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# Food Safety in the United States and the European Union: Sequel to a Case Study

Bryan Harris\*

## Introduction

Two years ago, RISK carried an article comparing the respective attitudes and approaches of regulations and regulators in the United States and European Union towards hazards to children from confectionery in which inedible material is imbedded.<sup>1</sup> The present article examines the response of U.S. and European Union regulators to a series of challenges relating to toys imbedded in candy.

Several points made in the earlier article have been illustrated by subsequent events, in particular:

- (1) the U.S. legislation relating to toys imbedded in candy is exemplified by the Food and Drug Administration's recognition that the hazard is real;
- (2) the complexity and uncertainty of the corresponding rules in the European community; and
- (3) the need to persuade European regulators that the hazard calls for action.

## The United States

Considering first the developments in the United States during the last two years, it is worth commenting on the *Ferrero* and *Nestlé* cases and the informed criticisms of the appropriateness of the regulations.

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1 See Bryan Harris, *A Comparison of U.S. and E.U. Product Safety Regulations: A Case Study*, 8 RISK 209 (1997).

At the time of the earlier article, Ferrero withdrew its suggestion that the rule on imbedded “non-nutritive objects” should not apply to its product, “Kinder Eggs”; on August 18, 1997, the importers of Kinder Eggs, Kreiner Imports Inc. of Chicago, recalled several thousands of the product. The milk chocolate Kinder Eggs contain an oval-shaped plastic capsule, with a toy inside. Despite Ferrero’s lack of knowledge of any injuries in the United States involving the product, it was recalled “to prevent the possibility of injury to children under three years of age.”<sup>2</sup>

Soon after publication of the earlier article, Nestlé USA Inc. introduced a new element. Nestlé planned to market a candy product in the United States called “Nestlé Magic,” consisting of a small plastic Disney character inside a plastic shell covered with chocolate. Instead of seeking an exemption for the product, as Ferrero had done, Nestlé adopted a different tactic: it formally submitted to the Food and Drug Administration (FDA) a Citizen Petition requesting the issuance of a regulation “to provide for the safe and orderly marketing of a combination food/toy product sold to children of all ages and adults.”<sup>3</sup> The Petition was dated June 25, 1997. Marketing of the product began early in July 1997. In a letter to Nestlé dated July 7, the FDA determined that Nestlé Magic is a confectionery candy product included with a non-nutritive object, that is, a plastic ball containing a toy imbedded inside the candy. The letter stated: “Nestlé markets the product at risk of agency enforcement action.”<sup>4</sup> In August 1997, the attorneys-general of twelve states petitioned the FDA to “take immediate action to address this blatant non-compliance, before an avoidable tragedy occurs.”<sup>5</sup> In addition, the attorney general of Minnesota, which has a state law comparable to the federal law, threatened to take legal action to ban the product from the state.<sup>6</sup>

<sup>2</sup> This paragraph is based on a press release (PRNewswire, dated August 18, 1997).

<sup>3</sup> Letter, from Steven B. Stainburn, Counsel for Nestlé USA Inc., to the Food and Drug Administration (June 25, 1997) (on file with the Food and Drug Administration).

<sup>4</sup> Letter, from Hubert H. Humphrey III, Attorney General, State of Minnesota, to Michael A. Friedmann, Lead Deputy Commissioner, Food and Drug Administration (August 27, 1997) (on file with the Food and Drug Administration).

<sup>5</sup> Letter, from Richard Blumenthal, Attorney General, State of Connecticut, to Dr. Fred R. Shank, Director of the Center for Food Safety and Applied Nutrition, Food and Drug Administration (August 27, 1997) (on file with the Food and Drug Administration).

Whether for these or for other reasons, on October 1, 1997, Nestlé withdrew its product.<sup>7</sup> This was not the end of the story; the thirteen attorneys-general pressed a hazardous product suit, resulting in a settlement of \$1.5 million, reached on March 10, 1999.<sup>8</sup>

When Nestlé withdrew its product, it stated that “an unresolved technical, legal problem” relating to the federal law which prohibits non-nutritive objects imbedded in confectionery was the reason for its voluntary withdrawal of the product and that “the absence of a final resolution of this legal issue has created an unfavorable environment to market the product.” Nestlé then petitioned the FDA seeking a resolution to the issue. The arguments contained in the company’s petition merit discussion, since they reflect a genuine misunderstanding of the purpose of the law.

In the petition, Nestlé requested that the FDA promulgate a regulation permitting confectionery to contain within it a ball or similarly shaped non-nutritive object, provided that it and its component parts are of sufficient size to prevent accidental ingestion and that they comply with all other applicable safety requirements. According to Nestlé’s petition, any non-nutritive items contained within the confectionery, such as a toy, would have to comply with the regulatory requirements of the Consumer Product Safety Commission, while the food content would have to comply with applicable regulations of the FDA.<sup>9</sup>

In other words, the safety of the confectionery would be separate from the safety of the non-nutritive object or objects within it: each of the two elements in isolation must satisfy certain tests or requirements, but not jointly. This is a seductive concept, and one that adds complexity to the discussion of how to deal with the problem. It is seductive in that it appears ostensibly reasonable: if each of the potential dangers is covered individually by appropriate regulations, it would appear that there is nothing more to worry about. Moreover, as a

<sup>6</sup> See Letter, from Hubert H. Humphrey III, Attorney General, State of Minnesota, to Mr. Robert W. Schultz, President and CEO, Nestlé USA Inc. (August 27, 1997) (on file with Nestlé USA).

<sup>7</sup> Washington Post, October 2, 1997.

<sup>8</sup> Reuters: Press Release from Nestlé USA Inc. (Mar. 11, 1999).

<sup>9</sup> A statutory provision cannot be amended in this way by a regulation; but it is to some extent open to “interpretation,” “application” or “implementation.”

general principle, the larger the non-nutritive object, over a given minimum, the smaller the danger of ingestion,<sup>10</sup> and indeed the Nestlé proposal contains a reference to a minimum size.

However, the argument for separating the two elements obscures both the essential feature of the federal law and the attempts to secure adequate consumer protection in countries which have no similar law. The federal law is intended to provide proper protection where edible and non-edible materials are combined. The heart of the law is that the combination of materials in itself creates a hazard. One hazard may reside in the quality of the confectionery; a second hazard may reside in the nature of the object imbedded in the confectionery; but the third hazard, and the one which the federal law addresses, is the combination of confectionery and other objects.<sup>11</sup> If young children were as sensible, discriminating and literate<sup>12</sup> as adults might wish, the third hazard might be greatly reduced. As it stands, the Nestlé proposal would virtually remove protection from the third hazard and would thereby take the heart out of the federal law.

Both Nestlé's petition to the FDA and a subsequent article discussing the petition<sup>13</sup> point out that the non-nutritive object might be safe by itself and, indeed, pass the kind of test which is applied to toys sold separately from confectionery. It needs to be emphasized that there is a difference between the type of hazard involved where objects are "commingled" and the type of hazard involved when they are imbedded. While the U.S. law does not extend to prohibit commingled objects within the context of "adulterated" foods,<sup>14</sup> the law in Europe tends in the opposite direction, with several national laws aimed at prohibiting commingled but not imbedded objects in food.

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<sup>10</sup> See discussion *infra* to the recently introduced Cadbury's product.

<sup>11</sup> See discussion *infra*.

<sup>12</sup> Labelling is no answer for the very young; and it is not always an adequate answer for older persons. There are, after all, limits to the extent to which the marketing of dangerous products can be defended on the basis of warning labels. (A slightly bizarre feature of the Ferrero case was that the warning labels on Kinder Eggs sold in the U.S. were in German. See *supra* note 2.)

<sup>13</sup> Fred H. Degan & Steven B. Steinborn, *Toys and Confectionery — A Legally Compatible Combination*, 53 Food Drug L. J. 9 (1998).

<sup>14</sup> S. Rep. No. 89-1217 ("The [Senate] committee did not feel that [an amendment prohibiting commingling] was germane to a measure principally concerned with safe food additives").

The petition attempts to limit the statutory meaning of the word “imbedding.” Inasmuch as the prohibition applies to objects imbedded in confectionery, it is fair to say that if the objects are not imbedded, the prohibition fails *in limine*. Much depends therefore on what exactly imbedding means. Webster’s definition cited in the article provides two similar but distinct meanings: (a) “to fix securely in a surrounding mass”; and (b) “to enclose in a matrix.” The analogies of stones imbedded in cement, girders in brickwork, or fossils in mountains<sup>15</sup> are not germane since it would be hard to imagine any edible substance with this type of consistency, especially with an inedible substance inside it. It follows that a broader definition is more realistic. Nevertheless, there is a useful point to be learned from this discussion. If the U.S. statute is amended, the prohibition as discussed would be weakened, whether by looser wording or otherwise; and, by the same token, when European laws catch up with U.S. laws in this field, the problem of finding the appropriate term for “imbedding” in each of the eleven official languages of the European Union will have to be examined with some care.<sup>16</sup>

### Europe: Developments at European Union Level

In Europe, the legal position has remained static since the earlier case study was prepared. The tendency is to treat the problem of objects imbedded in confectionery as analogous to either toy safety or product liability, rather than as adulterated food. As previously discussed, treating the matter as one of toy safety is only a part of the remedy. Rules on product liability may also prove a partial sanction; but the Birmingham case,<sup>17</sup> as referred to in the annex, illustrates that both the European rules and the ways in which those rules are transposed into national law result in a mass of potential pitfalls. Meanwhile, the Commission of the European Communities in Brussels has invited comments on how the product liability rules may be improved,<sup>18</sup> concluding that an amendment of the rules on product

<sup>15</sup> It should be added that, in the last event, even some edible substances imbedded in candy, such as nuts, may present some danger.

<sup>16</sup> European sources sometimes refer to objects “encapsulated” within confectionery. This is acceptable, provided it does not exclude the concept of being “wholly or partly” imbedded.

<sup>17</sup> *The Queen v. Birmingham City Council ex parte Ferrero Ltd.*, 154 J.P. 661 (Q.B. 1990).

liability would be a start. But the feeling is that a more effective approach will be through the development of specific and unambiguous rules on food safety. There is some evidence that suggests this feeling is at least partly shared by the Commission.<sup>19</sup>

One of the main problems with the general product safety approach is that applicable standards are not as rigorous as they are for food safety, and products which would automatically fall foul of rules on the adulteration of foodstuffs may or may not be regarded as unsafe products. Through the efforts of consumer and related associations, some progress has been made to persuade the authorities that inedible materials imbedded in confectionery is an adulteration of food and thus is an unacceptably unsafe product; however, the Emergency Committee convened by the Commission has repeatedly deferred action.<sup>20</sup>

Given that food safety rules, rather than product liability rules, may be the better way of dealing with the problem of inedible materials imbedded in confectionery, it is disappointing to see how little progress has been made during the last two years in the field of food safety in Europe. The Commission in Brussels published a Green Paper (a consultative document on possible legislation) in 1997 on the General Principles of Food Law in the European Union and invited comments.<sup>21</sup> The starting point for the Green Paper is salutary. "A high level of security and effective public control is necessary to ensure that the food supply is safe and wholesome and to ensure the effective protection of the other interests of consumers."<sup>22</sup> (Later in the Green

<sup>18</sup> The Commission confirmed by e-mail that it is seeking comments from interested parties.

<sup>19</sup> In the Green Paper, referred to in note 21 *infra*, the Commission refers to the difference between the concept of product safety and the requirement that food should be safe, wholesome and fit for human consumption. "For example, food may be adulterated with substances which do not of themselves present a health risk and would not make the foodstuff unsafe within the meaning of [the Product Safety Directive]. Nevertheless such foodstuffs would not normally be considered as fit for human consumption." (Part IV, point 7.1, second paragraph, page 45.)

<sup>20</sup> "The Commission can intervene only in respect of products which present a serious and immediate risk ... and if certain other conditions are fulfilled (Articles 9 and 11 of 92/59/EEC)." 1998 O.J. (C 196).

<sup>21</sup> The General Principles of Food Law in the European Union—Commission Green Paper, COM (97) 176 final [hereinafter the Green Paper].

<sup>22</sup> *Id.* at v. (The points are erratically numbered and paragraphs are not numbered at all. There are two points numbered 1 on page v: it is the first to which reference is made here.)

Paper, the phrase “safe, wholesome and fit for consumption,” is used.)<sup>23</sup>

What constitutes “a high level of protection” is discussed in detail mainly in the context of risk assessment and risk management. The Green Paper properly makes the distinction between the two and goes on to say that particular difficulties may arise in cases where, in the absence of data, a comprehensive risk assessment may not be feasible: “in such cases, in accordance with the obligation to provide a high level of protection, it would appear necessary to take a conservative approach to risk management through the application of the precautionary principle.”<sup>24</sup> The Green Paper reinforces this view by making reference to the relatively recent (1993) provisions of the Treaty on the European Union requiring:

- (1) that the Commission, in its internal market proposals concerning health, safety, environmental and consumer protection, take as its minimum a high level of protection;<sup>25</sup>
- (2) that health protection form a constituent part of the European Community’s other policies;<sup>26</sup> and
- (3) that the European Community contribute to the attainment of a high level of consumer protection through measures designed to promote the internal market.<sup>27</sup>

The Green Paper seeks as a basic requirement of food safety law, a product that is “safe, wholesome and fit for consumption,” but discusses, at great length, whether a general rule is sufficient or whether it should be spelled out in detail.<sup>28</sup> There is a possible analogy here between food safety law and the law of unfair competition. When, some years ago, the Commission sought to harmonize unfair competition rules, it found a fundamental difference between the two main approaches adopted by the member states. Some states, led by Germany, preferred to adopt the general rule “unfair competition in

<sup>23</sup> *Id.* at 10.

<sup>24</sup> *Infra* note 37. The Commission has since adopted a Communication on the Precautionary Principle: Commission Statement IP/00/96, dated February 2, 2000.

<sup>25</sup> Treaty Establishing the European Community, Feb. 7, 1992, O.J. (C 224) 1 (1992), [1992] 1 C.M.L.R. 573 (1992) [hereinafter E.C. Treaty].

<sup>26</sup> E.C. Treaty art. 152(1).

<sup>27</sup> E.C. Treaty art. 153(1).

<sup>28</sup> See the Green Paper, *supra* note 21.



trade is hereby prohibited,” leaving it to the courts to apply this general rule to individual cases. Others, led by France, preferred to specify each of the forms of unfair competition. Both approaches, in food safety law as in unfair competition law, have disadvantages. Reliance on a general provision results in legal uncertainty in specific cases; reliance on specified offenses leaves gaps in the protection afforded by the law. The two approaches need not be mutually exclusive. In English legislative drafting there is a common phrase which can bridge the difference: “without prejudice to the general rule ... [the following practices are prohibited].” Use of this phrase preserves the general rule but allows for specific prohibitions.

For several possible reasons, the urgency of the Green Paper has evaporated. The Green Paper was written at a time when continental Europe was in a feverish state about the dispute over British beef. The Green Paper was colored by this dispute; and now that the problem has changed its focus, perhaps the Green Paper, from the Commission’s point of view, has lost some of its priority. Another possible reason might be the convulsions in the Commission of the European Communities early in 1999, with the resignation of the entire Commission. Work certainly continued, but it is likely that the outgoing Commissioners were reluctant to commit their successors to new policies. New Commissioners were appointed and approved by the European parliament in September, 1999. The new Commissioner for consumer protection policy has recently expressed his views on the future direction of food safety rules.<sup>29</sup>

For an entirely different reason, in 1999, there were also substantial changes in the composition of the European Parliament. This change is likely due to the holding of elections in June, which resulted in a marked shift to right-wing membership. It is not yet clear where this will lead. More specifically, it is not clear what will happen to the petition addressed to the European Parliament before the election,

<sup>29</sup> The present Commissioner for Health and Consumer Protection is Mr. David Byrne, the Irish Member. At a meeting of the General Assembly of the European Consumers’ Organisation (BEUC) in Madrid on December 1, 2000, he said, “Our recent proposals on food law and the European Food Authority were very favorably received: States agreed with the need to make a clear distinction between risk assessment and management. They also insisted on the need for the future Authority to be independent and visible and to communicate fully with the wider public.” Particulars of the Commissioners and their public statements may be found on the European Union web-site, <http://europa.eu.int>.

seeking support for legislation to prevent the marketing of confectionery containing inedible substances. Mr. Phillip Whitehead was re-elected and is again a member of the Environment and Consumer Protection Committee. He formally introduced the petition, which was made by the families of children who had died after eating samples of the type of confectionery concerned. If the petition is revived, if it commands the support of the Legal Affairs Committee, and if the Committee's report is adopted in a plenary session of the European Parliament, there will be strong political pressure on the Commission to take action, though it will not be under a constitutional obligation to act.<sup>30</sup>

### Parliamentary Question

Petitions and Resolutions are not the only means to which the European Parliament can resort (though, constitutionally, it cannot initiate legislation). The other means available to it are Parliamentary Questions. Shortly after the publication of the previous article on this subject, a Written Question dated July 1997 elicited a reply from the Commission, in which, among other things, "the Commission confirms that it considers unwrapped non-food inedibles in foodstuffs a health problem."<sup>31</sup> The words used in the reply again suggest that the Commission is thinking not of imbedded but of commingled products.

A more pertinent Parliamentary Question was submitted in December 1997. It reads as follows:

The EU Product Safety Emergencies Committee has now on two occasions addressed the issue of the danger to consumer safety caused by toys inside food, but has so far not recommended specific action (most recent meeting 22/10/97).

Is the Commission aware that this type of product is banned in the USA and that a large food manufacturer has very recently been forwarded [sic] to withdraw such a

<sup>30</sup> Provisions on petitions to the European Parliament are contained in E.C. Treaty art. 194, Eur. Parl. Rules of Procedure 1999 O.J. (L 202/1) 156-158. For a discussion of the relationship between the European Parliament and the Commission, see *The Constitutional Law of the European Union*, Bryan Harris, Franklin Pierce Law Center, 1999.

<sup>31</sup> Commission Answer to Written Question 2479/97, 1998 O.J. (C 82). Later that year, the Head of Mrs. Bonino's Cabinet confirmed that she was "aware of" the article in RISK.

product from the US market in the wake of 12 reported accidents?

Why is the Commission not taking urgent action to protect our consumers, and especially our vulnerable children? Five children have been killed by this type of product in the EU.<sup>32</sup>

However, there are two respects in which the Question was unsatisfactorily worded. First, the reference to the Product Safety Emergency Committee placed the question in the context of general product safety rules, instead of the context of specific food safety rules, where it belongs. Second, the reference to “toys inside food” is still not explicit enough to signify imbedded toys, as distinct from commingled toys. Not surprisingly, the Commission’s formal Answer spoke of the member states’ view that the general product safety rules sufficed, that they had at their disposal the necessary legal powers to act and that there was no need for the Commission to intervene. The Emergency Committee was due to discuss the matter again on September 14, 1999, but consideration of the matter was yet again deferred.<sup>33</sup>

### Member States of the European Union

One reason for the Commission’s reluctance to act may be found in the formal Answer to the first of the Parliamentary Questions referred to above. In passing, the Commission “noted that all Member States already have the necessary legislation, either general or specific, which would allow them to take action against this category of products when they are present on the market.” In one sense, this is undeniably true, in that all the member states have had to implement the provisions of the General Product Safety Directive in their national law.<sup>34</sup> But, in another sense, it is somewhat disingenuous, since it is specific food safety which is at issue, rather than general product safety; and here the member states’ national laws vary considerably. The fact that Belgium had to introduce special legislation to cover the problem of commingled edible and non-edible elements (unfortunately failing to cover the more pressing matter of imbedded elements) illustrates the

<sup>32</sup> Commission of the European Communities: Written Question 3813/97, 1998 O.J. (C 196).

<sup>33</sup> Commission Answer to the Written Question, *supra* note 31. See also note 19.

<sup>34</sup> Council Directive 92/59/EEC of 29 June 1992, General Product Safety.

gap in one member state's law.<sup>35</sup> Similarly, both Greece and Portugal's proposals of new national laws concerning commingled foods during the last two years emphasizes not only previous legislative gaps, but also the gaps which continue to exist in the laws of the member states.<sup>36</sup>

Meanwhile, in Germany, the Robert Koch Institute in Berlin conducted research which has revealed a significant number of previously unreported accidents.<sup>37</sup> The researchers surveyed pediatric doctors and children's clinics, asking them to state whether they recalled any accidents caused by small toys marketed with sweets or other foods over the last eighteen months. A total of 29 replies were received, reporting 35 accidents of which 34 involved chocolate eggs. When these accidents are tallied to give a figure for the whole of Germany, they show that there may be as many as 80 accidents per year. Most of the accidents occurred because children placed the toy or its parts inside their mouths, thereby injuring throat, lungs and stomach. The average age of the children in question was 30 months. Germany has not, however, introduced special legislation to deal with the problem, and the offending products are still on sale.

In the United Kingdom, there has been more press coverage of the problem than in any other member state, with the possible exception of Italy,<sup>38</sup> where the press vigorously condemned attempts to control the situation. The British press prematurely reported that "Ministers had decided to act," following a campaign by the families of children who died as the result of accidents involving the combination of confectionery and non-edible substances.<sup>39</sup> Again, no special

<sup>35</sup> The background to the Belgian legislation was referred to in the previous article.

<sup>36</sup> The Portuguese law was passed on May 11, 1999: Decree-Law 158/99. It creates a distinction between "direct mixing" and "indirect mixing" of food and "gifts," corresponding approximately to imbedding and commingling. The text of the Greek law, which has not yet, at the time of writing, been adopted, is not available in English translation.

<sup>37</sup> Kurt Rainer et al., *Zur Gefährlichkeit von Kleinspielzeug in Verbindung mit Süßigkeiten* [On the danger of small toys marketed with confectionery] Nomos, Baden-Baden 1998.

<sup>38</sup> A spate of articles appeared in the Italian press on Nov. 26, 1998. *Il Giornale* had the striking headline: Londra dichiara guerra alla Ferrero (London declares war on Ferrero)! Similar reports appeared in *Il Sole* and (more restrained) in *Corriere della Sera*. These were all responses to the article in the *London Daily Express* (*infra* note 39).

<sup>39</sup> Daily Express and Daily Mail, Nov. 25, 1998. The Express article, under the headline, "Ministers act ..." said that, according to a junior minister, the government was "increasingly

legislation has been introduced. On the other hand, it is good to report that a new product, Yowie, is being marketed in the U.K. by Cadbury's, the British confectionery firm, which previously marketed a small chocolate egg product containing a toy under the name Majorette Surprise. The new product takes safety concerns into account. Yowie features a chocolate part of increased size; the toy is also much larger and solid in form. It is far less likely to cause risks to children because it cannot be broken down into easily swallowed parts. Ideally, confectionery and inedible materials should not be combined; but, in the absence of legislation, voluntary compliance with safety considerations is commendable.

A balanced view of pertinent safety considerations appear in a study by the British consulting firm, ICE Ergonomics, published in January 1998.<sup>40</sup> It is critical of reliance on warning labels: "because of the benign nature of toys and children's foodstuffs, warnings are unlikely to be effective in alerting parents to any hazards associated with the toys contained in the products." Among the conclusions drawn in the study are: (1) that choking is more likely to occur on spherical objects less than 32 millimeters in diameter, (2) that the greatest risk is to children under 36 months in age, (3) that children continue to place non-food items into the mouth long after the age of 36 months, so it is not possible to have an exact cut-off point where children can be said to be safe from choking on small parts, and (4) that the fatal choking incidents involving toys in food have mainly been associated with chocolate eggs and balls. The overall conclusion precisely states that "although toy safety standards have been very effective in reducing the number of accidents involving choking on the small parts of toys, the close association of toys and foods is a potential problem."<sup>41</sup>

With these findings, it may seem strange that the U.K. has no food safety law directed towards the type of problem presented by the "association of toys and foods." In the light of the Birmingham case, of concerned" about the issue. The action by the minister in question was "to ask whether the company had given any consideration to making their toys larger." The Daily Express returned to the charge in a further article on April 8, 1999: "the Express doctor on the sweets that can kill your child."

<sup>40</sup> Magdalen Page, *Expert Ergonomics Appraisal on the Inclusion of Non-Food Items in Food Aimed at Children*, ICE Ergonomics, Loughborough, 1998.

<sup>41</sup> *Id.* at 41-42.

which the transcript became available after the publication of the earlier article, there are three clues as to why there has been no legislative measures to curb this problem. First is the belief that the matter can be dealt with adequately under general product safety rules. The second is that if the toy imbedded or encapsulated in confectionery complies with toy safety rules, the matter is adequately covered by the law. The third is that, in practice, the implementation of the general product safety rules is full of procedural pitfalls; and, indeed, the Birmingham case turned more on procedural points than on the merits of prohibiting the product in question.<sup>42</sup>

### Conclusion

With the developments over the last two years, specifically, Nestlé's petition to separately consider the safety of food and nonfood items even when they exist together in one product, the European Union's focus on product safety rules during the Commission of the European Communities meeting in Brussels, the Commission's lack of specificity in outlining food safety rules in their Green Paper, and the Green Paper's recent loss of urgency, the authorities in the United States and the European Union are faced with certain options. In the United States, the existing food and drug law prohibiting non-nutritive objects imbedded in confectionery could be made less stringent, but a weaker rule would be a step back in consumer protection. More practically, the existing prohibition could be clarified, either by a definition of the word "imbedded" or by expanding the narrow meaning of the word with the addition of words such as "encapsulated" or "wholly or partly contained."

In the European Union, a shift of emphasis is needed from reliance on general product safety rules and on toy safety rules to rules on safety in food products. But whether the shift takes place or not, the desired end could be achieved in one of three ways. First, there could be an interpretative measure to the effect that, without prejudice to the general rule on product safety, the imbedding of inedible objects in confectionery is prohibited as an unsafe practice. Second, any general legislation concerning improvements in food safety law introduced by the Commission could include a specific provision concerning inedible

<sup>42</sup> See the Annex to this article.

objects imbedded in food products. Third, there could be a short, specific measure under the provisions on the harmonization of laws, whereby member states would be required to ensure the prohibition of imbedding inedible objects in confectionery. The first of these options has the disadvantage of tying the prohibition to the unsatisfactory rules on general product safety. The second option has the disadvantage that it may be years before a comprehensive measure on food safety reaches the European Union's "statute book." But, one way or another, action is needed if consumer protection standards in this area are to match those of the United States. Otherwise, the authorities of the European Union may be justly accused of failing to observe the spirit and letter of the treaty provisions on health, safety and consumer protection.

#### ANNEX: The Birmingham Case

The Queen v Birmingham City Council, ex parte Ferrero Ltd in the High Court of Justice, Queen's Bench Division, before Hutchison, J, 22.2.90

Mr Justice Hutchison: The applicants, Ferrero Limited, are makers of chocolate eggs which contain plastic kits from which can be made small toys. The kits are contained within plastic capsules which in turn are found within the egg. A variety of different toys are involved — they often feature well known cartoon characters. The product is plainly aimed at children, and since there is no means of deducing, from the packaging, which particular toy is to be found in the egg, it will be obvious that children who are minded to collect all the toys have an incentive to purchase the eggs, which are known as "Kinder Surprise."

On 5th November 1989, about a month after a new toy, the well known character Pink Panther, had been introduced into the United Kingdom, a tragic accident occurred. A little girl called Jennifer Ashton, just over 3 years old, swallowed one of the Pink Panther feet which lodged in her throat and caused her death from asphyxiation. The case occasioned much Press comment, some of it in very sensational terms. Three days later, on 8th November, the Birmingham Trading Standards Office issued a suspension notice under section 14 of the Consumer Protection Act 1987 prohibiting Ferrero Limited for a

period of six months from that date from supplying Kinder Surprise Eggs containing the Pink Panther toy. In these proceedings that decision, and subsequent decisions whereby the Council refused to lift the suspension order, are challenged.

The relief sought is, effectively, the quashing of the order. Of the various grounds set out in the notice of motion, those relied on are, in summary, the following:

- (1) There was no jurisdiction to make the order.
- (2) In making the order the Council failed to have regard to relevant considerations and took into account irrelevant considerations.
- (3) The Council breached the requirements of fairness in that they failed to afford to the applicants any opportunity to make representations before imposing the order.
- (4) They acted irrationally in failing to lift the order.

I must first consider the relevant statutory provisions ...

[Note: The judge then described the complex statutory requirements. After doing so, he:

- rejected the first of the four points;
- upheld the second point, saying that the Council had failed to take into account the British Standard and had wrongly taken into account regulations which had not yet come into force;
- upheld the third point, saying that there had been inadequate consultation with the manufacturers: "the complaint of procedural impropriety is made good";
- upheld the fourth point, saying that the procedure for asking the magistrates' court to lift the suspension order would not have been appropriate.

Judgment was therefore given for the applicants.]

### Comment

This case illustrates, first, the manner in which the requirements of the General Product Safety Directive were transposed into English law; second, the legal complexities in which the local authority banning the product in question was entangled; and, third, the reasons for the continued marketing of a variant of the products which the local authority considered to be dangerous.



In the event that the local authority which had issued a suspension order failed on the procedural grounds, on which the application to the Court had been based, the merits of the case and, in particular, the question of the danger presented by the product were lost to view.

In the context of the fourth point above, the judge referred to an argument by the applicants that “the local authority never took into account the vital fact that the order was having unintended and catastrophic consequences for the applicants’ trading.” He added: “here again, I have to say that I am impressed by the arguments relied on by the applicants.” The *reductio ad absurdum* of this is that, before a local authority issues a suspension order for a dangerous product, it must consult the manufacturer about the trading consequences. (This is a far cry from the statement in the Commission’s Green Paper, p. 49, that, “so far as food safety is concerned, there is no room for compromise ... if [products] are not safe, they cannot be permitted.”)

As it happens, the manufacturers undertook to remove the specific product from the market, that is, the Pink Panther referred to by the judge. But the manufacturers still sold chocolate eggs having an inherent danger similar to that of the Pink Panther; and it was a chocolate egg (produced by a different manufacturer) which was the cause of the next fatality, this time in Sheffield.

