REGULATORY APPRAISAL

THE INFANT FORMULA AND FOLLOW-ON FORMULA (AMENDMENT) (WALES) REGULATIONS 2004

PURPOSE AND INTENDED EFFECT OF MEASURE

1. The Regulations implement, in Wales, Commission Directive 2003/14/EC of 10 February 2003 amending Directive 91/321/EEC on infant formulae and follow-on formulae.

2. Parallel legislation will be made in England, Scotland and Northern Ireland.

The background

3. European Community controls on the composition and labelling of infant formulae and follow-on formulae were introduced in 1991 through Commission Directive 91/321/EEC. Article 6 of 91/321/EEC laid down a general requirement that infant formulae and follow-on formulae should not contain any substance in such quantity as to endanger the health of infants and young children and also stipulated that necessary maximum levels for such substances in baby foods should be established without delay.

4. In 1999, Directive 91/321/EEC was amended by Commission Directive 1999/50/EC which laid down a very low common limit of 0.01 mg/kg for any individual pesticide in infant formulae and follow-on formulae. At that time, 0.01 mg/kg was the minimum level detectable with available analytical methods. This provision was introduced primarily to resolve trade disputes between EU Member States and the 0.01 mg/kg limit was chosen as a precautionary level set pending case-by-case scientific evaluation of individual substances.

5. The EU independent Scientific Committee on Food (SCF) did not endorse this blanket limit of 0.01 mg/kg and pointed out that it might not be low enough to protect against residues of a few, very toxic, pesticides. Therefore, the Commission committed to introduce further controls at a future date. These have now been introduced through Directive 2003/14/EC which places tighter restrictions on a number of very toxic pesticides with Acceptable Daily Intakes (ADIs) lower than 0.0005 mg/kg/body weight.

6. Directive 2003/14/EC considers two groups of very toxic pesticides: those whose use was already prohibited in the EU at the time of drafting that proposal or would be by July 2003 and those which may still be used but whose safety is under review. For those whose use was already, or would soon be, prohibited it was recognised that they degrade slowly, may persist in the environment and thus may still appear in infant formulae and follow-on formulae; for each of these pesticides the Directive sets individual maximum residue levels of 0.003 mg/kg in the ready-to-eat

formulae. For pesticides whose use is still permitted, the Directive sets individual maximum residue levels below 0.003 mg/kg; these levels have been calculated using worst-case assumptions.

7. Directive 2003/14/EC only introduces new controls on maximum residue levels in infant formulae and follow-on formulae. It does not make any changes to the labelling requirements.

Decision not to consolidate

8. The Infant Formula and Follow-on Formula Regulations 1995 have already been substantively amended twice (in addition to the deletion of a couple of redundant provisions). However, the 1995 Regulations are quite lengthy and one of the amending SIs was very short. Furthermore, the other amending SI is not relevant to the changes now being made. Therefore, we have decided not to consolidate the 1995 Regulations on this occasion.

Provisions in the Regulations

9. The Infant Formula and Follow-on Formula (Amendment) (Wales) Regulations 2004 amend the Infant Formula and Follow-on Formula Regulations 1995, as amended, in relation to Wales. The 1995 Regulations extend to Great Britain. These Regulations

   - In implementation of Directive 2003/14/EC, prohibit the sale, or export to third countries, of infant formulae or follow-on formulae containing pesticide residues above certain levels. Different levels are set depending on the pesticide in question (regulations 4, 5, 7, and 10 and Schedule);

   - Make some consequential amendments (regulations 3 and 6);

   - In implementation of the final sentence of Article 6(2) of Directive 91/321/EEC as substituted by Commission Directive 1999/50/EC, make provision as to analytical methods for determining levels of pesticide residues (regulation 7);

   - Give port health authorities a role in enforcement (regulation 8)

   - Make some technical changes to the provision applying various provisions of the Food Safety Act 1990 (regulation 9).

Risk assessment

10. Infants and children are thought to be especially sensitive to the health risks posed by pesticides because their internal organs are still developing and in relation to their body weight, infants eat and drink more than adults thereby possibly increasing their exposure to pesticides in food. The former EU SCF expressed concern that the current common limit of

0.01mg/kg for any individual pesticide in infant formulae and follow-on formulae might not be low enough to protect against residues of a few, very toxic pesticides. Those regulations implementing 2003/14/EC have been drafted to address the risk that infants and young children might, under worst-case intake conditions, exceed the acceptable daily intake of certain very toxic pesticides with ADIs lower than 0.0005 mg/kg/body weight.

11. A large number of babies consume infant formulae and follow-on formulae. According to the 2000 infant feeding survey[1] 30% of mothers in the UK did not breastfeed at all and gave infant formula as the sole source of nutrition from birth. By the time babies were around four to ten weeks old, 58% had switched entirely to infant formula. Some breastfeeding mothers were also using infant formula making a total of 75% of mothers who were using infant formula at least to some extent for babies four to ten weeks old.

OPTIONS

12. Options for transposing the provisions of Directive 2003/14/EC are as follows:

    Option 1: do nothing, i.e. fail to implement the Directive

    Option 2: implement the provisions of Directive 2003/14/EC into national legislation according to the timetable set out in the Directive.

    Each of these options carries a number of risks to consumers, industry, enforcement authorities and Government which are discussed below.

13. Option 1: failing to implement would risk failing to take the opportunity to improve health protection for a particularly vulnerable population group, that is infant consumers of infant formulae and follow-on formulae. Failure to implement would also result in a serious breach of the UK's obligations under the EC treaty and would attract infraction proceedings by the Commission against the UK under Article 226 of the EC Treaty and the likelihood of heavy fines. Other Member States could also initiate action under Article 227. Ultimately, the UK would be forced to implement. Failure to implement could also have adverse implications for the acceptability of UK-produced goods elsewhere in the European Union.

[1] Infant Feeding 2000. A survey conducted on behalf of the Department of Health, the Scottish Executive, the National Assembly of Wales and the Department of Health, Social Services and Public Safety in Northern Ireland. The Stationery Office, 2002.

14. Option 2: implementing the provisions of 2003/14/EC into national legislation could be a disbenefit to manufacturers of these formulae if it meant they needed to undertake new testing of their products or find new ingredient sources so that their products complied with the new requirements in the Directive. In this case, it could also be a disbenefit to ingredient suppliers. This option could also be a disbenefit to enforcement authorities if extra resources were needed to enforce the new regulations.

15. The Directive offers only one area of flexibility in transposing its provisions: Article 2 states that trade in compliant goods shall be authorised by 6 March 2004 at the latest. Trade in such products is already permitted in the UK therefore there is no action to be taken. Article 3 of the Directive requires Member States to bring into force laws, regulations and administrative provisions necessary to comply with the Directive. There is no scope for introducing any other type of measure such as a voluntary code of practice.

Regulation 7- new Regulation 12A(5)

16. We have taken this opportunity to introduce a provision providing for implementation of a part of Article 2 of 1999/50/EC that was not formally implemented before. It formalises the requirement that analytical methods for determining levels of pesticide residues shall be generally acceptable standardised methods. This will have no impact on analytical practice and therefore will not introduce any new costs, neither does it further address risks nor bring new benefits. The provisions in new Regulation 12A(5) will not be considered further in this Regulatory Appraisal.

COST BENEFIT ANALYSIS

BUSINESS SECTORS AFFECTED

17. Those parts of the Regulations that implement the provisions of 2003/14/EC could affect businesses involved in the production of ingredients for the infant formulae and follow-on formulae industry and businesses involved in the production and sale of these formulae. Any charities and voluntary organisations that sell or supply such formulae in the course of their business could be affected by these new provisions; we are not aware of any charities or voluntary organisations that would be so affected.

18. According to Mintel[2] UK retail sales of baby foods and drinks in 2000 totalled £369.8 million with 167.5 million (45.3% of the total) accounted for by sales of infant formulae and follow-on formulae presented as dry products needing reconstitution with water and ready-to-feed products. The supply structure for infant formulae and follow-on formulae in the UK is heavily concentrated with three manufacturers dominating the supply

[2] Mintel report on Baby Food Drinks and Milk, October 2002

chain and accounting for 97% of sales. Infant formulae and follow-on formulae are distributed via a wide range of retail outlets, with around 25% sales by volume being through clinics.

EQUITY AND FAIRNESS

19. Those parts of the Regulations that implement the provisions of 2003/14/EC will be equally applicable to all business involved in the manufacture of infant formulae and follow-on formulae.

BENEFITS

20. The Regulations will provide increased safety margins for the protection of the health of infants and young children. Infants and children are thought to be especially sensitive to the health risks posed by pesticides for the reasons set out in paragraph 10 above.[3] It is difficult to quantify these risks: we have been unable to find evidence of infants suffering damage to health as a result of consuming infant formula containing pesticide residues. Therefore health effects have only been considered in the sensitivity analysis. Details are given in Annex 1 paragraphs 6-9.

21. Research has indicated that over 90% of the UK population believe that baby food should be free from artificial additives, fertilisers and pesticides.[4] It would be reasonable to assume that the same beliefs extend to infant formulae and follow-on formulae. Details are given in Annex 1 paragraphs 1-5.

22. Each of the options identified in paragraph 12 above brings with it a number of benefits to consumers, industry, enforcement authorities and Government.

23. Option 1, do nothing, would mean that existing legislation would still apply. This would provide a certain level of health protection, however we would expect no additional benefits in terms of improved consumer protection or improved consumer confidence to result. This option would carry some benefits to industry in that it would avoid the need for manufacturers to take steps to ensure that their products comply with the requirements laid down in 2003/14/EC, thus avoiding any costs (e.g. analytical tests for pesticides at the new lower limits) associated with complying with the stricter limits on pesticide residues. It would also benefit enforcement officers in that they would not have to enforce the new standards.

24. However, option 1, to not implement the Directive is not a viable option for the reasons set out in paragraph 13 above.

25. Option 2 brings consumer benefits in terms of improved health protection for consumers of infant formulae and follow-on formulae – a particularly vulnerable group of the population. Introduction of these Regulations will

[3] US EPA *Pesticides and Food: Why Children May be Especially Sensitive to Pesticides.*
[4] Research by the Gallup Organisation and HiPP (2000).

also benefit industry if purchasers have increased confidence in the safety of these products (see paragraph 21 above). Food safety as a product attribute is difficult to value; studies have shown that consumers have a tendency to be willing to pay more for products with improved food safety attributes.

26. Implementation of these provisions into national law will fulfil the UK's Community obligations under the EC treaty and so bring the benefit of avoiding infraction proceedings.

COSTS

Policy costs

27. Directive 2003/14/EC considers two groups of very toxic pesticides: those whose use was already prohibited in the EU at the time of drafting the proposal or would be by July 2003 and those which may still be used but whose safety is under review. Thus the costs of meeting the policy objective of increasing health protection for infants and young children have already been met, or will be met in future, by those complying with separate EC legislation on pesticide use.

Compliance costs for businesses

28. Implementation costs relating to the Directive, and hence to the Regulations, could be incurred by infant formulae manufacturers as a result of any new sourcing of ingredients necessary to ensure that products comply with the new requirements. Any such costs associated with securing new ingredients sources would be one-off costs. However, consultation suggests that businesses have already undertaken discussions with suppliers in anticipation of these regulations and this implies that the majority of this cost has been absorbed already. Because of this, sourcing costs have not been included in this analysis.

29. It is unlikely that pesticides listed in the Directive are used by ingredients suppliers, indeed some have been, or are in the process of being, phased out and use of others is under review. It is therefore unlikely that suppliers will have to change the treatment regime for the ingredients they produce and so costs to this group are assumed to be insignificant.

30. Ongoing costs to industry could result from any new analytical testing done to check compliance with the requirements of the Directive. Details of such costs, estimated under worst-case conditions, are given in Annex 2 paragraphs 2-5. It is important to note that it will, however, be up to individual businesses to decide on the level of testing they do in order to satisfy themselves that their products comply with the requirements of the Regulations.

Implementation costs for enforcement authorities

31. The regulations will be enforced by Food Authorities and, in relation to imported products, by Port Health Authorities. Ongoing costs could be incurred by local authorities due to the additional more detailed analytical testing and associated staff time which may be required to check compliance with the new regulations. However , there are no known manufacturers based in Wales and it is not anticipated that Welsh local authorities will therefore face any additional analytical testing

Research and development costs

32. There will also be research and development costs as we understand that new methods will need to be developed for the routine monitoring, by bodies other than those within the industry, of residues at the limits required by these regulations. Details are given in Annex 2 paragraph 8.

33. Currently, analysis for pesticide residues in infant formulae is done using multi-residue testing suites followed by targeted tests if necessary. At present, there are analytical tests that will detect seven of the pesticide residues listed in the Directive down to the new, low levels. Current tests for eight other residues listed in the Directive will allow detection down to lower levels than required by current legislation, at an additional cost, but will not allow detection at the new low levels required by the Directive. Detection of these residues at the new, low levels will involve new, additional costs due to method development and the higher expense of using more sensitive tests. For the final residue listed there is currently no method suitable for its routine monitoring and a new method will need to be developed.

34. The Central Science Laboratory, one of the key laboratories in the UK for pesticide residue testing, states that the cost of developing and validating methods for detection of the relevant pesticide residues down to the levels listed in the Directive is very difficult to estimate but that it will be in the order of several tens of thousands of pounds. During negotiations on the Directive, the European Commission was very clearly made aware of this situation but simply asserted that Member States should pool resources in order to develop the necessary new methods. There is work underway to develop more sensitive methods for two of the pesticides concerned however to the best of our knowledge there is a gap in the research for development of other methods.

35. There is concern that unless additional funding is made available to support the development and subsequent use of new expensive methods for residue testing in baby foods, the wider programme of national pesticide monitoring could suffer because CSL might have to reconsider the amount of sampling and testing of other commodities carried out. Any decisions taken would be made on the basis of risk assessment.

Costs to consumers

36. A proportion of any cost increases which manufacturers may face as a result of the regulations may be passed on to the consumer in the form of higher prices however, this represents a transfer cost and is therefore not considered in the appraisal.

Compliance Costs for Charities and the Voluntary Sector

37. Implementation of the Directive is not expected to result in additional costs for any charity or voluntary sector organisation.

Costs for a typical business

38. The market for infant formula is dominated by a small number of large firms, which account for 97% of sales[5]. The major, big businesses that produce infant formula were consulted through their trade association. We understand that, for these companies, implementation of the new pesticide provisions will not require any specific new action because their existing policy on pesticide residues already permits them to meet the new EC standards. However, these companies have stressed that earlier work completed to meet these standards had already necessitated substantial investment. Excellent traceability systems were already in place but liaison with suppliers and development of residue testing capability and ongoing testing has been time-consuming and expensive. These companies pointed to publicly-available statistics as confirming that their internal pesticide residue-monitoring systems are working effectively.

SMALL FIRMS' IMPACT TEST

39. This is not applicable as the market for infant formula is dominated by a small number of large firms. The remainder is made up of smaller (in terms of market share) players: Boots and HiPP both of which are also producers of baby foods. HiPP Nutrition UK Ltd is a subsidiary of the German manufacturer HiPP GMbH & Co Vertrieb KG, which claims to be the world's largest processor of organic foods, and has therefore not been considered as a small or medium-sized enterprise (SME). Neither is Boots an SME.

40. The Small Business Service commented only on the partial RA and did not comment on the Regulations.

Impact on Regions

41. The cost impact on local authorities will vary according to whether manufacturers of infant formulae and follow-on formulae are located within the boundaries of a particular authority, and whether they are responsible for funding a Port Health Authority (which will have responsibility for checking compliance of imported products).

[5] Heinz/Farley's (11%), Nutrica Baby Care who own both the Cow and Gate (31%) and Milupa (10%) brands, and SMA Nutrition (45%).

Summary of costs to businesses

42. Option 1, to do nothing, maintains the current regulatory situation and would bring no additional costs to businesses. Option 2 may impose costs on manufacturers of infant formulae and follow-on formulae.

Summary of discounted costs and benefits (£ millions)

	Discounted Benefits	Discounted Costs	Net Present Value
Option 1: Do Nothing	0	0	0
Option 2: Full Implementation	268.6	32.3	236.3

3.5% discount rate, real prices, over 10-year authorisation period

43. The above table provides information on the estimated costs and benefits associated with implementation of Directive 2003/14/EC. Despite extensive consultations with industry these estimates were based on limited data concerning the costs and benefits of implementing the directive. It should be noted that there is still considerable uncertainty surrounding the analytical costs as new testing methods will need to be developed.

44. Implementation will provide health benefits however these are difficult to quantify. Benefits were estimated from sensitivity analysis which incorporated consumer willingness to pay measures; this analysis suggests that benefits could be substantial although the specific nature of these regulations raises questions about the applicability of this more general willingness to pay evidence. However using conservative assumptions (i.e. consumer willingness to pay a 10% premium) generates a large net benefit; this premium only needs to be about 1% for this proposal to break even.

COMPETITION ASSESSMENT

45. The regulation will affect two sectors of the UK market for formulae. Infant formulae which are suitable for babies from birth onwards (70.8% of the market) and follow-on formulae designed for babies from six months to 24 months (22.0% of baby milk market). Three companies, Heinz/Farley's, Cow & Gate and SMA Nutrition dominate the market for infant formulae and follow-on formulae. Together these companies have a market share of 97%[6]. These companies are international in nature with a portfolio of established brands, they benefit from leverage in distribution promotion and manufacturing scale.

[6] Figures obtained from Mintel report on Baby Food Drinks and Milk, October 2002 and include the total milk sector which also includes Soya Milk (3.0% of sector) and Ready to Feed (4.3% of sector).

46. Option 2, implementation of the Directive, may bring some ongoing costs. However, it is not anticipated that the scale of these costs will be sufficient to have any appreciable impact on competition, neither will it have any disproportionate effects on firms in the relevant market. Although the increased costs to manufacturers will raise entry barriers slightly, it is not anticipated that this will be sufficient to discourage new entry into the market.

47. Option 1, under which current legislation is retained would not have an impact on competition within the UK, as it would maintain the status quo.

ENFORCEMENT AND SANCTIONS

48. The Regulations will be enforced by Food Authorities and, in relation to imported products , by Port Health Authorities . Ongoing costs could be incurred by local authorities due to the additional more detailed analytical testing and associated staff time which may be required to check compliance with the new Regulations. However there are no known manufacturers based in Wales and it is not anticipated that Welsh local authorities will therefore face any additional costs. .

49. As drafted, any person committing an offence under these Regulations will be liable on summary conviction to a fine not exceeding level 5 on the standard scale. The Home Office has confirmed that it is content with the offence and level of penalty set.

MONITORING AND REVIEW

50. No specific review date is provided for within the Directive.

CONSULTATION

51. Over 200 copies of the consultation documents (draft Regulations, partial Regulatory Appraisal) were sent out to interested parties including consumers organisations, individuals, health professional groups, manufacturers and retailers of baby foods and enforcement authorities. Other Government Departments including the Department for Environment, Food and Rural Affairs, Pesticides Safety Directorate, Medicines and Healthcare products Regulatory Agency, Department of Trade and Industry, Department for International Development, Foreign and Commonwealth Office and Home Office were also consulted. The formal consultation period lasted 12 weeks.

52. A total of ten responses were received, eight from consultees in England and two from Wales. Eight of these responses commented on the Regulations and two on the RA. Three groups concerned with breastfeeding and baby and infant feeding responded as well as the Breastfeeding Co-ordinator for Wales and one member of the Welsh Food Advisory Committee; they broadly welcomed the new Regulations and in general, suggested that the Regulations should go further than they do on

a number of issues. However, since the Regulations faithfully implement the Directive we have not amended the draft Regulations as a result of these comments.

53. One enforcement group, LACORS, commented as reported in the Section on Enforcement and Sanctions above.

54. The Small Business Service responded to consultation, not on the detail of the Regulations but on the content of the partial RIA.

55. Large businesses manufacturing baby foods responded to the consultation through their trade association; their comments stated they had already made significant investment in order to meet the new standards and that implementation would not require any further action. One smaller company responded to consultation and stated that compliance with the new requirements would not require new measure to be taken. These comments did not affect the drafting of the Regulations.

56. A large company that manufactures pesticides responded to the consultation; it commented on one aspect of the drafting of the Directive which it had also brought to the attention of the European Commission. We are not now able to change the wording of the Directive therefore the drafting of the implementing Regulations was unchanged.

SUMMARY AND RECOMMENDATION

57. The UK is obliged to implement the provisions of Directive 2003/14/EC. Option 2 allows us to fulfil this obligation so the recommendation is that this course of action should be supported.

DECLARATION

I have read the Regulatory Appraisal and I am satisfied that the benefits justify the costs.

Signed

Date

Jane Hutt AM, Minister for Health and Social Services

CONTACT POINT

Hilary Neathey
Food Standards Agency Wales
11th Floor, Southgate House, Wood St
Cardiff
CF10 1EW

Telephone: 029 20678911
Fax: 029 20678919
E-mail: hilary.neathey@foodstandards.gsi.gov.uk

ANNEX 1: QUANTIFIED BENEFITS

CONSUMER WILLINGNESS TO PAY (WTP) FOR REDUCTIONS IN PESTICIDE RESIDUES

1. There have been a number of studies which have estimated consumer WTP to avoid pesticide residues.[7] Hammitt (1990) reasoned that those consumers who purchase organic food reveal by their behaviour that they are willing to pay a premium to avoid pesticide residues. The revealed preference approach suggests that the price differentials between organic and conventional produce provide a lower-bound to the incremental value that consumers who choose to buy organic assign to their choice. Hammitt's analysis of the retail prices of 27 types of fresh produce found a median ratio of organic to conventional price of 1.45.

2. The research also reports the outcome of focus groups where participants were asked to state the maximum additional percentage they would be willing to pay to purchase whichever type of food they thought was safer, instead of the other. Purchasers of conventional foods reported low to moderate WTP, with a median of 10% (although none were willing to pay greater than 20% premium).

3. Organic buyers reported substantially higher WTP, with a median of 50%. This is consistent with the estimated median ratio of organic to conventional price of 1.45.

4. Research indicating that over 90% of the UK population believe that baby food should be free from artificial additives, fertilisers and pesticides[8] and the growing popularity of organic baby food potentially indicates a strong wish on the part of parents to avoid exposing their infant to pesticide residues.[9] It would be reasonable to assume that the same beliefs extend to infant formulae and follow-on formulae.

5. The estimated aggregate WTP to avoid pesticide residues in infant formulae and follow-on formulae can be calculated as follows:

- Research by Hammitt (1990) suggests a premium in the range of 10-50% although this does not specifically relate to produce which is to be consumed by infants – it could be argued that such a study would elicit a higher premium due to the higher vulnerability of infants in comparison to adults. As a conservative estimate the analysis estimates a premium of 10%.

---

[7] Including: Hammitt JK (1993) *Consumer willingness to pay to avoid pesticide residues* Statistica Sinica Volume 3, No. 2, pp351-366; Van Ravenswaay and Hoehn (1991) *Impact of Health Risk Information on Food Demand* in Caswell (ed.) Economics of Food Safety; and Hammitt JK (1990) *Risk Perceptions and Food Choice: an exploratory analysis of organic versus conventional-produce buyers* Risk Analysis Volume 10, No. 3, pp 367-374.

[8] Research by the Gallup Organisation and HiPP (2000).

[9] Although it should be noted that there are other reasons why parents may choose to purchase organic food for their children, for example the notion that organic food is better quality or has improved taste.

- Annual births (2000): 679,000[10]
- Infant feeding: over the first 12 months, an average of 76.5% of babies are fed 'other milk only' (which we have interpreted as indicating infant formula and follow-on formula only)[11]
- Average expenditure on formula milk: £600 (average of £50 per month in the first year)[12]

This gives an estimated aggregate annual WTP of £31.2 million which can be interpreted as an estimated benefit of the regulations.

REDUCED NEGATIVE HEALTH EFFECTS

6. Infants are thought to be especially susceptible to the health risks posed by pesticides implying that the new regulations could potentially result in a reduction in negative health impacts by reducing the maximum permitted residue levels for certain pesticides in infant formulae.

7. We could find no evidence in the UK of infant mortality or morbidity resulting from pesticide residues in food. Therefore the potential benefit of reduced health effects has not been included in the central scenario.

8. As a sensitivity analysis we have considered the number of cases of illness which would be required to be avoided by the regulations to create a situation where the net present value is estimated to be zero. The benefit of avoiding one incident has been estimated on the basis of NHS treatment costs[13] for poisoning (toxic effects or overdoses), the mean average of this is £798[14]. As this is an estimate based only on treatment cost it provides a lower-bound estimate as a more complete estimate would include an allowance for the pain and suffering caused by the episode and any other costs which were incurred. In addition, the situation we are considering would be one where an infant was the patient and therefore this may have an effect on treatment costs.

9. An estimate of the benefits of avoiding a mortality incident could be valued using the Department for Transport's average value of the prevention of a fatal accident.[15] This figure is £1,194,240 and is made up of medical and ambulance costs, human costs and an allowance for lost output, although it is important to note that it was derived in relation to road accidents and so can only provide a very rough approximation to the very different situation we are considering here.

[10] Source: National Statistics as reported in Mintel (2002) *Baby Food, Drinks and Milk*.
[11] Department of Health *Infant Feeding Survey 2000* reports that the proportion of infants who are fed breast milk only declines with the age of the baby.
[12] Papworth J *The painful cost of having a baby* The Guardian, Saturday March 29, 2003.
[13] NHS *Reference Costs 2002* contains unit costs of NHS treatment and procedures.
[14] Taken from Appendix 1A National Schedule of Reference Costs: NHS Trust Elective Inpatient HRG Data.
[15] Department for Transport *Highways Economics Note: 2001*.

ANNEX 2: QUANTIFIED COSTS

COSTS TO CONSUMERS

1. A proportion of any cost increases which manufacturers may face as a result of the regulations may be passed on to the consumer in the form of higher prices however, this represents a transfer cost and is therefore not considered in the appraisal.

COSTS TO MANUFACTURERS OF INFANT FORMULAE AND FOLLOW-ON FORMULAE

2. In response to the consultation, the IDFA[16] suggested that, in anticipation of the regulation changes and in order to meet their own high internal standards, member companies had made substantial investment which has involved liaison with suppliers, development of testing capability and ongoing testing. This investment is non-recoverable and so for the purposes of this appraisal can be treated as a sunk cost and will therefore not appear in the cost benefit analysis.

3. The response also suggest that implementation of the Directive into UK law will not necessitate any specific further action on the part of members. Therefore we have assumed that one-off costs will be zero.

4. There may however be compliance costs as the range and depth of the analytical tests will be increased. It has been suggested that, under current regulation, the typical cost of testing is £500 per product (although this varies according to composition). It has also been suggested that the need to prove compliance with these new requirements would double this testing cost. This information therefore implies an additional testing cost of £500 per product.

5. The total cost to a typical firm will depend on the specific testing regime which they use. It seems that typically each brand has around four product ranges which then come in a variety of product sizes and formats. A conservative estimate of the increase in sector costs can be calculated as follows:

- Assuming that each company has 12 ‘products’ which require testing.
- Assuming that testing is undertaken weekly.
- Assuming an additional cost of £500.
- There are six companies with a presence in the market.[17]
- This gives a sector total of £1.872 million.

COSTS TO SUPPLIERS OF INGREDIENTS

[16] Infant and Dietetic Foods Association, a trade association of which a high proportion of the market are members, including market leaders SMA Nutrition, Cow and Gate and Heinz/Farley’s.
[17] Mintel (2002) *Baby Food, Drinks and Milk*.

6. It has been suggested that the pesticides listed in the schedules to the regulations are unlikely to be used by ingredient suppliers. Indeed, some have been, or are in the process of being, phased out; the remainder are under review. It is therefore unlikely that suppliers will have to change the treatment regime for the ingredients they produce and so costs to this group have been assumed to be insignificant.

COSTS TO ENFORCEMENT AUTHORITIES

7. LACORS have indicated that , at the UK level , there could be additional costs to local authority food standards departments and port health authorities. There is no indication that enforcement authorities in Wales will be faced with any additional costs.

RESEARCH AND DEVELOPMENT COSTS

8. Pesticide residues in food are currently sought to 0.01mg/kg, where technically possible. For some of the pesticides included in the regulations (e.g. fentin) there are no methods suitable for routine monitoring. Therefore the regulations will create extra costs in terms of developing and validating methods for the compounds listed in the regulations at levels between 3 and 8ppb. It has been suggested that this could be in the order of 'several tens of thousands of pounds' per compound as specific methods will be required. Concern has been raised that monitoring at this level is impractical and will be prohibitively expensive.

Costs in this area have been estimated as follows:

- Assume an average development cost of £30,000.
- Assume that development costs will be borne by the Central Science Laboratory and will be incurred in year 0.
- There are 16 compounds listed in the schedules.
- This gives a total development cost of £480,000 which, for appraisal purposes, we have assumed can be split between this regulation and that relating to baby foods (as the same development work is required for each).
- This leaves a total cost applicable to this regulation of £240,000.