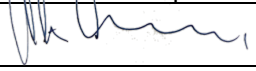
REGULATION 28: REPORT TO PREVENT FUTURE DEATHS

*NOTE: This form is to be used **after** an inquest.*

	REGULATION 28 REPORT TO PREVENT FUTURE DEATHS **THIS REPORT IS BEING SENT TO:** **1. Clive Schlee, Chief Executive of Pret-a-Manger** **2. The MHRA** **3. the Chief Executive of Pfizer makers of the Epipen** **4. Mr Michael Gove Secretary of State Department for the Environment, Food and Rural Affairs**
1	**CORONER** I am Dr Séan Cummings Assistant Coroner for the Coroner Area of London (Western Area)
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.
3	**INVESTIGATION and INQUEST** On 03/08/2016 I commenced an investigation into the death of Natasha Charlotte Rose Ednan-Laperouse, 15 years old. The investigation concluded at the end of the inquest on 28/09/2018.The conclusion of the inquest was (2) Anaphylaxis (4) Natasha Ednan-Laperouse died of anaphylaxis in Nice on the 17th July 2016 after eating a baguette, purchased from Pret-a-Manger at LHR T5. The baguette was manufactured to Pret specifications and contained sesame to which she was allergic. There was no specific allergen information on the baguette packaging or on the langar barker and Natasha was reassured by that.
4	**CIRCUMSTANCES OF THE DEATH** Natasha travelled with her father and friend for a short holiday in Nice on the 17th July 2016. She was allergic to sesame. She bought a baguette after checking the ingredients. She had eaten at Pret previously and was reassured by what she took to be their high standards. She ate the baguette. The baguette contained unlabelled sesame at a ratio of 2.41% expressly commissioned by Pret. She developed an anaphylactic reaction on the plane to Nice and despite best efforts succumbed to that, dying in hospital in Nice shortly after landing.
5	**<u>CORONER'S CONCERNS</u>** During the course of the inquest the evidence revealed matters giving rise to concern. In my opinion there is a risk that future deaths could occur unless action is taken. In the circumstances it is my statutory duty to report to you. The **MATTERS OF CONCERN** are as follows. – (1) That allergens were not labelled adequately or clearly on Pret-a-Manger packaging when prepared in their kitchens "pre-packed for direct sale"

	utilising regulation 5 of the Food Information Regulations. Regulation 5 allows for food outlets to avoid full food labelling requirements whether they prepare a small number of items in local shops or in the case of Pret, over 200 million items for sale by preparing these items in "local kitchens". These items prepared in "local kitchens" are in fact "assembled" in large parts from items made in factory style outlets to Pret specifications. I was left with the impression that the "local kitchens" were in fact a device to evade the spirit of the regulation. (2) In the case of Pret-a-manger there was no coherent or co-ordinated system for monitoring customer allergic reactions despite sales of more than 200 million items. In some cases concerns were notified to Customer Services and in some they were noted to the safety department. The two did not know what the other was responding to. It was clear that there was no overarching monitoring system in place. In response to questioning on this I was told that the manager responsible for safety now received all notifications and would monitor them. In my view this remains highly inadequate. In my view sales of 200 million items some with expressly commissioned but hidden allergens require a robust safety auditing system. The previous system was unsafe and the system proposed equally so in my view. (3) In the Emergency treatment of anaphylactic reactions Guidelines for healthcare providers the preferred needle length is 25 mm for adrenaline injectors to access muscle in most people. I heard during expert evidence that Epipen needle length was 16mm - suitable according to the UK Resuscitation Council for "pre-term or very small infants". The use of needles which access only subcutaneous tissue and not muscle is in my view inherently unsafe. An alternative autoinjector, Emerade has a 24 mm needle. (4) The dose of adrenaline in Epipen is 300mcg. The UK Resuscitation Council recommends a standard emergency dose of 500mcg. Emerade contains a dose including 500mcg. The combination of what my expert told me was an inadequate dose of adrenaline for anaphylaxis and an inadequate length needle raises serious safety concerns.
6	**ACTION SHOULD BE TAKEN** In my opinion action should be taken to prevent future deaths and I believe you (1) Clive Schlee Chief Executive of Pret-a-Manger; The MHRA; the Chief Executive of Pfizer and Michael Gove, Secretary of State 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 3rd December 2018. 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 (1) The Laperouse Family, (2) Clive Schlee Chief Executive Pret-A-Manger; (3) The MHRA (4) The Secretary of State Michael Gove and to the LOCAL SAFEGUARDING BOARD. 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	**8th October 2018**  Dr Séan Cummings Assistant Coroner London West