M. E. Voisin
His Majesty's Senior Coroner
Area of Avon

21st November 2022 REF: 9030

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** • **Food Standards Agency** • **UK Health Security Agency** • **Department of Health and Social Care** • [redacted] • [redacted] • **Royal College of Pathologists** • **British Society for Allergy and Clinical Immunology** • **British Retail Consortium** • **Food and Drink Federation** • **British Hospitality**
1	**CORONER** I am M E Voisin Senior Coroner for **Area of Avon**
2	**CORONER'S LEGAL POWERS** I make this report under paragraph 7, Schedule 5, of the Coroners and Justice Act 2009 and regulations 28 and 29 of the Coroners (Investigations) Regulations 2013. http://www.legislation.gov.uk/ukpga/2009/25/schedule/5/paragraph/7 http://www.legislation.gov.uk/uksi/2013/1629/part/7/made
3	**INVESTIGATION and INQUEST** On 17/01/2018 I commenced an investigation into the death of Celia Lindsey MARSH. The investigation concluded at the end of the inquest on 22nd September 2022. The medical cause of death was found by me to be: **1a) Anaphylaxis triggered by the consumption of milk protein.** Based on the evidence I considered that the appropriate wording for Section 3 of the Record of Inquest form answering the questions "How, when and where the deceased came by her death should be as follows: **Celia Marsh died on 27th December 2017 at Royal United Hospital, Bath. She had a known allergy to milk. On that day whilst in Bath City Centre she ate a super veg rainbow flatbread which she believed was safe to eat; she suffered an anaphylaxis reaction caused by milk protein which was in an ingredient within the wrap; this caused her to collapse and despite the efforts of the medical teams**

	involved she died. The conclusion of the inquest was a narrative which read as follows: **Celia was allergic to milk, she suffered anaphylaxis caused by the consumption of a wrap; the wrap was contaminated with milk protein. Celia was not aware that the wrap contained milk protein. The wrap contained a product which was marked as "dairy free coconut yogurt alternative", but despite this it contained milk protein, which was the cause of Celia's anaphylaxis. A product which is marked "dairy-free" should be, free from dairy. The contamination arose because an ingredient in the yogurt called HG1 had become cross-contaminated with milk protein during its manufacture. The manufacturer of the dairy free yogurt had in its possession documents which flagged this risk but this risk was not passed on to its customers.**
4	**CIRCUMSTANCES OF THE DEATH** Celia had known adult-onset allergy to cow's milk protein. On 27th December 2017 she was shopping with her family in Bath City Centre. She purchased a wrap from Pret a Manger and it appears likely that she had been reassured that the wrap was dairy-free. After eating the wrap, she suffered a severe anaphylaxis reaction to the milk protein in the wrap and died. An investigation by the Bath and North East Somerset Trading Standards and indeed others traced the dairy to a product in the wrap which was made by Planet Coconut and marketed as a dairy free coconut yogurt alternative. It was also found that the ingredient in the dairy free yogurt that caused the contamination was called HG1.
5	**<u>CORONER'S CONCERNS</u>** During the course of the inquest the evidence from a number of experts revealed matters giving rise to a concern. In my opinion there is a risk that future deaths will occur unless action is taken. In the circumstances it is my statutory duty to report to you. I indicated that my report would cover a number of areas to highlight the suggestions made by [redacted] and others during the inquest. I explained that a report is not to dictate what that action should be however in this case I considered that it was right that I should pass on to those organisations suggestions made by the experts and indeed others who have assisted me in my investigation, it is of course a matter for you what if any steps you take. The **MATTERS OF CONCERN** were as follows: Concerns were raised 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. This would need changes in the death investigation process and the wider investigation which would need assistance from the Food Standards Agency (FSA). I was made aware that there needs to be better education both to doctors and to patients in risk groups to prevent future deaths I was also advised that whereas the FSA would be required to assist with the above areas it could also assist in relation to the current practices of food labelling. Firstly in relation to **Pathology**, I am told that the current guidance is 10 years old, the suggestion is for this to be revisited and specifically: • If bloods are taken at hospital that they are not destroyed in a suspected case but retained for testing • That an early blood sample is taken after death and stored for late analysis • That the possibility that a death is due to anaphylaxis is raised with the Senior Coroner for the area where the death occurred at the earliest opportunity

- That an early blood sample is taken after death
- The post mortem examination should be prioritised.
- At the post mortem examination: that stomach contents are taken and frozen to enable testing and that tissue samples are taken

A standard protocol should be available to ensure appropriate samples are taken at the correct time to assist later investigation.

In relation to **doctors/patients:**

- To highlight, through public awareness and to the medical profession, that while the majority of food-allergic individuals are at very low risk of fatal reactions, a small subset of food-allergic individuals may be at significantly higher risk. These persons must be given appropriate advice as to the dangers of inadvertent exposure, since there may be no detectable safe level of allergen that can be present in a product for this group.
- To be aware that avoidance of foods in adults does not improve eczema and may result in more severe allergy to the food avoided particularly to cow's milk but tolerance can be maintained by continued regular exposure.

In relation to the **FSA**, the **UK Health Security Agency** and the **Department of Health and Social Care:**

- To establish 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.
- Such a system could involve *mandatory* reporting of anaphylaxis presenting to hospitals, analogous to the current system used for notifiable diseases (including some food-borne illnesses) whereby registered medical practitioners have a statutory duty to notify the 'proper officer' at their local council or local health protection team of suspected cases of certain infectious diseases. An example of such a reporting system for anaphylaxis already exists in the state of Victoria in Australia, and also allows for rapid alerts of serious cases to public health authorities to expedite investigation and evaluate the public health risk.

In relation to the **FSA**, the **British Retail Consortium**, **Food and Drink Federation** and **British Hospitality**:

- The wording used on food products, and the public's understanding of these phrases in terms of implying the absence of a particular allergen, can be potentially misleading. Examples include: "free-from" and "vegan". 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.
- With respect to those with the most severe food allergies, it may be necessary in the interim to clarify that foods labelled "free-from [X allergen]" may not be safe to consume.

In relation to the **FSA**:

- A hotline to the FSA to provide guidance in fatal cases due to suspected anaphylaxis, although a mandatory reporting system (suggested above) would address this need.
- Nationally recognised best practice and technical advice to assist those investigating such cases;

6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you have the power to take such action.
7	**YOUR RESPONSE** You are under a duty to respond to this report within 56 days of the date of this report, namely by 16th January 2023. I, the coroner, may extend the period. Your response must contain details of action taken or proposed to be taken, setting out the timetable for action. Otherwise you must explain why no action is proposed.
8	**COPIES and PUBLICATION** I have sent a copy of my report to the chief coroner and to the following interested persons: • Family of Celia Marsh • Pret a Manger Ltd • Planet Coconut • Bath and North East Somerset Counsel I have also sent it to the following who may find it useful or of interest. • [redacted] I am also under a duty to send the chief coroner a copy of your response. The chief coroner may publish either or both in a complete or redacted or summary form. He may send a copy of this report to any person who he believes may find it useful or of interest. You may make representations to me, the coroner, at the time of your response, about the release or the publication of your response by the chief coroner.
9	21/11/2022 Signature **M E Voisin Senior Coroner Area of Avon**

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The Coroner's Court, Old Weston Road, Flax Bourton, BS48 1UL