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A Comparison of U.S. and E.U. Product Safety Regulations: A Case Study*

Bryan Harris**

Background

This paper compares approaches toward product safety regulations in the U.S. and European Union (E.U.) with particular reference to a selected product sector, namely products in which edible and inedible materials are combined. This combination usually takes the form of a foodstuff, mainly — but not necessarily — confectionery, together with a toy, trinket or coin. As a marketing device, this sort of combination is far from new, but it appears to have been gaining ground in recent years.¹ Whether a particular combination is inherently dangerous, dangerous unless shown to be safe in individual cases, or safe unless shown in individual cases to be dangerous, are questions that illustrate possible differences in approach by concerned authorities.²

Products involving combinations of edible and inedible materials are typically potential hazards to children rather than adults. However, cases are sometimes reported in which adults are injured. One, recently prominent in the British press, concerned an adult who had choked (not

* This paper represents continuing research and follows a somewhat broader study (that cannot yet be distributed), comparing the administrative and legislative powers of the U.S. Food and Drug Administration (FDA) and the European Commission (E.C.) respectively. A shortened version of the paper was presented at the European Consumer Safety Assn., 5th International Conference on Product Safety Research, Barcelona, April 1997. Comments by Joel E. Hoffman are appreciated.

** Mr. Harris, MA (Oxon), formerly Division Head, Internal Market & Industrial Policy, Directorate on Approximation of Laws (then) Directorate-General III of the E.C., is an Adjunct Professor of Law at Franklin Pierce Law Center.

¹ Appendix A lists products marketed in various member states of the E.U., having some characteristics of the combination products of concern. Inclusion of products in the list does not imply any judgment as to safety or whether they would be allowed or prohibited elsewhere; the list simply shows the range of products and their characteristics.

² References to U.S. authorities generally mean the FDA, as well as to effects of U.S. legislation. References to E.U. authorities generally mean the E.C., as well as effects of E.U. Directives.

fatally), by a device in a beer can designed to give the beer a better head.³ But there are several respects which differentiate this case from those affecting children. Perhaps one of the most important differences was that the device was not intended to be detached from the can; the danger resulted from the fact that it became detached. In most cases affecting children, the danger arises precisely because the inedible element begins detached or is intended to be detached. A further characteristic of the beer can case was that the inedible element had a function. In this it resembled, e.g., the stick in a lollipop, which is functional but normally inedible. In a sense, the toy or trinket in confectionery may be functional, but its function is not directly related to the consumption or quality of the main product.⁴

Combinations of edible and inedible substances are not limited to confectionery. For example, it is common for packets of cereal and the like to contain plastic trinkets. Anyone, whether child or adult, may find the trinket in their plate and possibly even in their mouth. In a recent case in Belgium, an adult woman died after swallowing a plastic disc, known as a “pog” or “flippo”, included in a packet of potato chips.⁵ However, there is a distinction, both in practice and in law, between loose inedible objects and those imbedded in an edible substance. Both are potentially dangerous but may be treated differently under the law.

This difference is illustrated by the example, on the one hand, of the loose combination in cereals and, on the other hand, of the imbedding combination in the old English tradition of cooking a Christmas Pudding with “threepenny bits” in it. These coins, withdrawn many years ago, were slightly smaller than a dime; and it was fun for children to see whether their portion contained the treasure. Yet, the coins were often swallowed and increasingly safety-conscious

³ The Times (London), May 8, 1994.

⁴ Products in Appendix A illustrate various combinations of edible and inedible materials.

⁵ [Belgian] “Health Minister, Marcel Colla, wants to ban cardboard and plastic collectibles from crisp packets after an elderly woman choked on a Crocky-cap and died.” The Bulletin, Feb. 8, 1996. At the time of writing, the Belgian government has adopted an amendment to its food safety laws, which will come into force shortly, but the amendment in its present form covers only commingled and not embedded materials. The Portuguese government is also understood to be considering legislation, following a similar incident.

parents abandoned the tradition. For a time, "sixpenny bits" were used. Although these too were later withdrawn from circulation, they were bigger and more obvious — but, if swallowed, potentially more dangerous.⁶ In certain European countries, the Feast of the Three Kings continues to be celebrated with a special cake in which a trinket is imbedded. The person receiving the slice with the trinket is the King for the day. In France, for example, the Galette des Rois contains a trinket — la feve — usually in the form of a small ceramic figurine.

The risk in imbedding coins, toys or trinkets in food generally, and in confectionery in particular, is illustrated by a 1991 case reported from Sheffield, England.⁷ A child died after swallowing a toy imbedded in chocolate. It is not an isolated case; but for legal reasons the facts in such cases are not always readily available.⁸

There is a difference between the danger inherent in the objects imbedded in edible material and the danger inherent in imbedding objects in edible material. Some seem to be natural hazards for children, e.g., balloons and small jewellery.⁹ But some objects not otherwise dangerous may become a risk when imbedded in edible materials. It follows, as a general principle, that laws on dangerous toys may not, in themselves, adequately protect children against the hazards of eating materials containing imbedded toys or other objects. By the same token, toys, trinkets, coins, disks or gadgets, which satisfy normal safety tests, may not be safe when combined with foodstuffs, especially when imbedded in them.¹⁰

⁶ "Coins remain the most common foreign objects (52%) that are aspirated or ingested in children 0 to 3 years old." James S. Reilly & Margaret A. Walter, *Consumer Product Aspiration and Ingestion in Children*, AB-EA 1991. "But coins are not necessarily the most dangerous: spherical objects are most likely to cause asphyxiation." *Id.*

⁷ Publicly reported details are in Appendix B.

⁸ Claims against product manufacturers may be terminated by a confidential settlements. Also, in Europe, medical statistics are not compiled in such a way that accidents, fatal or not, due to consuming foodstuffs in which inedible materials have been mixed or embedded, are not separately identifiable from other accidents. See, E Petridou, *Injuries from Food Products Containing Inedibles*, (April 1997) Athens University Medical School.

⁹ See, *Childhood Deaths from Toy Balloons*, 144 *Am. J. Dis. Child.* 1221 (1990) and *Earring Aspirations and Other Jewellery Hazards*, 78 *Pediatrics* 494 (1986).

¹⁰ This point was missed in the Answer to a Parliamentary Question in the House of Lords. The question rightly referred to the possible danger when "small toys [were]

The dangers of swallowing inedible objects may depend largely on the person's age; and evidence suggests that the dangers are greatest for children up to the age of five. There is room for differences in the legal approach to the problem: Some jurisdictions regard the age of three as decisive. Yet, although differences may affect either the substance of the law or the type of warning products carry, they are only matters of degree. There seems to be more common ground in the objective determination of the size of objects which, if swallowed, are deemed dangerous to young children.¹¹ The question of age may determine the nature of any warning on the product, but the inclusion of a warning should not excuse marketing an inherently risky product.

To summarize the background to legal considerations influencing U.S. and U.K. legislators, products that combine edible and inedible materials raise several questions including:

- the purpose of the combination
- whether combinations are commingled or imbedded, and
- the age of persons potentially at risk.

Legal Considerations

If it is accepted that laws on product safety should apply, directly or indirectly, to combination products, it is open to legislators to frame the rules on the basis of the safety of:

- consumer products generally,
- toys (in the widest sense),
- food products generally or confectionery in particular, or
- combination products as such.

The following shows how problems are addressed by U.S. and E.U. legislators respectively.

included with foodstuffs in packets". But the Minister's reply was almost entirely concerned with the inherent safety of the toys themselves and ended with the observation: "When I consider the objects which small children throw at each other, this [the Pog] is probably one of the most harmless I have ever seen." H.L. Rep., 20 Feb. 1996, col. 968.

¹¹ On the question of age, *see, e.g.*, U.S. Consumer Products Safety Commission (C.P.S.C.), *Guidelines for Relating Children's Ages to Toy Characteristics* (1985). Regarding criteria for the size of objects that may cause a risk of choking, *see* 16 C.F.R. § 1501.4 (1996).

U.S. Regulations

In the U.S., the applicable rules are firmly contained in the laws on food safety.¹² These rules provide inter alia that the sale of adulterated food is prohibited. A food is deemed adulterated inter alia if “it bears or contains any poisonous or deleterious substance which may render it injurious to health...”¹³ Moreover, the statute provides that a food is adulterated “If it is a confectionery, and... has partially or completely imbedded therein any non-nutritive object...”¹⁴

This recently came to light when the FDA learned of plans to introduce a product called “Nestlé Magic” by Nestlé U.S.A. It is a hollow chocolate ball that contains a two toned plastic ball with a tiny Disney character inside. Nestle U.S.A. had planned to market the product this summer but is currently waiting for approval while the FDA’s inquires about its safety.¹⁵

The foregoing provision on adulteration is, however, subject to an important qualification:¹⁶

except that this subparagraph shall not apply in the case of any non-nutritive object if, in the judgment of the Secretary as provided by regulations, such object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health....

Thus the scheme of the rules prohibits confectionery in which any non-nutritive object is partially or completely imbedded, unless it can be shown (in practice, to the FDA) that two criteria are met. First, that the object is of practical functional value to the confectionery product and, second, that the object would not render the product injurious or hazardous to health. Both criteria must be met. It would not, for

¹² Federal Food, Drug and Cosmetic Act § 402, 21 U.S.C. § 342 (1997 supp.). It is therefore unnecessary to look at the first two categories in Legal Considerations, *supra*, although these are relevant to E.U. law.

¹³ 21 U.S.C. § 342(a)(1).

¹⁴ 21 U.S.C. § 342(d)(1) In adopting the current form of § 402(d) in 1966, Congress deliberately rejected an FDA proposal to overturn *Cavalier Vending*, *infra* note 18 because it wished to preserve the Court’s distinction between “commingled” and “embedded”. See also, Dorn *infra*.

¹⁵ See, Adrienne Dorn, *Introduction of Non-Food Items into Candy Raises Safety Concerns at FDA*, Food Chemical News, June 23, 1997, at 23–24. Just before going to press, Nestlé filed a rule-making petition to amend the FDA regulations.

¹⁶ 21 U.S.C. § 342(d)(1).

example, be enough to show that the lollipop stick was of practical functional value to the confectionery product (although that would generally be the case); it would also be necessary to show that the lollipop stick would not render the product injurious or hazardous to health (which might not always be the case). Moreover, the practical functional value must be related to the confectionery product: it would not be enough to show that the imbedded object had a practical functional value in some other context — as a toy, for example.¹⁷

It was explicitly decided in a case antedating the current statute, that commingling, as distinct from imbedding, is not necessarily prohibited. The Fourth Circuit held that commingling candy and trinkets in vending machines did not violate FDA's adulteration provision. The Court went out of its way to differentiate between objects contained with and objects placed alongside confectionery. In deciding that a violation had not been committed, the Court pointed out:¹⁸

We think it perfectly clear, however, that the trinkets, which correspond to the prizes contained in the candy "prize boxes" of an earlier day, are not contained within the gum or candy within any possible meaning of the Act. If we look to its language, the deleterious subject must be contained within the food product offered for sale, and the trinkets are not contained in the pieces of gum or candy but are merely sold along with them. Neither the gum nor the candy contains the trinkets but is contained along with the trinkets in the bowl of the vending machine.

By the standards set out above, it would appear that many products listed in Appendix A would probably pass muster, to the extent that the "object" and the confectionery or other foodstuff were separated. Yet, it would appear that the product described in Appendix B would have probably been prohibited under U.S. rules.

¹⁷ See arguments of counsel to the Department of Health & Human Services in FDA Docket #89P-0160/CP (concerned an application for exemption under the proviso, subsequently withdrawn).

¹⁸ *Cavalier Vending Corp. v. U.S.*, 190 F.2d 386 (4th Cir. 1951). Note that the decision was in the context of a *seizure* action, not administrative rule-making. If the question were to arise today in the context of an FDA regulation based on § 701 (a) and the general "added poisonous or deleterious" clause of § 402(a), the regulation would probably be upheld.

E.U. Rules (Regulations/Directives)

Rules at European level govern general product safety,¹⁹ the safety of toys,²⁰ products which, appearing to be other than they are, endanger the health or safety of consumers²¹ and materials and articles intended to come into contact with foodstuffs.²² Thus, the principal rules presently in force fall within the first two categories in Legal Considerations, *supra*. The more detailed rules, as seen below, do not fall squarely within the last two categories.

The Directive on the general safety of products requires producers to place only safe products on the market; to provide consumers with the relevant information to enable them to assess the risks inherent in a product and to take appropriate action including, if necessary, withdrawing the product in question from the market to avoid these risks.²³ In the absence of a general food safety directive corresponding to the provisions of the U.S. law quoted above, the general product safety directive may be the only form of general consumer protection in this field.²⁴ It is worth noting that the Directive contains provisions on warnings to consumers. These do not, however, exempt any person from compliance with the other requirements laid down in the Directive. On the other hand, the Directive provisions only apply so far as there are no specific provisions in rules of E.C. law governing the safety of the products concerned.²⁵ Thus the principle *lex specialis generalibus derogat* explicitly applies. Since the rules considered in the next few paragraphs do not appear to fully cover the type of case discussed in this study, the Directive may be considered to apply.

¹⁹ Council Directive 92/59 of 29 June 1992, General Product Safety, O.J. (L 228).

²⁰ Council Directive 88/378 of 3 May 1988, The Approximation of the Laws of the Member States Concerning the Safety of Toys, O.J. (L 187). (Subsequently amended.)

²¹ Council Directive 87/357 of 25 June 1987, The Approximation of the Laws of the Member States Concerning Products Which, Appearing to be Other Than They Are, Endanger the Health or Safety of Consumers, O.J. (L 192).

²² Council Directive 89/109 of 21 Dec. 1988, The Approximation of the Laws of the Member States Relating to Materials and Articles Intended to Come into Contact with Foodstuffs, O.J. (L 40).

²³ Council Directive 92/59, art. 3, 1992 O.J. (L 228).

²⁴ However, it appears that the Commission is preparing a Green Paper suggesting a general legislative text on foodstuffs. This may provide an opportunity to incorporate into E.U. law provisions both of a general nature and, perhaps, some more specific aspects referred to in this study.

²⁵ Council Directive 92/59, art. 1, 1992 O.J. (L 228) 2.

Much depends therefore on the manner in which the Directive is implemented in Member States.

Under the Directive on the safety of toys, it is provided that toys may be placed on the market only if they do not jeopardize the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behavior of children.²⁶ Member States are required to take all steps necessary to ensure that toys cannot be placed on the market unless they meet the essential safety requirements set out in the Directive;²⁷ and must not impede marketing of toys that satisfy its provisions.²⁸ However, in the type of case envisaged in this study, it is not necessarily the risk inherent in a toy that is at issue, but the risk of imbedding a toy (or other object), even if that toy itself is safe, in an edible product. Therefore, on its face, the Directive does not address the problem. Although the rules refer to the use of a toy "as intended or in a foreseeable way", it would be stretching the meaning of these words rather far to suggest that they cover the case of a toy embedded in an edible product.

Two other features of the Directive merit a brief mention. The first is that the Directive provides for an E.C. mark of safety.²⁹ It needs to be emphasized, however, that while a toy imbedded in an edible product may in itself qualify for a safety mark, the guarantee of safety implicit in the mark does not extend to the product in which the toy is imbedded. The second point is that the Directive includes a requirement that toys clearly intended for use by children under 36 months should be of such dimensions as to prevent their being swallowed or inhaled;³⁰ a European standard provides an objective test, similar to that applying in the U.S., of those dimensions.³¹ With regard to the age, the Directive does not specify how to determine whether the toy is intended for children under three years of age. A manufacturer's statement that the toys are not intended for those under

²⁶ Council Directive 88/378, art. 2, 1988 O.J. (L 187) 1.

²⁷ *Id.*, art. 3.

²⁸ *Id.*, art. 4.

²⁹ *Id. and passim*, at art. 11.

³⁰ *Id. and passim*.

³¹ EN 71-1 3.2.2.1 (prohibits toys or parts or both which fit into the simulated esophagus at 4.16 of the Standard).

three could render the anti-choking provisions inapplicable. (This contrasts with U.S. law, which provides for age grading guidelines as a means of determining the likely age group.)

Under the Directive on products which, appearing to be other than they are, endanger the health or safety of consumers, Member States have to take all the measures necessary to prohibit the marketing, import and either manufacture or export of the products concerned. At first sight, this Directive may seem to apply to the type of product considered in this study.³² The products to which this Directive applies are:³³

those which, although not foodstuffs, possess a form, odor, color, appearance, packaging, labelling, volume or size, such that it is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them, which might be dangerous and cause, for example, suffocation, poisoning or the perforation or obstruction of the digestive tract.

However, on closer examination, it is doubtful whether this wording covers inedible objects imbedded in edible materials. In the first place, the inedible object may satisfy the requirements of these provisions as regards its form, odor, color, appearance, packaging (if any), labelling (if any), volume and size. In the second place, it may not always be a question of confusing the inedible object with a foodstuff, but rather of swallowing the inedible object accidentally. It is the imbedding of an inedible object, rather than the confusing nature of the inedible object itself, which creates the hazard. A more characteristic target of the Directive is probably flavored india-rubber, which a child mistakenly believes he can eat. At the same time, it is often because the non-nutritive element is imbedded within the foodstuff that it may be confused with the foodstuff. As an Easter egg typically contains edible elements, a similar item containing elements which are inedible, but which have an edible odor may create a hazard.

Although the Directive on materials and articles intended to come into contact with foodstuffs also appears to be relevant to the type of case discussed in this study, a closer examination suggests that once

³² Council Directive 87/357, art. 2, 1987 O.J. (L 192).

³³ *Id.*, art. 1(2).

again it may not, at any rate when implemented by national law, succeed in catching inedible objects imbedded in edible foodstuffs. The materials and articles in question are those which, in their finished state, are intended to be brought into contact with foodstuffs.³⁴ However, this general provision is qualified, both in its wording and in the form taken by the series of Commission Directives applying it,³⁵ by the statement that these materials and articles must not:³⁶

- ... transfer their constituents to foodstuffs in quantities which could:
 - endanger human health,
 - bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

The qualification suggests that the typical target of this legislation is the kind of wrapping material which can transfer some of its qualities to the foodstuff making the foodstuff dangerous to eat. It does not directly address the problem of articles or materials whose hazard lies in the very fact of their being imbedded in edible products.

In all cases in which E.U. rules take the form of Directives, there is room for variation in the manner in which the rules are implemented.³⁷ It follows that, in some Member States, the Directives are incorporated into more complete and systematic codes of protection than in other Member States. The individual laws of the Member States are outside the scope of this study but Appendix C briefly compares the U.S. laws, E.U. laws and one Member State, France. It is hard to avoid the conclusion that, both at E.U. level and in the Member States as a whole, there are some gaps in protection afforded by the product, toy and foodstuffs safety laws and that one of these gaps is revealed by the type of case with which this study is mainly concerned.

³⁴ Council Directive 89/109, art. 1, 1988 O.J. (L 40) 1.

³⁵ *See*, Commission Directive 90/128 of 23 Feb. 1990, Plastic Materials and Articles Intended to Come into Contact With Foodstuffs, O.J. (L 75).

³⁶ Council Directive 89/109, art. 2, 1988 O.J. (L 40).

³⁷ E.C. Treaty, art. 189.

General Conclusions

Some differences between the U.S. and E.U. approaches to product safety laws lie in the different methods of legislating. U.S. legislation, like that of some individual Member States of the E.U., seems to allow for a more comprehensively codified set of rules. In a codified system, amendments seem to be more readily incorporated than the apparently piecemeal series of Directives briefly considered here. Moreover, the existence of an administrative body with targets as specific as those of the FDA has some advantages, in terms of the coherence of legislation in any given field, over a body with such widely based administrative responsibilities as the E.C.. There are various areas in which proposals are being made for some of the Commission's responsibilities to be transferred to more independent and specialized bodies.³⁸ Perhaps eventually there will be an E.U. agency similar to the FDA, to be given power to operate through directly applicable regulations, more closely resembling the U.S. regulatory system. As a result, a clearer pattern may emerge in the E.U. system at both the E.U. and national levels. It would, however, be rash to overlook the importance which Member States attach to the principle of subsidiarity³⁹ and the strong arguments which will be needed, going outside the terms of this study, to persuade Member States that a strong E.U. agency may be preferable to the fifteen different jurisdictions presently responsible for applying E.U. Directives.

Meanwhile, as this study suggests, the current approach in the E.U. to food safety, reflected in the absence of a codified set of rules or an equivalent to the FDA, fails to provide comprehensive consumer protection. The point is illustrated, without any judgment being passed on other areas of regulation, by the respective rules in the E.U. and U.S. governing products which involve a combination of edible and inedible materials. E.U. rules do not have the same sort of general prohibition on the adulteration of foodstuffs as is found in U.S. legislation; nor does it therefore have specific prohibitions of the sort found in the descriptions of adulteration, including the imbedding of inedible objects in edible materials; nor is there a mechanism of the sort envisaged in the proviso

³⁸ For example, in the field of enforcement of the rules on competition (antitrust). Germany is believed to strongly support this proposal.

³⁹ E.C. Treaty, art. 3(b).

to the prohibition, by which the imbedding in individual cases can be justified. As this study suggests, gaps of this kind may more likely arise under the E.U. system, partly because of the different system of legislation and partly because of the different system of administration. But this is not to suggest that the gap need be left open: a relatively simple E.U. Directive, or a relatively simple provision in a general food safety directive, can close it.⁴⁰

Appendix A

Non-Exhaustive List of Commingled and Embedded European Products

This indicates the proliferation of combined products, in the sense used in this study. Not all products are either "commingled" or "embedded." In some, the inedible elements are loose; in others, completely separate. Inclusion implies no judgment whatever as to whether products, separately or together, are safe or not nor whether, under any given jurisdiction, the products might be allowed unless specifically prohibited or prohibited unless specifically allowed. The presumption is that, under national and E.C. laws as they stand, the products are allowed.

Every effort has been made to ensure the correctness of this information. It is difficult, however, to ensure the correct transcription of some non-English names and to ensure that the products listed continue to originate from the same manufacturers as at the time when the list was prepared.

#	Where sold	Product Description
1	Germany	"Kipt 'n Kuck" by Borgmann. Yoghurt with toy in top compartment and yoghurt below under silver foil.
2	Germany	"Frufoo" by Onken. Yoghurt (or similar) in flat round pot with central removable plastic capsule containing toy.
3	Italy	"Supermario" by Zaini. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
4	France	"Tombola" by Chupa Chups. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
5	Greece	"Ovolino" by Mario Bulgari & Co. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
6	Greece	"Kinder [Greek word]" by Ferrero. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
7	Italy	"Small Surprise" by Orsi. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
8	Germany	"Power Rangers". Plastic face which opens in half and contains sweets in a bag and a toy.
9	Ireland	"Casper". Plastic face which opens in half and contains sweets in a bag and a toy.
10	Germany	"Glucksbox" by Haribo. Packet of chewy bears with a plastic container mixed amongst them containing a toy.

⁴⁰ See *supra* note 24.

- 11 Germany "Hanuta" by Ferrero. Small chocolate wafer biscuits wrapped in foil with a glittering sticker inside the foil.
- 12 France "Disney Family" by Nestle. Hollow chocolate sphere in wrapper with plastic capsule inside chocolate containing toy.
- 13 Greece "Tombola" by Chupa Chups. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy
- 14 Greece "Super Toy" by Algida. Ice cream in top of plastic tub with toy contained in hollow bottom under silver foil.
- 15 Greece "Karambola" by Evga. Ice cream in top of plastic tub with toy contained in hollow bottom under silver foil.
- 16 Greece "Laky-Cap" by Delta. Ice cream in top of plastic tub with toy contained in hollow bottom under silver foil.
- 17 Greece "Tapes" by Chipita. Packet of savoury snacks with a round cardboard object mixed in depicting a super-hero.
- 18 Greece "Goody's Junior" by Goody's restaurant. Children's meal in box by fast food chain, with a toy in wrapping inside box.
- 19 Greece "Buko Kid" by MD Food. Tube of cheese spread, the cap of which is a toy head.
- 20 Greece "Cornflakes" by Kelloggs. Box containing pack of cornflakes with football cards in wrapping among the cornflakes.
- 21 Greece "Pipilonia" by [?] Plastic tube full of chewing gum balls, the cap of which is a toy plastic dummy.
- 22 Austria "Playball" by Milky Way. Hollow chocolate sphere in wrapper with plastic capsule inside chocolate containing toy.
- 23 France "Pimousse" by V.P.S.A. Bag containing smaller bags of sweets and one bag with toy inside.
- 24 France "Power Rangers Tombola" by Chupa Chups. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 25 France "Kinder Surprise" by Ferrero France. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 26 Germany "Kinder Oberraschung" by Ferrero. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 27 Germany "Schleckbrause" by A. Eicheimaan KG. Plastic fruit-shaped containers filled with sherbet with screw-lids.
- 28 Germany "Frufoo" by Onken. Box containing 4 chocolate UFOs with milky filling, and one square plastic container with toy.
- 29 Germany "Push Pop" by Topps Ireland Ltd. Lipstick-shaped plastic with marker-pen type detachable lid containing push-up lolly sweet.
- 30 Germany "Bon-bon Sea-Schnulli" by Trawigo. Plastic pacifiers, the 'teat' of which is an edible 'jewel' made of sherbet sweet.
- 31 Germany "Bon-bon Dino-Ei" by Trawigo. Plastic egg which contains toy and small packet of 'swizzles' sherbet sweets.
- 32 Germany "Bon-bon Licksi-Lolly" by Trawigo. Imitation ice cream, coloured plastic cone and hard sherbet-sweet 'ice cream'.

- 33 Germany [No name] by Rodako. Plastic guitar shape with battery included to play tunes, opens, filled with various sweets in plastic wrapping.
- 34 France "Bob's" by Jacquot. Plastic bag contains mixture of sweets (choc cigs, bonbons) and toys (plastic capsule with blow pipe, toy lighter).
- 35 Italy⁴¹ "Dulcino" by Dulciar. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 36 Italy "Small surprise" by Orsi SNC. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 37 Italy "Puff Surprise" by Mon Desir SNC. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 38 Italy "Ovodi Sorpresa" by Mon Desir SNC. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 39 Italy "Ovolino" by CCIAA. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 40 Italy "Ciocco & Ciocco Sorpresa" by Ciocco & Ciocco. Wrapped hollow chocolate egg with plastic capsule inside chocolate containing toy.
- 41 Italy "Natal Surprise" by Nutal SNC. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 42 Italy "Supermario" by Zaini Luigi. Hollow chocolate egg in wrapper with plastic capsule inside chocolate containing toy.
- 43 Italy "Wunder Sorpresa" by Cedrinca. Hollow chocolate egg in wrapper with plastic capsule inside containing toy.

Appendix B

The Sheffield Case⁴²

This report was checked against confidential documents, kindly provided by HM Coroner for South Yorkshire (West). Apart from the misspellings of "Caren" and "Chupa Chups," the report seems clear and accurate.

Safety Dilemma after Egg Choking Tragedy

A chocolate egg containing a plastic container that led to the death of a four-year-old Sheffield girl had passed European and British safety tests, the distributors said this week. London-based Chupa Chuks [sic] UK Ltd said they would continue selling them despite the tragedy involving Caron [sic] Day of Newbould Crescent, Beighton.

Caron choked to death on the plastic container inside a 39p Bart Simpson novelty egg. The container holds a toy. Police and ambulance men tried to revive her and she was taken to hospital with the one-and-a-quarter inch diameter, one-inch long piece of plastic still in her throat, but doctors were unable to save her.

Tony Killeen, general manager of the distributors, said: "We have taken every step to make sure that this is a safe product. It has passed all the European and British safety tests.

⁴¹ All following Italian products were sold at the ISM trade fair.

⁴² From the Sheffield Telegraph, Friday, Nov. 8, 1991.

"These plastic containers are sold on their own in shops with toys by other distributors. They are also used in Christmas crackers and bubble gum is sold in them as well.

"There are in excess of 700 million of them sold in Europe each year. I have been in touch with trading standard officers in Sheffield and elsewhere and they say there is no reason why the product should not continue to sell.

"I sympathize with the family and their personal tragedy, but the police are investigating the matter and we have to wait until we have the true facts of the case."

Sheffield Trading Standards spokesman John Sheppard promised an investigation following the inquest. "Obviously because this tragic death involves sweets and toys we will be investigating the circumstances as soon as the precise cause of death is known.

"These children's novelties are already covered by strict regulations and usually carry warnings that they should not be given to children under the age of five."

Meanwhile shop owner Peter Clifton, who sold the egg that killed Caron, has taken them off the shelves of his store at High Green. "I am terribly upset by what has happened and I will not be selling these eggs again."

Caron's mother, Ann, wants the eggs taken off the shelves of every shop in Britain. She said Caron's aunt had bought four as a treat for her four children. "These things should be banned, they are not even safe for adults. You have to bite the plastic to open the capsule."

At the opening of Caron's inquest on Wednesday [November 6, 1991], coroner Christopher Dorries said: "the mother put her to bed around 7.30pm on November 2 and when she went to put her sister to bed she found her dead. She was taken to the Children's Hospital but was dead on arrival."

Appendix C
A Brief Comparison of the Laws of the U.S., E.U. and France

<i>Subject</i>	<i>U.S.</i>	<i>E.U.</i>	<i>France</i>
Embedded or commingled nutritive and non-nutritive elements	Section 402(d)(i) of the Federal Food, Drug and Cosmetic Act	No equivalent	No equivalent
Toy safety or hazardous products	Section 2(5) of the Federal Hazardous Substances Act	Toy Safety Directive	Implementing Decree 89-662
		Confusingly Similar Foodstuffs Directive	Implementing Decree 92-985
		General Product Safety Directive	No implementation (Pre-existing General Product Safety Law, 1983)
Safety Standards	Code of Federal Regulations (CFR)	EN71	NFEN 71
Anti-Choking Provisions	15 CFR Part 1501	EN71 Part 4.16	No additional requirements
Age Grading	15 CFR Part 1501	Toy Safety Directive Annex, II, Part II	No additional requirements
	CSPC Guidelines	No equivalent	No equivalent
Warning	"Warning choking hazard: small parts"	Must state that toy is unsuitable for under-3 and why	Also, consumer must be "sufficiently informed"
Enforcement	CPSC initiates action	Member States: no central agency	DGCCRF may order product withdrawal

