

INEDIBLES IN FOOD PRODUCT PACKAGING

FINAL REPORT

**prepared for
STOA, European Parliament**

RPA

December 2003

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prepared for

European Parliament – STOA

by

Risk & Policy Analysts Limited,
Farthing Green House, 1 Beccles Road, Loddon, Norfolk, NR14 6LT, UK
Tel: +44 1508 528465 Fax: +44 1508 520758
Email: post@rpald.demon.co.uk
Web: www.rpald.co.uk

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Prepared by:	Carolyn George, Researcher, RPA Dr Pete Floyd, Managing Director, RPA Jo Sibert, Professor of Community Child Health Dr Nia John, Speciality Registrar
Approved for issue by:	Dr Pete Floyd, Managing Director, RPA
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EXECUTIVE SUMMARY

The evolution of the food industry has contributed to the introduction of new forms of presentation and packaging, leading to the combination of edible and inedible components, such as toys, which may pose a hazard to consumer safety.

The information and knowledge available to policy makers, professionals and the public more generally on food products containing inedibles (FPCIs) is considered to be incomplete. The purpose of this study is to help clarify the situation through a critical review of available data and the presentation of a coherent and objective analysis. This will help the European Parliament understand if there are significant health risks associated with FPCIs and, if so, what could be done in this respect.

A consultation exercise was undertaken to provide further detail on past incidents (with particular regard to the period 1996-2002) and on the nature and numbers of FPCIs sold within the EU. The stakeholders contacted included injury surveillance organisations, consumer associations, paediatricians and manufacturers of FPCIs.

In broad terms, the response to the consultation was poor. In particular, national associations of paediatricians in all 15 EU Member States were contacted. Although several associations assisted with involving their members in the study, no data were provided by any of the associations or members contacted.

Data on 50 reported incidents over the period of interest indicate that the vast majority of FPCI incidents involve children and the entry of a 'small' item (as defined by the small parts cylinder test, EN 71-1: 2001) into the mouth and from there into the respiratory or digestive tract. In the period covered by the study, there have been two reported fatalities - one baby and one senior citizen.

Based on the limited data provided, it is estimated that FPCI incidents (involving ingestion, choking or suffocation) account for 1% of such incidents involving toys, which, in turn account for 5% of all such incidents amongst children aged 0 to 14. This results in an estimated 34 non-fatal FPCI incidents (where these require medical attention by qualified medical/first aid personnel) involving children per year across the EU. Since chocolate eggs containing inedibles are the dominant product containing small parts, most reported incidents relate to chocolate eggs. Furthermore, at a national level, it would appear that the observed number of incidents is more closely related to the numbers of chocolate eggs sold than to the number of child consumers.

In general terms, the industry is well aware of the safety concerns and has taken measures to ensure that, where possible, promotional inserts do not present a significant hazard to consumers. These measures include a move towards 'large' insets as well as safety and quality checks.

Although the causal link between eating the food product and a subsequent incident is not proven, the risks associated with FPCIs are demonstrably low. However the risks are not zero and it is worth concluding that some manufacturers have discontinued the use of promotional inserts in the interests of safety of the young consumer.

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1. INTRODUCTION

1.1 Background to Study

The evolution of the food industry has contributed to the introduction of new forms of presentation and packaging, with specific products targeted towards focused market sectors. Children and young people represent a significant proportion of consumers, and thus the food industry has made massive investments in advertising and marketing to promote their products to this sector.

These innovations in marketing have led to the combination of edible and inedible components, such as toys, which may pose a hazard to consumer safety. This is not a recent phenomenon, having been around at least since 1912 when Cracker Jacks (sold in the US) introduced toy prizes in every box, but such practice is becoming increasingly common, and is used by food manufacturers to promote a wide range of products including sweets, crisps, yoghurt, ice cream and cereal.

In recent years, a number of studies have highlighted the hazards posed by food products containing inedibles (FPCIs), particularly where the promotion appeals to children (Kehrt *et al.*, 1998; Metra Martech, 1998; Petridou, 1997). There is a possibility that a child may place the inedible object contained in the food product in or near their mouth, potentially causing ingestion, choking or suffocation. A number of such incidents, occurring in the EU since 1977, have been reported (ANEC, 2001; Ayser & Geisendorf, 2001; DTI, 1999; Kehrt *et al.*, 1998, Metra Martech, 1998; and Petridou, 1997). Changes in legislation during this period, such as the EU Toy Safety Directive of 1988, may have had some effect on reducing the number of incidents but incidents may still occur.

In general, these accidents are of minor severity, but in a few cases products have caused fatalities. Additional incidents and fatalities have also been reported outside of the EU, but these fall outside the scope of this study. Whilst the majority of cases involve children, adults may also be susceptible to the hazards posed by such products.

Whilst criticisms exist on what can be considered some of the key reports on FPCIs (see Croux, 1998 and 2000; Heinrich, 2000; Morra *et al.*, 2001), these are largely directed at the extrapolation of the reported incidents to a national or EU level, as this may overestimate the number of incidents due to the use of samples that are non-representative or too small. However, the main uses of Petridou (1997) and Kehrt *et al.* (1998) within this study are the actual incidents reported. Thus the weaknesses in estimating the total number of incidents are of less importance (but are noted).

The European Commission has been considering the issue of FPCIs for several years. In 1997, all Member States banned food products containing unwrapped inedibles presenting a risk. However, with regard to wrapped inedibles combined with food products, the European Commission requested Member States to restrict market access so that such combinations do not pose a threat to consumers.

Until recently, Commission-level discussions concerning FPCIs have fallen under the remit of the Product Emergencies Committee, set up under the General Product Safety Directive (92/59/EEC). In May 2000, the Committee concluded:

“In light of the information available to date, the risks associated with non-food products accompanying food products in a separate packaging seem to be no different to those presented by small toys in general or by toys containing small parts in general... Finally, the Committee considers that particular attention should be paid to every new development and fresh information making it possible to pinpoint any specific risk resulting from the association of food with non-food products in a separate package. In this context, a specific assessment should be conducted whenever new and relevant information occurs, to examine the possibility to establish European Standards specifically covering non-food products accompanying food products in a separate packaging.”

Since the conclusions of the Product Emergencies Committee, additional incidents have been reported. The continued interest in this subject, despite the Directive’s revision and subsequent adoption by the Commission as Directive 2001/95/EEC in December 2001, suggests the issue has not been resolved. This is demonstrated by reports that MEPs are demanding safety controls to be introduced, in respect of small toys inserted into food or food packages, in the upcoming revision of the Toy Safety Directive.

1.2 Scope of the Study

As indicated in the Project Specification, the information and knowledge available to policy makers, professionals and the public more generally on FPCIs is considered to be incomplete. The purpose of this study is to help clarify the situation through a critical review of available data and the presentation of a coherent and objective analysis. This will help the European Parliament understand if there are significant health risks associated with FPCIs and, if so, what could be done in this respect.

The approach to this study was revised following the Project Scoping meeting held in Strasbourg on 20th and 21st November 2002, the second Project Scoping meeting held in Brussels on 29th January 2003 and additional comments provided to STOA. Specifically, the Chairman of STOA concluded at the second Scoping Meeting that the study:

- will not report on brand names nor products nor companies;
- will not consult individual consumers;
- will consult consumer associations; and
- will examine detailed circumstances of incidents, in particular: form, size and shape of inedible objects.

1.3 Structure of Report

This report generally follows a risk assessment approach to the issue of FPCIs. As such, Section 2 describes the approach in more detail, while Sections 3 to 6 describe the stages of hazard identification, hazard characterisation, exposure assessment and risk characterisation respectively. Section 7 summarises the key findings and Section 8 contains the references. Finally, Annex 1 contains the questionnaires used in the consultation process.

2. APPROACH

2.1 Overview

In essence, the purpose of this study is to examine two issues:

- the potential of inedibles (within food or food packaging) to be the cause of adverse effects amongst consumers; and
- the probability and severity of adverse effects occurring following exposure to inedibles.

These two issues represent the ‘hazard’ and the ‘risk’ associated with inedibles respectively and the procedure by which these issues will be examined is a ‘risk assessment’. In a comprehensive report on these issues, DG SANCO (European Commission, 2000) has adopted the following definitions¹:

- **Hazard** – the potential of a risk source to cause an adverse effect(s)/event(s);
- **Risk** – the probability and severity of an adverse effect/event occurring to man or the environment following exposure, under defined conditions, to a risk source(s); and
- **Risk Assessment** – a process of evaluation including the identification of the attendant uncertainties, of the likelihood and severity of an adverse effect(s)/event(s) occurring to man or the environment following exposure under defined conditions to a risk source(s).

As can be seen, a risk assessment involves analysis of the hazard and derivation of the associated risk. The DG SANCO report further defines a risk assessment as comprising hazard identification, hazard characterisation, exposure assessment and risk characterisation² and it is this broad approach which was followed in this study.

Based on the requirements of the Project Specification, RPA grouped the necessary work into Tasks as follows:

- Task 1: Project Scoping;
- Task 2: Literature Review;
- Task 3: Consultation;
- Task 4: Data Analysis; and
- Task 5: Reporting.

These relate to the risk assessment framework as illustrated in Table 2.1.

¹ It is important to note that although such definitions do vary from source to source and from application to application, these definitions are consistent with those used elsewhere.

² This categorisation of risk assessment stages is closely matched by other bodies involved with food safety (such as WHO/FAO).

Table 2.1: Risk Assessment Framework and Equivalent Work Tasks		
Stage	Definition*	RPA Task
Hazard Identification	<i>The identification of a risk source(s) capable of causing adverse effect(s)/event(s) to humans or the environment, together with a qualitative description of the nature of these effect(s)/event(s).</i>	Task 1: Project Scoping
		Task 2: Literature Review
Hazard Characterisation	<i>The quantitative or semi-quantitative evaluation of the nature of the adverse health effects to humans and/or the environment following exposure to a risk source(s). This must, where possible, include a dose response assessment.</i>	Task 3: Consultation
Exposure Assessment	<i>The quantitative or semi-quantitative evaluation of the likely exposure of man and/or the environment to risk sources from one or more media.</i>	Task 4 : Data Analysis
Risk Characterisation	<i>The quantitative or semi-quantitative estimate, including attendant uncertainties, of the probability of occurrence and severity of adverse effect(s)/event(s) in a given population under defined exposure conditions based on hazard identification, hazard characterisation and exposure assessment.</i>	Task 5: Reporting
*Source: European Commission (2000)		

It should be noted that the framework presented in Table 2.1 is generic in nature and has been adapted as appropriate for this study. By way of example, this study is not concerned with the potential impacts on the environment of FPCIs.

2.2 Project Scoping

The approach to this study was revised following the Project Scoping meeting held in Strasbourg on 20th and 21st November 2002, the second Project Scoping meeting held in Brussels on 29th January 2003 and additional comments provided to STOA.

Further information relating to the scope of the project can be found in Section 3 - Hazard Identification.

2.3 Literature Review

A significant part of the literature review consists of epidemiological data. WHO (2000) recommends general guidelines for the evaluation of epidemiological research, including the development of a protocol for the review; identification of relevant studies; and the systematic assessment of the validity of epidemiological studies. These have been followed to the extent possible.

The main purpose of the review was to provide preliminary answers to the following questions:

1. How common is choking in childhood?
2. What objects cause the choking?
3. Are toys and other inedibles in food packaging a recognised cause of choking in childhood?

A literature search was carried out by the Support Unit for Research Evidence (SURE), Library Services, University of Wales College of Medicine. This included the databases listed in Table 2.2.

CINAHL	PAIS International (Public Health)
EBM Reviews	Premedline
ERIC	PsycINFO
Embase	Science Citation Index
Google (search for product recalls only)	SIGLE
HMIC	Social Science Citation Index
Medline	Social Work Abstracts
MDX Health Digest	Sociological Abstracts
Newspaper Abstracts	Toxline

The initial search yielded 1,750 abstracts once all duplicates were removed. A quick scan of the titles was carried out to exclude papers on plant thorns and seeds, shot gun/air rifle injuries and management/treatment of ingested/inhaled/implanted foreign bodies. The remaining abstracts (n=927) included some irrelevant articles since abstracts were excluded by a title scan only. The literature review also included a number of documents supplied from other sources, including those provided at the first Scoping Meeting (held on 20th/21st November 2002).

The resultant analysis further excluded papers:

- with no detail of the objects ingested;
- that have included minimal data in general injury review;
- purely clinical papers;
- irrelevant newspaper reports;
- foreign bodies outside the respiratory and gastro intestinal tract; and
- specific case reports regarding objects that are not toys.

Very few relevant papers were found, with less than 30 papers in the whole world literature fulfilling the criteria for inclusion. Additional literature has also been considered to provide further information on the issues surrounding the subject of inedibles in food product packaging.

2.4 Consultation

2.4.1 Overview

The aim of the consultation stage was to obtain data from a variety of sources in order to ensure that a full and accurate picture of the issue is presented. Specifically, the objectives of the consultation were to:

- collate further data on the number of incidents relating to FPCIs, where these may not be reported in the medical journals;
- ascertain whether a link can be made between choking incidents and the inedible being contained within food product packaging; and
- collate relevant information from industry concerning FPCIs.

Standard questionnaires were developed to facilitate data collection from a range of stakeholders in a consistent format, and these are presented in Annex 1³. It should be noted that the focus of this study is on incidents occurring within the European Union. Whilst it is recognised that incidents may have occurred elsewhere, differences in legislation would prevent these from being analysed on a comparable basis. Incidents occurring outside the European Union may be discussed in a qualitative manner where this would assist understanding of the issues involved.

Furthermore, quantitative data collection and analysis was limited to a seven-year period, from 1996 to 2002 inclusive, for the following reasons:

- significant interest in FPCIs appears to originate from the mid-1990s;
- an individual, or an organisation, will have limited recollection of events. Experience suggests that recollection beyond a seven-year period is not sufficient for valid data collection; and
- changes in legislation, for example the Toy Safety Directive, make comparison of data over a longer time frame more complicated, and less meaningful.

Information requests were sent (by e-mail or post) to the following stakeholders:

- relevant authorities;
- medical professionals;
- consumer organisations; and
- food producers.

Where no response was received, contacts were followed up by e-mail and/or telephone. Despite these efforts, the overall response was poor on eliciting data on both incidents and numbers of FPCIs being sold within the EU.

³ The questionnaires request information on brand names and/or manufacturer. This was for the purpose of ensuring that all relevant manufacturers were consulted and to identify those that responded. As agreed at the second Scoping Meeting, RPA will not be revealing any brand, product or company names.

2.4.2 Relevant Authorities

Organisations responsible for European and national injury surveillance systems in all 15 EU Member States were approached requesting data on incidents involving the inhalation or ingestion of foreign bodies (where this may be general, or involving toys). Limited data were provided by a few countries.

In an effort to obtain further information, RPA obtained direct access to the web-based database of the European Injury Surveillance System (Euphin) but obtaining useful data proved impossible⁴.

2.4.3 Medical Professionals

National associations of paediatricians in all 15 EU Member States were sent the ‘incident questionnaire’ to facilitate consultation with their members⁵. Several associations assisted with involving their members in the study, either through direct email contact or through a newsletter or a website, and they were asked to report any incidents that they were aware of. **No data were provided by any of the associations or members contacted.**

In addition, a brief article inviting comments was submitted to several medical journals but once again this produced no response.

2.4.4 Consumer Organisations

Consultation with consumer associations was conducted, primarily, through ANEC⁶. ANEC distributed copies of the questionnaire relating to FPCI incidents to over 30 organisations across the EU. Once again, the response rate was low with only several organisations providing any response.

2.4.5 Food Producers

Over 30 companies and trade associations were provided with the ‘industry questionnaire’ (see Annex 1). Several companies that did respond went to considerable lengths to provide detailed responses to the questions raised. However, most companies provided no response at all.

⁴ Indeed, RPA was advised by the Euphin helpdesk that “there is a problem with the fields Age and the fields that contains [a] date So querying on dates or age will ..[produce].. nothing.”

⁵ The ‘incident questionnaire’ was made available in four languages - English, French, German and Italian. Furthermore, the questionnaire could be accessed via RPA’s website.

⁶ ANEC is the acronym for the European Association for the Co-ordination of Consumer Representation in Standardisation.

2.5 Data Analysis and Reporting

Reports on the progress of the study have been previously reported in the Scoping and Interim Reports (RPA, 2003 and 2003a). The remainder of this (draft) Final Report provides the results of the data analysis and the resultant conclusions.

3. HAZARD IDENTIFICATION

3.1 Overview

Hazard identification is defined as the identification of a risk source(s) capable of causing adverse effect(s)/event(s) to humans and/or the environment, together with a qualitative description of these effect(s)/event(s). Hazard identification is conventionally regarded as the first step in risk assessment, and it defines the issues of concern for subsequent analysis.

According to European Commission (2000), hazard identification should:

- identify and characterise properly the risk source;
- determine what effects are the potential targets (e.g. humans, other species, environmental compartments);
- examine whether the experimental procedures(s) and/or field studies reflect the exposure conditions of concern and are of appropriate quality. It is also essential to establish that the risk source that has been used for testing purposes or human or field observations is for all practical purposes relevant for the risk source being assessed; and
- establish what is a significant adverse effect. It is important to thoroughly evaluate, for example, the arguments for a particular effect(s) being discounted.

3.2 Identification and Characterisation of Products

The Project Specification refers to “inedibles in food product packaging”. Thus, this study considers products which are primarily food items, but which include inedible ‘novelty’ items within the overall packaging. This covers both food products that are specifically marketed in combination with the novelty item, and those food products that may incorporate novelty items for a limited time-period as a promotional device. This definition includes sales from fast food restaurants, where inedibles may be included in the overall packaging of meals for children.

The study does not consider inedibles which are present within food products for functional and/or safety reasons. Nor does the study consider ‘combination’ items where this includes products which are primarily toys but which contain food items (generally confectionery). Such items are prolific at Christmas time but would appear to be less widely available at other times of the year. Whilst there may be exceptions to this statement, it is necessary to place boundaries on the scope of this study. Given that one of the main concerns is whether including inedibles items within food packaging introduces a specific risk, the above restriction seems reasonable.

It is acknowledged that there is a further group of ‘cultural’ inedibles, where examples would include the presence of coins in Christmas puddings and the presence of religious figures in Epiphany cakes. These tend to be home or locally produced. Whilst these were not the prime focus of this study, it is worth noting that none of the reported incidents (discussed in Section 4) involved such items.

Table 3.1 provides an overview of products that may contain inedibles. It should be noted that this list may not reflect the current situation since some products have been discontinued. However, in the absence of detailed information from industry, it has not been possible to generate a definitive list of products currently on sale in the EU.

Table 3.1: Overview of Products Containing Inedibles		
Type of Product	Description of Product	Type of Inedible
Biscuits	Small chocolate biscuits wrapped in foil with a glittering sticker inside the foil	Sticker
	Biscuits boxed with a plastic container containing a toy	Solid plastic toy
Bubblegum	Bubblegum packaged in plastic container with unwrapped stickers and marbles	Stickers and marbles
Cake	Cake co-wrapped with tattoo	Paper tattoo
	Cake co-wrapped with a surprise toy	Toy
Cereal	Cereal with inedible either mixed in or between inner and outer packet	Various
Chocolate egg	Hollow chocolate egg containing plastic capsule with a toy inside	Capsule + plastic toy in assembly kit form
		Capsule + solid plastic toy
Crisps	Crisp packet containing plastic sticker	Plastic sticker
	Crisp packet with a plastic toy wrapped in a small polythene bag	Solid plastic toy
	Crisp packet containing a cardboard toy	Cardboard disk
Fast food	Children's meal in box with a toy in wrapping inside box	Toy
Ice cream	Ice cream in top of plastic tub with toy contained in hollow bottom under silver foil	Toy
Savoury snacks	Packet of savoury snacks with a round cardboard object mixed in	Cardboard disk
Sweets	Plastic face which opens in half and contains sweets in a bag and a toy	Toy
	Solid chocolate eggs packaged with a plastic container with a toy inside	Capsule + plastic toy in assembly kit form
	Packet of sweets with a plastic container mixed amongst them containing a toy	Capsule + Toy
	Bag of sweets containing plastic container with a toy inside	Capsule + plastic toy in assembly kit form
	Bag containing smaller bags of sweets and one bag with toy inside	Toy
Yoghurt	Yoghurt pot moulded with a separate hollow centre containing plastic capsule with a toy inside	Capsule + plastic toy in assembly kit form
	Yoghurt pot, with a separate hollow bottom containing toy	Solid plastic toy
Based on Harris (1997) and Kehrt <i>et al.</i> (1998)		

From Table 3.1, it can be seen that there are four common types of inedibles:

1. plastic toys in assembly kit form (where these are normally contained within plastic capsules);
2. solid plastic toys (wrapped in a plastic bag or contained within a capsule);
3. cardboard discs (wrapped in a plastic bag); and
4. tattoos or stickers (wrapped in a plastic bag).

3.3 Risk Population

Potentially, a person of any age may be exposed to FPCIs and it should be made clear that this study is not restricted to the consideration of only those incidents affecting children. Discussions to date have tended to focus on childhood choking and ingestion incidents since these form the majority of reported incidents, and would appear to be where the main concerns lie.

3.4 Relevant Legislation and Test Requirements

Harris (1997) and RoSPA (2001) both examine the regulations which could potentially be used to control FPCIs. However, at the present time, the only regulation relating to FPCIs is the Toy Safety Directive (88/378/EEC) which specifically relates to the inedible rather than the whole product.

The Directive applies to toys, defined as “any product or material designed or clearly intended for use in play by children of less than 14 years of age”. It sets out the safety criteria or “essential requirements” which toys must meet during manufacture and before being placed on the market. The safety criteria cover general risks (protection against health hazards or physical injury) and particular risks (physical and mechanical, flammability, chemical properties, electrical properties, hygiene, and radioactivity). The degree of risk has to take into account the ability of the user and, if appropriate, the toy must contain a label that specifies a minimum age.

This latter point is considered further in Annex II to the Directive, with reference to the physical and mechanical properties of toys. It states that “toys, and their component parts, and any detachable parts of toys which are clearly intended for use by children under 36 months must be of such dimensions as to prevent their being swallowed and/or inhaled”. Annex IV details the requirement for toys to be accompanied by “appropriate clearly legible warnings in order to reduce inherent risks” and specifically that “toys which might be dangerous for children under 36 months shall bear a warning ... together with a brief indication, which may also appear in the instructions for use, of the specific risks calling for this restriction”. Clearly, products bearing such a warning are deemed compliant with these requirements of the Directive and, thus, can be legally sold within the EU.

Non-mandatory standards are available, based on the essential requirements set in the Directive. In relation to inedibles, the relevant standards are:

- EN 71-1: 2001 Safety of Toys – Part 1: Mechanical and physical properties; and
- EN 71-6: 1995 Safety of Toys – Part 6: Graphical symbol for age warning labelling.

EN 71-1: 2001 introduces the small parts cylinder test to reduce the risk of choking on small toys, or parts of toys. The cylinder test was developed in the US in 1979, and has a diameter of 3.17cm and a depth between 2.54cm and 5.71cm. At that time, there was little scientific data on the sizes of objects that could choke a young child, thus the dimensions were derived from recommendations provided jointly by the American Academy of Paediatrics and the toy industry's trade association (Deppa, 1995).

Toys, or detachable parts, which fit completely in the small parts cylinder (without the application of pressure) are deemed not suitable for children under three years of age, and therefore, in the EU, must bear a warning “Not suitable for children under 36 months”, together with an indication of the reason – such as “contains small parts”.

RoSPA (2001), Rider and Wilson (1996), and Deppa (1995) all suggest that children of all ages have been known to choke on larger pieces, suggesting that the dimensions of the test cylinder need to be reconsidered, and other factors taken into account. A study by Stool *et al.* (1998) used computerised models of the airways and oral cavities of children of various ages, thereby developing anatomically accurate, age-indexed models of children's body cavities in order to assess the hazards of toys and small parts. Using this method they show how some toys, which meet the legal standards for safety using the Small Parts Test Fixture, still pose a substantial risk of injury or risk of choking.

In 1987 it was suggested by the New York State Attorney's Office that the diameter of the small parts test cylinder be increased to 4.27cm. Subsequent research by the US Consumer Product Safety Commission concluded that the cylinder addressed the problem it was designed to address and was left unchanged. However, additional standards have been introduced for certain toys, such as rattles and, more significantly, small figures (Rimell *et al.*, 1995). These may be similar to the test templates A and B given in EN 71-1: 2001, which are applicable for children who are too young to sit up unaided (approximately children under 12 months).

The small parts cylinder test is taken to be an appropriate reference for the size of inedibles and the associated risk of choking, in relation to the age of the consumer, although it is noted that there is some debate about its effectiveness for identifying choking hazards.

3.5 Type of Adverse Effects

A critical element of hazard identification is the decision on what constitutes an adverse effect. In accordance with the Project Specification, this study is focusing on the more likely hazards arising from FPCIs, which can be defined as follows (Nixon *et al.*, 1995):

- **Choking** - internal obstruction of an airway by a foreign body or food;
- **Suffocation** - external obstruction of the airway by covering the nose and mouth or through starvation of oxygen through enclosure of the airways; and
- **Ingestion** - the swallowing of an object, which travels through the gastro intestinal tract (mouth, oesophagus, stomach, small and large intestine).

At this stage of the study it is not considered appropriate to restrict the severity of the incident to be considered, since differences in severity can be accounted for in the later stages of the risk assessment procedure.

An issue of concern is whether the marketing of an inedible with an edible component increases the risk of adverse effects. Thus it is relevant only to consider the potential for inedibles to be placed in or over the mouth, and not the potential for inedibles to be placed elsewhere, such as the nose or ear. Whilst objects placed in the nose may cause obstruction of the airway, it is unlikely to result from its association with food.

3.6 Conclusions of Hazard Identification

1. The study is concerned with food products containing inedibles (FPCIs), and four common types of inedibles have been identified.
2. The risk population is potentially any consumer, but greater emphasis has been placed on incidents involving children (aged 0-14) by previous work. The study is concerned with data relating to incidents and products occurring within the EU between 1996 and 2002.
3. The Toy Safety Directive (88/378/EEC) is applicable to the majority of inedible components. As such, the small parts cylinder test (defined by EN 71-1:2001) can be used to indicate potential choking hazards for children under 36 months. It is noted that there may be some reservations as to the suitability of this test.
4. Incidents involving choking, suffocation or ingestion will be considered. There is no restriction on the severity of the incident since this can be accounted for in later stages of the risk assessment procedure.

4. HAZARD CHARACTERISATION

4.1 Overview

The first stage of a risk assessment is primarily a question of identifying the effects that are considered as adverse. The second stage, hazard characterisation is defined as the quantitative or semi-quantitative evaluation of the nature of the adverse health effects to humans and/or the environment following exposure to a risk source(s).

With respect to inedibles, hazard characterisation includes⁷:

- a review of the factors relating to the nature of the inedible, the consumer and the exposure route;
- an evaluation of the health effects (consequences); and
- an analysis of the dose-response relationship.

These factors will influence whether particular inedibles are more or less likely to be introduced into the mouth and whether such actions are likely to result in an incident. The associated consequences may range from no effect (for example, child inserts inedible partially into mouth and then removes it) through to injuries and, very rarely, death.

4.2 Review of Relevant Factors

4.2.1 Nature of the Inedible

As previously suggested, four common types of inedibles have been identified:

1. plastic toys in assembly kit form (where these are normally contained within plastic capsules);
2. solid plastic toys (wrapped in a plastic bag or contained within a capsule);
3. cardboard discs (wrapped in a plastic bag); and
4. tattoos or stickers (wrapped in a plastic bag).

Rimell *et al.* (1995) and Rider and Wilson (1996) both discuss the characteristics of small parts causing aspiration, ingestion or choking in children. Objects are characterised according to their size, shape and consistency.

In relation to size, as previously indicated, toys are required to be tested using the small parts cylinder. Consultation with industry has indicated that, in some cases, companies will use a test cylinder with larger dimensions to reduce the potential choking hazard. However, at this stage inedibles may be defined as being either small

⁷ The approach to microbiological hazard characterisation suggested by European Commission (2000) is considered to be the most appropriate approach to follow, rather than that for chemicals.

or large depending on whether they fit inside the small parts cylinder (as defined in EN 71-1: 2001).

Rimell *et al.* (1995) and Rider and Wilson (1996) suggest that objects can be assigned to one of five categories according to shape:

- three-dimensional (3D) bulky – e.g. ball, pen cap;
- 3D angular – e.g. wood screw;
- two-dimensional (2D) solid – e.g. coin;
- 2D nonsolid – e.g. paper clip; or
- conforming – e.g. balloon, plastic wrapping.

In addition, there are three categories of consistency:

- rigid – e.g. coin, hard plastic;
- conforming – e.g. balloon, plastic wrapping; or
- semi-rigid – e.g. eraser.

Where the inedible component is a plastic toy in assembly kit form, it is generally the case that this consists of small parts, which would fit inside the test cylinder. In line with the Directive, these products are marked with a warning that the toy is not suitable for children under 36 months as it contains small parts which might be swallowed or inhaled. Adult supervision may also be recommended. The parts of the toy are generally rigid, being made of hard plastic, but may be a variety of shapes.

The capsule containing the toy does not fit completely inside the cylinder, but sits on top, with the hemispherical end partially inside the cylinder. This makes it a large object, made of hard plastic, which is a 3D bulky shape.

The size of solid plastic toys will vary depending on the product which they are packaged with. For example, cereal manufacturers are generally not limited by the size of the inedible which may be incorporated in the packaging of their product. Thus a solid plastic figure packaged with cereal may be larger than one sold with a chocolate egg, and may, according to the requirements of the small parts cylinder test, be suitable for children under 36 months. It is likely that the toy is made of hard plastic but this may not always be the case, and it may be a variety of shapes.

Cardboard (or plastic) discs, tattoos and stickers may be of any size, but in general appear to be large. However, a cardboard disc will be rigid in consistency and 2D solid in shape, since it is similar in appearance to a large coin. In contrast, tattoos and stickers are 2D in shape and semi-rigid in consistency. The plastic wrapping (used to package the inedible) may be 2D in shape and conforming in consistency. Whilst it is noted that inedible items are required to be wrapped (see Section 1.1), the wrapping is included in this analysis for completeness.

The nature of the inedibles is summarised in Table 4.1 below.

Table 4.1: Characteristics of Inedibles Packaged with Food						
	Type of Inedible				Inedible Packaging	
	Assembly kit toy	Solid toy	Cardboard disc	Tattoo or sticker	Capsule	Other wrapping
Size						
Small	Y	Y				NA
Large		Y	Y	Y	Y	
Shape						
3D Bulky	Y	Y			Y	
3D Angular	Y	Y				
2D Solid	Y*		Y	Y		Y?
2D Nonsolid	?					
Conforming						
Consistency						
Rigid	Y	Y	Y		Y	
Conforming						Y
Semi-rigid	Y*	?		Y		
*Note: An assembly kit toy may contain paper instructions which might be considered as a 2D solid with semi-rigid consistency						

4.2.2 Nature of the Consumer

The review of epidemiological literature suggests that a person’s age is the most likely characteristic to influence a person’s susceptibility to any risk posed by FPCIs. The anatomy of a child’s respiratory tract changes dramatically in the first few years of life, and these anatomical changes will affect the risk associated with choking, aspiration or ingestion of food and toys for the various age groups. Choking occurs by blocking the airway to both lungs, and DTI (1996) reports that the diameter of the cricoid, the narrowest part of the trachea, is about 6 mm at 12 months, rising to 8 or 9 mm by the age of four.

Rimell *et al.* (1995) found that two-thirds of choking deaths among children (under 14) occurred under 3 years of age. Altmann *et al.*, (1997) looked at the frequency of non-fatal asphyxiation and foreign body ingestions and found that food-related asphyxiation peaked in infants less than 1 year of age, and declined to low levels by 3 years. The rate of non-food related asphyxiation was relatively constant to 3 years of age and then declined by 6 years of age. Banerjee *et al.* (1988) also found those under three to be most vulnerable in relation to inhalation of a foreign body into the respiratory passage.

Steen and Zimmerman (1990) found suffocation to be a distinct problem in the baby and toddler age group, with 65% of the children affected being under 3 years of age.

No children younger than 6 months were found in their study, probably because the ability to manipulate a small object successfully into the mouth is not present at this age.

Reilly *et al.* (1996) narrows the range, suggesting that the peak incidence of all foreign body ingestions and aspirations for children is between the ages of 9 and 24 months. The introduction of solid foods combined with a lack of the full complement of teeth for chewing, would account for an increase in frequency in the 20 months age group. In addition, developing young children are not sufficiently mature to distinguish food from non-food items.

DTI (2002) studies the mouthing behaviour of children up to the age of five. Whilst overall mouthing activity shows little relationship with age (which covers mouthing of dummies, fingers, toys and other objects), the average mouthing time of toys peaks for the 6-9 month age group. Whilst older children (>3 years) may spend less time on average mouthing toys, the extreme cases may spend time that is equal or greater than the average of younger children.

Altmann *et al.* (1997), Reilly *et al.* (1996), Rider and Wilson (1996), and Rimell *et al.* (1995), all suggest that the risk of choking and ingestion remains beyond the age of 3, and generally extends until 6 years of age. Weizmann and Krugliak (1998) state that although the median age for choking incidents is usually between 2.5 and 3 years old, ages range from 4 months to 16 years.

Nixon *et al.* (1995) identified 136 children (99 boys and 37 girls) who were less than 15 years of age and who died from mechanical asphyxia in England and Wales between 1990 and 1991. The modal age for girls was found to lie in the first year of life while for boys there were two modal peaks, one at less than 1 year of age and the second in the early teenage years. Reilly *et al.* (1996) also suggests that a second group of children (average age 10 years) have been shown to be at risk. Aspiration of non-food items occurs more frequently in this group, often when the children are play-acting and are placing objects into their mouths.

A summary of the age for peak incidence of choking, suffocation or ingestion, and the main age range at risk, is presented in Table 4.2.

Fatalities, and non-fatal accidents resulting from choking appear to disproportionately affect boys as opposed to girls (Metra Martech, 1998; and DTI, 1999). Towner and Errington (2002) review a range of studies, and report boy:girl ratios of 1.4:1, 2:1, and 9:1 amongst choking-related fatalities, and 2:1 and 3:1 for injuries.

Table 4.2: Incidence of Choking, Ingestion and Suffocation Incidents by Age

Source	Months						Years											
	6	12	18	24	30	36	4	5	6	7	8	9	10	11	12	13	14	15
DTI, 2002		Peak	Risk	Risk	Risk	Risk	Risk	Risk										
Weizmann & Krugliak, 1998		Risk	Risk	Risk	Risk	Peak	Risk	Risk	Risk	Risk	Risk	Risk	Risk	Risk	Risk	Risk	Risk	Risk
Altmann <i>et al.</i> , 1997	Peak	Peak	Peak	Peak	Peak	Peak	Risk	Risk	Risk									
Reilly <i>et al.</i> , 1996		Risk	Peak	Peak	Risk	Risk	Risk	Risk	Risk				Peak					
Rider & Wilson, 1996	Peak	Peak	Peak	Peak	Risk	Risk	Risk	Risk	Risk									
Nixon <i>et al.</i> , 1995	Peak	Peak														Peak	Peak	Peak
Rimell <i>et al.</i> , 1995	Peak	Peak	Peak	Peak	Peak	Peak	Risk	Risk	Risk									
Steen & Zimmerman, 1990		Peak	Peak	Peak	Peak	Peak												
Banerjee <i>et al.</i> , 1988	Peak	Peak	Peak	Peak	Peak	Peak												
Key	Peak	Peak	Risk															

4.2.3 Nature of the Exposure Route

Behavioural studies suggest that children, as a part of their normal development and exploration of their surroundings, frequently place small parts, such as toys, into their mouths. Within four weeks of birth, some infants will make contact with stationary objects within their reach, and an active grasp becomes evident by twelve weeks of age. Thereafter, the infant becomes more adept at making contact with objects brought within reach and often brings them to the midline and to the mouth for visual and oral exploration. Between 6-7 months of age, the infant's grasp and pincer grasp become more refined, such that a small pellet may be accurately picked up. Normal one-year-olds mouth objects for long periods of time. As they get older, this mouthing decreases, so that by the time they are 4 years of age, mouthing plays a smaller part in their exploratory behaviour.

There is a strong relationship between the level of the child's development and the mechanism of the accident. Young children who are more likely to choke on objects are in the 'oral phase' of their development, when they naturally place objects into their mouths or they may be being introduced to more solid foodstuffs as part of the weaning process.

DTI (2002) provides data on the average mouthing time for toys per day, i.e. the amount of time for which a toy is near on in a child's mouth, for children under five. This is presented in Table 4.3, and this shows that the frequency of mouthing toys declines with age. Further data on the proportion of that time spent on different mouthing activities such as licking/lip touching, sucking/trying to bite; and biting or chewing, is presented in Table 4.4. It can be seen that that average mouthing time of toys peaks for children under 1 year and that this age group is most likely to suck on the toys. There is little pattern in mouthing activity by age.

Age of Child	% of Day
Under 1 year	4.10%
1 year	2.49%
2 years	1.92%
3 years	1.73%
4 years	0.46%
5 years	0.28%

Source: DTI (2002) Tables 2 and 3

Age of Child	Lick	Suck	Bite	Total
Under 1 year	0.18	0.55	0.27	1.00
1 year	0.17	0.42	0.41	1.00
2 years	0.41	0.26	0.33	1.00
3 years	0.31	0.24	0.46	1.00
4 years	0.47	0.34	0.19	1.00
5 years	0.36	0.37	0.27	1.00

Source: DTI (2002) Table 7 (highest proportions by age are shaded)
Note that in this and subsequent tables, all entries have been rounded.

Generally speaking, children are discouraged from putting toys or other foreign objects in their mouths. One of the concerns expressed over FPCIs is that, by association, children may be being encouraged to place inedible objects in their mouths. By way of example, RoSPA (2001) considers that, in the case of chocolate eggs containing inedibles, the association of the chocolate covering (including the odour as well as small chocolate deposits) considerably increases the risk to children. This can be compared to an experiment, carried out by the Istituto Italiano Sicurezza dei Giocattoli (nd), which aimed to study the ability of children aged from 3 to 6 years to perceive differences in smell between novelty items which had and had not been in contact with chocolate. With a sample of 50 children, testing four different inedibles, the ‘correct’ results (i.e. those identifying the inedibles that had been in contact with chocolate) fell below the required 23 out of 50 (to be significant at 5%), suggesting that the choices made were due to chance.

A similar experiment, conducted by Mäntylä and Carelli (1998), examined preschool-aged children’s behaviour when interacting with chocolate eggs containing inedibles. Thirty-two children were involved in the experiment, aged 3-6 years, and they were observed under three experimental conditions; toy enclosed in chocolate, toy with but separated from chocolate, and toy only. The results of the study showed that however the toy was presented, the incident of risk-related behaviours was non-existent. In this sense, ‘risk behaviour’ was defined as a child’s attempt to put a toy or a part of a toy close (<10 cm) to the mouth.

The experiments conducted by the Istituto Italiano Sicurezza dei Giocattoli (nd) and Mäntylä and Carelli (1998) both appear to be unique studies, carried out on small numbers of children. More specifically, with consideration to the results of Mäntylä and Carelli, mouthing of objects is a normal part of development and is seen usually from the age of 6-7 months onwards (for example, see DTI (2002)). A 3-year-old child would tend not to mouth objects as part of normal behaviour, and this study would seem to exclude the group of children who are most likely to put these toys into their mouths. However, this would be because the brand of chocolate eggs used carry a warning that they are not suitable for children under 3 years old.

Morra *et al.* (2001) suggest that it has never been demonstrated that inedible items sold with food pose a higher risk of choking than that item does on its own. In a more recent study, Benelli *et al.* (2002, which also includes Morra) report the results of an experiment designed to:

1. measure the aptitude of three different FPCIs present on the market to be recognised by children aged 3-6 as products with a 'double nature', that is formed of food and non-food parts; and
2. evaluate whether there are differences in children's manipulation-play behaviour (particularly mouthing activity) between a toy derived from a FPCI and a toy presented alone of the same kind and complexity.

Three FPCIs (a chocolate egg, a bag of crisps, and chocolate spread and bread sticks) were tested on a sample of 48 children aged 3-6 years of age. The chocolate egg proved to be the best recognised product with a 'double nature', with significantly different results to that of the crisps which was least recognised. It was further concluded that the approach to play was no different between the toy presented with the food and the toy presented on its own, neither did the presence of food nor the activity of eating the edible part affect the frequency of mouthing episodes (with only one toy, presented on its own, being mouthed by a 3 year old).

There is little, if any, consideration as to whether incidents of choking occur whilst eating the food item. This is supported by Durodié (nd), which discusses one of the three fatalities resulting from FPCIs in the UK. It is suggested that, in 1985, a toy lorry from a chocolate egg was assembled by the child's father, and mostly cleared up by his mother after it was broken during play. The boy (aged 3) choked on the wheel and axle which was not cleared up after it was broken. Furthermore, Metra Martech (1998) conclude that the two fatal cases involving FPCIs in the UK since 1986 both occurred sometime after the original packaging had been opened and the toy separated from the food. At this time the toy was being used as "just another toy" and the connection with food was remote.

In contrast, Weizmann and Krugliak (1998) report one case where a four year old boy was admitted to hospital half an hour after eating a chocolate egg. Although the child was aware that the egg contained a toy, having had one before, he had tried to lick the plastic piece inside and accidentally ingested the toy.

Clearly, the assessment of whether the combination of edible and inedible items increases the risk of choking, ingestion or suffocation is important in determining whether FPCIs are intrinsically more hazardous than other objects with which children come into contact.

4.3 Evaluation of the Potential Health Effects

4.3.1 Classification of Incidents

The potential health effects caused by inedibles are likely to be a specific incident of either choking, suffocation or ingestion, caused by the inedible being placed either over or inside the mouth. The associated consequences may range from no effect (for example, child inserts inedible partially into mouth and then removes it) through to injuries and, very rarely, death.

It is possible to use data from injury surveillance systems to review the more serious incidents. Using the International Classification of Diseases (ICD) it is possible to compare data from a number of countries, although both the 9th (ICD-9) and 10th (ICD-10) versions are or have been in use in Europe over the period studied (1996-2002). Some of the relevant classifications for incidents involving foreign bodies are compared in Table 4.5. Incidents are classified by both location of the object and the cause of the incident. Diagrams of the respiratory and digestive tracts are given in Figures 4.1 and 4.2 respectively.

Table 4.5: Classification of Location of Foreign Bodies and External Causes	
ICD-9	ICD-10
933.0 Pharynx	T17.2 Pharynx
933.1 Larynx	T17.3 Larynx
934.0 Trachea	T17.4 Trachea
934.1 Main bronchus	T17.5 Bronchus
934.8 Other specified parts	T17.8 Other and multiple parts of respiratory tract
934.9 Respiratory tree, unspecified	T17.9 Respiratory tract, unspecified
935.0 Mouth	T18.0 Mouth
935.1 Oesophagus	T18.1 Oesophagus
935.2 Stomach	T18.2 Stomach
936 Intestine and colon	T18.3 Small intestine
	T18.4 Colon
	T18.8 Other and multiple parts of alimentary canal
938 Digestive system, unspecified	T18.9 Alimentary tract, part unspecified
Causes:	
E911 Inhalation and ingestion of food causing obstruction of respiratory tract or suffocation	W79 Inhalation and ingestion of food causing obstruction of respiratory tract
E912 Inhalation and ingestion of other objects (not food) causing obstruction of respiratory tract or suffocation	W80 Inhalation and ingestion of other objects (not food) causing obstruction of respiratory tract

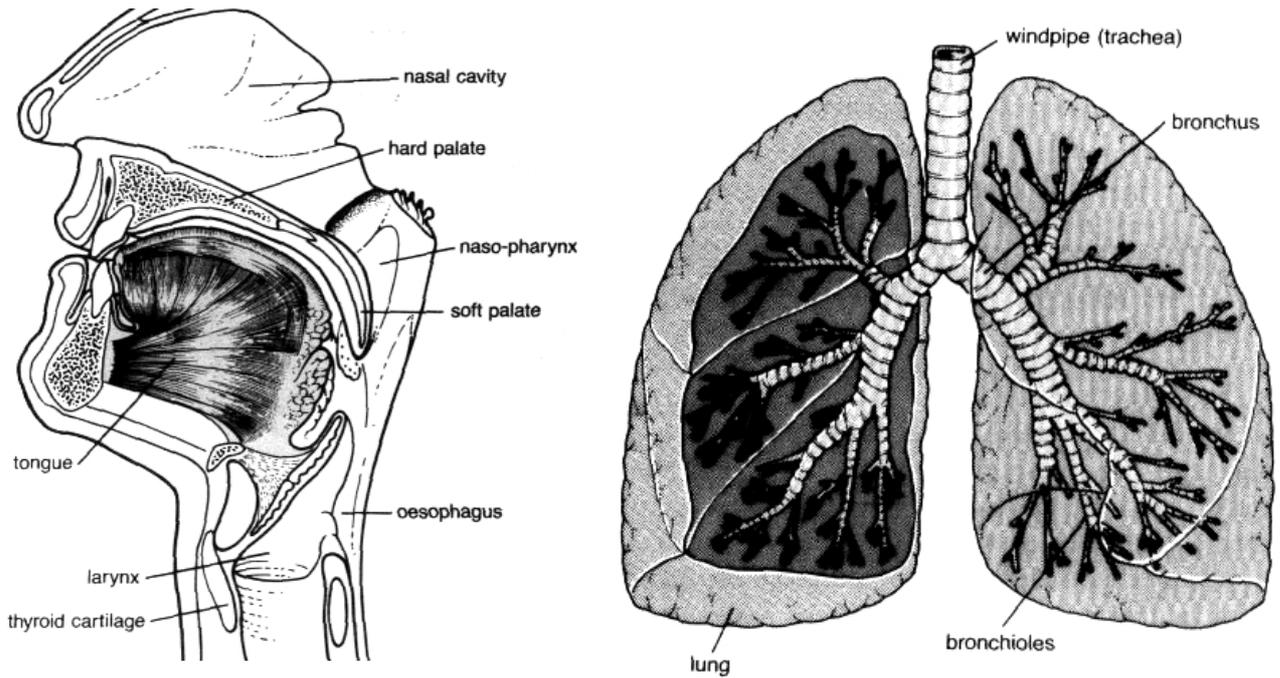
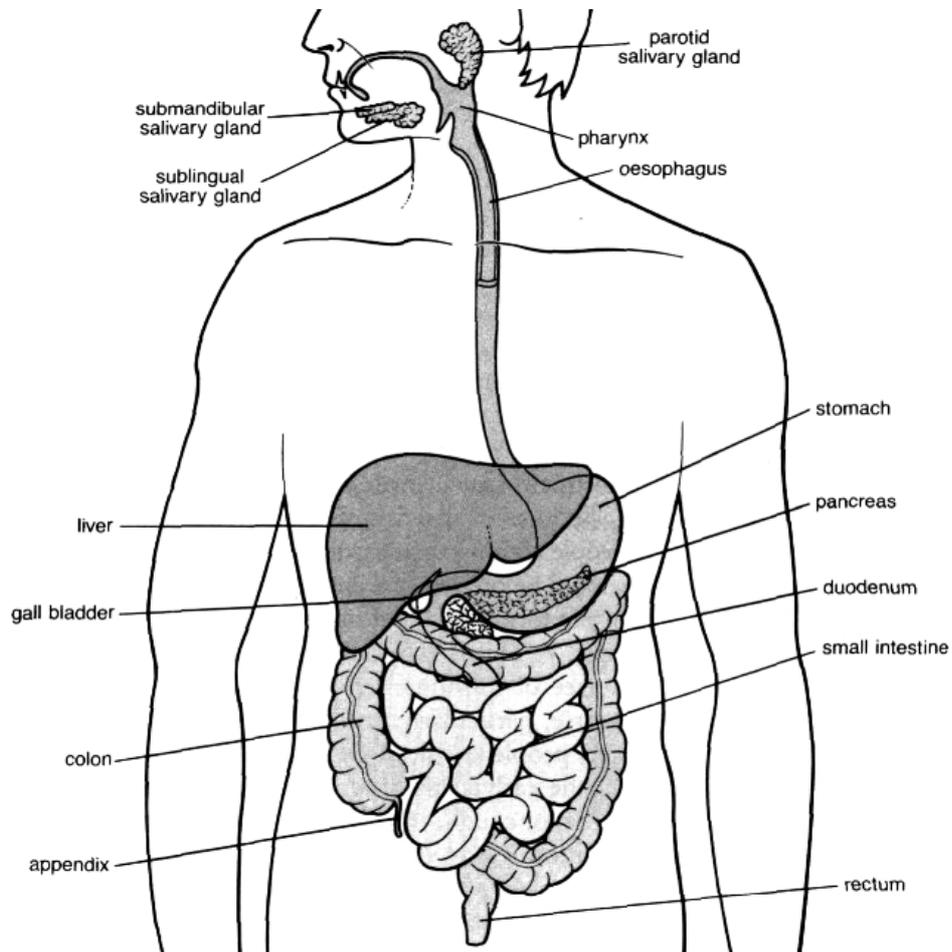


Figure 4.1: The Respiratory System (source: Youngson, 1995)

Figure 4.2: The Digestive System (source: Youngson, 1995)



4.3.2 National Data

Introduction

A review of data from the 1980s and early 1990s (DTI, 1996) concluded that there were over 400 deaths of children under ten from choking each year in the EU. In addition, there are over 50,000 non-fatal choking accidents each year (for the same age group). Data for EU countries are presented in Table 4.6, and range from 0.4 (Sweden) to 3.4 (Greece) deaths per 100,000 children.

Country	Deaths		Accidents	
	Rate	Number per Year	Rate	Number per Year
Austria	1.2	11	102	970
Belgium	1.1	13	164	1,990
Denmark	0.6	4	148	910
Finland	0.5	3	119	710
France	0.5	41	-	<i>9,240</i>
Germany	1.2	94	-	<i>10,000</i>
Greece	3.4	36	-	<i>1,290</i>
Ireland	-	5	125	610
Italy	1.0	55	-	<i>7,120</i>
Netherlands	0.5	11	85	1,670
Portugal	2.4	28	359	4,220
Spain	2.1	81	-	<i>4,820</i>
Sweden	0.4	4	-	<i>1,290</i>
UK	0.5	34	88	6,140
Overall	1.0	418	123	50,980

Source: DTI (1996)
Notes: Rates are given as incidents per year, per 100,000 children under 10.
Where a rate is not given, data were not available and the number of incidents has been estimated from the average rate for other countries and the population. Such estimates are shown in italics.
Non-fatal choking incidents are referred to as "accidents"; fatal accidents are referred to as "deaths".
Most death figures are based on averages for 1989 to 1993 but some averages cover the period for 1984 to 1993. Accident figures relate to variable periods from 1987 to 1993.
Given the time periods involved, some of these choking incidents may relate to incidents occurring before the implementation of the EC Toy Safety Directive.

As a result of the consultation, more recent general data on incidents have been made available from several countries - with particular regard to Italy, Luxembourg, the Netherlands and the UK. The results are summarised in the following sub-sections.

Italy

In 1999, incidents amongst children (aged 0-14) accounted for 45% of the 6,372 hospital admissions classified by ICD9 933-938. In 1998, children (aged 0-14) accounted for 10% of the 225 fatalities classified by ICD9 933-938.

Based on the population data⁸ provided by Eurostat, the associated incident rates by age band are presented in Table 4.7.

Age	Population (x 1000)	Number (per year) of		Rate (per 100,000 per year)	
		Hospital admissions	Fatalities	Hospital admissions	Fatalities
<1	535	662	13	124	2.43
1 - 4	2133	1180	6	55	0.28
5 - 14	5659	1028	3	18	0.05
0 - 14	8327	2870	22	34	0.26

Source: Istituto Superiore Sanità

Luxembourg

Between 1996 and 2001, children accounted for 2 of the 19 deaths due to incidents classified by ICD9 933-938 or E911-913 (1996 - 1997) and ICD10 T17/T18 or W79/W80 (1998-2001). Based on the population data provided by Eurostat, the associated incident rates by age band are presented in Table 4.8.

Age	Population (x 1000)	Number of Fatalities (per year)	Fatality Rate (per 100,000 per year)
<1	6	0.2	3.60
1 - 4	23	0.2	0.87
5 - 14	54	0	0.00
0 - 14	82	0.4	0.48

Source: Statistics Information, Luxembourg

Netherlands

A review of choking incidents in the Netherlands has recently been published (Ridder *et al.*, 2003). The Dutch data considers fatalities, hospital admissions, and visits to hospital for emergency aid (i.e. without admission). Data relating to those incidents resulting in blockage of the airway for deaths and hospitalisations are presented in Table 4.9 and 4.10.

⁸ In this and subsequent analysis, the base population data set used is that for the year 2000 (the most recent year for which Eurostat provides comprehensive data). Although there will be minor changes (generally less than 1%) in population from year to year, such changes do not significantly affect the analysis.

Table 4.9: Data for the Netherlands for Incidents involving Blockage of Airway (1998-2000)

Age	Population (x 1000)	Number of Fatalities (per year)	Fatality Rate (per 100,000 per year)
<1	202	3.3	1.65
1 - 4	782	4.0	0.51
5 - 19	2943	3.3	0.11
0 - 19	3927	10.7	0.27

Source: Ridder et al. (2003)

Table 4.10: Data for the Netherlands for Incidents involving Blockage of Airway (1998-2000)

Age		Hospital Admissions/year		%Hospital Admissions		
		number	rate (per 100,000)	were fatal	due to food	with male patient
<1	202	45	22.3	7.4%	82%	47%
1 - 4	782	90	11.5	4.4%	42%	59%
5 - 19	2943	39	1.3	8.5%	41%	56%
0 - 19	3927	174	4.4	6.1%	52%	55%

Source: Ridder et al. (2003)

United Kingdom

The Hospital Episode Statistics (HES) for England provide information on admitted patient care delivered by National Health Service (NHS) hospitals. Data are available for 1998 to 2002 and summary data on admissions of children are presented in Table 4.11.

Table 4.11: National Incident Data for England (1998-2002)

Age	Population (x 1000)	Primary Diagnosis	Annual hospital admissions	
			Number	Rate (per 100,000)
0 - 14	9451	T17 Foreign body in respiratory tract	2460	26.0
0 - 14	9451	T18 Foreign body in alimentary tract	1462	15.5

Source: Hospital Episode Statistics, available from www.doh.gov.uk

Further analysis of recent data (1996-99) of incidents involving children (aged 0 - 14) is presented in Towner and Errington (2002). The Home Accident and Leisure Accident Surveillance Systems (HASS and LASS) provide data on hospital visits (which may or may not result in admission) from 18 UK hospitals which represent a notional 5% sample and data on all fatal accidents is also collated.

Relevant data are summarised in Tables 4.12 and 4.13.

Table 4.12: Data (HASS/LASS) on Visits to Hospitals involving Children and Choking (1996-99)

Age	5% UK Population (x 1000)	Visits to hospital per year		%Hospital visits	
		number	rate (per 100,000)	due to food	with male patient
<1	36	32	90.7	42%	41%
1 - 4	145	104	71.5	50%	54%
5 - 14	387	106	27.4	65%	52%
0 - 14	568	242	42.6	56%	51%

Source: Towner and Errington (2002)

Table 4.13: Data (HADD) on Fatalities involving Children and Choking (1996-99)

Age	Population - England & Wales (x1000)	Fatalities per year		%Hospital visits	
		number	rate (per 100,000)	due to food	with male patient
<1	632	28	4.40	68%	55%
1 - 4	2565	24	0.94	77%	65%
5 - 14	6836	10	0.15	72%	64%
0 - 14	10033	62	0.62	72%	60%

Source: Towner and Errington (2002).

Summary

Although the basis on which data is collected (and analysed) varies from country to country, the data relate, primarily, to fatalities, hospital admission and incidents involving visits to hospital (or other first aid centre). The data are summarised below.

Table 4.14: Summary Data on Choking Incidents (rate per 100,000 children per year)

Area (period)	Age	Fatalities	Admission	First Aid	Source
EU (pre 1996)	0-9	1.0 (0.4-3.4)	123 (85-359)		Table 4.6
Italy (1998/99)	0-14	0.26	34		Table 4.7
Luxembourg (1996-01)	0-14	0.48			Table 4.8
Netherlands (1998-00)	0-19	0.27	4.4		Tables 4.9/4.10
UK (1996-99)	0-14	0.62	42.6		Tables 4.12/4.13
UK (1998-02)	0-14		41		Table 4.11

Variation by Age

The available data suggest that the incident rates generally decrease with age - although, as illustrated in Table 4.2, the highest rates are likely to be for toddlers aged 12-24 months. Using the data presented above, it was possible to derive relative fatality and incident rates by age as shown in Tables 4.15 and 4.16.

Age	Italy	Luxembourg	Netherlands	UK	Mean
<1	9.35	7.50	6.11	7.10	7.5
1 - 4	1.08	1.81	1.89	1.52	1.6
5 - 14	0.19	0.0	0.41	0.24	0.2
0 - 14	1.0	1.0	1.0	1.0	1.0

Source: Tables 4.7, 4.8, 4.9 and 4.13. Note for the Netherlands, upper age band was 5-19.

Age	Italy	Netherlands	UK	Mean
<1	3.65	5.07	2.13	3.6
1 - 4	1.62	2.61	1.68	2.0
5 - 14	0.53	0.30	0.64	0.5
0 - 14	1.0	1.0	1.0	1.0

Source: Tables 4.7, 4.10 and 4.12. Note for the Netherlands, upper age band was 5-19.

This variation by age is consistent with the information presented in Section 4.2.2 (and Table 4.2). Based on recent data from Towner and Errington (2002), it is likely that the variation of the incident rate (relative to the overall incident rate for children 0-14) will be of the form shown in Figure 4.1.

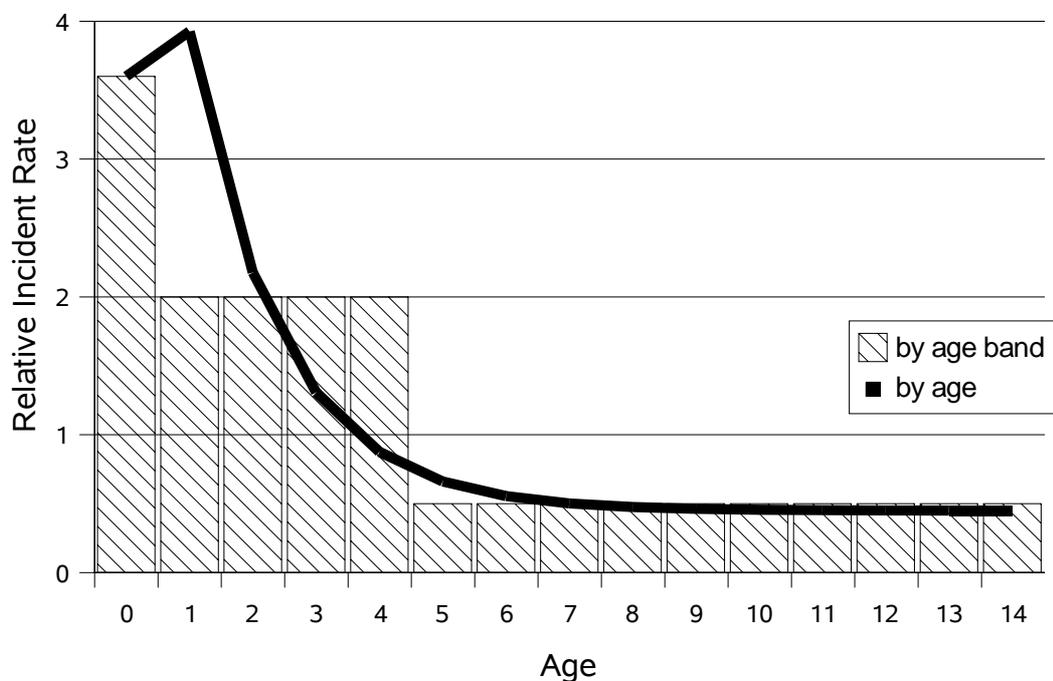


Figure 4.1: Relative Choking Non-fatal Incident Rate by Age and Age Band (1 = Overall Incident Rate for Children 0-14)

Variation by Object

There is a general consensus that food is the most likely cause of choking accidents (see, for example, Cohen *et al.*, 1980; and Marandian *et al.*, 1984). This is confirmed by the Dutch and UK data presented above with food accounting for 52% and 56% of incidents respectively. Interestingly, although the UK data shows the relative importance of food increasing with age (see Table 4.12), the Dutch data reveals the converse (see Table 4.10).

The available literature suggests that toys account for about 5% of non-fatal choking incidents. Furthermore, the distribution of the consequences (i.e. severity) of such incidents is very similar to that of choking incidents generally. The relevant data are presented in Tables 4.17 and 4.18.

Reference	Scope of Data	Total Number of Incidents	Incidents Caused by Toys	
			Number	Percentage
Altmann & Ozanne-Smith (1997)	1987-95: Children <15, Victoria, Australia	343	19	5.5%
DTI (1996)	1989-1993: Children <10; Denmark	648	99	15.3%
DTI (1999)	1986-1996: Children <4, average yearly figure England and Wales	2,624	167	6.4%
Rimell <i>et al.</i> (1995)	1993: All children, Pittsburgh, US	165	9	5.5%
Rothmann & Boeckmann (1980)	1954-79: Children <15, Akram, Ohio, USA	225	0	0%
Stevens <i>et al.</i> (1996)	1994: All children, Christchurch, New Zealand	139	4	2.9%

Severity	Total	Toy or Part of Toy
	Percentage by Severity	Percentage by Severity
Trivial	10.2	15.0
Minor	77.3	74.3
Serious	5.8	7.8
Very serious	0.4	1.5
Fatal	0.9	0.6
Unknown	5.4	1.2
Total	100	100

Source: DTI (1999) Tables 3 and 4

4.3.3 Incidents Involving FPCIs

Introduction

Data on incidents involving FPCIs are not routinely recorded at a national or international level. However, in recent years, a number of studies have highlighted the hazards posed by such products, particularly where the promotion appeals to children (Kehrt *et al.*, 1998; Metra Martech, 1998; and Petridou, 1997).

However, the number of such incidents appears to be relatively small and this is perhaps one explanation as to the lack of response from questionnaires sent to paediatrician associations in all 15 EU Member States.

FPCI Incidents 1996-2002

Table 4.19 summarises the available data on incidents involving the inhalation/ingestion of FPCIs within the EU during the period 1996-2002. There are a number of important points to be made in reviewing the data:

- perhaps most importantly, there does not appear to have been a single fatality involving FPCIs since 1997;
- there is a considerable variation in reporting from country to country;
- the ‘seriousness’ of an incident is often disputed. By way of example, a child may be taken to hospital and admitted for observation (an apparent serious incident) but in the event, the small object swallowed is passed naturally with no adverse effects;
- the incident itself is often disputed. By way of example, a child may be taken to hospital and admitted for observation but in the event, no trace of, say, a swallowed object is found; and
- there is a general lack of precise data.

Country	Year	Age	What Happened	Product Involved	Source of Data
Austria			No incidents reported		
Belgium	1996	68	Victim swallowed cardboard disc and died of asphyxiation	Crisps	Petridou (1997) /ANEC (2001)
	1997	??	Two children choked on parts of toys contained in food products	Not given	Durodié (nd)
Germany	1996	<1	Small figure lodged in respiratory tract in pharynx. Resulted in breathing difficulties and capillary bleeding. Object removed with forceps, and baby stayed in hospital overnight	Chocolate egg	Kehrt <i>et al.</i> (2001) - but note cases not confirmed in consultation
		1	Object in pharynx/larynx (933). Coughed out spontaneously.	Chocolate egg	
		2	Object in windpipe (934) and clinically removed	Chocolate egg	
		3	Object in mouth/oesophagus/stomach (935). Spontaneous removal	Chocolate egg	

Country	Year	Age	What Happened	Product Involved	Source of Data
Germany (cont.)	1996 (cont.)	3	Object in mouth/oesophagus/stomach (935). Spontaneous removal after 4 days in hospital	Chocolate egg	Kehrt <i>et al.</i> (2001) - but note cases not confirmed in consultation
		3	Object in digestive system (938). Spontaneous removal	Chocolate egg	
		4	Object in windpipe (934) and clinically removed. 3 days in hospital	Chocolate egg	
		4	Object in digestive system (938). Spontaneous removal	Chocolate egg	
	1997	4	Object in mouth/oesophagus/stomach (935). Spontaneous removal	Chocolate egg	
		1	Part of toy lodged in pharynx restricting breathing. Coughed out spontaneously after manual compression of thorax	Chocolate egg	
		1	Aspiration of small plastic component of toy, causing pneumonia. Foreign body removed by bronchoscopy. Child kept in hospital for seven days	Bag containing sweets and toy	
		2	Object in mouth/oesophagus/stomach (935). Spontaneous removal (x3)	Chocolate egg (x3)	
	2				
	6				
2000	??	Object ingested and clinically removed	Chocolate egg	Consultation	
	??	Object ingested and clinically removed	Chocolate egg		
>2000		A regional 'poison centre' reported no such incidents amongst 10 million inhabitants since 2000			
Denmark			No incidents reported		Consultation
Spain	1997	??	Object ingested and passed naturally	Chocolate egg	Consultation
Finland	1998	??	Object ingested and passed naturally	Chocolate egg	Consultation
France	1996	??	Object ingested and clinically removed	Chocolate egg	Consultation
	1997	<1	Baby swallowed plastic particle and died as a result of choking	Sweet?	Petridou (1997)/ ANEC (2001)
		??	Object ingested and clinically removed	Chocolate egg	Consultation
		??	Object ingested and passed naturally	Chocolate egg	Consultation
1998	??	Object ingested and passed naturally	Chocolate egg	Consultation	
Greece	1996	8	Swallowed a toy soldier. Admitted to hospital for three days	Chocolate egg	Petridou (1997) & Consultation
		<1	Chewed on cardboard disc. Out-patient visit and counselling of parents	Crisps	Petridou (1997) & Consultation
		4	Swallowed part of a toy mouse. Out-patient visit and X-rays revealed object	Chocolate egg	Petridou (1997) & Consultation
		7	Playing with and then swallowed small axe. Out-patient visit and X-rays.	Chocolate egg	Petridou (1997) & Consultation
	1997	5	Playing with and then swallowed small plastic hammer. Out-patient visit and X-rays.	Chocolate egg	Petridou (1997) & Consultation

Country	Year	Age	What Happened	Product Involved	Source of Data
Greece (cont.)	1998	4	Choked on axle of toy car and taken to hospital	Chocolate egg	ANEC (2001) & Consultation
		4	Boy formed wrapper into ball and swallowed it. Taken to hospital for X-ray	Chocolate egg	Consultation
	1999	<1	Swallowed object and taken to hospital for X-ray	Chocolate egg	Consultation
		3	Swallowed small plastic animal and taken to hospital for X-ray	Chocolate egg	ANEC (2001) & Consultation
	2001	1	Swallowed head of small doll and taken to hospital for X-ray	Chocolate egg	Consultation
		10	Child swallowed disc and taken to hospital for X-ray	Crisps	Consultation
Ireland			No incidents reported		
Italy	1997	??	Object ingested and clinically removed	Chocolate egg	Consultation
Luxembourg			No incidents reported		
Netherlands			No incidents reported		
Portugal			No incidents reported		
Sweden	1996	??	Object ingested and clinically removed	Chocolate egg	Consultation
	1997	??	Object ingested and passed naturally	Chocolate egg	Consultation
	1997	7	Plastic small ball from product got into child's throat	Not given	Godis & Leksak (2003)
	2001	1	Plastic coin, 4cm in diameter, got stuck in child's throat. It cut soft palate, child vomited blood and toy came out with gastric contents	Cereal	Godis & Leksak (2003)
		7	Toy tin soldier got stuck in child's gastric channel. Removed by hospital surgeons.	Chocolate egg	Godis & Leksak (2003) & Consultation
	2002	1	Plastic capsule got stuck in child's throat. Removed by parents (both doctors).	Chocolate egg	Consultation
UK	1996/97	2 Adults	Two cases involved adults (with learning difficulties) choking on plastic discs. No lasting injuries	Crisps (or similar?)	Consultation
	1997	??	Object ingested and passed naturally	Chocolate egg	Consultation
	2001	3	Child opens egg and then places part of toy in mouth. Parent promptly removes object from mouth.	Chocolate egg	Consultation
	2002	4	Child inhales capsule which blocks airway. Parent delivers first aid.	Chocolate egg	Consultation

Based on the data on 50 incidents presented in Table 4.19, a number of observations can be made:

- the vast majority of incidents involved children aged below 10;
- even where data collection is rigorous, it would appear that it is unlikely that there has been more than several incidents (requiring hospital/medical attention) involving FPCIs per country per year;
- the vast majority of incidents involved chocolate eggs;
- most of the objects involved appeared to be 'small'; and
- some incidents required clinical intervention to remove the object.

One of the key findings to emerge is that there are very few cases in which a direct link is claimed between the act of eating the food product and the consequent ingestion/inhalation of an associated inedible item. However, in most cases, the precise circumstances of the incident, with particular regard to the time between the consumption of the food product and the associated inedible item, are uncertain.

4.4 Conclusions of Hazard Characterisation

1. Data sets on choking incidents and FPCI incidents have been reviewed. Choking incidents are more common amongst younger children (less than five) than older children.
2. Apart from age, the key parameter is the size of object. The available data suggests that most FPCI incidents involve 'small' parts (i.e. those that pass through the 'small parts cylinder').
3. The consequences of an FPCI incident are very varied. In many cases, a small part is ingested and passes through the body without incident. Occasionally, an item becomes lodged in the respiratory or digestive system requiring medical treatment. There are two reported cases of fatalities (within the EU during the period 1996-2002) resulting from an FPCI incidents.
4. The lack of detailed data has prevented the development of a detailed dose-response model which accounts for the full range of potentially influential factors (such as shape and consistency of the inedible item for example).

5. EXPOSURE ASSESSMENT

5.1 Overview

Exposure assessment is concerned with the likely actual levels and duration of exposure to the risk source of human and environmental species, and can be defined as the quantitative or semi-quantitative evaluation of the likely exposure of man and/or the environment to risk sources from one or more media. An exposure assessment characterises the nature and size of human populations and/or ecological communities exposed to an emission source and the magnitude, frequency and duration of that exposure.

5.2 Population at Risk

There are over 60 million children within the EU. Population data for children aged 0 to 14 within each EU Member State were obtained from Eurostat and the results are summarised in Table 5.1.

Country	Age of Children			
	<1	1 to 4	5 to 14	0 to 14
Belgium	113	464	1,228	1,805
Denmark	66	274	641	981
Germany	771	3,176	8,949	12,897
Greece	100	403	1,097	1,599
Spain	380	1,465	4,063	5,907
France	734	2,865	7,477	11,076
Ireland	54	210	562	826
Italy	535	2,133	5,659	8,327
Luxembourg	6	23	54	82
Netherlands	202	782	1,962	2,946
Austria	78	345	942	1,364
Portugal	114	425	1,103	1,641
Finland	57	240	645	943
Sweden	88	380	1,171	1,640
United Kingdom	711	2,897	7,749	11,357
EU-15	4,008	16,081	43,301	63,391

Source: Eurostat data for 2000 (note that numbers are rounded)

5.3 Magnitude of Exposure

It is estimated that the order of five billion FPCIs are sold per year within the EU. It is important to emphasise that this is a very uncertain figure based on extrapolation of the limited data gained through the consultation exercise (and associated background research). Most of the FPCIs sold are targeted towards children and Table 5.2 presents an overview of the estimated consumption by children of the main product groups.

Type of Product	No. of FPCIs sold within EU (million)	% consumed by children (0-14)	EU consumption per child per year (0-14)	Countries with highest per child consumption
Chocolate eggs (and related products)	2000	65%	20	Italy, Germany, Luxembourg
Crisps (and related products)	890	33%	4.6	Spain, Portugal, Greece
Breakfast cereals	710	70%	7.8	UK, Germany, Portugal
Meals for children from fast food restaurants	850	100%	13	Sweden, UK, Austria

Source: Consultation and background research
Note: All figures are RPA estimates based on extrapolation of limited data

There are, of course, other products which are not listed in the above table due to their more limited markets. By way of example, pots of yoghurt/ice cream containing a toy are popular in some countries, such as Greece, but are not sold EU-wide.

Nevertheless, the data presented in Table 4.2, suggests that, on average, each child within the EU will consume an FPCI product once per week. Of course, the consumption will vary widely from country to country and from child to child. It is by no means impossible that some children will consume perhaps as many as ten FPCIs per week.

5.4 Discussion of Exposure Factors

5.4.1 Size of Object

There are two critical parameters in determining the size for promotional inserts:

- the constraints of the product packaging; and
- whether or not they pass the small parts cylinder test.

There is an increasing tendency for companies to ensure that promotional inserts used in food products are not classified as comprising ‘small parts’. By way of example, the constraints of the packaging of breakfast cereals and fast food restaurant meals for children are not severe. As a result, inserts no longer contain ‘small parts’.

For crisps and similar products, packaging is restrictive. In some countries (notably the UK), snacks tend to be sold in small individual packages. However, there is a general requirement to minimise the presence of ‘small parts’. As a consequence of these two factors, most inserts are ‘large’ 2D items (plastic/cardboard discs, stickers, scratch cards, etc.). Of note, is that in one recent promotion, the insert was a ‘large’ 2D plastic card with press-out parts to construct a 3D toy with small parts - and, as

such, was provided with a warning label that it was not suitable for children under 36 months (as required by the Toy Safety Directive, see Section 3.4).

For chocolate eggs (and similar products), one of the prime features is the presence of a capsule containing, in most cases, an assembly kit and, as a consequence, ‘small parts’.

5.4.2 Testing of FPCIs

The main suppliers of FPCIs carry out testing to ensure that promotional inserts are, as far as possible, safe to consumers. In some cases, the time taken from concept to appearance in retail outlets can be two or three years. During this time, the design and selection of materials (for both the insert and associated wrapping) are often subject to a risk assessment as well as laboratory tests (usually by an independent certified laboratory) to ensure compliance with various standards. Furthermore, quality control checks are provided to ensure that high standards of safety (and other features) are maintained during the sales of the FPCIs to consumers.

5.4.3 Labelling

It would appear that, as a broad generalisation, all FPCIs containing ‘small parts’ carry the necessary warning labels (with particular reference to not being suitable for children under 36 months). Indeed, even where the promotional insert is ‘large’, there are numerous examples of warning labels being provided as a precaution.

However, many products which are sold internationally provide warning labels in several languages which can reduce the legibility of the warning. In a recent survey (2003) by the Finnish Consumer Agency, the vast majority of labels on chocolate eggs were found to be unreadable without first opening the wrapping.

5.4.4 Recalls

Very occasionally, FPCIs are recalled due to safety concerns. During the period of interest (1996-2002), there have been few recalls of FPCIs within the EU⁹.

One example involved the sale of chocolate eggs containing ‘growing insects’ which expanded significantly on contact with water. Following approaches from the Finnish Consumer Agency, the eggs were voluntarily withdrawn in 2002 and, by a different importer, in 2003.

It is understood that yoghurt products have also been voluntarily recalled from sale in Denmark and the UK, but the details have not been confirmed.

⁹ More generally, in 2001, two fast food chains in North America recalled products following reports of children choking on parts of the toys accompanying meals for children.

6. RISK CHARACTERISATION

6.1 Overview

The final stage of the analysis is to relate the level of risk to individuals, with particular regard to children within the EU. As such, this involves making predictions of the numbers of FPCI incidents and comparing the results with those FPCI incidents which have been identified.

6.2 Rate of Incidents

The first stage of the risk characterisation is to provide an overall estimate number of FPCI incidents based on population data. As such, this assumes that all children are exposed to the same degree of hazard, irrespective of their country of residence.

The extent of FPCI incidents is based on the following hypothesis:

- 5% of all choking (and related) incidents are caused by toys; and
- 1% of all choking (and related) incidents caused by toys involve FPCIs

In order to estimate the number of FPCI incidents using the above assumptions, it is first necessary to provide baseline figures. Based on the information presented in Table 4.14, it would appear that the overall fatal choking incident rate for children (0 to 14) is of the order of 0.5 fatalities per 100,000 per year.

In relation to non-fatal accidents, there are a number of values presented in Table 4.14 based on different criteria. As already indicated (see Section 4.3.3), the differentiation between incidents involving visits to hospital and those involving hospital admission is not always helpful. By way of example, prompt medical intervention following an FPCI choking incident may be considered to be more serious than the admission of child to hospital for observation following a possible ingestion of an object from an FPCI. For the purposes of this analysis, it will be assumed that non-fatal FPCI choking incidents requiring medical attention (by qualified medical/first aid personnel) whether or not they result in admission to hospital have an incident rate of the order of 100 per 100,000 per year. In other words, this assumed figure has been taken to be somewhat higher than any of the individual values entered for admissions and/or first aid in Table 4.14 for Italy, the Netherlands and the UK.

Using these assumed baseline figures, it is then possible to estimate the overall number of FPCI incidents amongst EU children by country. These are then further adjusted to account for the variation of relative incident rates (RIRs) by age using the data provided in Tables 4.15 and 4.16 - as reproduced in Table 6.1. By way of explanation, if the overall non-fatal incident rate is X incidents per 100,000 per year for children aged 0 to 14, then the non-fatal incident rate amongst children aged less than one would be 3.6X (per 100,000 per year) and that for children aged 5-14 would be 0.5X.

Age	RIRs for Fatal Incidents	RIRs for Non-fatal Incidents
<1	7.5	3.6
1 - 4	1.6	2.0
5 - 14	0.2	0.5
0 - 14	1.0	1.0

Source: Tables 4.15 and 4.16

The results of the calculations are presented in Table 6.2 together with the maximum number of FPCI incidents involving children reported in any one year (from Table 4.19).

Country	Non-fatal incidents amongst children				Fatal incidents (0-14)	Max. no. reported per year
	<1	1 to 4	5 to 14	All		
Belgium	0.2	0.5	0.3	1.0	0.00	2
Denmark	0.1	0.3	0.2	0.6	0.00	no data
Germany	1.4	3.2	2.2	6.8	0.03	9
Greece	0.2	0.4	0.3	0.9	0.00	4
Spain	0.7	1.5	1.0	3.2	0.02	1
France	1.3	2.9	1.9	6.1	0.03	3
Ireland	0.1	0.2	0.1	0.4	0.00	no data
Italy	1.0	2.1	1.4	4.5	0.02	1
Luxembourg	0.0	0.0	0.0	0.0	0.00	no data
Netherlands	0.4	0.8	0.5	1.6	0.01	no data
Austria	0.1	0.3	0.2	0.7	0.00	no data
Portugal	0.2	0.4	0.3	0.9	0.00	no data
Finland	0.1	0.2	0.2	0.5	0.00	1
Sweden	0.2	0.4	0.3	0.8	0.00	2
United Kingdom	1.3	2.9	1.9	6.1	0.03	1
EU-15	7.2	16.1	10.8	34.1	0.16	9
1996-2002	51	113	76	239	1.13	

Sources: Based on data presented in Tables 4.19, 5.1 and 6.1 (and associated text)

Clearly, the highest numbers of predicted incidents are associated with those countries with the greatest populations of children (i.e. Germany, UK, France and Italy) with fewer than 10 incidents predicted per year. The one predicted fatality during the period 1996-2002 is consistent with the one fatality reported in France (the second reported fatality involved a senior citizen - see Table 4.19).

Amongst those countries with the highest predicted or reported numbers of incidents in any one year, Germany and Greece have more reported incidents than predicted whilst France, Italy and the UK have fewer reported incidents than predicted.

One possible reason for this apparent discrepancy is that children in different countries are exposed to different levels of exposure to those FPCIs which contain

‘small parts’. In particular, it would be expected that the relative national sales of chocolate eggs containing ‘small parts’ would provide a more reliable indicator of the expected number of incidents than the numbers of children in each country. The calculations were repeated on the following basis:

- retain the overall EU predictions of incidents presented in Table 6.2; and
- determine the distribution by country according to the estimated numbers of chocolate eggs (and similar products) sold at a national level (in other words, if a country has 10% of the market share, then 10% of the overall number of incidents would be expected to occur in that country).

The revised predictions are presented in Table 6.3.

Country	Non-fatal incidents amongst children				Fatal incidents (0-14)	Max. no. reported per year
	<1	1 to 4	5 to 14	All		
Belgium	0.1	0.2	0.1	0.4	0.00	2
Denmark	0.1	0.2	0.1	0.3	0.00	no data
Germany	2.5	5.5	3.7	11.7	0.06	9
Greece	0.2	0.4	0.3	0.9	0.00	4
Spain	0.5	1.2	0.8	2.5	0.01	1
France	0.9	2.1	1.4	4.5	0.02	3
Ireland	0.0	0.1	0.0	0.1	0.00	no data
Italy	1.9	4.3	2.9	9.1	0.04	1
Luxembourg	0.0	0.0	0.0	0.1	0.00	no data
Netherlands	0.1	0.3	0.2	0.6	0.00	no data
Austria	0.2	0.4	0.3	0.9	0.00	no data
Portugal	0.1	0.3	0.2	0.7	0.00	no data
Finland	0.1	0.1	0.1	0.3	0.00	1
Sweden	0.1	0.3	0.2	0.6	0.00	2
United Kingdom	0.3	0.7	0.5	1.5	0.01	1
EU-15	7.2	16.1	10.8	34.1	0.16	9
1996-2002	51	113	76	239	1.13	

Sources: Based on data presented in Tables 4.19, 6.1 and consultation

Amongst those countries with the highest predicted or reported numbers of incidents in any one year, the situation is now different from that associated with predictions based on population alone. Germany, France and the UK¹⁰ have similar numbers of reported and predicted incidents, whilst Italy has fewer reported incidents than predicted and Greece has more reported incidents than predicted.

Overall, it would appear that the numbers of FPCIs containing ‘small parts’ consumed by children is a more reliable indicator of the numbers of FPCI incidents involving

¹⁰ In a recent survey of 520 A&E (accident and emergency) departments in the UK, 10 doctors reported being aware of an incident of a child being brought to their A&E department (RAM, 2003) as a result of an FPCI incident involving a chocolate egg. This is consistent with the predicted 10 non-fatal UK incidents over the period 1996-2002 (1.5 x 7 = 10.5).

medical attention than the numbers of people at risk. This is because the level of exposure (i.e. the consumption of FPCIs containing 'small parts') varies from country to country. However, rigorous statistical confirmation of this view would require a much more comprehensive data set on both incidents and sales of FPCIs containing 'small parts'.

6.3 Risk Reduction Measures

6.3.1 Level of Risk

The level of risk associated with FPCIs is very low. As a basis for the estimates presented in the previous section, the hypothesis was that FPCI incidents accounted for 1% of those (choking) incidents involving toys which, in turn, account for about 5% of all choking incidents amongst children. This hypothesis generated predicted numbers which were consistent with the available data on actual FPCI incidents.

Clearly, there remain considerable uncertainties. However, if the FPCI incident rate was several times higher, then one would expect a much greater number of reported incidents. It is acknowledged that, in the case of Greece, the observed 'cluster' of four cases in 1996 has yet to be fully explained - although the average rate of 1.6 incidents per year (for the period 1996-2002) is much closer to the predicted rate 0.9 per year (see Tables 6.2 and 6.3). It is also accepted that the national number of incidents in Greece may be somewhat higher if those reported incidents are restricted to the main population areas. However, extrapolation of such data would lead to results which are not consistent with those incidents reported in other countries.

Another approach to reviewing the risk is to consider the following:

- the predicted number of FPCI incidents involving children in the EU is estimated to be 34 incidents per year;
- the consumption of chocolate eggs (and related products) containing inedibles by children is estimated to be 1300 million per year (2000 x 65% - see Table 5.2);
- if all the predicted FPCI incidents involving children are due to these products; then
- the risk is about 1 incident per 40 million eggs consumed.

If a particular child consumed one chocolate egg (or similar product) per day, then the risk of suffering an incident would be about 1 chance in 100,000 per year (with an associated risk of death of 1 chance in 20 million per year).

One of the issues to be addressed by this study is the linkage between the food product and the inedible item. In some cases, an incident may involve an inedible item but the fact that the item was originally associated with a food product has no bearing on the incident (for example, a child is playing with a toy many hours after acquiring it and ingests part of it). One means of determining the linkage is the time between consumption of the food product and the incident. In most of the cases presented in Table 4.19, this time has not been determined with certainty. In a few cases, it would appear that the two events were closely linked. Although one might suggest that

about 10% of the incidents were influenced by the originating food product, providing a robust defence of such a figure is not possible based on the available information.

Overall, although the risks associated with FPCIs are low, they are not zero. Clearly, if products are sold without inedible promotional inserts, then the risks are eliminated. Some of the companies contacted during the consultation exercise have followed this path and no longer sell FPCIs.

6.3.2 Size of Object

The available data on FPCI incidents (see Table 4.19) indicate that size of the FPCI is a critical factor. Items which are classified as ‘large’ are far less likely to lead to incidents than ‘small parts’ (as determined by small parts cylinder test).

6.3.3 Labelling

Products containing ‘small parts’ are provided with warning labels. As a consequence, it would be expected that the FPCI incident rate amongst the youngest children would be lower than for choking incidents more generally.

Table 4.19 lists 32 incidents involving children for whom the ages were specified. Based on the Eurostat population data (see Table 5.1), it was possible to derive incident rates per 100,000 people by age as well as the relative incident rates. These were then compared with the general choking rates derived in Table 4.16 as shown in Table 6.4.

Age	No. of Incidents	Incident Rate (per 100,000)	Relative Incident Rate (RIR)	RIR for General Choking Incidents
<1	4	0.10	2.0	3.6
1 - 4	21	0.13	2.6	2.0
5 - 14	7	0.02	0.3	0.5
0 - 14	32	0.05	1.0	1.0

Source: Tables 4.16, 4.19 and 5.1

Table 6.4 shows that the incidence of FPCI incidents amongst the youngest children (i.e. those less than one) is less than would be expected if the distribution by age was the same as for choking incidents generally (2.0 compared to 3.6). This suggests that some heed is being taken of warning labels not to give those products containing ‘small’ parts to very young children.

Nevertheless, and apart from concerns over the legibility of some labels (see Section 5.4.3), the provision of a label does not of itself ensure that very young children will not have access to ‘small’ parts.

6.3.4 Capsules

At least two incidents listed in Table 4.19 involved the plastic capsule containing a toy within a chocolate egg. In some cases, the plastic capsule has ventilation slots to prevent the possibility of the capsule completely blocking the airway¹¹. However, in other cases, the capsule is vacuum sealed thus requiring adult assistance to open it and to minimise the transfer of chocolate traces to the toy (and, presumably, vice-versa).

In short, whilst the provision of ventilation slots on the capsule may appear attractive this may lead to a greater occurrence of incidents due to a greater degree of association between the chocolate egg and the inedible item inside the capsule.

¹¹ For many years, pen caps have been provided with ventilation ‘holes’ to prevent such events.

7. KEY FINDINGS

It is estimated that the order of five billion FPCIs (food products containing inedibles) are sold per year within the EU, most of which are targeted towards children. There is a risk that these inedibles (often referred to as promotional inserts) will result in an incident involving ingestion, choking or suffocation.

In order to clarify the degree of risk, a consultation exercise was undertaken to provide further detail on past incidents (with particular regard to the period 1996-2002) and on the nature and numbers of FPCIs sold within the EU. The stakeholders contacted included injury surveillance organisations, consumer associations, paediatricians and manufacturers of FPCIs.

In broad terms, the response to the consultation was poor. In particular, national associations of paediatricians in all 15 EU Member States were contacted. Although several associations assisted with involving their members in the study, no data were provided by any of the associations or members contacted.

Data on 50 reported incidents over the period of interest indicate that the vast majority of FPCI incidents involve children and the entry of a 'small' item (as defined by the small parts cylinder test, EN 71-1: 2001) into the mouth and from there into the respiratory or digestive tract. In the period covered by the study, there have been two reported fatalities - one baby and one senior citizen.

Based on the limited data provided, it is estimated that FPCI incidents (involving ingestion, choking or suffocation) account for 1% of such incidents involving toys, which, in turn account for 5% of all such incidents amongst children aged 0 to 14. This results in an estimated 34 non-fatal FPCI incidents (where these require medical attention by qualified medical/first aid personnel) involving children per year across the EU. Since chocolate eggs containing inedibles are the dominant product containing small parts, most reported incidents relate to chocolate eggs. Furthermore, at a national level, it would appear that the observed number of incidents is more closely related to the numbers of chocolate eggs sold than to the number of child consumers.

In general terms, the industry is well aware of the safety concerns and has taken measures to ensure that, where possible, promotional inserts do not present a significant hazard to consumers. These measures include a move towards 'large' insets as well as safety and quality checks.

Although the causal link between eating the food product and a subsequent incident is not proven, the risks associated with FPCIs are demonstrably low. However the risks are not zero and it is worth concluding that some manufacturers have discontinued the use of promotional inserts in the interests of safety of the young consumer.

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ANNEX 1: CONSULTATION QUESTIONNAIRES

Incidents Involving Food Products Containing Inedibles

Innovations in marketing have led to the combination of edible and inedible components, such as toys and other items, which may pose a risk to consumer safety.

A number of incidents have been reported in recent years where people (particularly children) have accidentally inhaled or ingested inedible items packaged with food. Changes in legislation, such as the EU Toy Safety Directive of 1988, may have had some effect on reducing the number of incidents but, even where products comply with the relevant regulations, incidents may still occur.

The information and knowledge on food products containing inedibles (FPCIs) is considered to be incomplete. Risk & Policy Analysts Ltd (RPA) has been contracted by the Science and Technological Options Assessment Bureau (STOA) of the European Parliament to clarify the situation through a review of available data. This will help the European Parliament understand if there are significant health risks associated with FPCIs and, if so, what could be done in this respect.

If you have knowledge or experience of incidents involving such products you are requested to complete a copy of this form for each incident you are aware of. The information you provide will help us to understand the type of incidents which occur and will inform future recommendations. However, please bear in mind the following restrictions:

- The incident must have occurred within the **European Union between 1996 and 2002** inclusive.
- The incident must have involved the inedible being **placed over the mouth** (suffocation) or **into the mouth** (choking or ingestion).
- The inedible object must be a **'novelty/promotional' item** (i.e. have no function related to the food) and have been **included within the overall packaging** of a food product, for example, chocolate eggs, breakfast cereals, crisps, biscuits, yoghurts, ice cream, fast food, etc.
- There is no restriction on the age of the person involved in the incident.
- There is no restriction on the severity of the incident to be reported.

Please answer as many of the following questions as possible. All responses will be confidential and only aggregated data will be presented in RPA's report to STOA.

For more information on this project, and RPA more generally, please contact us or visit our website (www.rpaltd.co.uk).

Thank you very much for your assistance.

Please return your completed form(s) to
Risk & Policy Analysts Ltd as soon as possible
and by **31 August 2003** at the latest.

See end of form for return address details.

Incident Involving Food Products Containing Inedibles

A) Your Details (all responses will be confidential)

Name:			
Name of Organisation/Hospital/Surgery etc. represented (if applicable):			
Address:			
Country:			
Telephone:		Fax:	
Email:			

1. Please indicate the type of organisation/hospital/practice etc. that you represent (if applicable):

General hospital	<input type="checkbox"/>
Paediatrics hospital	<input type="checkbox"/>
General practice	<input type="checkbox"/>
Paediatrics practice	<input type="checkbox"/>
ORL practice	<input type="checkbox"/>
Consumer association	<input type="checkbox"/>
Food safety association	<input type="checkbox"/>
Injury/accident prevention association	<input type="checkbox"/>
Other (please specify) <input style="width: 300px;" type="text"/>	<input type="checkbox"/>

If you are a medical professional, please indicate your specialism:

General practitioner	<input type="checkbox"/>
Paediatrics	<input type="checkbox"/>
ORL	<input type="checkbox"/>
Other (please specify) <input style="width: 300px;" type="text"/>	<input type="checkbox"/>

B) Patient Details

2. Age of patient (at time of incident):

Years

Months

3. Sex of patient:

Male

Female

4. Area of residence:

5. Country of residence:

C) Incident Details

6. Date of incident:

Day

Month

Year

7. Please indicate which of the following best describes the incident:

Type of incident

Definition

Choking

Internal obstruction of an airway by a foreign body

Suffocation

External obstruction of the airway by covering nose and mouth

Ingestion

Swallowing of an object

Other (please specify)

Don't know

<input type="checkbox"/>

8. Please indicate the location of the object inhaled or ingested:

Location

Pharynx		
Larynx		
Trachea		
Bronchus		
Lung		
Other and/or multiple parts of respiratory tract	Please specify:	
Unspecified part of respiratory tract		
Mouth		
Oesophagus		
Stomach		
Small intestine		
Large intestine/Colon		
Other and/or multiple parts of digestive system	Please specify:	
Unspecified part of digestive system		
Other	Please specify:	
Don't know		

9. Please indicate which of the following best describes the severity of the incident:

Injury severity	Description	
None (no injury):	A brief event with no physical findings	
Mild injury:	Persistent coughing or other subtle symptoms	
Moderate injury:	Physical findings, including respiratory abnormalities	
Severe injury:	Emergency transport and medical intervention	
Injury in-extremis:	Respiratory arrest, possible neurological damage	
Death		
Don't know		

10. Please indicate the outcome of the incident:

No treatment needed	
Treated at home by relatives	
Treated by General Practitioner	
Treated in hospital accident and emergency	Name of Hospital:
Referred to General Practitioner /other hospital	
Admitted for <1 day	
Admitted for 1 day	
Admitted for 2 days	
Admitted for 3 days	
Admitted for >3 days	
Admitted for unknown time	
Transferred to another hospital	
Died	
Don't know	

D) Details of Foreign Body

11. Please indicate whether the object was:

The capsule containing a toy/item	
A whole toy/item	
Part of toy/item	
Other (please specify)	
Don't know	

12. Please indicate the consistency of the object:

Consistency	Example	
Conforming	balloon, plastic wrapping	
Rigid	coin, hard plastic	
Semi-rigid	eraser, rubber toy	
Don't know		

13. Please indicate the shape of the object:

Shape	Example of Shape
Spherical	marbles, balls
3-dimensional bulk	pen cap
3-dimensional angle	wood screw
2-dimensional solid	coins
2-dimensional nonsolid	paper clip
Conforming	balloon, plastic wrapping
Don't know	

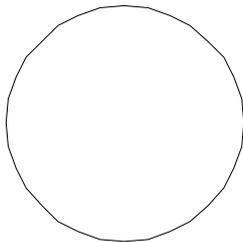
14. Please indicate the size of the object:

Diameter

<3.17 cm (1.25 inch) i.e. it would fit inside the circle below

>3.17 cm (1.25 inch) i.e. it is larger than the circle below

Exact diameter if known:



Length

<2.54 cm (1 inch) i.e. shorter than Line A

2.54-5.71 cm (1-2.25 inch) i.e. longer than Line A but shorter than Line B

>5.71 cm (2.25 inch) i.e. longer than Line B

Exact length if known:

A



B

E) Product Details

15. Please indicate the type of food which was packaged with the object:

Biscuits	
Cereal	
Chocolate egg/ball	
Crisps	
Fast food	
Yoghurt	
Other (please specify)	
Don't know	

16. Please give the product name, if known:

Product name:		Don't know	<input type="checkbox"/>
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17. Please give the product manufacturer, if known:

Product manufacturer:		Don't know	<input type="checkbox"/>
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F) Other Details

18. What was the patient doing at the time of the incident?

Eating the food	
Playing with the toy	
Other (please specify)	
Don't Know	

19. Please indicate the approximate time between the patient eating the food and the incident occurring:

Less than 15 minutes	
15-30 minutes	
30-45 minutes	
45-60 minutes	
1-2 hours	
More than 2 hours	
Don't know	

20. How did the patient come into contact with the product/object?

- Bought it themselves
- Bought by relative/friend for them
- Bought for older sibling/friend
- Don't know

<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>
<input type="checkbox"/>

21. In your opinion, did the incident occur as a result of the object being packaged with a food product?

Yes

No

Don't know

Please explain your answer:

22. Please summarise the incident in your own words, and/or provide any further details which you think may be important:

Please return your completed form(s) to:

**Carolyn George
Risk & Policy Analysts Ltd
Farthing Green House
1 Beccles Road, Loddon
Norfolk, England NR14 6LT**

**Phone: +44 1508 528 465 Fax: +44 1508 520 758
e-mail: carolyn@rpaltd.demon.co.uk**

INEDIBLES IN FOOD PRODUCT PACKAGING

A) Contact Details (your response will be confidential)

Company:	
Contact Person:	
Position:	
Contact Address:	
Telephone:	
Fax:	
Email:	

Average EU Turnover per year:	
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B) Product Information

- Please give the names of any product your company manufactures, for sale in the EU, which may contain an inedible component, either temporarily as a promotional device, or at all times. If the product name varies between EU countries, please give all the variations.

1	
2	
3	
4	
5	

- Please indicate the percentage of your EU turnover which can be attributed to the above products.

Product	% of EU Turnover
1	
2	
3	
4	
5	

3. For each of the products that you have listed, please indicate (with a 'X') the main food type of that product.

Food Type	Products Listed in Qu.1				
	1	2	3	4	5
Biscuits/cakes					
Cereal					
Chocolate egg/ball					
Crisps/chips					
Fast food					
Ice cream					
Yoghurt					
Sweets					
Other (please specify)					

4. For each of the products, please could you provide the following sales information for the most recent year that data are available for.

Data relating to(year)	Products Listed in Qu.1				
	1	2	3	4	5
Total EU Sales (in Euros)					
AND/OR					
Total EU Sales (number of items/packets)					
Average price per item (in Euros)					
% of items/packets containing an inedible (approximately if necessary)					
AND/OR					
Number of inedible items produced/purchased by Company					

5. For each of the products, can you please indicate the percentage of sales by EU country?

EU Country	Products Listed in Qu.1 - % of Sales				
	1	2	3	4	5
Austria					
Belgium					
Denmark					
Finland					
France					
Germany					
Greece					
Ireland					
Italy					
Luxembourg					
Netherlands					
Portugal					
Spain					
Sweden					
United Kingdom					

6. Considering other similar products, please indicate the market share (%) represented by your product(s) in each EU country .

EU Country	Products Listed in Qu.1 - % Market Share				
	1	2	3	4	5
Austria					
Belgium					
Denmark					
Finland					
France					
Germany					
Greece					
Ireland					
Italy					
Luxembourg					
Netherlands					
Portugal					
Spain					
Sweden					
United Kingdom					

7. Is the distribution of products containing inedibles by EU country the same as that for sales given in Qu. 5?

Yes
(If yes, please go to Qu.6)

No
(If no, please give the percentage of products containing inedibles by country below)

EU Country	Products Listed in Qu.1 - % of inedibles				
	1	2	3	4	5
Austria					
Belgium					
Denmark					
Finland					
France					
Germany					
Greece					
Ireland					
Italy					
Luxembourg					
Netherlands					
Portugal					
Spain					
Sweden					
United Kingdom					

8. We are considering incidents which may have occurred in the EU between 1996 and 2002. To place this in context we need to understand whether the markets for food products containing inedibles have changed during this time. Please describe any significant changes in the market of your products, either by size or distribution, since 1996.

Product	Description of Sales since 1996
1	
2	
3	
4	
5	

9. For each of the products, please can you indicate the percentage that you expect to be consumed by the following age groups.

Age Group	Products Listed in Qu.1 - % of consumption				
	1	2	3	4	5
Under 3 years old					
3 year olds					
4 year olds					
5 year olds					
6 year olds					
7-10 year olds					
11-14 year olds					
Over 14 years old					

C) Information on Inedibles

10. For each product, please list the percentage of inedibles that are of the following types.

Type of Inedible	Products Listed in Qu.1 - % of Inedibles				
	1	2	3	4	5
Plastic capsule containing a plastic toy in assembly kit form (i.e. several parts)					
Plastic wrapping containing a plastic toy in assembly kit form (i.e. several parts)					
Plastic capsule containing a solid plastic toy (i.e. one part only)					
Plastic wrapping containing a solid plastic toy (i.e. one part only)					
Plastic wrapping containing a cardboard disc/pog					
Plastic wrapping containing a sticker or tattoo					
Other (please specify)					

11. For each product, please describe how the inedible and edible components are packaged together (i.e. mixed together, separate container, etc.)

Product	Description of Packaging
1	
2	
3	
4	
5	

D) Relevant Legislation and Action Taken

12. Is the size of the inedible items tested according to the small parts cylinder given in EN 71-1:1998, or do you use an alternative testing cylinder? Please mark with a 'X' as appropriate for each product

Size Testing	Products Listed in Qu.1				
	1	2	3	4	5
Items are tested according to the small parts cylinder					
Items are tested according to an alternative testing cylinder					
Items are not tested for size					

If an alternative test cylinder is used, please give details of its dimensions:

13. Does your product(s) contain a warning label relating to the inclusion and/or size of the inedible components? If yes, please describe the warning below and/or provide a sample of the relevant packaging

Product	Description of Warning
1	
2	
3	
4	
5	

14. Since 1996, have you received reports of any accidents involving the above products and/or customer complaints regarding potential health risks? If yes, please give details (continue on a separate sheet if necessary).

15. Since 1996, have any of the above products been subject to recalls in any EU country as a result of the inedible component? If yes, please give details (continue on a separate sheet if necessary).

16. Does your company have a specific policy relating to inedibles in food product packaging and/or have you taken any specific action to reduce the potential for accidents? If yes, please give details (continue on a separate sheet if necessary).

17. If you have taken any specific action, were there costs associated with this action (e.g. changes in manufacturing process)? If yes, please provide estimates of these costs to the extent possible (continue on a separate sheet if necessary).

18. Finally, if you have any further comments on this subject, please let us know (continue on a separate sheet if necessary).

Please return your completed questionnaire to:
Carolyn George, Risk & Policy Analysts Ltd, Farthing Green House,
1, Beccles Road, Loddon, Norfolk, NR14 6LT, UK
by **30th June 2003**