

M.E Voisin  
Senior Coroner  
Coroner's Court  
Old Weston Road  
Flax Bourton  
Bristol  
BS48 1UL

16 January 2023  
[REDACTED]

Dear Ms Voisin,

**REGULATION 28 REPORT TO PREVENT FUTURE DEATHS – CELIA MARSH:  
RESPONSE BY THE FOOD STANDARDS AGENCY**

Thank you for sending me the Regulation 28 report of the Coroners (Investigations) Regulations 2013 following the inquest into the tragic death of Celia Marsh (deceased 27 December 2017) from a severe anaphylactic reaction.

I would like to extend my deepest sympathies and those of the Food Standards Agency (FSA) to the family of Mrs Marsh.

We have considered the matters of concern you have raised, and the actions which you have recommended should be taken and would like to offer the following response.

Whilst considering our response, we have made contact with other recipients of your report to discuss the relevant recommendations.

**The investigation process**

In introducing your detailed recommendations you highlighted broader concerns “...in relation to the immediate investigation into a suspected death from anaphylaxis, that the evidence obtained at this time, with the right approach, can be invaluable to preventing deaths, but that to achieve this changes are required” and noted that “this would need changes in the death investigation process and the wider investigation which would need assistance from the Food Standards Agency (FSA)”.

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Before addressing your detailed recommendations, I thought it might be useful to set out our role as the Central Competent Authority (CCA), when notified of incidents where there has been serious illness and/or fatalities linked to food.

Our responsibilities are to:

- **support the enforcing authority with the necessary policy and expert advice that will result in unsafe food being removed from the market.**
- **notify and liaise with international Food Safety Officials if there is distribution outside of the UK.**

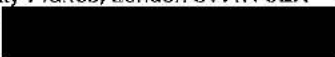
In the UK, authorised food officers within local authorities have responsibility for official controls in relation to food law enforcement and therefore have the responsibility and powers for investigating in such instances. The FSA is responsible for issuing and maintaining the Food Law Code of Practice and associated Practice Guidance, which set out our expectations for how official controls in relation to food, including incident investigations, should be delivered by local authorities in line with their responsibilities under food law.

The actions and nature of the FSA's support to local authority investigations depends on when we are notified of the incident. In the main, local authorities are required to categorise food hazards, and notify the FSA by the quickest possible means if an incident is either a widespread, or a localised but serious hazard.

At the time of this incident, the Food Law Code of Practice, England, 2017 was in place, which required notification to the FSA for 'allergy' incidents or if 'any deaths associated with the incident,' occurred. These requirements were strengthened in a review of the practice that led to the March 2021 version. This provides more details on requirements to notify the FSA as a result of an incident linked to an allergy. It now requires that the FSA is notified if there are 'undeclared allergens, a serious anaphylaxis reaction requiring medical intervention as a result of allergens in food, hospitalisation, or death as a result of allergens in food'.

The FSA requests timely notification in the initial stages of the incident to allow for appropriate assessment and provision of food safety advice from the FSA, to inform food safety action to be swiftly taken by the food business, on advice and instruction from the competent authority, ordinarily the Local Authority, who is the enforcing authority. It is also not uncommon for the FSA to be notified of an incident by the coroner, at the inquest stage or to learn of deaths as a result of exposure to food from the press on conclusion of an inquest. In such an instance, the FSA's role is limited to providing the necessary policy advice, access to subject matter experts, international communications through the International Food Safety Authorities Network (INFOSAN).

As part of routine improvements and drive for efficiency, the FSA is currently producing an internal standard operating procedure for dealing with serious illness and fatality incidents, which includes incidents of anaphylaxis. Our aim is to ensure we take a robust and consistent approach to such occurrences. This procedure will include detail of how we can make local authorities aware of such occurrences at the earliest time possible (if the FSA is notified through other means in the first instance). Additionally, the FSA is developing training for local authorities on incident

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management, including detection, reporting and incident response to compliment the Food Law Code of Practice, and the Practice Guidance, that is planned for roll out in 2023/24.

You have also noted that The FSA could assist with *current practices of food labelling*". The FSA is responsible for food safety labelling in England, Wales and Northern Ireland and I will discuss this in more detail later in this response.

Your concerns regarding pathology have been noted, however this is not an area where the FSA has policy responsibility. I can see that your report has been directed to the Department for Health and Social Care (DHSC) and the Royal College of Pathologists who may be able to offer a response to these concerns. We are however, open to assisting other government departments where we can.

### Reporting and recording

You recommended establishing "... a robust system of capturing and recording cases of anaphylaxis, and specifically, fatal and near-fatal anaphylaxis, to provide an early warning of the risk posed to allergic individual by products with undeclared allergen content" and noted that such a system could involve mandatory reporting and indicated how this might work.

The FSA is responsible for food safety labelling and food allergy policy in England, Wales and Northern Ireland (Food Standards Scotland have this responsibility in Scotland). When a food business considers or has reason to believe that a food it has placed on the market is injurious to health, they are required to notify competent authorities such as a local authority who are in turn required to notify the FSA of serious or widespread incidents (or notify the FSA directly where we are the competent authority, e.g. food businesses approved by the FSA).

There are, however, circumstances where no, or no timely, notification is provided. In these cases, a mechanism by which the FSA is made aware of cases of anaphylaxis (fatal or near fatal) would be very helpful. You have suggested a "*mandatory reporting of anaphylaxis presenting to hospitals*" similar to the system in place for notifiable diseases. The FSA would not be able to introduce such a system as it would fall within the remit of DHSC.

I would however, like to make you aware of the following:

The FSA-funded NHS Data project<sup>1</sup> was established to monitor trends in the occurrence of severe, food induced allergic reactions. This work includes the establishment of a UK Anaphylaxis Registry to collect data relating allergic reactions to both food and non-food triggers. While the Registry is not aimed at aiding the investigation of incidents, the questionnaire completed by patients when reporting reactions to the Registry is being updated to includes details on how to contact their local authority's food safety team to report an incident.

<sup>1</sup> [www.food.gov.uk/research/food-allergy-and-intolerance-research/using-nhs-data-to-monitor-trends-in-the-occurrence-of-severe-food-induced-allergic-reactions](http://www.food.gov.uk/research/food-allergy-and-intolerance-research/using-nhs-data-to-monitor-trends-in-the-occurrence-of-severe-food-induced-allergic-reactions)

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Additionally In 2021, the FSA provided one-off funding to enable the UK Fatal Anaphylaxis Register (UKFAR) to be updated and maintained. The UKFAR, overseen by the British Society for Allergy and Clinical Immunology, is an active register of deaths from anaphylactic reactions, including food allergies which provides a long-term source of data to improve our understanding of the causes of anaphylaxis related fatalities. This work will help the FSA in its work to reduce numbers of food-related anaphylactic reactions.

### Wording used on products

You raised concern that the “*publics understanding of...*” phrases such as “free from and “vegan” “...in terms of implying the absence of a particular allergen, can be potentially misleading”. You also stated that “*Foods labelled in this way must be free from that allergen, and there should be a robust system to confirm the absence of the relevant allergen in all ingredients and during production when making such a claim.*”

You also suggested that as an interim measure, it may be necessary to clarify that foods with such claims may not be safe for those with the most severe food allergies.

‘Free-from’ and ‘vegan’ labelling have different purposes – a “free-from” allergen claim is an absolute claim and should only be used following a rigorous assessment of the ingredients, process and environment.

Vegan labelling is not intended to be food safety labelling and there is currently no legal definition of the term “vegan”; veganism is a lifestyle choice based on a range of factors, including ethical, environmental, and nutritional choice.

While vegan food should not contain animal products the Vegan Society advise that their Vegan Trademark can be used on food carrying a precautionary allergen label (a voluntary statement such as “may contain” to communicate the risk of the unintentional presence of an allergen in a food) for animal products provided that the labelling decision is based on a thorough risk assessment of cross-contamination.

There is no specific UK legislation covering “free-from” (with the exception of “gluten-free”) or “vegan” claims. Any such claims are therefore regulated in accordance with the provisions of General Food Law which provides that voluntary labelling information shall not mislead the consumer or be ambiguous or confusing to the consumer.

For any free-from claim to be considered not misleading, it would need to be an analytical zero (where the allergen concerned cannot be detected using the best and most appropriate method of detection).

There is information on this subject on our website. There is also FSA endorsed guidance from the Food and Drink Federation (FDF) regarding the use of vegan and free from claims on food. The FDF promotes this guidance regularly and the FSA also signposts businesses to it for best practice.

We are in the process of updating our allergen technical guidance to say that precautionary allergen statements should not be used in combination with a ‘free from’ statement for the same allergen. This work is ongoing and will be put out for further consultation shortly.

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We will consider how best to promote the current guidance to businesses producing foods with these claims to encourage best practice more widely and continue to consider it alongside our work on precautionary allergen labelling.

Additionally, to improve our understanding of consumer perceptions in these areas we are considering carrying out some behavioural research looking at vegan foods with the prospect of an educational campaign around vegan food not always being suitable for those with food hypersensitivities (those with a food allergy, intolerance or coeliac disease).

### **Investigation hotline and best practice**

You recommended a *"hotline to the FSA to provide guidance in fatal cases due to suspected anaphylaxis"* and *"nationally recognised best practice and technical advice to assist those investigating such cases."*

As mentioned above, the responsibility and power for such investigations does not sit with the FSA, therefore we would not be best placed to provide such a hotline.

The FSA Food Law Code of Practice for local authorities includes guidance on contacting the FSA at the earliest opportunity where affected (potential) hazardous food is distributed beyond the authority's boundaries and/or where the hazard is serious, within the local authorities boundaries. A direct phone line and 24/7 365 days per year email address is in place at the food incidents teams at the FSA to receive these notifications. The Food Law Code of Practice also confirms that cross borough issues require agreement for one authority to take a lead to investigate. The FSA provide support and communications through food alerts etc.

### **The FSA's commitment to improve the quality of life for people with a food hypersensitivity**

Reducing harm from food hypersensitivity is a fundamental part of the FSA's remit and our work in this area aims to improve the quality of life for people living with food hypersensitivity and support them to make safe, informed food choices to effectively manage risk.

Since we published our new FSA Strategy (2022 to 2027) and workplan last year, the FSA is facing additional pressures, including significant new areas of work which in order to deliver has meant making some difficult decisions in some areas of our proposed programme. In addition to our core activities on food hypersensitivity we will ensure that the review of Retained EU Law retains current protections for people with a food hypersensitivity. In our wider food hypersensitivity programme we will focus on a smaller subset of priorities in three key areas:

- **Precautionary Allergen Labelling (PAL) will be the priority amongst the three, focusing on improving the way PAL is applied by industry, and its effectiveness as a consumer information tool.**

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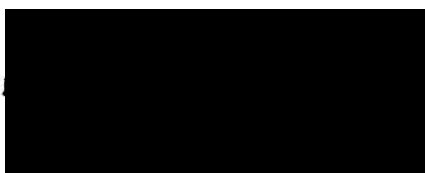
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- improving the provision of information for consumers in the non-prepacked sector (out of home), with a focus on the accuracy of information.
- enabling a step-change in the knowledge, skills and food safety culture of staff in the 'non-prepacked' sector through training.

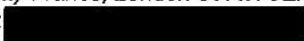
Key to the success of this work is ensuring food businesses, consumer groups, enforcement bodies and other government departments work together on this important issue and the FSA will continue its role as a convener to ensure that this happens.

I would once again like to extend the FSA's deepest condolences to the family of Celia Marsh and hope that the work we are doing will help to prevent future occurrences of incidents like this.

Yours sincerely



  
Chief Executive

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