# leatherhead food research



## To warn or not to warn: when to advise on the risk of choking

Assessing choking risks and labelling options

Oliver Leedam

A Leatherhead Food Research white paper

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## To warn or not to warn: when to advise on the risk of choking

With no specific regulations requiring companies to inform consumers if their food and beverage product poses a choking risk, companies can wonder where their responsibility begins and where it ends. In this white paper, Oliver Leedam looks at relevant regulation and gives guidance to companies on how to assess the choking risk of their product and how best to inform consumers.

Approximately 16,000 cases of choking are treated in UK hospitals each year. In the main, choking accidents involve food and half the fatalities involve the elderly. Elderly people are more prone to choking, because their swallowing mechanism does not function as well as it does in younger people.

Furthermore, wearing dentures results in less chewing pressure being exerted on the food than human teeth, they interfere with the way food feels in the mouth and they make it more difficult to chew food thoroughly.

2,600 of choking cases every year in the UK involve children under four years of age<sup>1</sup>. Parents of young children are generally alerted by healthcare professionals to the risk of their child choking on food or small objects. The risk increases as the child begins to eat solid foods and becomes mobile enough to explore objects previously out of reach. As infants and young children are inexperienced in or unable to chew, they may attempt to swallow large pieces of food, which can become lodged in

their throat. Tragically, in just under 1% of choking cases, this is fatal.

No company wants to put their consumer at risk, but where does a company's responsibility lie regarding the risk of choking? What is the right balance to strike between informing customers about a legitimate risk of choking and adding information to a product label which might cause unnecessary concern?

### What legislation is there in relation to the risk of choking?

One of the most famous pieces of legislation regarding choking is the USA Food, Drug, and Cosmetic Act which bans confectionery from containing any embedded non-nutritive substance (unless approved as functionally necessary)<sup>2</sup>. This led to Kinder Surprise Eggs being banned in the US, with approximately 60,000 eggs being confiscated at the US Canadian border in 2011, with reported fines of up to \$1,200 per egg.

<sup>&</sup>lt;sup>1</sup> Choking risks to children, Department of Trade and Industry

<sup>&</sup>lt;sup>2</sup> USA Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq) § 342.(d)

What about legislation covering choking in the EU? In 2003, the European Union permanently banned the food additive E425 konjac, konjac gum or konjac glucomannan in jelly confectionery (Commission Decision 2004/374/EC), following earlier reports that they could pose a risk of death by choking, particularly to children and old people.

Aside from choking risks associated with particular products, there are no general regulations in the EU regarding the hazard of choking on food.

In the absence of other specific legislation we are left with the general food safety regulations from Article 14 of EU regulation 178/2002

Food safety requirements from Article 14 of EU regulation 178/2002 states that:

- 1. Food shall not be placed on the market if it is unsafe.
- 2. Food shall be deemed to be unsafe if it is considered to be:
- (a) injurious to health;
- (b) unfit for human consumption.
- 3. In determining whether any food is unsafe, regard shall be had:
- (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
- (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

which set out food safety requirements (see detail in box in left hand column).

Irish legislation<sup>3</sup> also picks up on the EU regulation, stating that: 'a food business operator is guilty of an offence if the food business operator places unsafe food on the market or otherwise contravenes Article 14 of the EC Regulation'.

According to the food safety regulations in Article 14 of the EU regulation, choking caused by consuming a product would in theory fall under the definition of an adverse health effect. Food and beverage manufacturers should therefore consider whether their product poses their consumers a significant risk of choking and whether consumers need to be informed of the risk.

With no specific EU standards on choking on food, this leaves only the non-food European Standard on the Safety of Toys4 which details the mechanical and physical properties to which toys must conform. The main point here is that it deals with the assessment of choking hazards. Here an international standard applies to toys or toys with removable parts that fit into a cylinder with the dimensions shown in Figure 1; those that fit completely into the cylinder without pressure are deemed to be a possible choking hazard. The dimensions of the cylinder are defined in European Standard BSEN 71-1: 1998 (Safety of Toys - Specification for Mechanical and Physical Properties).

<sup>&</sup>lt;sup>4</sup> EN 71-1:2011+A3:2014 E



<sup>&</sup>lt;sup>3</sup> EU regulation 178/2002 is implemented in Irish Legislation by <u>Statutory Instrument 747/2007</u>

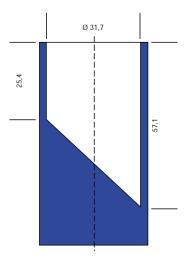


Fig. 1: Small parts cylinder to determine possible choking hazard (dimensions in mm, not to scale)

Warning labelling is required for certain toys in the EU and toys not intended for children under the age of 36 months in the form of "Not suitable for children under 36 months" together with a description of the hazard, such as "contains small parts".

The Child Safety Protection Act (CSPA) of 1994 in the US details similar requirements, with the same size test cylinder defined for small parts testing. A small parts warning label is also required in the US: "Warning: CHOKING HAZARD: Small parts. Not for children under 3".

### How to proceed in the absence of clear regulation?

So with no formal standard established for labelling choking hazards on food, but a clear indication under European law that information should be provided to the consumer if a product could be the cause of an adverse health effect, what should manufacturers do regarding the risk of choking?

Manufacturers need first to be clear about whether their product poses a risk of choking and the level of risk.

One option if you are manufacturing food that is being marketed for children up to 36 months of age, is to invest in a small parts cylinder as detailed above and determine whether your product is a choking hazard. If it fits into the cylinder, you should consider whether it is suitable for that age, or whether you can add instructions for the treatment of the food by the purchaser such that it ceases to be a choking risk.

If this is not possible, then appropriate warning labels should be considered. Ideas could be taken from the toy industry where for example the labels show in Figure 2 are used.





Fig. 2: Warning labels used in the toy industry

With the 0-3 warning sign being the standard used under the European Standard on the Safety of Toys, its use could be considered for food and beverage products, as parents should recognise it already.

Changes in consumer behaviour shows how manufacturers need to reassess the risks that their products pose. There has been a growth in the last 5 years, for example, in baby-led weaning, where babies of weaning age are given solid food approximately the size and width of a baby's finger. In response to this, the Food Safety Authority of Ireland say in their "Best Practice for Infant Feeding in Ireland" that "An infant should never be left unsupervised with a finger food due to the risk of choking."

For standard products such as grapes or cherries which may pose a choking hazard, the supplier may wish to add a warning phrase such as "Not suitable for children under 36 months without further preparation."

As ever, Leatherhead Food Research is on hand via your membership helpline (legislation@leatherheadfood.com; +44 (0)1372 822241) to help you navigate through these gaps in regulation, understand your responsibilities and advise how best to safeguard your consumers.



#### How Leatherhead can help

If you are unsure as to the risk posed by your product and whether it is covered by warnings on the label, we have a department of over 30 regulatory advisors, covering all major international markets, with great experience of checking labels who are ready to help. We offer consultancy and can also provide training on food legislation and give advice on additives, flavourings and ingredients, as well as label and formulation checks.

#### About the author

Oliver Leedam is a Senior Regulatory Advisor at Leatherhead Food Research with over 20 years' experience in the food industry, with experience of providing regulatory support and training to both regulators and industry, and working in the soft drinks, food additives, ready meals, meat products and breakfast cereals industries. A highlight has been providing training on the European Commissions' Better Training Safer Food courses across Europe on their Better Training Safer Food sessions, for two years being one of the specialist trainers on the nutrition and health claims section of the course. Oliver covers English, Irish, American and European food legislation.

#### Further reading:

Article 14 of EU regulation 178/2002

Choking risks to children under four from toys and other objects, Department of Trade and Industry



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#### About Leatherhead Food Research

Leatherhead Food Research provides expertise and support to the global food and drink sector with practical solutions that cover all stages of a product's life cycle from consumer insight, ingredient innovation and sensory testing to food safety consultancy and global regulatory advice. Leatherhead operates a membership programme which represents a who's who of the global food and drinks industry. Supporting all members and clients, large or small, Leatherhead provides consultancy and advice, as well as training, market news, published reports and bespoke projects. Alongside the Member support and project work, our world-renowned experts deliver cutting-edge research in areas that drive long term commercial benefit for the food and drink industry. Leatherhead Food Research is a trading name of Leatherhead Research Ltd, a Science Group Company.

help@leatherheadfood.com T. +44 1372 376761 www.leatherheadfood.com

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info@sciencegroup.com

www.sciencegroup.com

