requirement to declare barley in the statement of ingredients, next to the ingredient name for the cultured quail cells.

If the food is not required to bear a label, the information must be displayed in connection with the display of the food or provided to the purchaser on request (section 1.2.1—9 of Standard 1.2.1).

4.1 Proposed approach

FSANZ is proposing existing allergen declaration requirements would apply to food products containing the applicant's cultured quail cells as a novel food ingredient.

If gluten from barley is present in a food product for sale containing cultured quail cells, gluten and barley would need to be declared on the label.

4.2 Date marking

Labelling requirements for date marking of packaged food are set out in Standard 1.2.5 (Information requirements – date marking of food for sale) in the Code.

Subsection 1.2.5—3(1) requires most foods for sale to have either a use-by date, if the food must be consumed before a certain time for health and safety reasons, or a 'best-before' date. Date marking for safety reasons may be warranted (in addition to specific directions for use and storage) to ensure the food product containing cultured quail cells is microbiologically safe for consumption. Food manufacturers are responsible for determining the appropriate date mark for their food product.

FSANZ considers existing date marking requirements are appropriate for a packaged food product containing cultured quail cells as an ingredient.

4.2.1 Proposed approach

FSANZ is proposing existing date marking requirements would apply to packaged food products containing the applicant's cultured quail cells as a novel food ingredient.

4.3 Directions for use and storage

Standard 1.2.6 (Information requirements – directions for use and storage) in the Code requires directions for use and storage to be provided on the label of a packaged food under certain circumstances. These include where:

- specific storage conditions are required to ensure that the food will keep until the use-by date or the best-before date, a statement of those conditions (paragraph 1.2.6—2(a)), and
- the food must be used or stored in accordance with certain directions for health and safety reasons, those directions (paragraph 1.2.6—2(b)).

If the food for sale is not in a package, the directions relating to use and storage in paragraph 1.2.6—2(b), if relevant, would apply and must be stated in labelling that accompanies the food for sale (paragraph 1.2.1—9(4)(a)).

Section 4.1 of SD1 states the final microbiological safety of the food for sale containing the cultured quail cells may be influenced by the addition of ingredients, shelf life, packaging, storage conditions and consumer preparation. Consistent with date marking requirements, the onus is on the supplier of the food to provide appropriate directions for use and storage and any storage conditions relating to their food product.

FSANZ considers these labelling provisions are appropriate for food products containing the applicant's novel food ingredient.

4.3.1 Proposed approach

FSANZ is proposing the existing labelling requirements for directions for use and storage would apply to food products containing the applicant's cultured quail cells as a novel food ingredient.

4.4 Nutrition information

As noted in section 2.2.5 of the 1st CFS report, FSANZ's nutrition risk assessment did not identify any nutritional concerns regarding the consumption of cultured quail cells. FSANZ has therefore considered how generic labelling requirements for nutrition information apply to the applicant's novel food ingredient.

Standard 1.2.8 (Nutrition information requirements) in the Code requires a nutrition information panel (NIP) to be provided on the label of a food unless exempt. The NIP must include the average quantity of energy, protein, fat, saturated fat, carbohydrate, sugars, and sodium on a per serve and per 100 g or 100 ml of food. These requirements apply only to packaged food.

If products containing cultured quail cells do become available for purchase in a retail setting, these existing nutrition information requirements would apply. This will enable consumers to compare the amount of sodium, protein and other nutrients mandated for declaration in products containing cultured quail cells with other packaged foods. The NIP would reflect the nutrient composition of the mixed food.

Subparagraph 1.2.8—5(2)(a)(ix) exempts poultry that comprises a single ingredient or a category of ingredients from the requirement for a NIP. This exemption would not apply to the applicants' cultured quail cells because it is intended be used as a novel food ingredient in a mixed food (i.e. not a single ingredient), and it is not poultry meat in accordance with the definition of 'meat' (as noted in section 1.3.4 of the 1st CFS report).

4.4.1 Proposed approach

FSANZ is proposing existing nutrition information requirements would apply to packaged food products containing the applicant's novel food ingredient, except for the exemption for poultry that comprises a single ingredient or a category of ingredients from the requirement for a NIP, which would not apply.

4.5 Nutrition content and health claims

In the Code, Standard 1.2.7 (Nutrition, health and related claims) in conjunction with Schedule 4 sets out the requirements for the use of voluntary nutrition content and health claims on foods, including the criteria that must be met before claims can be made. Manufacturers that choose to make voluntary nutrition content or health claims about foods containing the applicant's cultured quail cells would need to meet these requirements.

Section 1.2.7—16 sets out requirements for making a comparative claim that directly or indirectly compares the nutrition content (amount) between one food (the claimed food) and another food (the 'reference food'). 'Reference food' is defined in part to mean a food that is a dietary substitute for the food in the same food group as the food for which the claim is made. The definition of 'food group' includes 'meat, fish, eggs, nuts, seeds and dried legumes' (subsection 1.1.2—2(3)).

While FSANZ acknowledges that cultured quail cells are not 'meat' as defined, it considers that a mixed food containing cultured quail cells (e.g. patties) is suitable as a dietary substitute for a mixed food containing conventional quail meat. This proposed approach is similar to the existing approach for comparative claims made between meat and meat analogues.

4.5.1 Proposed approach

FSANZ is proposing the existing requirements for nutrition content and health claims would apply to food products containing the applicant's cultured quail cells as a novel food ingredient.

4.6 Characterising ingredients

A characterising ingredient is an ingredient that is mentioned in the name of the food or is usually associated with the name of a food by the consumer or is emphasised on the label of a food in words, pictures or graphics (subsection 1.1.2—4(1)).

Standard 1.2.10 (Information requirements – characterising ingredients and components of food) in the Code requires that percentage labelling information for characterising ingredients be provided, unless the food does not contain a characterising ingredient (for example, a food such as white bread may have no characterising ingredients), or unless the food is specifically exempt from the requirement in section 1.2.10—3.

FSANZ considers the following existing exemptions for information about a characterising ingredient are not relevant to the applicant's cultured quail cells:

- a food for sale that is in a small package (paragraph 1.2.10—3(c)) (FSANZ considers it highly unlikely that the novel food ingredient would be used in a food sold in a small package)
- an infant formula product (paragraph 1.2.10—3(d))
- cured and/or dried meat flesh in whole cuts or pieces (paragraph 1.2.10—3(e) (cultured quail cells are not 'meat' as defined in the Code)
- a standardised alcoholic beverage (paragraph 1.2.10—3(f))
- a beverage containing no less than 0.5% alcohol by volume, other than a standardised alcoholic beverage (paragraph 1.2.10—3(g)).

However, FSANZ considers the following existing exemptions for information about cultured quail cells as a characterising ingredient should not apply to:

- prepared fill rolls, sandwiches, bagels or similar products (paragraph 1.2.10—3(a))
- a food for sale that is sold at a fund raising event (paragraph 1.2.10—3(b)).

Noting the labelling risk management principles in section 2 of this report, FSANZ considers it is appropriate for information about cultured quail cells as a characterising ingredient to be provided for these foods. This information would inform consumer choice, highlight the presence of the novel food ingredient in the food for sale and thus reduce the risk of consumers being misled.

Paragraph 1.2.10—8(1)(a) requires the proportion of the characterising ingredient to be declared as a percentage and it must appear in the statement of ingredients of a packaged food immediately following the common, descriptive or generic name of the ingredient.

This provision would apply to a food for sale that is represented as a quail food product and includes the proposed required statement 'cell-cultured' in the name of the food (and in conjunction with the name of the novel food ingredient in the statement of ingredients).

The Code includes requirements for the provision of information about characterising ingredients when the food is not required to bear a label. Subsection 1.2.1—9(7)(e) states that if the food for sale is not required to bear a label because of subsection 1.2.1—6(4) (i.e. if the food is unpackaged) or paragraph 1.2.1—6(1)(a) (i.e. if the food is made and packaged on the premises from which it is sold), information about characterising ingredients must be displayed in connection with the display of the food or provided to the purchaser on request.

FSANZ considers characterising ingredient information requirements for these types of retail sales are appropriate for food products containing the applicants' cultured quail cells. As noted in section 4.7 below, FSANZ is proposing the food name and/or ingredient name information requirements would apply for other retail sales of food that are listed in subsection 1.2.1—6(1) as exempt from the characterising ingredient information requirements (e.g. the food for sale is packaged in the presence of the purchaser, or the food is displayed in an assisted service display cabinet).

4.6.1 Proposed approach

FSANZ is proposing existing characterising ingredient declaration requirements would apply to food products containing the applicant's novel food ingredient, except for the exemption for prepared filled rolls, sandwiches, bagels or similar products (paragraph 1.2.10—3(a)) and the exemption for a food for sale that is sold at a fund raising event (paragraph 1.2.10—3(b)), which would not apply.

4.7 Information requirements for food for sale that is not required to bear a label

Information requirements in section 1.2.1—9 about the name of food (paragraph 1.2.1—9(7)(a)) apply if the food for sale is not required to bear a label. Subsection 1.2.1—9(6) requires the information to be displayed in connection with the display of the food or provided to the purchaser on request.

However, information about ingredients for these types of sales does not need to be provided unless the information is expressly required by section 1.2.1—9 (e.g. information relating to irradiated food).

FSANZ considers that information that the food for sale contains cultured quail cells as an ingredient should apply to all types of sales, including whether the food is packaged/unpackaged, and represented as a quail food product or not.

If a food sold in a restaurant setting is represented as a quail food product, the statement 'cell-cultured' should be included in the name of that food (for instance, 'cell-cultured quail roll'). A 'cell-cultured quail patty' that is displayed for sale in an assisted display cabinet is another example of a food for sale where the required statement would be included in the name of the food.

Where a food for sale is not required to bear a label and is not represented as a quail food product, the presence of cultured quail cells should still be declared. That is, the statement 'cell-cultured' should be used in conjunction with the ingredient name (for example, 'contains cell-cultured quail') in information provided to a consumer at the point of sale. The intent is not to require a full statement of ingredients for the food for sale.

FSANZ considers these food name and/or ingredient name information requirements should be stated in labelling that accompanies the food or is displayed in connection with the display of the food. It should not be left to purchasers (in these cases, the consumers) to request the information. The proposed approach is appropriate for cultured quail cells as a novel food ingredient, given the importance of consumers having adequate information to make informed choices and to not be misled that the quail ingredient is sourced from conventional quail, and is therefore consistent with the labelling risk management principles in section 2 of this report.

4.7.1 Proposed approach

For food for sale that is not required to bear a label, FSANZ is proposing to require the statement 'cell-cultured' to be included:

- if the food is not represented as a quail food product—in conjunction with the ingredient name.
- if the food is represented as a quail food product—in the name of the food.

The statement 'cell-cultured' is information that would be required to be stated in labelling that accompanies the food or is displayed in connection with the display of the food.

4.8 Food sold to a caterer and other sales of food

Section 1.1.1 of this report refers to information that can be requested in relation to a food sold to a caterer (section 1.2.1—17), and in relation to other food sales, such as sales between an ingredient supplier and a manufacturer (i.e. the purchaser) (section 1.2.1—21). The intent of these provisions is ensuring caterers and manufacturers have a mechanism by which to request information about a food, or of another food using it as an ingredient, so they can comply with any labelling or declaration requirement in the Code.

Sections 1.2.1—17 and 21 capture labelling and declaration requirements that are not already specified in labelling provisions in Divisions 3 and 4 of Standard 1.2.1 (e.g. a process declaration for edible oils, in accordance with section 2.4.1—4 of the Code).

FSANZ considers it is appropriate to apply these requirements to the applicants' novel food ingredient. This approach is no different to other labelling or declaration requirements that are not specified in Divisions 3 and 4 but are mandated by other provisions in the Code. The onus would be on caterers and purchasers to ensure they have the information to meet their regulatory labelling obligations for retail sales of food containing cultured quail cells.

4.8.1 Proposed approach

FSANZ is proposing that existing labelling information requirements will apply for food sold to a caterer containing cultured quail cells, and for other food sales when information can be requested.

5 Summary of the proposed approach

For food for sale that contains the applicant's cultured quail cells as a novel food ingredient, FSANZ's proposed approach is to:

- require the following labelling elements:
 - the statement 'cell-cultured' in labelling for food identification purposes.
 - if the food for sale is not represented as a quail food product—apply the existing food name requirements.
 - if the food for sale is represented as a quail food product—in addition to existing food name requirements, require the statement 'cell-cultured' to be included in the name of the food.
 - apply existing ingredient naming requirements to packaged food products, except:
 - require the statement 'cell-cultured' to be used in conjunction with the name of the novel food ingredient in the statement of ingredients, and
 - the generic ingredient name 'poultry meat' would not apply.
 - apply existing nutrition information requirements to packaged food products, except for the exemption for poultry that comprises a single ingredient or a category of ingredients from the requirement for a NIP, which would not apply.
 - apply characterising ingredient declaration requirements, except for the exemptions for prepared filled rolls, sandwiches, bagels or similar products and for a food for sale that is sold at a fund raising event, which would not apply.
 - for food for sale that is not required to bear a label:

- if the food is not represented as a quail food product—require the statement ‘cell-cultured’ in conjunction with the ingredient name.
 - if the food is represented as a quail food product—require the statement ‘cell-cultured’ to be included in the name of the food.
 - the statement ‘cell-cultured’ is information that would be required to be stated in labelling that accompanies the food or is displayed in connection with the display of the food.
- apply existing requirements for the following labelling elements:
 - declaration requirements for certain foods (allergens).
 - date marking requirements to packaged food products.
 - directions for use and storage.
 - nutrition content and health claim requirements.
 - information relating to a food sold to a caterer, and for other food sales.

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