



A review of the RPA report *Inedibles in food product packaging*

Prepared for STOA, European Parliament

INTRODUCTION

This review has been prepared under the terms of a contract between EASAC and STOA, which provides for EASAC to undertake peer review of the scientific aspects of reports commissioned by STOA from external consultants. The task assigned to EASAC is to give expert, independent comment on the report in question: it is not our role in this instance to draw conclusions about the issue under consideration, still less to make policy recommendations.

The report being reviewed is entitled *Inedibles in food product packaging* (draft final report, September 2003) and was written by Risk & Policy Analysts Ltd (RPA). Additional material made available to the reviewers – for information rather than for formal review – was a letter dated 15 October 2003 from Ewa Klamt MEP and 20 co-signatories, and a report dated 28 February 2003 and published on the internet in June 2003 by Paul Deheuvels entitled *Development of a method allowing to define security rules for particular classes of products, to be enforced through technical standards by European bodies under mandate of the European Commission*. The RPA report was circulated to members of the STOA Panel and, in addition to the Ewa Klamt letter, two further letters were received from Hans Blokland and Professor Nisticò. A few comments on this additional material have been included below.

The process used by EASAC was to identify suitable experts through the networks of the member Academies of EASAC, brief them about the task and send them the material, collate their reviews into a single document, review that document and submit it to STOA. The process of collation is intended to produce as coherent and accessible a document as possible while respecting the sometimes divergent opinions of the reviewers. So far as possible, the experts' own words have been used, with a minimum of editing to improve fluency between passages and provide for a connected text. Where the personal pronoun is used, it is one of the reviewers speaking. As a general rule, all indented material is taken more or less verbatim from the experts' reviews. The aim has been to present the spirit of each set of comments rather than to give an 'average' position. As a result, it sometimes happens that mutually contradictory statements are juxtaposed.

The four experts whose reviews are collated in this document came from Finland, France, Greece and Ireland. Their expertise covered food packaging technology, paediatrics, public health medicine and statistics. In keeping with normal practice, the names of the individual reviewers remain confidential. Also in keeping with normal EASAC practice, the reviewers were not paid for their reviews.

All reviewers were asked to complete a declaration of interests form. None declared any interests that might be deemed to impede their ability to give a disinterested review, though one referred to having recently published a closely related report. EASAC itself is formed by the independent national Academies of the EU Member States, and has no prejudicial interest whatever in the topic of inedibles in food product packaging.

At no point during this work has there been any contact between EASAC and RPA.

SUMMARY

One of the reviewers regards the RPA report as irredeemably biased, particularly against chocolate eggs. All the others, however, while conscious of the report's shortcomings, consider that RPA have done a reasonable and balanced job on a very difficult topic.

Most of the reviewers thus endorse the report's conclusion: the risk of an adverse incident associated with FPCIs is clearly very small in the context of all FPCIs consumed in the EU each year, and it is small even in the context of all choking incidents; equally clearly, it is not zero. Whether the level of risk is acceptable in relation to other risks and in relation to the benefits accruing to those who bear the risk, and whether proportionate steps should be taken to reduce it, are matters of judgement that policy-makers must determine in the light of whatever considerations they deem relevant to the issue.

BACKGROUND

The RPA study arises out of concern that the combination of edible and inedible components in some food products – particularly in connection with innovative marketing – could constitute a health hazard for some consumers. Information on the nature and scale of any such health hazard was considered inadequate, and RPA was awarded a contract to undertake a critical review of the available data and present a coherent and objective analysis. The terms of reference were extensively debated at meetings of the STOA Panel, and were expressed in the report as being to examine:

- 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.

The report itself begins with a review of the literature on choking in childhood which, after considerable effort, found fewer than 30 papers relevant to the study. It then presents the results of an extensive search for epidemiological data over the period 1996 – 2002. There follow chapters describing and characterising the range of possible hazards associated with inedibles in food product packaging and reporting known incidents related to them. Assessments of the extent to which the population of the EU is exposed to these hazards, and of how this can be used to address the level of risk to individuals, then lead to the concluding chapter reporting key findings. The summary conclusion of the RPA report is that:

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.

EVIDENCE-GATHERING

Most of the EASAC reviewers were broadly content with the RPA approach to the literature review and the consultation process, though they had some significant criticisms and suggestions for ways in which it could have been improved. One reviewer, however, stated that 'data collection within the report appears to have been biased'.

(i) Literature review

A serious gap in the literature review is the absence of reference to the Deheuvels report published in June 2003, as noted also by MEPs. I totally agree with Ewa Klamt *et al.* The Deheuvels report must absolutely be critically discussed in the final version of RPA Report. However, I do not agree with all the conclusions presented in the Deheuvels report.

The literature review should be extended in time and in geographical scope: the anatomy of people around the world is the same and the risks for health are similar everywhere if the food products containing inedibles are similar. It could also usefully have included a comparison of the situation and regulations concerning food products containing inedibles (FPCIs) in the US and the EU. The writers of the RPA report actually consider by themselves the need of additional literature on page 7.

The authors of the report repeatedly complain about the scarcity of incidental data on the subject. On the other hand, they limit strictly their investigations to the period 1996-2002. This is questionable, and it seems that an extension of the observation period would have been advisable to collect a larger and more conclusive data set.

In the literature review mainly medical journals and relevant research reports, several with epidemiological data, were covered. The reference list includes 46 references, some of which were given in such a form that it was impossible even to try to catch them. For example one of the key references, Kehrt R *et al.* (1998 or 2001 ?) gives only the name of the publication and the country, without any more specific information on the type of publication or the publisher. Similarly, the ANEC (2001) publication could not be found from the given internet address <http://www.anec.org>.

I think focusing on the younger age groups was correct. The literature review of hazard characterisation was adequate in that the peak age for highest incidence was defined in children <3 years.

I thought that the literature review should have looked at Food Safety Legislation.

(ii) Other evidence-gathering

RPA sought epidemiological evidence, by direct contact, by questionnaire and by notice on the internet (via the RPA website), from the relevant authorities, medical professionals, consumer organisations and food producers. However, neither insurance organisations nor legal organisations were approached with the questionnaire. These might have had some relevant data and statistics about the incidents where inedibles in food product packages have caused injuries to consumers. Injuries may have led to legal cases and compensations from insurance companies.

The authors did not mention Food Safety Regulatory Authorities or environmental health officers/health inspectors. They are often first point of contact for people who have food complaints and I think this would have been useful.

Data collection was not based on routine surveillance. Incidents involving food products whether inedible or not are difficult to capture through routine data. There are surveillance systems in Norway, Denmark and to a lesser extent the Netherlands for adverse events in foods usually to detect allergies such as anaphylaxis, but these appear not to have been approached. However there are no routine sources of information for this type of incident. Some of the best EU surveillance systems are in infectious diseases and congenital anomalies where diagnoses are clear and easy to categorise.

A difficulty with data collection may have been the methodology used in estimating risk. A pilot study could have identified the difficulties in obtaining data by a consultation process. Also I thought the questionnaire was too long and did not focus on the main objectives. The fact that no medical professionals responded to the questionnaire may be explained by only targeting paediatricians. Using hospital accident & emergency and ENT (ear, nose and throat) departments and also general practitioners might have yielded more information. However it is extremely difficult to get a good response from busy physicians and the authors acknowledge their constraints in this area. Also patients may self treat and not go to their doctor.

The response rate to the RPA approaches to the various professional stakeholders was poor, especially from the medical professionals. However, the poor response rate does not jeopardise the report, because with the cases reported in literature there was a total of 50 incidents where inedibles had caused severe risk to or injured the health of consumers, mainly small children, two of the incidents having been fatal.

The low response rate does not jeopardise the report but it does make it read more like a qualitative study than a formal quantitative risk assessment.

Rare events cannot be easily studied with traditional epidemiological means. Moreover, underreporting in this instance is the rule rather than the exception, since the priority of the emergency physician or pediatrician is to treat the young patient, rather than document the epidemiological coordinates of the event.

For one reviewer, the data set from the literature survey and consultation is heterogenous and cannot be considered as being representative of the problem.

IDENTIFICATION AND CHARACTERISATION OF HAZARDS

(i) Toy or food regulations

In chapter 3 it is said that 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. This is an important note, and I think that the Toy Directive is not necessarily the right place to regulate inedibles in food packages because the consumer buys a food product which includes an inedible item, he/she does not buy a toy. Maybe FPCIs should be considered rather in general product safety or food safety regulations.

The food industry has a duty of care to consumers. Industry should ensure the safety of food including products and packaging. It is hard to understand why only the regulations within the Toy Safety Objective apply.

To respect its goals, the report should have set itself within the framework of the EEC General Directive on Product Safety, with explicit mentions of the EEC Toy Safety Directive. This is absolutely necessary to appreciate which among the incidents correspond to a compatible or incompatible product use, and whether the current regulations are sufficient to protect the consumers against the corresponding risks. Almost nothing is said concerning whether the incidents occur in a situation which is banned by regulations or standards.

The first conclusion that existing data and the response to requests for information were poor is correct and factual. Estimating that FPCI incidents (choking etc) account for 1% of all such incidents involving toys might have been better expressed as incidents involving food.

(ii) Toys in food vs toys not in food

The authors of the report cannot bring any evidence to support the idea that the toys sold jointly with food in the FPCI packaging should bring, for young children, some aggravated risks of accident with respect to similar toys marketed independently of any kind of food product. In most cases, the incident, if any, occurs some time after that the foodstuff has been eaten. If such is the case, then one should investigate jointly the risks of such toys without making a reference to the fact that they are marketed with foodstuffs or not. This is especially relevant with respect to risk reduction. How could one expect a serious reduction of the consumer risk generated by FPCIs when the latter (say) are supposed to (according the report) generate an average of 1.67 yearly (non-fatal) incidents in the UK for children aged 0-4, and when, at the same time 255 yearly choking accidents are observed on the same population with coins only?

In their comments on the RPA "Draft Final Report" Ewa Klamt *et al.* complain that the "Final Report" does not provide explicit answers to the two fundamental questions:

- (i) whether FPCIs represent choking/suffocation/ingestion risks higher/different than those represented by the single inedible items, usually toys, when these are sold alone; and
- (ii) whether there exist precise data about the period of time between the consumption of the food and the ingestion/inhalation of inedible item to justify placing FPCIs in a separate risk category.

I do not agree that these two questions are fundamental. Why is it important to know whether FPCIs represent higher/different risks than single inedible items? The point is that inedible items in food product packaging are not sold separately from the food, but the consumer is forced to buy both of them. Thus at the moment of purchase the whole system represents the risk, not the inedible component alone.

The second question is irrelevant. The reason is principally the same as above. The risk begins already when the consumer buys the food product packaging including the inedible item. The period of time between the consumption of the food and the ingestion/inhalation of the inedible item has nothing to do with the risk of choking or other injuries.

Hans Blokland writes *The key finding is that the causal link between eating the food product and a subsequent incident is not proven. Then the conclusion must be that there is no difference between toys inserted in food products and toys that are not inserted in food products*. I disagree with Hans Blokland; there is a very clear difference in respect to the safety of the consumer. I think that toys of that size which are hiding inside the food products are not sold separately!

(iii) Comparisons with the USA

I would like to add into chapter 3.4 a discussion about the relevant legislation in the U.S.

The reference on p.14 to a suggestion by the New York State Attorney's Office to increase the size of the small part test cylinder gives a very partial view of the US attitude towards toy safety and FPCIs. In the first place, this suggestion was not followed by a regulatory change, and second, the authors should refer to a very thorough discussion of the US system given in the Deheuvels report. In particular, the RPA report appears to give only credit to the arguments aiming to ban FPCIs in general, whereas a recurrent discussion within the US has consistently enforced their legal existence, as well as approved their compliance to the general security rules of the US regulatory system.

(iv) Incidents involving FPCIs

The most important part of the whole report is table 4.19 on pages 33-35, where all the certified incidents in the EU during the period 1996-2000 are presented. The table includes the statistics that tell the seriousness and the history of injuries caused by inedibles in food packaging. From table 4.19 it can be found clearly that in 76 % of the reported incidents chocolate eggs were involved. So this is a fact, not an anti-chocolate eggs bias as some MEPs in their letter claim. I strongly suggest that the key section 4.3.3 be enlarged and the incidents presented in table 4.19 discussed more thoroughly. These incidents are reliably reported and they can be used as a basis for the scientific discussion and reasoning. Other parts of chapter 4 are written properly.

For another reviewer, the report is 'perfectly unfair and biased when it mentions on p36 that "the vast majority of incidents involved chocolate eggs".'

ASSESSMENT OF EXPOSURE AND RISK TO INDIVIDUALS

(i) Overall levels of exposure

In chapter 5 uncertainty comes to the picture when the writers produce figures as a result of estimation based on extrapolation of limited data. Fortunately they warn about the uncertainty. In section 5.4 two important exposure factors, namely size of the object and labeling, are discussed. In Finland it has been found that many of the warning labels are difficult to read or even to find on the package.

The fatalities presented in the report illustrate mostly the absence of any relevant FPCI incident, in the midst of thousands of choking incidents due to other causes. The irrelevance of the data is flagrant in the case of the 5 month old child, who should not be supposed to eat candy anyway at an age where liquid foodstuffs constitute the standard. To mention bluntly such incidents without commenting on their circumstances aims obviously to let the reader conclude to the existence of serious FPCI risks. We consider therefore that the displays on pp.42-43 are inconsistent with the observed fatality data, especially with respect to the reference given to "Chocolate eggs".

One of the highlights of the report is its predictive analysis of the risk per item of "Chocolate eggs" on p.44: "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)." Such a statement is obviously absurd (except for obese youngsters), but yet based on the thumb-rule that there should be 200 non-fatal FPCI incidents for 1 fatality. Following the lines of these computations, we reach the conclusion that the report evaluates the risk of a fatality caused by 1 chocolate egg to be as high as 1 in 8 billion. We wish to compare this figure with the fact that there has been no record within the EEC of any fatality related to chocolate eggs since 1991. In any case, it is public knowledge that there has been no "Chocolate Egg" fatality within the EEC in a period of 22 years. This shows that the report overestimates by factors the risks pertaining to "Chocolate eggs", and does present in this case some very controversial figures.

(ii) 'Cultural inedibles'

The report recognises the existence of a "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 ... involved such items."

One reviewer takes issue with this: 'The position defended here is again in obvious contradiction with facts. The authors of the report seem to completely ignore that "Easter Eggs" constitute a 'cultural product', which often consists of a chocolate egg with a variety of objects (edible or not) inside. Moreover, it appears that, in the UK only, a yearly average of 255 choking accidents for young children are due to coins. Would it be possible that a mere 1% of such incidents might be due to coins in Christmas puddings? It seems that the authors of the report did not care at all to investigate this question, in spite of the fact that it does concern FPCIs, and that it does fall within the scope of the study, as described on pp.1-10.'

For another reviewer, this category merits special consideration: 'If a toy is sold with a food and poses a risk of fatal choking, no matter if the risk is minimal. The question should be asked if it should be

included at all. After all it has no dietary value, it is merely a marketing tool. On the other hand we have long traditions of Halloween rings in Barm Brack which would be affected if all non-edible products were prohibited from packaging.'

(iii) Risks to individuals

In chapter 6 there is an attempt to relate the level to consumers, especially to children within the EU. Here the problem of scarce data partly complicates the analysis, because predictions are made on the basis of identified FPCI incidents. While calculating the rate of incidents several assumptions are made which causes uncertainties and even discrepancies between the predicted and reported FPCI incidents in different EU countries. Finally it was found that 'the number of FPCIs containing "small parts" consumed by children is a more reliable indicator of the number of FPCI incidents involving medical attention than the numbers of people at risk'. My impression is that the writers try to calculate statistical risks based on too small data bases. However, unquestionably the physical risks caused by small inedible items inside food products are real, as can be seen in table 4.19.

Section 6.3.1 (Level of Risk) contains considerable uncertainties. The writers force themselves to produce quantitative predictions of risk. My comment is that this subchapter must be read with great care; conclusions are not necessarily right.

At the end of section 6.3.1 the writers address one more issue, the linkage between the food product and the inedible item. According to them, 'one means of determining the linkage is the time between consumption of the food product and the incident'. I think this not the crucial point. The key point is that a consumer is forced to buy the inedible item with the food. The buying of the product already causes the risk, not the time between consumption of the food and the incident. I agree with the writers' simple conclusion that if products are sold without inedible promotional inserts, then the risks are eliminated.

Labeling is not a satisfactory preventive measure, since very young children are not always closely monitored by an older person and, even when they are, they are well-known for inventive and risky behaviors. Nor is it a satisfactory claim that food items with inedibles will not be made available to very young children, since the latter may have older siblings with access to them.

The report mentions that there are very few cases of incidents possibly related to FPCIs, and that the corresponding data is either nonexistent, or scarce and unreliable. In that spirit, the report mentions, pp.33-34 and in its Executive Summary, that:

- there does not appear to have been a single fatality involving FPCIs since 1997;
- 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;
- even when the 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
- 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 ... 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.

These statements are in clear contradiction with the affirmative conclusions made elsewhere in the report.

The two fatality cases are very important. First, they constitute the only fatalities which the report could find in relation with FPCIs. Second, they are isolated from the general context of choking accidents, and presented here as conclusive evidence. For example, it is most surprising that the report gives pp.42-43, Tables 6.2 & 6.3 two displays giving *“Predicted FPCI Incidents amongst children per year”* and *“Predicted FPCI Incidents amongst children per year – based on Estimated Sales of Chocolate Eggs”*, both giving the same figure of *“predicted fatal incidents”*, namely: 1.13 (with two digits!), with the comment on p.42 that the one predicted fatality during the period 1996-2002 is consistent with the one fatality reported in France.

The fact that the report is severely biased becomes very much obvious. In the first place, neither of the recorded fatalities has anything to do with *“Chocolate eggs”*. Since the figures of 1.13 predicted fatalities in the period 1996-2002 are identical, up to the second digit, in Tables 6.2 & 6.3, these predictions should obviously be singled out from the document body by the average reader, as to conclude from the display on p.43 that *“Chocolate eggs”* should constitute a serious hazard. This idea is supported in the report by the *“consistent evidence”* that the (at least) 1 observed fatality should appear as a near perfect prediction, when compared to 1.13. We could argue in the same way that, since the observed data is of 0 fatalities related in any way to *“Chocolate eggs”* in the period 1996-2002, the displays on pp.42-43 are unconvincing. At this point we should mention that we are not arguing for or against *“chocolate eggs”*. The question we raise is why the authors seem to focus 99% of their interest to this specific class of FPCIs, up to the point of losing much of their credibility.

The first sentence of the last paragraph in chapter 7 is not quite clear to me. I agree that there is no causal link between eating the food product and subsequent incident. I also agree that 'the risks associated with FPCIs are demonstrably low'. But I do not understand how these two assertions are related, as was written in the report.

CONCLUSIONS

(i) Summary statements

My conclusion is that this is a fair and balanced report giving the constraints involved in carrying out the assessment, though further work may need to be done to answer questions posed by the Parliament. The authors were careful not to draw strong conclusions because of insufficient data and this was correct.

Overall I thought the report was balanced. The topic is difficult. The events are rare and possible exposures are immense. The authors generalised rates of choking based on meta analysis of literature.

In chapter 7 the paragraph summarizing the 50 reported incidents including two fatalities is written properly. But the following paragraph contains again estimated figures about the FPCI incidents and may be confusing. You cannot conclude from the data that chocolate eggs were clearly the dominant product containing small inedible parts, but you can conclude that most of the reported incidents involved chocolate eggs, as can be found in table 4.19.

Professor Nisticò criticises the RPA study for that it has been carried out in a superficial and preconceived way. But the data in table 4.19 clearly shows the real risk for consumers health or safety; these cases are not superficial. With the second claim that the study has been carried out in a preconceived way I do not agree. In that respect the study has been carried out properly.

Finally prof. Nisticò writes that *the conclusions of RPA study in general are not in line with the relevance of objective data*. I think that the main conclusions are in line with the data given in table 4.19, but the calculations for producing the statistical risks must be looked with care.

Ewa Klamt *et al.* claim that there is an anti-chocolate egg bias in the Report. I do not agree with that claim. Table 4.19 in the Report shows unquestionably that in most (76 %) incidents involving FPCIs in the EU in the period 1996-2002 chocolate eggs were involved. If this not correct then all the data in table 4.19 is incorrect!

The figures provided in the RPA report are in the order of magnitude of side effects of vaccination procedures. Vaccination procedures, however, are the principle weapon against an important risk, a claim that can hardly be made for inedibles in food packaging.

The report is neither complete, nor coherent, and very far from being objective. On the contrary, it appears to be deliberately biased against certain categories of products (in particular, chocolate eggs), with inconclusive evidence based upon a truncated analysis of incidental data. Moreover, it does not provide a coherent analysis of the health risks associated with FPCIs, and its conclusions are confusing and, most often, misleading. The report appears to give an incomplete treatment of the subject with great many controversial claims which are not supported by evidence.

(ii) General suggestions for improvement

I think more could be made of the role of industry with regard to food safety.

The authors could quantify the risk if they conducted a probabilistic risk assessment.

A study of death certification may help to elucidate objectively the fatalities.

Contact with the European Consumers Organisation based in Brussels (BEUCC) would be important in understanding consumer concerns and issues.

30 November 2003