

NATIONAL PRODUCT SAFETY GROUP

UK practitioner experts for product safety & compliance

Supported by The Office for Product Safety and Standards



The UK Food Imitations (Safety) Regulations 1989 Guidance

Record of Amendments			
Version	Date	Amendment	Section/page affected
1		First Publication	

LEGAL NOTICE

This document contains guidance only. It is intended to explain obligations and how to fulfil them. However, readers are reminded that the text of the original regulation, directive or standard is the only authentic legal reference and that the information in this document does not constitute legal advice.

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1. Introduction

The UK's Food Imitations (Safety) Regulations 1989 ("the Regulations") implement 87/357/EEC Council Directive on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers ("the Directive"). The Regulations outline the requirements that all companies must meet when placing non-food items that look like food onto the UK market.

The Regulations state that:

"no person shall supply, offer to supply, agree to supply, expose for supply or possess for supply any manufactured goods which are ordinarily intended for private use and are not food, but which

- a) have a form, odour, colour, appearance, packaging, labelling, volume or size which is likely to cause persons – in particular, children – to confuse them with food and, in consequence, to place them in their mouths or suck them or swallow them; and
- b) where such action as is mentioned in (a) above is taken in relation to them, may cause death or personal injury"

The obligation to supply a safe product rests with the whole supply chain, including retailers. It is their responsibility to comply with the Regulations and decide whether to market a product or not.

2. Scope

This document is a guide to the UK Regulations which cover all products intended for private use with three specific exemptions:

- Marbles
- Imitation food intended for use in dolls' houses or model scenes
- Products made entirely of food

It should be noted that the Directive does not include these exemptions.

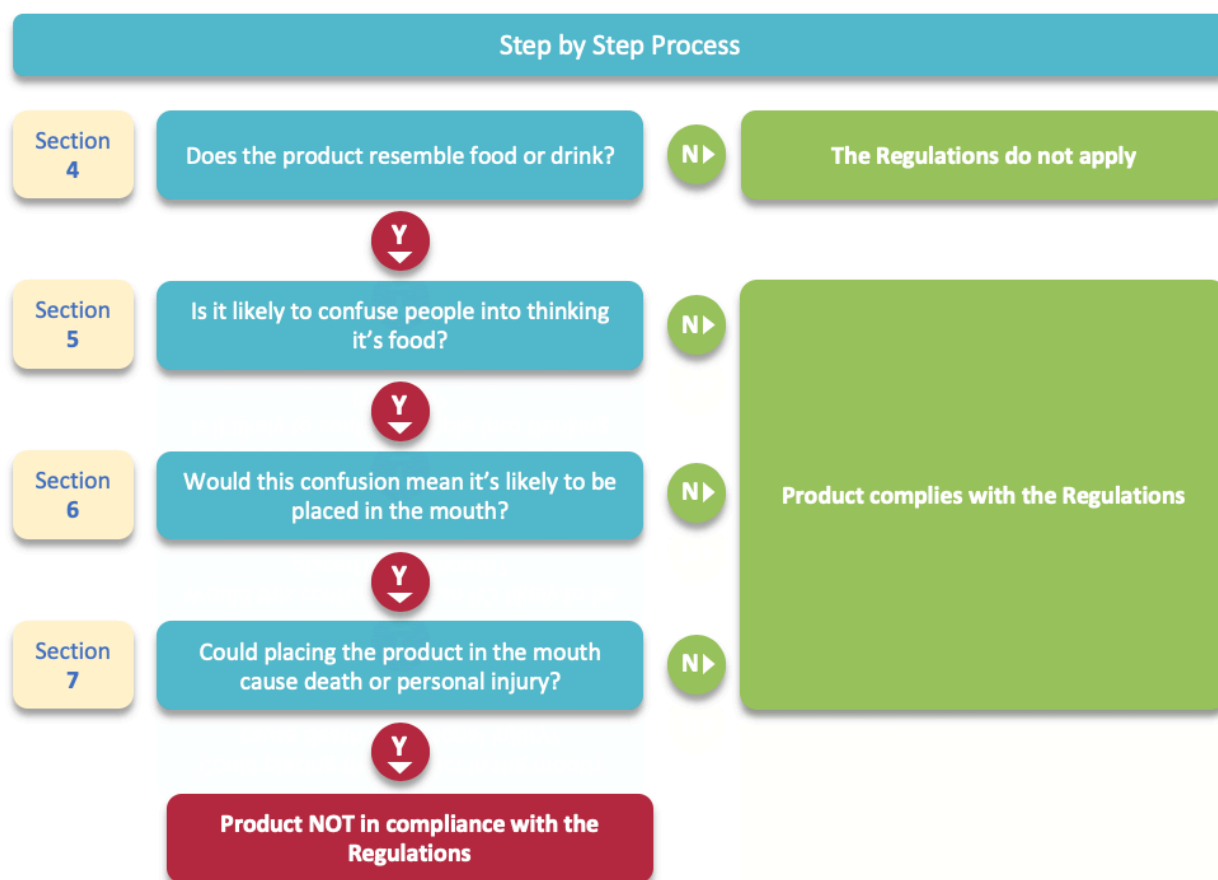
The Regulations (and the Directive) only prohibit the supply of imitation food which is likely to be confused with food AND may cause death or personal injury. They do not prohibit the supply of imitation food.

3. How to use this guide

The following flow chart shows the decisions to be made when determining if a product complies or otherwise with the Regulations. The guide is broken down into sections which reflect each step.

It is important that the product be considered with and without packaging at each stage and on a case by case basis as the packaging can be an important factor in making decisions regarding potential to confuse, the hazard presented etc.

A worksheet has been provided for use in Appendix I



4. Does the product resemble food or drink?

This question needs to be answered to determine if the product is within the scope of the Regulations only, no assessment of the potential to confuse or the safety of the product is required at this stage.

It is likely to be a combination of factors that could lead a product to resemble food, therefore the product should be considered both with and without its packaging.

If the product is intended to mimic food in any way or is marketed in such a way that it resembles food, then the product should be further assessed. If the product or the packaging does not resemble food, then the Regulations do not apply.

Does the product resemble food or drink? N Y

Regulations do not apply

Go to section 5

5. Is it likely to confuse people into thinking it is food?

In order to be confused with food the item must have the following attributes, singly or in combination, which is likely to cause persons – in particular, children – to confuse it with food:

- Form
- Odour
- Colour
- Appearance
- Packaging
- Labelling
- Volume or size

It would be unusual for one attribute alone to lead a person into confusing a product with food, more likely a combination of factors would be required.

The fact the product is not intended for children is irrelevant – it is still possible that a child or a vulnerable adult could be given or get access to the product.

Is it likely to confuse people into thinking it's food? N Y

Product complies with the Regulations

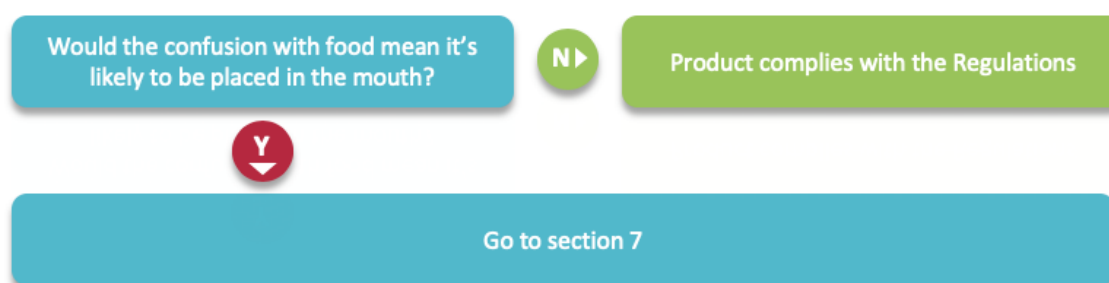
Go to section 6

6. Would this confusion mean it's likely to be placed in the mouth?

Just because an item could be confused with food, it does not mean that the item will be placed in the mouth, sucked or swallowed. In most cases the product needs to be picked up or handled in order to place it in the mouth. It may be immediately apparent, even to a child, that the product is not food the moment it is picked up - texture or feel can make this obvious.

In addition, if a product is inaccessible e.g. wall or ceiling mounted or inside a permanent casing it is unlikely that the product or the food imitating part will be placed in the mouth.

Note that the Regulations are not intended to cover the risk of "role play". The Regulations are intended to cover products that can be genuinely confused with food and present a risk if they are placed in the mouth. If a product is intended to be used for role play by children, then the 2009/48/EC Toy Safety Directive requirements apply.



7. Could placing a product in the mouth or swallowing a product cause death or personal injury?

Products should be assessed in the state where confusion with food may lead to the placing of the product into the mouth, this may or may not include the packaging.

There are various injury scenarios that need to be considered when assessing a product's potential to cause personal injury. According to the Cambridge English Dictionary 'personal injury' is defined as "physical or mental harm that is caused to someone, especially when this is the fault of another person or an organization".

The Directive gives examples such as suffocation, poisoning, and perforation or obstruction of the digestive tract. Other potential hazards are lung infection caused by a foreign body getting into the lungs, or mouth injuries.

There are two routes to personal injury that need to be considered.

1. Risk of physical injury related to the mechanical and physical properties of the product
2. Toxicological risk related to the ingestion or inhalation of substances that may cause harm

It is not necessary for the product to present both a mechanical and physical risk AND a toxicological risk to contravene the Regulations. If a product presents one or the other, it is in non-compliance with the Regulations so further assessment of other hazards may not be necessary.

7.1 Mechanical and Physical Hazard and Risk

Mechanical and Physical Hazards and risks that are associated with this are:

- Small parts, hazardous shapes – choking, asphyxiation, suffocation, inhalation, obstruction of the digestive tract, lung infections caused by aspiration of a foreign body
- Sharp edges, sharp points, pinch points - injuries to the mouth, perforation of the digestive tract
- Expanding materials – obstruction of the digestive tract, suffocation and asphyxiation

The best way to assess the risk to a consumer who places the product in their mouth is to carry out a risk assessment that considers the following non-exhaustive list:

- Ensure that the product complies with all the requirements set out for toys for children under 36 months and for toys intended to be placed in the mouth (regardless of the age grade of the product). This includes requirements for small parts, small balls etc before and after use and abuse testing.
- Consider the principles related to size and shape, preschool play figures, hemispherical shapes found in EN71-1
- Use clauses from EN71-1 to demonstrate that the product does not present a risk from sharp edges or points
- Consider the expanding material clause from EN71-1 to ensure that the product is not at risk of causing obstruction of the intestine
- Consider the likelihood and ability of a child to bite hazardous small parts from the product. Bite tests are found in standards e.g. EN716-2, EN1400 and US CFR bite test, however these may not always be appropriate to determine the actual hazard where the force required to liberate a small part far exceeds what would normally be expected of the food which the item is said to resemble.
- Carry out an additional assessment with regards to any other mechanical and physical hazards that may be present that are not addressed by standards, e.g. lip/tongue pinching and potential to injure the mouth

7.2 Toxicological risk

In order to determine if the product may cause death or personal injury if it were placed in the mouth or swallowed it is necessary to consider if the product presents a toxicological risk.

In order for something to present a toxicological risk the dosage of any harmful substances that may be ingested as a result of the product being swallowed or placed in the mouth needs to be considered. Using measures intended to induce vomiting to prevent harm as a means to comply with the Regulations is not acceptable.

7.2.1 Solid Products

If it is apparent that an item is not food the moment it is placed in the mouth, then it is unlikely that the user will be exposed to any significant toxicological risk as they will not continue to mouth, chew, suck or lick the product.

If the product is such that it is unlikely to remain in the mouth, due to mouth feel or other factors the product is unlikely to be mouthed, chewed, sucked, licked or swallowed and therefore will not present a toxicological risk.

N.B. Products still need to be safe and comply with the applicable regulations and directives, e.g. cosmetic products must comply with Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) and toys must comply with 2009/48/EC Toy Safety Directive with regards to chemicals and substances.

Products that, when placed in the mouth, are not immediately identifiable as non-food products should be assessed with this in mind. If it is considered that prolonged mouthing, chewing and

sucking will occur then it would be prudent to apply the requirements of 2009/48/EC Toy Safety Directive for toys intended to be placed in the mouth, this would include EN71-3, substances restricted in Appendix C of 2009/48/EC Toy Safety Directive and Regulation (EC) No 1907/2006 (plus subsequent amendments) of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Annex XVII restrictions for toys and articles able to be placed in the mouth.

Note: Historically EN71-3 has been used to demonstrate that a product is chemically safe, if it is confused with food and placed in the mouth. However, this standard is inappropriate as it contains limits that reflect continual chewing, sucking or mouthing over a period of time. This is a behaviour exhibited by children with toys that are intended or likely to be mouthed regularly and over a long period e.g. rattles, teethers etc. More recently there are other requirements for substances that have been included in 2009/48/EC Toy Safety Directive for products intended to be placed in the mouth or for children under 3 years. Again, the limits reflect continual chewing, sucking or mouthing. As such it is not appropriate to apply such limits to imitation foods as standard

7.2.2 Mixtures

Mixtures are products such as bubble bath, bath bombs, liquid paints, inks, cosmetics, etc.

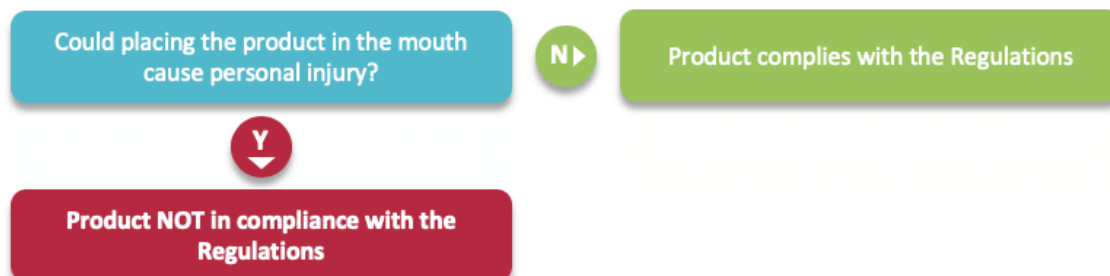
Assuming the mixture is placed to the mouth, it is necessary to carry out an assessment of the actual risk posed to individuals e.g. how much of a substance could be ingested before a person realised it was not food?

Similar to solid items, if it is apparent that a mixture is not food (or drink) the moment it is placed in the mouth, then the amounts ingested will be reduced. If a product tastes unpleasant less may be consumed. Any addition of an embittering agent may reduce the risk and this should form part of the risk assessment. Expert advice may need to be sought. Conversely, if the mixture has a pleasant taste, or feels like food in the mouth it is more likely to be ingested.

In cases where the contact with the mouth is brief, such mixtures should not be *acutely toxic, corrosive, irritating to mucous membranes* or be likely to be considered an *aspiration hazard* according to the CLP Regulation.

Mixtures where the amount ingested may be more significant (e.g. where confusion persists) must not be classified as *hazardous* according to the CLP Regulations. Furthermore, a toxicological assessment will be required to show that there is a low risk of harm, particularly with regard to acute oral exposure.

For cosmetic products, the cosmetic safety assessment alone may not be sufficient since this does not always address unintentional ingestion.



8. Other Considerations

It is important to note that the Regulations only prohibit the supply of imitation food which is likely to be confused with food AND may cause death or personal injury. They do not prohibit the supply of imitation food.

If the product contravenes the Regulations, labelling products with additional guidance / warnings such as “not suitable for young children”, “use only under adult supervision”, and “not food” cannot not be used to mitigate the hazard. If the product is in compliance with the Regulations, additional warnings and consumer advice is permitted.

Where there is not sufficient expertise in-house, external expertise should be sought to carry out a Food Imitation assessment (according to 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety). It may be prudent to use a laboratory or external expert that understands the product and its foreseeable uses and is familiar with food products available on the marketplace they are likely to be confused with.

Appendix I Worksheet

The UK Food Imitation (Safety) Regulations 1989

Request No

Date of Publication

Product

Product Picture

Is this likely to confused people into thinking that its food?

Would this confusion mean it's likely to be placed in the mouth?

Can placing a product in the mouth or swallowing a product cause personal injury?

Consider the following:

Mechanical and Physical Aspects

Toxicological Aspects

Conclusion and Recommendations
