

DRAFT INITIAL REGULATORY IMPACT ASSESSMENT

1. Title of proposal

- 1.1 This Initial Regulatory Impact Assessment (RIA) concerns the establishment of enforcement arrangements for the EU food hygiene legislation applying on farm in England.

2. Purpose and intended effect

(i) The objective

- 2.1 To establish enforcement arrangements for the food hygiene legislation applying to farming and growing primary production activities (see paragraphs 2.7 and 2.8) in England. To apply the new legislative framework so that it protects consumers, is practicable and proportionate and can be equitably and consistently enforced.
- 2.2 It is proposed that enforcement arrangements will be introduced from 1 December 2006 and reviewed after 12 months.

(ii) Background

- 2.3 A package of new EU food hygiene regulations applied from 1 January 2006¹, its foremost objective being the optimisation of public health protection through the consolidation and modernisation of the previous EU legislation to be more risk-based.
- 2.4 The new regulations introduced 'horizontal' legislation across the food chain from 'farm to fork' and extended, for the first time, basic food hygiene requirements to the primary production sector. The new legislation requires registration and enforcement arrangements to be in place.
- 2.5 A Final RIA titled 'Consolidation of EU Food Hygiene Legislation' (henceforth referred to as the 'Final RIA') has already been produced on the legislation and was signed off by the then Minister for Public Health in July 2005. The Final RIA provides a detailed examination of the legislation's impact on all food industry sectors (including primary producers) and upon the existing enforcement bodies.²
- 2.6 The work to put in place food hygiene enforcement arrangements for primary production activities throughout the UK is being taken forward as a managed project by Food Standards Agency officials. The Agency is working with the relevant industry, enforcement and Government

¹ Background to the legislation, including links to pdf copies of the Regulations can be found on the Agency's web site at: <http://www.food.gov.uk/foodindustry/regulation/europeleg/eufoodhygieneleg/>

² The most recent version of the Final RIA can be viewed on the Agency's web site at: <http://www.food.gov.uk/multimedia/pdfs/EURegulationsRIA.pdf>

stakeholders in each UK country. The enforcement arrangements will necessarily differ in operational detail reflecting the different enforcement bodies and agricultural landscapes across the UK, but co-ordination within the Agency across the UK will ensure an overall consistency of approach. Separate RIAs will be produced in Scotland, Wales and Northern Ireland, reflecting the differing situations in those countries. This RIA describes the situation in England only.

- 2.7 Primary production sectors such as dairy, eggs, fishing and live bivalve molluscs, had been subject to specialist hygiene rules under the previous legislation and there were already existing enforcement arrangements in place covering those sectors. These have been retained in relation to the new legislation.³
- 2.8 It can be considered therefore, that for the purposes of this RIA, where primary production activities are mentioned, that this refers to farming and growing activities for which food hygiene enforcement arrangements do not currently exist.
- 2.9 Figures suggest that primary production holdings⁴ not currently covered will be approximately 107,000. The legislation is directed to food businesses; the number of primary production food businesses is likely to be lower than the number of holdings since businesses may comprise several holdings.
- 2.10 The food hygiene legislation states that “It is appropriate for the hygiene requirements applicable to primary production and associated operations to differ from those for other operations.”⁵ The Agency is working to put in place pragmatic enforcement arrangements for primary production that reflect the legislative approach and acknowledges the differences (e.g. to the control of hazards) between primary production and other food businesses closer to the consumer.
- 2.11 When the Final RIA was completed, no formal decision had been taken as to the body or bodies that would undertake the enforcement for primary production activities not already covered. The Final RIA could not therefore provide any substantive information as to the impact on any particular enforcement body.⁶
- 2.12 In March 2006, the Agency’s Board accepted the recommendation that, in England, Local Authorities would undertake the enforcement of primary production. A number of criteria supported the choice of Local Authorities providing the enforcement function. Local Authorities

³ The Food Hygiene Regulations do not apply to “the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer” Regulation (EC) 852/2004, Article 1, 2(c).

⁴ Holding numbers are issued by Defra. In most cases, a ‘holding’ corresponds to a historic farm ‘unit’. Where holdings may have been added to a farm business, the holding numbers are retained and there may be therefore several holdings in one farm business. The figures quoted are a reconciliation between 2004 Agricultural Census data and Local Authority breakdown.

⁵ Regulation (EC) 852/2004, Recital 11.

⁶ Research undertaken in January and February 2002, by ADAS Consulting Ltd, Project B18004, *Work to Inform the Preparation of a Regulatory Impact Assessment* on behalf of the Agency, did look, amongst other issues, at the potential impact on an enforcement body, but provided little substantive evidence.

already have local infrastructures delivering a full range of hygiene enforcement services from inspections through to formal enforcement action, in manufacturing, catering and retail; on-farm responsibility would therefore provide a 'whole food chain' role for Local Authorities.

- 2.13 Local Authorities are already active on-farm in areas of Animal Health and Welfare and feed enforcement. Although the extent of feed law enforcement activities can vary between Local Authorities, many Local Authority officers will already have experience of on-farm inspections. Under existing legislation, Local Authorities are responsible for the registration of farms that mix feed containing certain additives. Furthermore, from January 2006, Local Authorities have had responsibility for the inspection of other farms to enforce the EU Feed Hygiene Regulation⁷.
- 2.14 The inspections are likely to be undertaken by Trading Standards Officers (TSOs) in the majority of cases, but in Unitary Authorities, the work might be undertaken by Environmental Health Officers (EHOs). Local Authorities can make decisions locally as to which authorised officers undertake the work.
- 2.15 More information is available on the costs and benefits to Local Authorities arising from the establishment of these enforcement arrangements. Work is being taken forward on the nature of the enforcement arrangements contemporaneously with work to develop this RIA and may well reveal information on the costs, if any, and benefits to primary producers that result.
- 2.16 The initial indications (from informal consultation) are that extra costs to primary producers deriving from the enforcement arrangements would be minimal. From the outset, the Agency has set out to establish enforcement arrangements commensurate with the nature of the industry. The majority of primary food products from farmers and growers undergo processing later down the food production 'chain', where controls based on HACCP principles established by the food hygiene legislation are in place. Primary producers are required by the legislation to control hazards with regard to later processing. The measures for primary producers as set out for primary production are laid down in Annex I of Regulation 852/2004 (in full in **Annex 3** in this RIA), and amount, in effect, to basic hygiene procedures. These measures are summarised in **Annex 1** of this RIA.
- 2.17 As part of the work being taken forward to establish the enforcement arrangements, the Agency is regularly meeting and taking the advice of the major stakeholders in this area, notably Local Authorities, the industry and from Farm Assurance schemes.
- 2.18 It is proposed that membership of recognised Farm Assurance schemes is used in determining frequency of inspection. This is expanded on later in this RIA.

⁷ EU Regulation (EC) 1831/2003

- 2.19 The opportunity will be taken to newly establish pragmatic enforcement arrangements in line with Better Regulation principles.
- 2.20 The Food Standards Agency is responsible for the audit of Local Authority food law enforcement⁸. To help Local Authorities adjust to the new organisational demands, monitoring by the Agency of the new enforcement regime is unlikely to start until the new regime has bedded down. It is anticipated that there will be an opportunity to review the operations after 12 months to consider monitoring arrangements.
- 2.21 The RIA will be developed further in the light of information gathered from on-going work to establish the enforcement arrangements (including informal contact with stakeholders) as well as from a formal consultation.

iii) Rationale

- 2.22 There are three fundamental reasons for the establishment of enforcement arrangements at primary production level. The arrangements will,
- satisfy the UK's Treaty obligations to properly apply EU legislation. EU legislation also lays down broad principles for official controls in relation to food law⁹;
 - contribute to public health protection by helping to ensure that good food hygiene standards for farming and growing activities are both maintained and improved through effective monitoring and inspection on an on-going basis and may lead to increased confidence among consumers about the safety of food; and,
 - establish a consistency of enforcement activity throughout the food chain, from 'farm to fork'.

3. Consultation

(i) Within Government

- 3.1 Views have been sought, both in formal consultations and informally, from the Department for Environment, Food and Rural Affairs (Defra) (in England) throughout the negotiations on the regulations. Contact with Defra continues on the work establishing food hygiene enforcement arrangements.

⁸ This audit of Local Authority food law enforcement is conducted against the requirements of the Standard set out in the Framework Agreement on Local Authority Food Law Enforcement. The Standard sets out the minimum levels of performance expected in relation to the full ranges of local authorities' food and feed law enforcement activity.

⁹ EU Regulation (EC) 882/2004

- 3.2 In order that funding be obtained for Local Authorities under Section 31 of the Local Government Finance Act, Ministerial policy approval and Treasury consent is required. HMT approval was granted on 13 July 2006 and policy approval is being sought through correspondence within the Ministerial Committee on Local and Regional Government.
- 3.3 Liaison with the Office of the Deputy Prime Minister (now the Department for Communities and Local Government) was necessary in seeking reassurance that the Agency had obtained approval in principle from Local Government Association / LACoRS and other stakeholders sufficient to satisfy HMT and make the Section 31 payments.
- 3.4 Stakeholders, including those representing industry and enforcement, were asked for their views on 'primary production issues' as part of the consultation on the Food Hygiene (England) Regulations 2005, which closed on 31 January 2005. Comments included the need for consistent and pragmatic interpretation of the regulations, training for those carrying out and auditing inspections. The possibility of using information from industry Farm Assurance schemes was also raised. The Agency has carefully considered these comments when formulating policy in this area and is reflected in the Agency's preferred option.
- 3.5 This RIA (in a partial form) is subject to a full public consultation in late August 2006 along with other consultation material on the proposed operation of the new enforcement arrangements. Information drawn from the consultation responses will be used to further inform and update this RIA.

4. Options

- 4.1 The Agency identified three options in considering the establishment of food hygiene enforcement arrangements for primary production. Those options are identified below:

Option A - Do nothing. Failure to put in place enforcement arrangements for primary production could lead to action (in the form of infraction procedures) being taken against the UK by the European Commission. It would also mean missing an opportunity to put in place enforcement arrangements that could raise standards of food hygiene in the industry thereby leading to greater long-term public health protection.

Option B - The standard approach to enforcement currently used for food businesses other than primary production. The wording of the food hygiene legislation¹⁰ reflects the situation that with many primary products, processing activities further down the

¹⁰ Regulation (EC) 852/2004, Annex I, Part II, 1(2) "As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo."

supply chain will eliminate hazards to human health that might be introduced at this point in the food chain. The legislation does not require HACCP-based procedures for primary production and associated activities (see **Annex 2.**) This suggests that the adoption of the same enforcement procedures for primary producers as for other types of food businesses, even were primary producers to be considered 'low risk' and therefore subject to the minimum level of inspection as stated in the Food Law Code of Practice, would not recognise the particular nature of primary production. This could lead to disproportionate levels of inspection and would be burdensome both on farmers and Local Authorities.

Option C - An evidence-based enforcement approach. In considering the arguments against the use of a standard enforcement approach as outlined in paragraph 4.1 (b), and in the light of Better Regulation principles, the Agency wanted to explore the opportunity for a new approach to the enforcement of food hygiene legislation that recognised the particular nature of primary production activities. The enforcement arrangements currently being put together reflect therefore the relatively low-risk, overall, of the majority of primary production activities (as compared to the impact of processing and handling closer to the final consumer) enabling the evidence provided by membership of Farm Assurance Schemes (and other intelligence gathered by Local Authorities) to be considered when considering the rate of inspection frequency (see **ANNEX 4.**) The arrangements would be subject to review after operating for a suitable period of time, probably one year.

5. Costs and Benefits

i) Sectors and Groups affected

5.1 The groups affected are Local Authorities and those primary production farming and growing sectors where enforcement arrangements do not currently exist (i.e. all, except the dairy and eggs sectors.)

5.2 The likely impact on primary producers in terms of compliance with the regulations has been covered in the Final RIA. However, when putting together the Final RIA, neither the body undertaking the duties nor an exact picture of the enforcement arrangements (e.g. inspection frequency, nature of inspections) was known.

ii) Costs and Benefits for the Options (A – C) identified at paragraph 4.1

Option A - Do nothing

Costs

- 5.3 Failure to put in place enforcement arrangements for primary production could lead to the European Commission instigating infraction procedures against the UK including fines.

Benefits

- 5.4 None identified.

Option B - The standard approach to enforcement

Costs

- 5.5 The financial impact on Local Authorities would be nil or minimal. The established principle that requires Government Departments proposing initiatives and policies constituting new burdens on Local Authorities to quantify the likely costs and transfer resources accordingly would apply - this would need to have been undertaken had this approach been adopted. It is estimated that the cost would have been £3,228,036 (see paragraphs 5.10 to 5.13 below for the calculation).
- 5.6 However, determining what that cost might have been (i.e. for the enforcement arrangements to be wholly in line with the enforcement of other premises where Local Authorities undertake inspections, such as shops, caterers and some manufacturers) requires considerable assumption. Notably, that enforcement arrangements would continue without consideration of policy that recognises the benefits of a unique approach to primary production (or, more precisely, to those producers covered by Annex 1 of Regulation 852/2004.)
- 5.7 Assuming that a standard approach was adopted, the best guide (for the purposes of this RIA) to the determination of inspection nature and frequency would be the Food Law Code of Practice¹¹(CoP). The CoP sets out the criteria Local Authorities' Authorised Officers (such as TSOs and EHOs) should consider when determining inspections.
- 5.8 Even were it considered that primary producers would be determined collectively as 'Low Risk', Annex 5.2.3(xi) of the CoP states that such premises should still be subject to an "alternative enforcement strategy not less than once in any 3-year period".
- 5.9 On the basis therefore that farmers and growers would be subject to a visit, on average, once in each three years, and using the figures for holdings of 107,000 (see paragraph 2.9) this would lead to approximately 35,660 inspections per year in England.
- 5.10 This 35,660 number would need to be moderated by those inspections that could be 'doubled-up' with existing visits to farms for other purposes by Local Authority Authorised Officers. This would be 2036¹² existing visits to farms by TSOs for the purposes of feed hygiene law,

¹¹ A pdf copy of the current Food Law Code of Practice can be accessed on the Agency's web site at: <http://www.food.gov.uk/multimedia/pdfs/codeofpracticeeng.pdf>

¹² Total number of inspections January 2005 – December 2005.

an approximate 3,000 per annum other visits for a range of other legislation¹³ and approximately 4,000 visits (2,400 for food hygiene and 1596 for food standards¹⁴) by EHOs/TSOs visiting farm premises to enforce food hygiene and food standards legislation. This would result in 9,036 visits where there might be the extra duty of enforcing the hygiene legislation. It would be reasonable to add 10% to the cost of those inspections with the added duty of enforcing the food hygiene legislation. This would be £99,396 (calculated as 10% of 9,036 X £110 = £993,960).

- 5.11 Subtracting 9,036 from 35,660 = 26,624 new visits per annum. Assuming an average half day (or 3.5 hours) per visit including journey time (this could of course vary widely depending on location) would mean two visits realistically per day. With costs estimated at £30¹⁵ per hour multiplied by 7hours for a working day = £210 per day or £110 per half day. So, on the basis of one visit either morning or afternoon, this would be 26,624 multiplied by £110 = £2,928,640 per annum.
- 5.12 The cost of training could be considered to be approximate to that being allocated for Option C (below) and which is £200,000 per annum.
- 5.13 The total cost would therefore be £99,396 + £2,928,640 + £200,000 = £3,228,036.
- 5.14 The impact on primary producers would be minimal. The costs would be farmers and growers' time incurred by inspections, which would be less than 3.5 hours in three years. **Question: Your views are welcome as to the extra burdens the Option B arrangements might have incurred.**

Benefits

- 5.15 This enforcement approach is 'tried and tested'. The main benefit would be consistency of approach along the food chain, already well established and reflecting the 'farm to fork' approach of the legislation.
- 5.16 Enforcement arrangements would contribute to public health protection by helping to ensure that good food hygiene standards for farming and growing activities are both maintained and improved as effective monitoring and inspection will lead to a higher level of compliance with the new laws.

Option C - An evidence-based enforcement approach

Costs

¹³ Approximately 70,000 activities per quarter for welfare, horse passports, cattle records etc. However the actual number of visits would be much smaller. The 3,000 therefore approximation seems reasonable when considering other TSO visits.

¹⁴ Figures cover 2004 / 2005 financial year based on Local Authority returns to the Food Standards Agency's Local Authority Enforcement Division.

¹⁵ Figures provided by the Agency's Local Authority Environmental health Division. Costs per visit based on £25 - £35 per hour.

- 5.17 The costs to Local Authorities of implementing the proposed enforcement arrangements should be nil or minimal, for the following reasons. There is an established principle that requires Government Departments proposing initiatives and policies constituting new burdens on Local Authorities to quantify the likely costs and transfer resources accordingly. Consequently, the Agency has secured funding.¹⁶ In considering the amount of funding for the new enforcement arrangements, information was drawn from work undertaken over several years by the Dairy Hygiene Inspectorate on behalf of the Agency.¹⁷ It is not envisaged that Local Authorities would need to undertake inspections beyond that for which funding has been provided. The enforcement arrangements will be reviewed.
- 5.18 The EU food hygiene regulations require all food businesses, including farmers and growers to be registered with the 'competent authority'. The costs to farmers and growers of this requirement would be minimal - the Final RIA noted that for most farmers and growers this will not be a burden as existing forms of registration (e.g. information held by the Rural Payments Agency) can be used for this purpose. This is fully in line with the Better Regulation principle that Government Departments should share data where there are not legal barriers. The options for achieving this without requiring a specific registration action by farmers are being pursued. **Question: Your comments are welcome on the extra burdens the proposed arrangements may incur.**
- 5.19 The costs to farmers and growers in time incurred by inspections would also be minimal. **Question: Your comments are welcome on the extra burdens the proposed arrangements may incur.** The proposed frequency of inspection would result in an average 2% inspection rating for those farms in recognised Farm Assurance schemes, with Local Authorities utilising other intelligence to determine any raising of the frequency in certain farming and growing sectors. Those farms not in Farm Assurance schemes or with negative local intelligence would be subject to an average 25% inspection rating.
- 5.20 Although feed law enforcement can vary between Local Authorities, many Local Authority officers will already have experience of on-farm inspections. Either way, this will mean that Local Authority Officers will, in many cases, be able to combine inspections for food hygiene

¹⁶ The total amount of funding available in England for enforcement is £1.2 million per annum. Of that, £200,000 will be retained for centrally provided support and training and the remaining £1 million will be distributed to individual Local Authorities under Section 31 of the Local Government Finance Act. An initial part year payment will be made available from December 2006, which will be £500,000 for enforcement and £100,000 for training and support. From April 2007, £1 million will be paid for enforcement and a further £200,000 will be retained for training and support. From April 2008, £1.2 million will be transferred to the Revenue Support Grant (RSG) for distribution to Local Authorities under the formula grant.

¹⁷ The Dairy Hygiene Inspectorate have conducted on farm dairy hygiene work on behalf of the Food Standards Agency for a number of years, and the costs related to this work been used when considering the hygiene inspections under the new regime. It is estimated that for the £1.2m funding provided for the new hygiene enforcement work up to 15,000 inspections p.a. could be conducted. Determining a precise figure is not yet feasible and will be significantly influenced by the potential for enforcement bodies to combine a number of inspections in a single visit – informal consultation suggests that industry prefer combined inspections as it lowers the overall number of visits.

purposes with existing inspections for Animal Health and Welfare and Feed Hygiene potentially reducing the time burdens on farm businesses.

- 5.21 The table at **Annex E to the consultation** sets out the detail of the proposed inspection frequency.

Benefits

- 5.22 The proposed enforcement arrangements will contribute to public health protection by helping to ensure that good food hygiene standards for farming and growing activities are both maintained and improved as effective monitoring and inspection will lead to a higher level of compliance with the new laws. By using both risk ratings and available sources of hygiene related evidence inspections will be closely targeted to any business causing concern.
- 5.23 The use of Farm Assurance scheme membership as a criterion in determining frequency of inspection (i.e. membership of recognised schemes effectively lowering the number of inspections for a farmer or grower) may act as an incentive for farmers and growers to join such schemes. This would lead, in England, to a higher proportion of primary products produced under Farm Assurance schemes and to increased consumer confidence about the safety of UK produce (food produced under Farm Assurance schemes is identified as such by its labeling.)

6 Charities and Voluntary Organisations

- 6.1 No particular added burdens to charities and voluntary organisations have been identified. Charities or voluntary organisations undergoing primary production activities will not be subject to any more burdens than any other similar food business.

7. Competition Assessment

- 7.1 Initial considerations suggest that a Competition Assessment would not be relevant. This will be re-considered at a later stage.

8. Sustainability

- 8.1 The three Options' costs and benefits have each been detailed in Section 5 in terms of the economic and social pillars of sustainability. No substantive impacts on the environment were identified - there is likely to be an increase to the overall number of inspections in rural areas and therefore increased vehicle journeys, but it is not expected to be significant (see Option 3 below).

- 8.2 In terms of the relative sustainability of each option, for

- Option 1, by not complying with its obligations under EU legislation, significant costs to the UK could result following infraction procedures being taken against the UK by the European Commission. This is not set off against any benefits and therefore not sustainable.
- Option 2, suggests low costs to government and minimal costs to primary producers. Although the estimated low costs to Government are based on the assumption that those primary producers for which this RIA is concerned would all be considered 'low risk' and this might not be the case. However, there would be benefits in terms of health protection, which might outweigh the costs, although this seems unlikely.
- Option 3, suggests minimal costs both to Government and to primary producers. The costs are more accurately known than for Option 2 and, for most producers fewer visits than in Option 2, with no reduction in terms of health protection. The evidence-based approach of Option 3 seeks to avoid duplication where possible, including of inspections (saving time, lowering any pollution caused by journeys etc). There is therefore a better balance of costs and benefits with Option 3 and so this is the most sustainable.

9. Enforcement, sanctions and monitoring

- 9.1 The question of whether a Public Services Threshold Test will be developed will be considered.

EU FOOD HYGIENE LEGISLATION

Regulation (EC) 852/2004 *on the hygiene of foodstuffs*

The requirements on primary producers in Regulation (EC) 852/2004 are:

1. Primary producers will need, as far as possible, to ensure that primary products are protected from contamination, having regard to processing that primary products will subsequently undergo.
2. Primary producers must respect other existing legislation in terms of fertilisers, veterinary medicines, plant protection products, feed additives, zoonoses and disposal of waste.
3. Primary producers are required to keep facilities, vehicles, equipment etc clean and, as necessary, disinfected. They will need to use potable or clean water where necessary, ensure staff handling foodstuffs are in good health and trained on health risks, as far as possible control pests and take account of any test results. They need to take a precautionary approach to the control of diseases transmissible to humans via food and report suspected outbreaks of such diseases to the competent authority. They will need to keep some records and comply with requirements for food chain information. In practice, the requirements are expected to entail relatively modest change to current practice.
4. The controls can be addressed in Good Practice Guides to be developed by industry with support from other stakeholders.
5. As with other food businesses, primary producers have to be registered with competent authorities.
6. The rules applying to primary production also cover certain associated operations such as the transport, storage and handling of primary products from the place of production to an establishment.
7. Primary producers will **not** be required to apply HACCP based procedures.

EU FOOD HYGIENE LEGISLATION

Regulation (EC) 852/2004 on the hygiene of foodstuffs

General description of the features of the package of Regulation (EC) 852/2004

- the paramount concern to protect human health;
 - the principle of a 'farm to fork' approach to food safety;
 - the use of procedures based on HACCP principles (but not necessarily HACCP *per se*) to identify, control and monitor critical food safety points in food businesses (except primary producers);
 - the adoption of microbiological criteria and temperature control measures;
 - the development of good practice guides to aid compliance;
 - the monitoring of food hygiene by the competent authorities of the Member States; and,
 - the obligation on food business operators to ensure that only foodstuffs not harmful to human health are placed on the market.
2. It applies to all stages of production, processing and distribution of food (including primary production) other than:
- primary production for private domestic use
 - domestic preparation, handling or storage of food for private domestic consumption and
 - the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments supplying the final consumer (controlled nationally).
3. The Regulation contains "horizontal" rules which are those which will apply across all food sectors.
4. Food businesses need to be registered with the competent authority so that enforcers know where food businesses are and may factor them into official control programmes.
5. This proposal also lays down basic hygiene requirements for premises, staff, packaging, storage, transport, and handling of foodstuffs.
5. With regard to primary production, the Regulation does not require the application of HACCP procedures at this level. It does however require that primary producers control the hazards associated with their operations. As with other food sectors, good practice guides may need to be produced.
6. The requirement that food imported into the Community complies with same or equivalent standards. It also contains the capacity for Member States to adapt certain of the provisions (without compromising the objectives of the Regulation) in certain circumstances, subject to Commission "approval" under comitology.

ANNEX 3*ANNEX I***PRIMARY PRODUCTION****PART A: GENERAL HYGIENE PROVISIONS FOR PRIMARY PRODUCTION AND ASSOCIATED OPERATIONS****1. Scope**

1. This Annex applies to primary production and the following associated operations:

- (a) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;
- (b) the transport, storage and handling of primary products at the place of production, provided that this does not substantially alter their nature;
- (c) the transport of live animals, where this is necessary to achieve the objectives of this Regulation; and
- (c) in the case of products of plant origin, fishery products and wild game, transport operations to deliver primary products, the nature of which has not been substantially altered, from the place of production to an establishment.

II. Hygiene provisions

2. As far as possible, food business operators are to ensure that primary products are protected against contamination, having regard to any processing that primary products will subsequently undergo.

3. Notwithstanding the general duty laid down in paragraph 2, food business operators are to comply with appropriate Community and national legislative provisions relating to the control of hazards in primary production and associated operations, including:

- (a) measures to control contamination arising from the air, soil, water, feed, fertilisers, veterinary medicinal products, plant protection products and biocides and the storage, handling and disposal of waste;

and

- (b) measures relating to animal health and welfare and plant health that have implications for human health including programmes for the monitoring and control of zoonoses and zoonotic agents.

4. Food business operators rearing, harvesting or hunting animals or producing primary products of animal origin are to take adequate measures, as appropriate:

- (a) to keep any facilities used in connection with primary production and associated operations, including facilities used to store and handle feed, clean and, where necessary after cleaning, to disinfect them in an appropriate manner;
- (b) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, equipment, containers, crates, vehicles and vessels;
- (c) as far as possible to ensure the cleanliness of animals going to slaughter and, where necessary, production animals;
- (d) to use potable water, or clean water, whenever necessary to prevent contamination;
- (e) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;

(f) as far as possible to prevent animals and pests from causing contamination;

- (g) to store and handle waste and hazardous substances so as to prevent contamination;
 - (h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority;
 - (i) to take account of the results of any relevant analyses carried out on samples taken from animals or other samples that have importance to human health;
- and
- (j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.

5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:

- (a) to keep clean and, where necessary after cleaning, to disinfect, in an appropriate manner, facilities, equipment, containers, crates, vehicles and vessels;
 - (b) to ensure, where necessary, hygienic production, transport and storage conditions for, and the cleanliness of, plant products;
 - (c) to use potable water, or clean water, whenever necessary to prevent contamination;
 - (d) to ensure that staff handling foodstuffs are in good health and undergo training on health risks;
 - (e) as far as possible to prevent animals and pests from causing contamination;
 - (f) to store and handle wastes and hazardous substances so as to prevent contamination;
 - (g) to take account of the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health;
- and
- (h) to use plant protection products and biocides correctly, as required by the relevant legislation.

6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.

III. *Record-keeping*

7. Food business operators are to keep and retain records relating to measures put in place to control hazards in an appropriate manner and for an appropriate period, commensurate with the nature and size of the food business. Food business operators are to make relevant information contained in these records available to the competent authority and receiving food business operators on request.

8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:

- (a) the nature and origin of feed fed to the animals;
- (b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods;
- (c) the occurrence of diseases that may affect the safety of products of animal origin;

(d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health;

and

(e) any relevant reports on checks carried out on animals or products of animal origin.

9. Food business operators producing or harvesting plant products are, in particular, to keep records on:

(a) any use of plant protection products and biocides;

(b) any occurrence of pests or diseases that may affect the safety of products of plant origin;

and

(c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.

10. The food business operators may be assisted by other persons, such as veterinarians, agronomists and farm technicians, with the keeping of records.

PART B: RECOMMENDATIONS FOR GUIDES TO GOOD HYGIENE PRACTICE

1. National and Community guides referred to in Articles 7 to 9 of this Regulation should contain guidance on good hygiene practice for the control of hazards in primary production and associated operations.
2. Guides to good hygiene practice should include appropriate information on hazards that may arise in primary production and associated operations and actions to control hazards, including relevant measures set out in Community and national legislation or national and Community programmes. Examples of such hazards and measures may include:

- (a) the control of contamination such as mycotoxins, heavy metals and radioactive material;
- (b) the use of water, organic waste and fertilisers;
- (c) the correct and appropriate use of plant protection products and biocides and their traceability;
- (d) the correct and appropriate use of veterinary medicinal products and feed additives and their traceability;
- (e) the preparation, storage, use and traceability of feed;
- (f) the proper disposal of dead animals, waste and litter,

protective measures to prevent the introduction of contagious diseases transmissible to humans through food, and any obligation to notify the competent authority;

(g) procedures, practices and methods to ensure that food is produced, handled, packed, stored and transported under appropriate hygienic conditions, including effective cleaning and pest-control;

(h) measures relating to the cleanliness of slaughter and production animals; measures relating to

(i) record-keeping.

PROPOSED INITIAL PRIMARY PRODUCTION INSPECTION FREQUENCIES

Farm type ¹	Assured ²	Other Intelligence ³	Inspection Level %
Non livestock – general cropping ⁴	Yes	Nil/positive	2
Non livestock – general cropping	No	Positive	
Non livestock – can be eaten raw crops ⁴	Yes	Nil/positive	
Non livestock – can be eaten raw crops	No	Positive	
Livestock	Yes	Nil/positive	2
Livestock	No	Positive	
Farms not featuring in other categories	Yes	Negative	25
Farms not featuring in other categories	No	Nil/Negative	

¹ Where farms are mixed, the highest inspection rating will determine the frequency. It will be left to enforcement authority discretion and planning to determine the need to inspect other aspects.

² Membership of a recognised assurance scheme.

³ Examples of local or other intelligence which the enforcement authority may use to consider whether inspection is necessary include membership of a 'recognised' farm assurance scheme, a change of activity, track record of compliance, Intelligence generated by other statutory inspections.

⁴ In relation to crops and plant products, a distinction has been made between those products that will be processed before they reach the consumer and those that can be consumed raw. More details are in the table in Annex D.