



Office for Product  
Safety & Standards

Office for Product Safety and Standards  
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James Edward Thompson  
HM Assistant Coroner  
Coroner's office  
Lower ground floor, Block 1, Civic Centre  
Barras Bridge  
Newcastle upon Tyne  
NE1 8QH

*Sent via email*

18 December 2023

Dear Mr Thompson,

**Regulation 28: Prevention of Future Deaths Report**  
**Karlton Noah Donaghey**

Thank you for your Regulation 28 Report (Prevention of Future Deaths) dated 23 October 2023, following your investigation and inquest into the death of Karlton Noah Donaghey, who died on 29 June 2022 as a result of diffuse hypoxic ischaemic encephalopathy and asphyxia following a helium balloon accident.

May I first say how sorry I was to hear of Karlton Donaghey's death. If you have the opportunity, please convey my deepest sympathy to his family.

The Office for Product Safety and Standards (OPSS) is the UK's national product regulator, responsible for the safety of all consumer products except food, vehicles and medicines. OPSS takes the safety of consumers, and in particular vulnerable consumers such as children, very seriously, and works alongside Local Authority Trading Standards to ensure that manufacturers, importers and distributors meet their obligations for product safety.

I would like to set out the analysis we have undertaken which has indicated further steps we can take to seek to reduce the risk of such tragic events occurring in the future.

Analysis

UK law requires all consumer products to be safe. The Toys (Safety) Regulations 2011 (TSR) establishes essential safety requirements that toys must meet. Where there are any inherent risks or hazards associated with a toy, the Regulations require that warnings be provided on the product itself, and/or on the packaging or instructions.

OPSS has considered the requirements in law and helium inhalation risks. Helium-filled balloons that are designed or intended for use in play by children are subject to the requirements established by the TSR, and we believe that helium inhalation is an inherent risk to children and is reasonably foreseeable. Those responsible for the safety of helium-filled balloons placed on the market in the UK therefore have an

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The Office for Product Safety and Standards (OPSS) delivers consumer protection and supports business confidence, productivity, and growth. It is part of the Department for Business and Trade.

obligation to provide information and warnings about any helium inhalation risks of their products. This includes products supplied at fairgrounds whether as prizes or purchases. Where this is not the case, those manufacturing or supplying such products may be in breach of the law.

While standards are voluntary they can be used by businesses to help demonstrate how they comply with the law. The government is able to 'designate' certain voluntary standards which, when followed by manufacturers of relevant products, confer on those products a rebuttable presumption of conformity with relevant regulations. Overriding this, as above, is the essential safety requirement that all toys placed on the market are safe when it is reasonably foreseeable that they are intended to be used by children. While designated standards can help manufacturers understand and meet their obligations in those regulations, the responsibility of safety rests with those who place toys on the market. OPSS has identified that the Toy Safety Standard EN71, which is currently designated, does not require warnings to be provided on helium-filled balloons about the risks of helium inhalation.

### Action

OPSS will write to the British Standards Institution, as the UK's national standards setting body, to recommend it considers updating the standard to reflect the risks of helium inhalation to children.

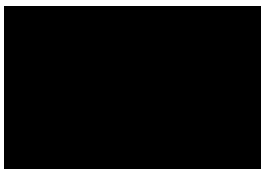
OPSS has powers to restrict designated standards and we are considering placing a restriction on EN71 given the current absence of helium inhalation warnings. We would set out our rationale for this restriction with accompanying guidance aimed at ensuring compliance with the TSR.

We will write to relevant trade organisations such the British Toy and Hobby Association and the British Retail Consortium to advise them of OPSS' concerns about the risks posed by helium-filled balloons, and ask them to help ensure the industry is meeting its obligations in the TSR. We will also write to Local Authority Trading Standards authorities advising them of the risks from these products.

I am grateful to you for bringing this matter to my attention. While nothing we can do can address the loss that Karlton's family have experienced, I hope that this demonstrates the importance we place on protecting consumers, including children, from unsafe products. The actions we are taking are intended to help prevent the circumstances that tragically led to Karlton Donaghey's death from happening in the future.

I am copying this letter to Newcastle City Council Trading Standards.

Yours,



**Chief Executive**  
**Office for Product Safety and Standards**

