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Supporting document 2

Labelling requirements – Application A1269

Cultured quail as a novel food

Executive summary

FSANZ is assessing an application to permit the use of cell-cultured quail as an ingredient in food for sale. Cell-cultured foods are not currently permitted for sale in Australia and New Zealand.

In its assessment to inform the 1st Call for Submissions (CFS), FSANZ considered how existing generic labelling requirements in the Australia New Zealand Food Standards Code (the Code) would apply to cell-cultured quail and whether additional labelling measures are warranted (see Supporting Document 4 (SD4) to the 1st CFS). FSANZ also considered information requirements for food for retail 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).

For the 1st CFS and for this CFS, the proposed approach was underpinned by a labelling risk management framework, comprising of risk management principles based on FSANZ's priority order objectives (see section 2 in SD4 of the 1st CFS) and informed by:

- a risk assessment for harvested cultured quail cells (SD1 to the 1st CFS)
- 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 to the 1st CFS).

The assessment at 2nd CFS has been further informed by:

- submitter comments to the 1st CFS (see Appendix 1 to the 2nd CFS), and
- the findings of a systematic literature review undertaken by the University of Adelaide examining consumers' levels of awareness, understanding, perceived risks and benefits, and prospective behaviour regarding alternative proteins, including cell-cultured meats (see section 2.2.1 and SD3 to the 2nd CFS).

This SD discusses the proposed regulatory approach at 2nd CFS for food identification issues (terminology, name of ingredient, name of the food, use of the term 'meat'), characterising ingredients, food for sale that is not required to bear a label and food sold to a caterer or other sales of food. The revised regulatory approach includes labelling requirements for cell-cultured foods as a distinct category of food, and specific labelling requirements that would apply to cell-cultured quail.

Labelling requirements – food for retail sale

The following requirements are proposed for a food that contains a permitted cell-cultured food as an ingredient and that is sold at retail sale or as suitable for retail sale without any further processing, packaging or labelling:

- to apply the Code's existing ingredient name requirements, and:
 - also require either the statement 'cell-cultured' or 'cell-cultivated' (*the statement*) to appear in conjunction with the name of the cell-cultured ingredient in the statement of ingredients
- to apply existing food name requirements if the packaged food for sale is not represented as being from the animal from which the cell-cultured ingredient was sourced (e.g. quail in the case of a food for sale containing cell-cultured quail as an ingredient)
- for a packaged food that is represented as being from the animal from which the cell-cultured ingredient was sourced— in addition to generic food name requirements, the same statement and the name of the cell-cultured ingredient to must also be in the name of the food.
- to apply characterising ingredient declaration requirements, including for the following foods which will not be exempt: prepared filled rolls, sandwiches, bagels or similar products; and for a food for sale that is sold at a fund raising event.
- if the food is not required to bear a label or is unpackaged—require the statement in conjunction with the name of the cell-cultured ingredient.

Division 2 of proposed Schedule 25A will set additional labelling requirements for a food for retail sale that contains a cell-cultured quail as an ingredient:

- prohibit use of the generic ingredient name 'poultry meat' in the statement of ingredients and the words 'poultry meat' elsewhere in the label, and
- the word 'meat' can only be used under the following circumstances:
 - in conjunction with the statement and the name of the cell-cultured quail ingredient
 - if the packaged food for sale is represented as a quail food product—in the name of the food in conjunction with the statement and the name of the cell-cultured quail ingredient.

Labelling requirements – food sold to a caterer and other types of sale

For cell-cultured food sold to a caterer, FSANZ proposes to require the statement 'cell-cultured' or 'cell-cultivated' in conjunction with name of the cell-cultured food to be stated:

- if the food is packaged—in the label on the package
- if the food is unpackaged—in labelling that must be provided to the caterer with the food.

This requirement will apply whether the cell-cultured food is an ingredient in a food sold to a caterer or is sold to a caterer separately as a food.

For other food sales, FSANZ proposes to require the information necessary to comply with the labelling requirement and this information must be provided in writing if requested or required.

Generic labelling requirements

FSANZ is proposing to maintain the preferred approach at 1st CFS (see SD4 to the 1st CFS) and apply the following generic labelling requirements to food that contains a cell-cultured food for:

- mandatory declaration for certain foods (allergens)
- date marking
- directions for use and storage
- nutrition information, and
- nutrition content and health claims.

Submitter comments relating to these labelling requirements have been considered in Appendix 1 to the 2nd CFS.

The draft variations and draft explanatory statement are at Attachment A and Attachment B of the 2nd CFS, respectively.

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1. Introduction

FSANZ is assessing an application to permit the use of cell-cultured quail as an ingredient in food for sale. Cell-cultured foods are not currently permitted for sale in Australia and New Zealand. FSANZ's approach for the assessment that informed the 1st Call for Submissions (CFS) included considering how existing generic labelling requirements would apply to cell-cultured quail and whether additional labelling measures are warranted (see Supporting Document 4 (SD4) to the 1st CFS).

The following generic labelling requirements in Part 1.2 (Requirements to have labels or otherwise provide information) of the Australia New Zealand Food Standards Code (the Code) were identified as relevant:

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

FSANZ also considered information requirements for food for retail 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).

FSANZ's preferred approach at the 1st CFS was informed by:

- a risk assessment for harvested cultured quail cells (SD1 to the 1st CFS)
- 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 to the 1st CFS).

In considering food identification requirements for cell-cultured quail, FSANZ also 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.

The proposed approach has been underpinned by a labelling risk management framework, comprising of risk management principles based on FSANZ's priority order objectives (see section 2 in SD4 to the 1st CFS).

The assessment at 2nd CFS has been further informed by:

- submitter comments to the 1st CFS (see Appendix 1 to the 2nd CFS), and
- the findings of a systematic literature review undertaken by the University of Adelaide examining consumers' levels of awareness, understanding, perceived risks and benefits, and prospective behaviour regarding alternative proteins, including cell-cultured meats (see section 2.2.1 and SD3 to the 2nd CFS).

Based on this assessment FSANZ is proposing to maintain the preferred labelling approach at 1st CFS to apply existing generic labelling requirements (see SD4 to the 1st CFS) to food that contains the cell-cultured quail for:

- mandatory declarations for certain foods (allergens)
- date marking

- directions for use and storage
- nutrition information, and
- nutrition content and health claims.

Submitter comments relating to these labelling elements have been considered in Appendix 1 to the 2nd CFS.

The proposed regulatory approach is for the Code to regulate cell-cultured foods as a distinct category of food, as opposed to regulate one food product only – cell-cultured quail. Certain labelling requirements will apply to cell-cultured quail. This SD discusses the proposed regulatory approach at 2nd CFS for food identification issues (terminology, name of ingredient, name of the food, use of the term ‘meat’), characterising ingredients, food for sale that is not required to bear a label and food sold to a caterer or other sales of food.

In this SD, the ‘primary variation’ means the draft Standard 1.5.4 Cell-cultured foods, the ‘Schedule’ means the Schedule 25A Permitted cell-cultured foods, and the ‘consequential variation’ means the draft consequential variation (see Attachment A to the 2nd CFS).

2. Terminology

2.1 Previous consideration

At the 1st CFS, FSANZ proposed a regulatory approach to promote labelling consistency across different products. FSANZ also considered it was important to ensure products made with cell-cultured quail are adequately labelled so consumers can distinguish them from conventional quail products. The proposed regulatory approach met the labelling risk management framework principles (see section 2 in SD4 to the 1st CFS) and was consistent with relevant policy guidance (see section 3.1.5.1 in SD4 to the 1st CFS).

Requiring a specific statement was considered more appropriate than a descriptor or statement that did not specify the term or words for the following reasons: it would promote labelling consistency across products; promote consumer understanding; reduce the risk of consumers being misled; and assist them to make informed choices. A mandatory statement would also provide regulatory clarity for both industry and enforcement agencies. This proposed approach was considered 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 had considered cell-cultured foods for approval at this time (see section 3.1.5.2 in SD4 to the 1st CFS).

FSANZ proposed to require the statement ‘cell-cultured’. This term was one of three terms (the other terms being ‘cell-cultivated’ and ‘cell-based’) that consumers found to be most descriptive for accurately identifying cell-cultured food products, and one of two terms (the other being ‘cell-cultivated’) that performed best relating to consumers’ perceived allergenicity of cell-cultured foods that are also known allergens.

FSANZ also considered the statement ‘cell-cultured’ accurately described the applicant’s food product (that is, harvested cultured quail cells), and that it best represented the technology going forward (including, for example, the formation of structured meats from cells mixed outside the bioreactor post-harvest) (see section 3.1.5.3 in SD4 to the 1st CFS).

Finally, based on available evidence, FSANZ considered one term to indicate the food product is cell-cultured would be clearer for individuals with food allergy. The term ‘cell-cultured’ was assessed as the best term to meet the labelling risk management principle for the protection of public health and safety (see section 3.1.5.4 in SD4 to the 1st CFS).

FSANZ therefore proposed to require the statement 'cell-cultured' to enable consumers to identify foods that are produced using this new technology.

2.2 Submitter comments

Some submitters did not support the statement 'cell-cultured' because they considered it misleading, misrepresentative, uninformative, unappealing and/or confusing for consumers. Two submitters noted that 'cultured' is misleading because of its use in other contexts, for example as a term associated with traditionally fermented products or used to describe a person's demeanour.

A number of submitters expressed a preference for the terms 'cultivated' or 'cell-cultivated' for the following reasons: the term 'cultivated' has higher levels of consumer appeal and acceptance than 'cultured'; 'cultivated' provides consumer clarity and supports informed choices; it aligns with consumer values relating to environmentally responsible and ethically produced food options; would become established terminology for other cell-cultivated products thus reducing the possibility of misidentifying cultivated seafood from conventional aquafarming before cell-cultivated seafood becomes commercially available; and is consistent with global trends and regulations. These submitters considered the term 'cultivated' would remain suitable as cellular agriculture develops as a technology.

One submitter supported a specified term for consistency, however noted both 'cell-cultured' and 'cell-cultivated' could meet this need equally well in terms of consumer understanding and use. This submitter suggested FSANZ consider the pros and cons of each term in relation to implications on trade, consumer understanding, and technical correctness, before finalising the statement.

2.3 Consumer evidence

Findings of a more comprehensive systematic review undertaken by the University of Adelaide (see section 2.2.1 and SD3 to the 2nd CFS) are broadly consistent with the findings of FSANZ's rapid systematic review (see SD2 to the 1st CFS). The University's systematic review found terms that incorporate the word 'cell' (e.g. 'cultivated from the cells of_', 'grown directly from the cells of_', 'cell-based' or 'cell-cultured') are best understood by consumers when differentiating cell-cultured products from conventional meat and fish.

2.4 Discussion

FSANZ notes some submitter comments relate to the term 'cultured' without the word 'cell', which is not what was proposed. FSANZ maintains the statement 'cell-cultured' is appropriate for food identification purposes based on the reasons provided in its assessment that informed the 1st CFS (see section 3.1 in SD4 to the 1st CFS).

As noted previously, matters relating to the extent to which certain terminology may support consumer acceptance of foods produced using cell-culturing techniques is not part of FSANZs' consideration of food identification labelling requirements (see section 2 in SD4 to the 1st CFS).

Submitter comments regarding a preference for 'cultivated' terminology are noted. Sustainability and the ethical production of food are consumer values issues reflecting consumer perceptions and ethical views. Such matters are generally within the purview of consumer protection legislation rather than food regulation.

However, FSANZ is proposing to revise the approach to require either the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the ingredient that is a cell-cultured food (see section 1.5.4—5 of the primary variation) for the following reasons:

- FSANZ's rapid systematic evidence review found both terms performed best in relation to consumers' objective understanding, descriptiveness of the food and perceived allergenicity (see SD2 to the 1st CFS).
- The findings of a subsequent literature review undertaken by the University of Adelaide were similar to FSANZ's rapid systematic evidence review, thus further supporting the use of either statement (see SD3 to the 2nd CFS).
- FSANZ previously noted a specific statement would ensure labelling consistency across products and promote consumer understanding and familiarity over time (see section 3.1.5.2 in SD4 to the 1st CFS). Noting the potential for confusion if statements are not consistent on a product, FSANZ is proposing to require the same statement be used in the labelling of a cell-cultured quail product.
- While acknowledging use of a single term could have greater significance when there is a public health and safety risk to manage (see section 3.1.5.4 in SD4 to the 1st CFS), the primary intent of the proposed terms 'cell-cultured' and 'cell-cultivated' is to inform consumers of the presence of cell-cultured food and prevent misleading and deceptive behaviour. Consistency for these terms is less important given they both performed equally in relation to consumer understanding of allergenicity.
- Use of either term would satisfy the Ministerial Policy Guideline on the Labelling of foods produced or processed using new technologies (2014)¹.
- The revised approach provides flexibility for suppliers of cell-cultured food. There continues to be overseas regulatory developments and FSANZ is aware both 'cell-cultivated' and 'cell-cultured' are being used by overseas regulatory counterparts. For example, 'cell-cultivated' is being used in public facing communications by regulators in the United Kingdom and Canada. Providing flexibility on the use of both 'cell-cultivated' and 'cell-cultured' will facilitate international harmonisation in the future.
- Previously FSANZ considered the term 'cell-cultured' more accurately describes the production process (including as the technology evolves) and the end product for the applicant's harvested cultured quail cells (see section 3.1.5.3 in SD4 to the 1st CFS). Industry submitters considered 'cultivated' terminology could be used to describe future production processes involving post-harvest cell-mixing and 3D printing. Noting consumer evidence indicates both 'cell-cultured' and 'cell-cultivated' are understood by consumers, FSANZ now considers how technically accurate the statement is in describing the production process is not so relevant.

In regard to other submitter comments, FSANZ considers the presence of the word 'cell' in the term 'cell-cultured' would be sufficient to inform consumers that the food containing cell-cultured product is not a traditionally fermented product such as yoghurt. FSANZ also considers the inclusion of the word 'cell' in 'cell-cultured' and 'cell-cultivated' is sufficient for consumers to understand that such food is different to its conventionally produced comparator food and will enable them to distinguish it from food produced using conventional

¹ Ministerial Policy Guideline on the labelling of foods produced or processed using new technologies (2014). Food Regulation. Available online at: <https://www.foodregulation.gov.au/resources/collections/ministerial-policy-guidelines>.

aquafarming or other traditionally fermented food products.

2.5 Conclusion

FSANZ is proposing to require either the statement 'cell-cultured' or 'cell-cultivated' in labelling for food identification purposes.

3. Name of ingredient

3.1 Code requirements

Paragraph 1.2.4—4(b) of 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
- a name that describes its true nature; or
- a generic ingredient name if one is specified in Schedule 10 – Generic names of ingredients and conditions for their use.

3.2 Previous consideration

FSANZ concluded it was appropriate to apply existing requirements and require either 'cell-cultured' or 'cell-cultivated' to be used in conjunction with the name of the cell-cultured ingredient in the statement of ingredients. The requirement would apply to all packaged products containing cell-cultured quail.

Information that the quail ingredient is 'cell-cultured' or 'cell-cultivated' would assist consumers to distinguish between food products containing the cell-cultured quail from conventional quail. This requirement would therefore meet 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. Section S10—2 of Schedule 10 in the Code includes the generic name 'poultry meat' without any conditions for its use. Generic ingredient 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 considered the generic ingredient name 'poultry meat' by itself would not be appropriate for cell-cultured quail as an ingredient because consumers would not be informed of its true nature. Further, there would be potential for consumers to be misled if this generic name was used in conjunction with the statement 'cell-cultured' as proposed. For example, 'cell-cultured poultry meat' as an ingredient name could mislead consumers that other poultry species are also being produced using cell-culturing techniques. FSANZ also considered that, given the nature of the cell-cultured ingredient, another generic name would not be appropriate. FSANZ therefore proposed to prohibit the use of the generic ingredient name 'poultry meat' for cell-cultured quail.

In relation to the animal source of the cell-cultured ingredient, FSANZ considered mandating the species name as part of the name of the ingredient to be unnecessary and that existing requirements of a common name or a name that describes its true nature would be sufficient.

3.3 Submitter comments

Submitters commented on the proposed terminology (see section 2 above), however no submitters commented on the proposed approach to require a statement to be used in conjunction with the name of the cell-cultured quail ingredient in the statement of ingredients, or to not permit the generic ingredient name 'poultry meat' to cultured quail cells.

3.4 Discussion

FSANZ is proposing to maintain the approach proposed at 1st CFS to apply existing ingredient naming requirements to cell-cultured quail. If cell-cultured quail is used as an ingredient in a packaged retail food for sale, it must be declared in the statement of ingredients using a name by which the ingredient is commonly known or one that describes its true nature in conjunction with either 'cell-cultured' or 'cell-cultivated' (see section 2 above).

As previously proposed, FSANZ is not applying existing requirements for generic ingredient names. A labelling condition is provided to make clear this existing provision does not apply to food for retail sale that has cell-cultured quail as an ingredient (see subsection S25A—5(4) of the Schedule). The effect is the generic ingredient name 'poultry meat' cannot be used in the statement of ingredients.

FSANZ notes section S10—2 of Schedule 10 in the Code also specifies 'meat' as a generic ingredient name. This generic ingredient name is proposed to be permitted under certain circumstances (see section 5 below).

FSANZ notes generic name requirements for ingredients in section 1.2.4—4 of the Code relate to their use in a statement of ingredients. FSANZ considers the reasons for not permitting the generic ingredient name 'poultry meat' (i.e. that it may be misleading; see section 3.3 in SD4 to the 1st CFS) would also apply to 'poultry meat' when used elsewhere on the label. Therefore, a labelling condition that the label on a package of cell-cultured quail for retail sale must not contain the phrase 'poultry meat' is included (see subsection S25A—5(2) of the Schedule).

3.5 Conclusion

In addition to existing ingredient labelling requirements, FSANZ is proposing to:

- require either statement 'cell-cultured' or 'cell-cultivated' to appear in conjunction with the name of the cell-cultured food in the statement of ingredients.
- for cell-cultured quail as an ingredient in a food for sale:
 - prohibit use of the generic ingredient names 'poultry meat' and 'meat' in the statement of ingredients, except the term 'meat' will be permitted under certain circumstances (see section 5 below).
 - the use of 'poultry meat' will not be permitted elsewhere in the label.

4. Name of the food

4.1 Code requirements

Standard 1.2.2 (Information requirements – food identification) in the Code sets out the labelling provisions for names of foods. 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 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)).

4.2 Previous consideration

FSANZ noted cell-cultured quail would be added as an ingredient to a mixed-food product such as, but not limited to, logs, rolls and patties. FSANZ determined it was not appropriate to prescribe a name for such a mixed food product as there was no safety issue relating to the consumption of cell-cultured quail. However, FSANZ considered the requirement in subparagraph 1.2.2—2(1)(b)(ii) to include the additional words 'cell-cultured' (see section 3.2 in SD4 to the 1st CFS) in the name of the food should apply if a food for sale is represented as a quail food product (e.g. 'quail patties') (for example, 'cell-cultured quail patties').

FSANZ concluded that this approach would meet its labelling risk management principles to ensure consumers are provided with adequate information to make an informed choice and are not being misled (see section 2 of SD4 to the 1st CFS).

4.3 Submitter comments

Two submitters commented that any term used to describe an ingredient should match that used in the food name, with one of these submitters noting this would avoid potential confusion and indicate likely allergenicity.

4.4 Discussion

FSANZ is proposing to maintain the approach proposed at 1st CFS, to apply existing food name requirements for food for sale that contains cell-cultured quail as an ingredient and is not represented as a quail food product. That is, a name or description sufficient to indicate the true nature of the food.

For food for sale that is represented as a quail food product, the same statement and the name of the cell-cultured quail ingredient (e.g. 'cell-cultured quail') in the statement of ingredients will be required in the name of the food (e.g. 'cell-cultured quail patties'). That is, the same statement (either 'cell-cultured' or 'cell-cultivated') must be used in both locations (see section 1.5.4—6 of the primary variation).

Representations are words, images or both as being from the animal from which the cell-cultured food was sourced. This means that an image of a quail in the label on a package of cell-cultured quail patties would be a representation that the food for sale is a quail food product. FSANZ has provided examples to section 1.5.4—6 of the primary variation for clarity of intent.

However, a provision has been included to clarify that a reference in a statement of ingredients to the animal from which the cell-cultured food was sourced would not constitute such a representation (see subsection 1.5.4—6(2) of the primary variation).

The labelling requirement for the name of the food applies to a packaged food for retail sale, noting such representations are most likely to be made on a product label rather than in a shelf label for an unpackaged food or food not required to bear a label. For those types of

retail sales, FSANZ is requiring the statement in conjunction with the name of the cell-cultured ingredient to be provided (see section 6 below).

4.5 Conclusion

FSANZ proposes to apply the following food name requirements for a packaged food for retail sale:

- apply existing food name requirements if the food is not represented as being from the animal from which the cell-cultured ingredient was sourced (e.g. quail in the case of a food for sale containing cell-cultured quail as an ingredient).
- for a packaged food that is represented as being from the animal from which the cell-cultured ingredient was sourced—in addition to generic food name requirements, the same statement and the name of the cell-cultured ingredient in the statement of ingredients must be in the name of the food.

5. Use of the term ‘meat’

5.1 Code definition

FSANZ has stated cultured quail cells is not ‘meat’ or ‘meat flesh’ as defined in subsection 1.1.2—3(2) of Standard 1.1.2 (Definitions used throughout the Code) in the Code (see section 1.3.4 of the 1st CFS). Therefore, these terms cannot be used to describe a food containing cell-cultured quail (e.g. ‘quail meat patties’), or as the ingredient (e.g. ‘quail meat’).

5.2 Previous consideration

FSANZ acknowledged that manufacturers may also wish to include the term ‘meat’ when referring to the cell-cultured ingredient as part of the ingredient name or in the name of the food. FSANZ considered the available evidence regarding consumer understanding and ability to correctly identify cell-cultured meat and conventional meat. FSANZ noted 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 to the 1st CFS).

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.

5.3 Submitter comments

One submitter considered the term ‘meat’ should be prohibited for use in the name of the product to avoid misleading consumers because the ingredient consists of quail fibroblasts and no skeletal muscle tissue.

Another submitter supported the use of the term ‘meat’ in the name of the food or as part of the ingredient name, provided it is accompanied by a qualifying term.

5.4 Discussion

FSANZ notes submitter comments, however available evidence indicates the term ‘meat’ when used in conjunction with ‘cell’-type terminologies (e.g. cell-based meat, cell-cultivated meat and cell-cultured meat) is useful for consumers to distinguish cell-cultured meat from conventional meat or plant-based meat alternatives and unlikely to be misleading (see section 3.4 of SD4 to the 1st CFS).

In addition to existing requirements for the food name and ingredient name to reflect the true nature of the food, FSANZ considers the proposed labelling requirements, when combined with the term ‘meat’ (e.g. ‘cell-cultured quail meat’), can assist consumers to make informed choices.

FSANZ is proposing specific labelling conditions for the use of ‘meat’ in labelling of food for retail sale that contains cell-cultured quail as an ingredient, such that the word ‘meat’ can only be used:

- in conjunction with the statement and the name of the cell-cultured quail ingredient (see paragraph S25A—5(3)(a) of the Schedule).
- If the packaged food is represented as a quail food product—in the name of the food in conjunction with the statement and the name of the cell-cultured quail ingredient (see paragraph S25A—5(3)(b) of the Schedule).

5.5 Conclusion

FSANZ is proposing the term ‘meat’ can only be used in labelling under the following circumstances:

- in conjunction with the statement and the name of the cell-cultured quail ingredient.
- if the packaged food is represented as a quail food product—in the name of the food in conjunction with the statement and the name of the cell-cultured quail ingredient.

6. Characterising ingredients

6.1 Code requirements

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) of the Code).

Standard 1.2.10 (Information requirements – characterising ingredients and components of food) in the Code requires 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.

The exemptions in section 1.2.10—3 include:

- prepared filled 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))
- a food for sale that is in a small package (paragraph 1.2.10—3(c))
- 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))
- 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)).

Paragraph 1.2.10—8(1)(a) requires the proportion of the characterising ingredient to be declared as a percentage. Paragraph 1.2.10—8(2) requires it appear in the statement of ingredients of a packaged food immediately following the common, descriptive or generic name of the ingredient.

The Code also 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.

6.2 Previous consideration

FSANZ considered the existing labelling exemptions in paragraphs 1.2.10—3(c) to (g) were not relevant to cell-cultured quail when used as an ingredient in food.

However, FSANZ concluded the following existing exemptions for providing 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)).

FSANZ considered it would be appropriate for characterising ingredient information about cultured quail cells to be provided in these scenarios because it would inform consumer choice, highlight the presence of the cell-cultured quail in the food for sale and thus reduce the risk of consumers being misled. These reasons supported the labelling risk management principles set out in section 2 in SD4 of the 1st CFS.

The requirement in paragraph 1.2.10—8(1)(a) would apply to a food for sale that is represented as a quail food product and the proposed required statement 'cell-cultured' or 'cell-cultivated' included in the name of the food (and in conjunction with the name of the cell-cultured quail ingredient in the statement of ingredients).

Further, characterising ingredient information requirements for food that is not required to bear a label were considered appropriate for food products containing cell-cultured quail as an ingredient.

6.3 Submitter comments

Several submitters expressed concern over perceived labelling exemptions for prepared filled rolls, sandwiches, bagels or similar products and for foods sold at a fund-raising event.

6.4 Discussion

FSANZ acknowledges submitter concerns, however notes the intention is for characterising ingredient labelling requirements to apply to certain foods that would otherwise be exempt. This means that percentage labelling information for characterising ingredients will be required for prepared rolls, sandwiches, bagels or similar products; and for foods sold at fund raising events.

FSANZ is proposing a provision in Standard 1.2.10 to specify that paragraphs 1.2.10—3(a) and (b) do not apply in relation to a characterising ingredient that is a cell-cultured food (see items 13 and 14 of the consequential variation).

The requirement for 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured quail ingredient (e.g. 'contains cell-cultured quail' or 'made with cell-cultivated quail') will trigger the requirement for characterising ingredient labelling for an unpackaged food or a food for sale not required to bear a label.

However, FSANZ notes under paragraph 1.2.1—9(7)(e) of the Code, requirements for information about characterising ingredients about a food for sale not required to bear a label is limited to food made and packaged on the premises from which it is sold (paragraph 1.2.1—6(1)(a) of the Code); and food not in a package (subsection 1.2.1—6(4) of the Code).

There are other sale scenarios where prepared rolls, sandwiches, bagels and similar products may be food for sale not required to bear a label in subsection 1.2.1—6(1) of the Code, including food:

- packaged in the presence of the purchaser
- delivered packaged, and ready for consumption, at the express order of the purchaser (other than when the food is sold from a vending machine)
- displayed in an assisted service display cabinet.

Further, there is no requirement for a food sold at a fund raising event to bear a label containing characterising ingredient information.

FSANZ is proposing a new provision to apply characterising ingredient information about cell-cultured food to paragraphs 1.2.1—6(1)(a), (b), (d) – (f) of Standard 1.2.1. The requirement would also apply to unpackaged food in subsection 1.2.1—6(4) (see item 11 of the consequential variation). The information would need to be displayed in connection with the display of the food or provided to the purchaser on request (subsection 1.2.1—9(6) of the Code).

Characterising ingredient information will also apply to a packaged food for retail sale that contains cell-cultured quail as an ingredient and is represented as a quail food product (paragraph 1.2.1—8(1)(j) of the Code).

6.5 Conclusion

Characterising ingredient declaration requirements are proposed to apply to food containing a cell-cultured food as an ingredient, including for the following foods which will not be exempt:

- prepared filled rolls, sandwiches, bagels or similar products
- a food for sale that is sold at a fund raising event.

The requirement for characterising ingredient information is also proposed to apply to food for sale not required to bear a label or is unpackaged.

7. Food for retail sale not required to bear a label

7.1 Code requirements

Information requirements for food for sale not required to bear a label are set out in Standard 1.2.1 (Requirements to have labels or otherwise provide information) of the Code.

Information requirements about the name of the food apply to food for retail sale not required to bear a label (paragraph 1.2.1—9(7)(a)). 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. Certain information specified in subsection 1.2.1—9(3) (e.g. a warning statement required by section 1.2.3—3, or information relating to foods produced using gene technology) must accompany or be displayed with the food in accordance with subsection 1.2.1—9(2).

However, there is no requirement for ingredient information to be provided about food for these types of sales unless the information is expressly required by section 1.2.1—9 (e.g. advisory statements and declarations).

7.2 Previous consideration

FSANZ concluded that information about a food for sale containing cell-cultured quail as an ingredient should apply to all types of sales, including whether the food is packaged or unpackaged, and if it is represented as a quail food product or not.

If a food sold in a restaurant setting is represented as a quail food product, FSANZ considered the statement ‘cell-cultured’ should be included in the name of the food (for instance, ‘cell-cultured quail roll’). A ‘cell-cultured quail patty’ that is displayed for sale in an assisted service display cabinet was another type of retail sale where the required statement is proposed to 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, FSANZ was of the view the presence of cell-cultured quail should still be declared. That is, the statement ‘cell-cultured’ should be used in conjunction with the food (for example, ‘contains cell-cultured quail’) in information available to a consumer when they are making a purchase decision.

FSANZ considered these food name and/or ingredient name information requirements should be mandatory in labelling that accompanies the food or is displayed in connection with the display of the food, given the importance of consumers having adequate information to make informed choices and not be misled that the quail ingredient is sourced from conventional quail. This approach was consistent with the labelling risk management principles set out in section 2 of SD4 to the 1st CFS.

7.3 Submitter comments

Some submitters commented that clear labelling of cell-cultured food sold in restaurants was important to prevent consumers from being misled and to inform choice.

Another submitter asked whether the statement ‘cell-cultured’ would be required with the name of the food printed on menus.

7.4 Discussion

Consistent with the policy principles detailed in the Ministerial Policy Guideline on the labelling of foods produced or processed using new technologies (2014)² and the labelling risk management framework (section 2 of SD4 to the 1st CFS), consumers should have access to clear labelling about the nature of such food.

The intent of the requirements is to ensure information relating to the cell-cultured food is available to consumers for all retail sale scenarios, including if the food is unpackaged or is a food for sale not required to bear a label (e.g. a mixed ingredient food containing cell-cultured quail sold in a restaurant setting).

The provision of information (e.g. the statement in conjunction with the name used for cell-cultured quail) on menus, as suggested by the submitter, could be one method of supplying this information. However, FSANZ considers it is unnecessary to mandate where the information must appear. Under existing Code requirements, the information must be stated in labelling that accompanies the food or is displayed in connection with the display of the food in accordance with subsection 1.2.1—9(2) of the Code. This approach ensures the information is readily accessible for consumers, provides flexibility for the supplier of the food and is consistent with requirements for other foods for retail sale not required to bear a label (including information relating to food produced using gene technology and irradiated food). FSANZ is proposing a new paragraph in subsection 1.2.1—9(3) of the Code to specify the information includes information relating to a cell-cultured food (see item 10 of the consequential variation).

FSANZ is proposing to apply the same requirement for the statement and the name of the cell-cultured quail ingredient in a statement of ingredients to a food for retail sale not required to bear a label or is unpackaged (see section 1.5.4—5 of the primary variation). The intent is to ensure the cell-cultured quail ingredient is always indicated to consumers.

However, FSANZ considers it is unnecessary to require this information to also appear in the name of the food for these retail sale scenarios. It would be onerous for suppliers to provide the statement and ingredient name twice (e.g. 'made with cell-cultured quail' in relation to the ingredient and 'cell-cultured quail patties' in relation to the food name), or when a label does not include text or images representing the food as a quail food product to include the information as part of the name of the food (e.g. 'cell-cultured quail patties'). As noted above, FSANZ's revised approach would ensure consumers are made aware the food contains a cell-cultured food ingredient while also giving suppliers choice in how they name their mixed food for retail sale. Further, section 1.5.4—6 of the primary variation makes it clear information requirements about cell-cultured food in the name of the food for retail sale apply only to packaged food for retail sale.

7.5 Conclusion

For a food for retail sale not required to bear a label or is unpackaged and has cell-cultured food as an ingredient, FSANZ is proposing to require the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured ingredient.

² Ministerial Policy Guideline on the labelling of foods produced or processed using new technologies (2014). Food Regulation. Available online at: <https://www.foodregulation.gov.au/resources/collections/ministerial-policy-guidelines>.

8. Food sold to a caterer and other sales of food

8.1 Code requirements

As noted in the 1st CFS, generic provisions in Standard 1.2.1, Division 3 (Sales of food to caterers) and Division 4 (Other sales) of the Code apply to novel foods and novel food ingredients (see section 1.1.1 in SD4 to the 1st CFS). In particular:

- 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.
- section 1.2.1—21 is similar, except that it applies to other food sales, such as the sale of an ingredient by an ingredient supplier to a manufacturer of food. The information for other food sales must be provided in writing if requested by the purchaser or required by the relevant authority.

The intent of these provisions is to ensure caterers and manufacturers have the means by which to request information about a food, or of another food using it as an ingredient, so they can comply with Code requirements.

Further, for food sold to a caterer, section 1.2.1—15 refers to information about certain listed foods (e.g. food produced using gene technology) to which labelling requirements apply. These requirements include that the information must be provided on the label of the package (in accordance with section 1.2.1—12) or, if the food is not required to bear a label, provided in labelling to the caterer with the food (section 1.2.1—13).

8.2 Previous consideration

FSANZ's proposed approach was to apply the requirements of sections 1.2.1—17 and 21 to food sold to a caterer containing cell-cultured quail as an ingredient. FSANZ considered this approach would be 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 other purchasers to ensure they have the information to meet their regulatory labelling obligations for retail sales of food containing cell-cultured quail.

8.3 Submitter comments

One submitter commented that, for food sold to a caterer and for other sales of food, the onus should not be on the caterer to request information about the food. Rather the onus must be on the supplier to provide required labelling information to caterers and, for other food sales, to other purchasers.

8.4 Discussion

Noting submitter comments, FSANZ now considers an approach consistent with information requirements for other foods subject to pre-market assessment would be appropriate. A new provision has been included to specify information relating to cell-cultured food (see item 12 in the consequential variation).

As noted in section 2 above, the proposed requirement is the use of the statement ('cell-cultured' or 'cell-cultivated') in conjunction with the name of the cell-cultured quail ingredient (e.g. 'cell-cultured quail').

Subsection S25A—4(1) of the Schedule specifies that cell-cultured quail must not be a food offered for retail sale. Therefore, a separate provision is proposed to enable cell-cultured quail to be sold as a single ingredient food to caterers and food manufacturers.

The requirements for the information therefore depend on how cell-cultured quail is sold:

- as an ingredient in a mixed food e.g. in a patty or roll (section 1.5.4—5 of the primary variation).

This provision applies to food for sale, including retail sales, food sold to a caterer and other sales (e.g. to a food manufacturer).

- as a single ingredient food (section 1.5.4—7 of the primary variation).

This provision applies only to non-retail food sales (i.e. food sold to a caterer and other sales).

If the food sold to a caterer is a packaged food, the information is required to be on labelling for packaged food (subsection 1.2.1—12(1) of the Code). If the food is not required to bear a label, labelling containing the information must be provided to the caterer with the food (section 1.2.1—13 of the Code).

For other food sales, FSANZ has retained the approach proposed at the 1st CFS because it is consistent with the existing regulatory approach for information relating to food produced using gene technology and irradiated food. This means a purchaser may request, or the relevant authority may require, information necessary for the purchaser to comply with any labelling or declaration requirement in the Code. The information must be provided in writing (section 1.2.1—21 of the Code). These requirements apply generally to packaged and unpackaged food sold by a supplier to a manufacturer, although FSANZ understands the nature of cell-cultured quail as a single ingredient food is that it would need to be packaged.

Whilst the onus is on the food manufacturer to request that additional information (e.g. from the supplier of food containing cell-cultured quail, or the cultured quail cells sold separately), it is in both parties' best interests to ensure all necessary information is supplied.

However, FSANZ notes the Code requires a packaged food sold to a manufacturer to bear a label that states the name of the food (paragraph 1.2.1—20(2)(c) of the Code). Therefore, if the food is sold to a manufacturer as a single ingredient food, the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name used for cell-cultured quail would need to be in the label because the name of the cell-cultured quail is the name of the food (section 1.5.4—7 of the primary variation).

8.5 Conclusion

FSANZ is proposing to require the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured ingredient in a food or separately as a food to be provided to the caterer:

- if the food is packaged—in the label on the package
- if the food is unpackaged—in labelling that must be provided to the caterer with the food.

For other food sales, existing requirements for the provision of information will apply, where the information is the statement in conjunction with the name of the cell-cultured ingredient in a food or separately as a food.

9. Summary of the regulatory approach

Labelling requirements – food for retail sale

The following requirements are proposed for a food that contains a permitted cell-cultured food as an ingredient and that is sold at retail sale or as suitable for retail sale without any further processing, packaging or labelling:

- to apply the Code’s existing ingredient name requirements, and:
 - also require either the statement ‘cell-cultured’ or ‘cell-cultivated’ (*the statement*) to appear in conjunction with the name of the cell-cultured ingredient in the statement of ingredients
- to apply existing food name requirements if the packaged food for sale is not represented as being from the animal from which the cell-cultured ingredient was sourced (e.g. quail in the case of a food for sale containing cell-cultured quail as an ingredient)
- for a packaged food that is represented as being from the animal from which the cell-cultured ingredient was sourced— in addition to generic food name requirements, the same statement and the name of the cell-cultured ingredient to must also be in the name of the food.
- to apply characterising ingredient declaration requirements, including for the following foods which will not be exempt: prepared filled rolls, sandwiches, bagels or similar products; and for a food for sale that is sold at a fund raising event.
- if the food is not required to bear a label or is unpackaged—require the statement in conjunction with the name of the cell-cultured ingredient.

Division 2 of proposed Schedule 25A will set additional labelling requirements for a food for retail sale that contains a cell-cultured quail as an ingredient:

- prohibit use of the generic ingredient name ‘poultry meat’ in the statement of ingredients and the words ‘poultry meat’ elsewhere in the label, and
- the word ‘meat’ can only be used under the following circumstances:
 - in conjunction with the statement and the name of the cell-cultured quail ingredient
 - if the packaged food for sale is represented as a quail food product—in the name of the food in conjunction with the statement and the name of the cell-cultured quail ingredient.

Labelling requirements – food sold to a caterer and other types of sale

For cell-cultured food sold to a caterer, FSANZ proposes to require the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the cell-cultured food to be stated:

- if the food is packaged—in the label on the package
- if the food is unpackaged—in labelling that must be provided to the caterer with the food.

This requirement will apply whether the cell-cultured food is an ingredient in a food sold to a caterer or is sold to a caterer separately as a food.

For other food sales, FSANZ proposes to require information necessary to comply with the labelling requirement and this information must be provided in writing if requested or required.

Generic labelling requirements

FSANZ is proposing to maintain the preferred approach at 1st CFS (see SD4 to the 1st CFS) and apply the following generic labelling requirements to food that contains a cell-cultured food for:

- mandatory declaration for certain foods (allergens)
- date marking
- directions for use and storage
- nutrition information, and
- nutrition content and health claims.