EXPLANATORY MEMORANDUM TO

THE QUICK-FROZEN FOODSTUFFS (ENGLAND) REGULATIONS 2007

2007 No. 191

1. This explanatory memorandum has been prepared by the Food Standards Agency and is laid before Parliament by Command of Her Majesty.

2. Description

2.1 This Statutory Instrument provides the administration and enforcement provisions for Commission Regulation 37/2005 on the monitoring of temperatures in the means of transport, warehousing and storage of Quick-Frozen Foodstuffs (QFF) intended for human consumption. It also carries forward, and consolidates, the existing requirements on conditions that must be fulfilled by quick-frozen foodstuffs from Council Directive 89/108/EEC and the existing requirements on sampling procedures and official methods of analysis of temperatures of quick-frozen foods from Commission Directive 92/2/EEC.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Background

4.1 Commission Directive 92/1/EEC established temperature monitoring regimes for the cold chain handling of QFF to ensure that temperatures required by Council Directive 89/108/EEC were met. Commission Directive 92/1/EEC has been repealed and replaced by the directly applicable Commission Regulation 37/2005 which requires temperature monitoring equipment used in the transport, warehousing and storage of QFF to achieve agreed, Europe-wide standards established by the European Committee for Standardisation (CEN).

4.2 There are three main points of difference between Directive 92/1/EEC and Regulation 37/2005. First, in the case of transport there is no longer a requirement for competent authorities to approve the temperature measuring instruments used. Also from 1 January 2006, all new measuring instruments used in transport, warehousing or storage of QFF must comply with the relevant European standards. Finally, from 1 January 2006 the legislation applied to rail transport for the first time. However, it is important to note that there are significant transitional provisions. Measuring instruments installed up to 31 December 2005, which met the legislative requirements at the time, can continue to be used until 31 December 2009.

4.3 This SI is, therefore, being made to provide the administration and enforcement provisions for Commission Regulation 37/2005 and consolidate the other existing requirements for QFF from Council Directive 89/108/EEC and Commission Directive 92/2/EEC. The Quick-frozen Foodstuffs Regulations 1990 (as amended) will be revoked.

5. Extent

5.1 This instrument applies to England. Separate but similar legislation is being developed in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Standards regarding instruments for monitoring and recording air temperatures have been established recently by the European Committee for Standardisation (CEN). Commission Regulation 37/2005 repeals and replaces Directive 92/1/EEC from 1 January 2006 and requires temperature monitoring equipment to achieve these agreed common CEN standards. Therefore, Regulation 37/2005 removes a potential barrier to trade by harmonising temperature monitoring equipment to meet accepted international standards.

7.2 Approval of temperature recorders in the UK has been linked to specifications laid down in national Regulations, and the equipment has been deemed to be approved if it met this specification. The European standards are more exacting than the current national specifications and bring in electrical safety and performance requirements under more severe conditions of use.

7.3 The requirements of Commission Regulation 37/2005, being in the form of a Regulation, are directly applicable in all Member States. However, national Regulations are required to provide the related administration and enforcement provisions for Commission Regulation 37/2005. The other EC Directives 89/108/EEC and 92/2/EEC on QFF remain unchanged, so this SI also carries forward, and consolidates, the existing requirements on conditions that must be fulfilled by QFF and existing requirements on sampling procedures and official methods of analysis of temperatures of QFF.

7.4 This SI specifies the provisions of Regulation 37/2005. The key new requirements are:

- all new temperature monitoring equipment / instruments used in the transport, warehousing and storage of QFF must comply with three European standards from 1 January 2006;
- extensive transitional provisions for 4 years for existing temperature monitoring equipment;
- the new temperature monitoring requirements now apply to transport by rail;
- documents to prove that equipment / instruments conform to the relevant European standard must be kept.

There are derogations from the new requirements of Regulation 37/2005 for: (i) retail display cabinets; (ii) transport of QFF in the course of local distribution; (iii) cold store facilities of less than $10m^3$ used for storing stock in retail outlets. These exemptions mean that there will be no additional burdens on businesses in these sectors, particularly small and medium-sized firms.

7.5 It should be noted that the legal requirements of the QFF Directives and Regulation only apply to foods meeting the definition of QFF and if they are labelled as 'quick-frozen'.

7.6 Failure to provide enforcement provisions for Commission Regulation 37/2005 would leave the UK open to infraction proceedings from the EC. The Regulation is directly applicable in all Member States and related national enforcement provisions should have been in place on 1 January 2006 but there have been some unavoidable delays in taking this forward. Despite the delay, we do not expect the Commission to start any immediate action. An 'interim position' letter was sent to UK stakeholders at the start of 2006 advising them of the new requirements, in particular that new temperature monitoring equipment should meet the relevant European standards from 1 January 2006, and that relevant national enforcement rules would be made at the earliest opportunity. Therefore, stakeholders were aware of the new requirements and that the new, consolidated Regulations were being drafted and due to be consulted upon.

7.7 A 15-week public consultation of about 200 interested parties was carried out on this SI and an accompanying partial Regulatory Impact Assessment (RIA), which concluded on 2 November 2006. Two responses were received to the England consultation from a trade association and a public body representing Local Authorities. Responses to the parallel consultations carried out in the devolved administrations on the proposed SI were also considered. All responses were supportive of the proposed approach taken in the draft SI to revoke and replace the existing, national Regulation with a single, consolidated up-to-date text. Specific comments made related to points of clarification concerning enforcement responsibilities and powers, which the Agency has addressed in correspondence to the consultee. Another comment related to the suggestion of additional text to the consultation draft of the SI but this suggestion was not included as it was considered not to add any further clarity.

8. Impact

8.1 A Regulatory Impact Assessment (RIA) has been prepared for this Statutory Instrument and is attached to this memorandum at Annex 1.

9. Contact

Helen Chapman at the Food Standards Agency (Tel: 020 7276 8639) or E-mail: helen.chapman@foodstandards.gsi.gov.uk) can answer any queries regarding the instrument.

FULL REGULATORY IMPACT ASSESSMENT

1. Title of Proposal

1.1 The Quick-Frozen Foodstuffs (England) Regulations 2007.

2. Purpose and Intended Effect

Objective

2.1 To provide for the enforcement, in England, of Commission Regulation 37/2005/EC on the monitoring of temperatures in the means of transport, warehousing and storage of Quick-Frozen Foodstuffs (QFF) intended for human consumption.

2.2 To consolidate the national legislation to make it easier for all stakeholders to reference.

2.3 The Commission Regulation requires the application of a uniform standard for temperature monitoring equipment and will ensure temperature-monitoring equipment complies with harmonised technical requirements and a common approval system across the EU. By establishing these requirements, the Regulation is concerned with maintaining food quality.

2.4 The Commission Regulation was published on 12 January 2005, the provisions apply from 1 January 2006 for new temperature monitoring equipment and from 1 January 2010 for equipment installed before 1 January 2006. The EC Regulation is directly applicable in all Member States but enforcement provisions in UK law were required to be in place by 1 January 2006. There have been some delays in taking this work forward. An interim position letter was sent to UK stakeholders at the start of 2006 outlining the new provisions, and no comments were received in response. The majority of interested parties were, therefore, aware that enforcement regulations were being drafted.

Background

2.5 Commission Directive 92/1/EC established temperature monitoring regimes for the cold chain handling of QFF to ensure that the temperatures required by QFF Directive 89/108/EC were met. When this Directive (92/1/EC) was adopted, standards for the instruments used to monitor temperatures for transport, warehousing and storage of QFF had not been established. Member States were required to approve equipment nationally and many Member States set up their own standards and testing regimes for temperature recorders and thermometers.

2.6 Standards regarding the instruments for recording air temperatures and thermometers have since been established by the European Committee for

Standardisation (CEN), in 1999[1], 2001[2] and 2002[3]. A new Commission Regulation, 37/2005/EC, published on 12 January 2005, repeals and replaces Directive 92/1/EC and requires temperature monitoring equipment to achieve these agreed common standards.

2.7 Specifically, Regulation 37/2005/EC requires that:

- all new temperature monitoring equipment must comply with the CEN standards from 1 January 2006 (temperature recorders must comply with EN 12830, thermometers must comply with EN 13485 and verification of the operation of both types of instruments must comply with EN 13486);
- existing measuring instruments installed up to 31 December 2005 (prior to the Regulation coming into force) must comply by 1 January 2010 and in the meantime must be compliant with the standards set out in the existing legislation (1990 QFF Regulations (as amended));
- the derogation in 92/1/EEC as regards transport by rail no longer applies. The draft Regulation will apply to all transport including by rail from 1 January 2006.

2.8 The QFF Regulations 1990[4] implemented, in the UK, Council Directive 89/108 EEC relating to QFF for human consumption. These Regulations came into force on 10 January 1991. The Regulations defined a QFF, laid down packaging and labelling requirements for a QFF, list the conditions that must be fulfilled by a QFF sold for human consumption and laid down requirements for standards of equipment used in control of QFF.

2.9 These Regulations were amended in 1994[5]. The amendment Regulations implemented in the UK, Commission Directive 92/1/EEC on the monitoring of temperatures of QFF during transport, warehousing and storage, and 92/2/EEC laying down sampling procedures and the official method of analysis for the official control of the temperatures of QFF. The amendment Regulations came into force on 1 September 1994 and provided that those handling QFF should fit their means of storage or transport (excluding rail transport) with appropriate instruments for monitoring or measuring air temperature and that records of air temperatures recorded during storage and transport should be kept for at least one year. Further requirements as to which instruments should be fitted and specifications for these instruments are given in the schedule to the amendment Regulations.

2.10 The Regulations were further amended in 2004 by The Food Safety (Act of Accession concerning the Czech Republic and other States) (Consequential Amendments) (England) Regulations 2004[6]. This Regulation made provision

[1] EN 12830:1999 Temperature recorders for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice-cream – Tests, performance and suitability
[2] EN 13485:2001 Thermometers for measuring the air and product temperature for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice-cream – Tests, performance, suitability
[3] EN 13486:2002. Temperature recorders and thermometers for the transport, storage and distribution of chilled, frozen, deep-frozen/quick-frozen food and ice-cream – Periodic verification
[4] The Quick-Frozen Foodstuffs Regulations 1990 SI 1990/2615
[5] The Quick-Frozen Foodstuffs (Amendment) Regulations 1994 SI 1994/298
[6] The Food Safety (Act of Accession concerning the Czech Republic and other States) (Consequential Amendments) (England) Regulations 2004 SI 2004/2145

for the term 'Quick Frozen' to be translated as appropriate in the languages of the accession Member States.

2.11 Approval of temperature recorders in the UK has therefore been linked to specifications laid down in the domestic Regulations, and the equipment has been deemed to be approved if it meets this specification. The CEN standards are a little more exacting and bring in safety (electrical) and performance requirements under more severe conditions of use.

Devolution

2.12 The proposed legislation will apply in England only. Separate, parallel legislation will be made in Scotland, Wales and Northern Ireland.

Rationale for government intervention

2.13 One of the key aims of this Regulation is to ensure the quality of food labelled as being QFF in terms of its maintained transport, warehousing and storage conditions. Failure to provide enforcement provisions for Commission Regulation 37/2005/EC may leave the UK open to infraction proceedings from the European Commission.

3. Consultation

Within government

3.1 The Department for Transport (DfT) and the devolved administrations in Scotland, Wales and Northern Ireland have been consulted during the development of the proposed Regulations and have been kept informed of new developments as they have arisen.

Public consultation

3.2 A partial RIA accompanied a formal 15-week public consultation launched on 20 July 2006 to gain stakeholder comments on the proposed draft England Regulation. Around 200 interested parties, including consumer organisations, industry associations and enforcement authorities were consulted. Two responses were received to the England consultation from a trade association and a public body representing Local Authorities. Responses to the parallel consultations carried out in the devolved administrations on the proposed legislation in similar terms were also considered. All responses were supportive of the proposed approach taken in the draft Regulation to revoke and replace the existing, national Regulation with a single, consolidated text. Specific comments made related to points of clarification concerning enforcement responsibilities and enforcement powers which the Agency has addressed in correspondence to the consultee. Another comment related to suggestion of additional text to the consultation draft of the Regulation but this suggestion was not included as it was considered not to add any further clarity.

4. Options

There are three possible options:

- Option 1: Do nothing

- Option 2: Amend the existing QFF Regulations 1990 (as amended) in line with the new EC changes

- Option 3: Revoke the QFF Regulations 1990 (as amended) and re-make so that there is new QFF Regulations which consolidates the existing QFF rules and the new EC changes, within a single SI

Option 1:

4.1 This option will not achieve the intended objective of establishing enforcement provisions for the new European standards for instruments used to monitor air temperatures to which QFF are subject during transport, warehousing and storage. Failure to establish such enabling enforcement provisions in national legislation may leave the UK open to infraction procedures from the Commission (under Article 226 of the EC Treaty). Option 1 is, therefore, not a practical or viable option.

Option 2:

4.2 This option would have the desired effect in that it would establish enforcement provisions for the new EC requirements, however, a large number of detailed amendments would be needed and this could create difficulties for all stakeholders as both the principal regulation and several sets of amending regulations would need to be consulted. The regulatory impact would be similar to Option 3 but with the disadvantage that it would be time-consuming for enforcement and industry to refer to several sets of amending regulations to check on all the relevant requirements for QFF.

Option 3:

4.3 Re-making the QFF regulations would fulfil the UK's obligations under the EC Treaty, and allow UK manufacturers to operate freely and competitively within the single market. In addition this would also meet the objective of consolidating the national regulations to make it easier for all stakeholders to reference and ensure an aspect of the quality of QFF for consumers.

5. Costs and Benefits

Sectors and Groups affected

5.1 It is estimated that a total of around 600 UK businesses would be affected. There are no cost effects expected for the voluntary sector. The business sectors potentially affected by this proposal would be food manufacturers (of which there are two major and approximately five smaller businesses who label their products QFF), cold storers/warehousers (of which it is estimated there are 156), distributors (of which it is estimated there are 450 – although

some may also store QFF), 1 major retailer, and a small number of temperature monitoring equipment manufacturers (estimated at 20).

Quick Frozen Food Market

5.2 The QFF Regulations only apply to foods labelled 'Quick Frozen'. Trade bodies have estimated that food labelled as 'Quick Frozen' accounts for a maximum of 15-20% of the total Frozen Food (FF) market (this upper percentage is estimated at approx. £862 million in 2005)[7]. The voluntary labelling of foods as having been 'Quick Frozen' is generally used as a marketing/consumer information device, although in practice it is not currently a term widely recognised by consumers although those that do would view it as a quality indication.

5.3 The frozen food market is characterised by own label products, which account for more than 47% of total value sales[7]. Intelligence from Trade Bodies suggests that only one major retailer and two major manufacturers label their QFF as such, along with some smaller manufacturers.

Benefits

5.4 The amount of benefits associated with each option are dependent upon the nature of individual businesses. However these are against the baseline that under the 1990 Regulations these businesses must already monitor air temperature during the transport, warehousing and storage of QFF, and keep temperature records for at least a year.

5.5 There is no legal requirement to label QFF as such, and the requirements do not apply to frozen products that are not labelled as QFF.

5.6 Targeted consultation with main stakeholders in the frozen food industry, LACoRS and consumer groups was undertaken during negotiations in 2004 and 2005 on the new Commission Regulation on QFF. During negotiations industry voiced some concerns about the rationale behind the introduction of the Regulations and the financial impact of replacing existing equipment with equipment that conforms to the standards. However, following UK lobbying for a longer transition time, the Commission agreed to extend the transition period for existing equipment to comply with CEN standards from 1 Jan 2008 (in the initial draft Regulations) to 1 Jan 2010, following a request from the UK at the June 04 EC Standing Committee. This should help to reduce costs of implementation by providing firms with added flexibility and thereby address industry concerns. In addition, the CEN standards will have been in place for 10 years by 2010.

Option 1 – Do nothing

5.7 There do not appear to be any significant benefits (economic, environmental or social) associated with this option.

Option 2 – Legislative change to amend QFF 1990 Regulations

[7] Mintel Report: Frozen Food UK. November 2001. Frozen Food market projected to be £4,309 M in 2005.

5.8 Application of a uniform standard will ensure temperature-monitoring equipment (TME) complies with harmonised technical requirements and a common approval system across the EU. This will remove the current barrier to trade (see para. 2.5) and increase national and international competition between TME manufacturers. Previously, although there was mutual recognition for vehicles with temperature recorders travelling within the EU, the system was inefficient of resources, and made it very expensive for equipment manufacturers to sell their temperature recorders in different Member States. A UK manufacturer of temperature recorders that wanted to market their equipment in Europe would have to ensure it complied with the separate standards of each Member State having its own system of approval.

5.9 Businesses who are compliant are likely to benefit in terms of marketing advantage. Early compliance with the CEN standards indicates that companies take legislation and standards seriously, and that they are supplying a product that is fit for purpose.

5.10 There are no significant social or environmental benefits associated with this option, although the significant transitional period should help minimise the unnecessary turnover of equipment outside of normal business cycles so helping to minimise compliance costs and conserve resources.

Option 3 – Legislative change to re-make QFF 1990 Regulations into a new single SI

5.11 The benefits of this option are identical to those for Option 2 above (see para. 5.8-5.9). In addition the option of re-making the QFF Regulations 1990 into a single, consolidated SI will bring together in one place the new requirements for measuring instruments (Commission Regulation 37/2005) with the existing requirements on conditions that must be fulfilled by QFF (Council Directive 89/108) and existing requirements on sampling procedures and official methods of analysis of temperatures of QFF (Commission Directive 92/2). This will provide enforcement bodies and industry with a single text against which compliance with the law on QFF can be measured and the associated advantages that this will bring in terms of saving time and resources by only having to consult one set of Regulations. Unfortunately, the time and resources saved cannot be precisely quantified as although the partial RIA invited stakeholders to estimate the number of hours potentially saved/reduced as a result of having a single set of legislation, this information was not provided.

5.12 The environmental benefits are as discussed in para 5.10 above, and there appear to be no significant social benefits associated with this option.

Costs

5.13 In order to estimate the likely additional administrative burden for industry relating to the reading and familiarisation required with the new single set of legislation, we have taken the time that the Local Authority Co-ordinators of Regulatory Services (LACoRS) will need to invest in these activities (2 hours per authority) and factored this up by the industry population. In addition, we

have included an extra hour per company for necessary internal dissemination of the new single set of legislation to key staff. Given that approximately 600 firms are required to read the new legislation and using a relevant hourly wage rate (including overhead uplift) of £22.15, this equates to an approximate one-off administrative cost to industry of £40,000. Again the degree of costs associated with each option are dependent upon the nature of individual businesses. However these are against the baseline that under the 1990 Regulations these businesses must already monitor air temperature during the transport, warehousing and storage of foods labelled as QFF, and keep records for at least a year.

5.14 The following estimates of implementation and policy costs are estimates using the available information. The consultation process did not provide more detailed data on these issues.

Option 1 – Do nothing

5.15 There may be some disadvantages to UK businesses in terms of restricting trade (as there may be less market for non-compliant equipment), necessitating development of new products and a lack of business certainty if CEN-compliant standards are not fully enforced.

5.16 There would also be costs to the UK government in relation to infraction proceedings as a result of non-implementation of EC legislation.

5.17 There are no significant environmental or social costs associated with this option.

Option 2 – Legislative change to amend the existing QFF Regulations

i) Administrative costs

5.18 There will be a one-off administrative cost to industry and enforcement in terms of reading and familiarising themselves with the amending Regulations. There will also be an ongoing and unchanged administrative cost to enforcement authorities in terms of monitoring and enforcing the amendment Regulations, and for industry and enforcement in terms of having to refer to several sets of amending regulations to check on all the relevant requirements for QFF.

5.19 It is estimated by LACoRS that it would take one local authority officer in each of the 499 local authorities in the UK about 1 hour to read the new Regulations. It is also estimated that up to another hour would be needed for officers to familiarise themselves with the relevant aspects of the CEN standards. With an hourly pay rate of £22.15 (as salient to business and public service professionals, including an overhead uplift – ONS, ASHE 2006) this would be equivalent to a one-off administrative cost of £22,100. It is considered that this total cost of up to £22k would be the global maximum figure which is not likely to be exceeded.

5.20 Local Authority enforcement bodies already have responsibility for the enforcement of the current QFF Regulations 1990. The new provisions are

not considered to represent a substantive extension of their responsibilities given that new provisions relate mainly to ensuring that, from 1 January 2006, all new measuring instruments used in the transport, warehousing, or storage of QFF comply with the relevant CEN standards. This requirement also applies now to transport of QFF by rail but as mentioned below (see para 5.35) there is very little, if any, such transport in the UK so the resource implications for enforcement bodies in this respect is considered to be minimal.

5.21 In addition, it should be noted that there are significant transitional provisions in that measuring instruments installed up to 31 December 2005 which met the legislation and standards in force at the time, can continue to be used until 31 December 2009. Thus, for such measuring instruments enforcement bodies can continue to enforce existing requirements with which they are already familiar.

5.22 In terms of enforcing the provisions relating to conditions to be fulfilled for QFF *per se* and the sampling and official control of temperatures of QFF, these are existing requirements and so there will be no additional enforcement costs in these respects. The same zero incremental impact applies for inspection of temperature records by authorised officers which is already an existing requirement, the main addition being that they would also need to satisfy themselves that documentation verifying conformation to CEN standards was available for relevant measuring instruments.

5.23 Given that the Regulations are concerned with maintaining food quality, compliance checks may be less frequent than for legislation concerned with food safety. It is understood that temperature monitoring of QFF is carried out as part of other inspections, and not normally during every inspection. Enforcement of QFF rules consists of a staged sequence of examinations and measurements, as described in the existing Code of Practice, the first step being a check of air temperature and any air temperature monitoring records; only if there is reasonable doubt about compliance with the Regulations does an authorised officer proceed to the next step. There is extensive Guidance for enforcement bodies on procedures to be followed on the staged approach to enforcement. Both the Code of Practice and Guidance are being revised to reflect the new legislative changes on QFF and will be subject to a separate public consultation when the statutory Food Law Code of Practice and Guidance is consulted upon in their entirety.

5.24 In light of the above, LACoRS has confirmed that there will be minimal incremental resource implications for enforcement, other than up to a total of £22k for enforcement bodies to become familiar with the new single SI and the CEN standards. **Therefore, the ongoing enforcement costs will be the same as before but with an additional, maximum one-off cost of £22k for familiarisation with the new Regulations.**

ii) Costs to industry

5.25 The degree of costs will be dependent on the size and nature of the sector affected and the individual business. Again costs relate only to those companies involved in the trade of QFF labelled as such. A proportion of

these additional costs are likely to be passed on downstream. To that extent, whilst we present a full monetisation of costs to transporters, warehousing and storage businesses as well as manufacturers and retailers, we recognise that some of these costs may already have been accounted for by the temperature monitoring equipment (TME) manufacturers at manufacturing level.

Temperature Monitoring Equipment (TME) Manufacturers

5.26 Discussion with companies manufacturing TME for both the transport & distribution and storage sectors of the QFF chain indicate that there is already high compliance with the new CEN standards (estimated by a Trade Association that 30-40% of all TME in use is already compliant). For example, the largest manufacturer of TME for the UK refrigerated transport industry, who account for approximately 60% of the market, have been fully compliant for some time now.

5.27 The cost to TME manufacturers of ensuring that new TME products developed are compliant with the new standards has been estimated by a major manufacturing firm to be in the region of £4,000-10,000 for each new product (median £7,000). Figures for the number of new products likely to be manufactured per year are not available.

5.28 It has been estimated that there are around 20 manufacturers of TME in the UK. Assuming that each manufacturer launches 5 new TME products each year, the total cost to TME manufacturers will be in the region of £700,000. **In practice however, the additional cost to UK manufacturers of TME will be minimal as the costs outlined above do not necessarily represent a new or additional burden to industry, as previously businesses were required to ensure that equipment met the standards laid out in the 1990 regulations.**

Distribution, Warehousing and Storage businesses

5.29 Interested parties consulted about costs for new temperature monitoring equipment have indicated that costs would be minimal. In addition, administrative costs will be reduced as industry has been given plenty of notice, through consultation during EC negotiations and other means, of the new requirements. This will allow them to use existing equipment installed before 31 December 2005 for another four years.

5.30 As a result of the new Regulations distribution, warehousing and storage businesses who do not have compliant TME will have to meet costs in relation to purchasing, installation and testing of new compliant TME prior to the end of 2009. Once again discussions with affected firms indicates that there is already high compliance with the new standards. This is confirmed by data from industry sources who have estimated that 30-40% of TME in use is CEN compliant.

5.31 The cost of replacing non-compliant equipment will obviously be heavily dependent on the nature of individual businesses and their equipment needs. Discussions with suppliers of TME indicate that temperature monitoring units

can cost from £44 up to around £500 and the software required to log and store the data on computer costs in the region of £60. Additional installation costs of between £150 and £200 may also apply, although this will be dependent upon the exact specification of the equipment used and the location of the installation.

5.32 While the total cost to individual companies of replacing non-compliant equipment will again vary depending on the size of the business and their specifications, on the basis of discussions this may be expected to be in the region of £2K-10K per company (we here assume an average cost of £5K per company).

5.33 A Trade Association body has estimated that 30-40% of TME equipment in use is already compliant with the new CEN Standards. If we assume that the remaining 65% of equipment that is non-compliant is evenly distributed across the distribution, warehousing and storage sectors of the QFF market, we estimate the gross UK-wide costs associated with upgrading this equipment to be compliant will be approximately £2 million spread over 4 years[8].

5.34 However, TME has a typical life-span of around 5-10 years and the estimated gross cost of compliance of £2M does not take account of those companies who would already be expecting to update or replace their equipment during this period up to 2010 as part of a regular business investment cycle of equipment updating. It is also key to recognise that the net cost of upgrading to compliant equipment for businesses will be significantly lower as it is, in reality, based on the differential cost of replacing non-compliant TME with compliant TME, rather than with a newer non-compliant model given that the upgrade occurs within the commercial business investment cycle. The price differential between compliant and non-compliant equipment is likely to be minimal and has been estimated to be in the region of £500[9] per firm. **Therefore the actual cost to UK businesses is likely to be in the region of £195,000 over 4 years[10] (or £50k per annum for 4 years).** In addition these costs (especially those facing the minority of companies whose investment cycle has been speeded up to ensure compliance) could be off-set by the sale to non-QFF businesses of the non-complaint equipment being replaced, as noted at para 5.42.

Rail transport

5.35 Under the earlier 1990 QFF Regulations (as amended), transport of QFF by rail was exempt from the specified temperature monitoring standards. Under

[8] Assuming that 10% of non-compliant businesses per year update their equipment from now until 2010 when the remainder of businesses will have to change, then in the first year 15 storage businesses and 45 transporting businesses will need to buy new equipment at a cost of e.g. £5,000. This would translate to a cost of £300,000 per year (for 4 years i.e. 2006 till 2009) until 2010. Then in 2010 the remaining 30% would change their outstanding non-complaint equipment.

[9] Estimate based on the assumption (following discussion with industry) that there is a 10% difference between the average cost (estimated at £5000 in para 5.32) of replacing non-compliant equipment with compliant equipment, rather than simply with a newer non-compliant model.

[10] Assuming a 7.5 year average investment cycle for TME equipment and that the estimated 65% of currently non-compliant equipment come 2010 is the next in line to be replaced. Then over the salient four years, approximately 50% of all TME equipment (320 of the 600 company equivalents) would be anyway due for replacement, leaving a little over 10% whose replacement would require speeding up, and then only by a year or so.

the new EC regulations this derogation no longer applies. From discussions with industry it is understood that rail transport has historically been a very small proportion of the transport of QFF, and nowadays it is likely that there are only 1 or 2 trains transporting QFF to the more inaccessible parts of the UK. **Therefore the financial impact of removing this exemption is considered to be minimal.**

Manufacturers and retailers

5.36 From discussions with Trade Associations and industry contacts we understand that only 2 major manufacturers, a few smaller manufacturers (estimated to be around 5) and one major retailer fully label their products as 'Quick Frozen'.

5.37 Manufacturers and retailers may face costs related to ensuring that the TME installed in their in-house storage and, where appropriate, display facilities are compliant with the new standards. The degree of these costs will again be dependent upon the proportion of their business that is QFF. The costs of new TME will be comparable to the costs to distributors/stores/warehousers described above in para 5.34.

5.38 Information from the British Retail Consortium (BRC) indicates that their members are already compliant with the new legislation, therefore compliance costs will only apply to retailers who are non-BRC members and QFF manufacturers, of which we know there are only a few. It is estimated that it will cost approximately £242,500 over 4 years in order to ensure that those UK retail and manufacturing companies not already compliant with the new CEN standards are now compliant[11].

5.39 However once again in practice the cost will be significantly lower as it relates only to the differential cost between replacing non-compliant equipment with compliant equipment. **The cost of replacing each piece of TME is estimated at £25[12], giving an actual cost to UK wide retailers and manufacturers of approximately £12,500 over the 4 year transition period.**

5.40 Manufacturers and retailers may also be impacted financially if TME manufacturers and distributors and warehousing/storage companies pass on some or all of their costs associated with compliance. These costs are described above (para 5.28 and para 5.34) and as such do not represent additional costs to the QFF chain.

5.41 There is a risk that if retailers and manufacturers consider the cost of replacing temperature monitoring equipment is prohibitive they may simply no longer label their products as 'Quick Frozen'. This would consequently have potential

[11] We have estimated that there are around 25 regional distribution and warehousing units across the UK which service non-BRC retailers and manufacturers of QFF. We have assumed that each depot operates on average 10 lorries and comprises 10 cold stores and that each lorry and store will have at least one sensor and associated central logging equipment. We are aware that TME costs between £44 and £500 with software costing in the region of £60, and installation costs between £150 and £200 (see para 5.31). Taking a median of these costs, it will cost £485 per piece of TME replaced.

[12] Estimate of £25 based on assuming a 10% differential cost between the median cost of compliant and non-compliant equipment (estimated at around £250 based on cost of compliant equipment ranging from £44-£500).

spill over effects downstream with companies who store or transport such products.

iii) Policy costs

5.42 There may be some environmental sustainability issues associated with the proposed Regulation in relation to the replacement and disposal of non-compliant equipment. Discussions with interested parties indicates that TME manufacturers will be able to market non-compliant equipment to businesses who do not operate in the QFF chain, but who still wish to monitor temperatures. It is likely that other affected businesses replacing non-compliant equipment will be in a similar position, and there should therefore not be a significant increase in the disposal of older equipment. We therefore do not consider there to be any significant environmental costs associated with this option.

5.43 There are no significant social costs associated with Option 2.

Option 3 – Legislative change to re-make the QFF Regulations into a single SI

i) Administrative costs and costs to industry

5.44 The costs of this option are identical to those outlined for Option 2 above. However, additionally the recommended option of re-making the QFF Regulations 1990 into a single, consolidated SI will bring together in one place the new requirements for measuring instruments (Commission Regulation 37/2005) with the existing requirements on conditions that must be fulfilled by QFF (Council Directive 89/108) and existing requirements on sampling procedures and official methods of analysis of temperatures of QFF (Commission Directive 92/2). This will provide added benefits to consumers, industry and enforcement bodies with a single text against which compliance with the law on QFF can be measured and the associated advantages that this will bring in terms of saving time and resources by only having to consult one set of Regulations.

ii) Policy costs

5.45 The policy costs associated with this option are the same as those outlined above for Option 2.

Summary

5.46 There is a concern over the sustainability of Option 1 as it would leave the UK open to infraction proceedings from the EU. The costs and benefits identified above do not give rise to concerns about the overall sustainability for Options 2 and 3. The impacts identified in the costs and benefits section are relatively minor. There are no race equality or disability impacts associated with this proposal.

6. Small Firms Impact Test

6.1 Initial discussions with industry have indicated that there will be some limited impact associated with the new Regulations on small businesses, and the degree of this impact is likely to be comparable to the impact on other businesses. Several small businesses, including a manufacturer of Temperature Monitoring Equipment (TME), a company who freeze and store QFF and a company who transport and distribute QFF have been contacted to discuss the impact of the proposed amendments.

6.2 Each of the small businesses contacted were aware of the new legislation and standards, were either already wholly or partly compliant, and were therefore able to provide information on the cost to their business of compliance. In all cases although only a proportion of their frozen food business was QFF, they routinely apply the higher temperature monitoring standards associated with the QFF regulations across their whole business.

6.3 The costs to established businesses of replacing temperature monitoring equipment with equipment that is compliant with the new standards will vary depending on the size and nature of the business, and also the equipment specification required by the purchaser. Details of costs to small businesses can be found in Annex 1.

6.4 As a result of discussions with small businesses, it has been concluded that a more detailed analysis of the impact on small firms was not necessary, as the effect on small businesses was not considered to be significant or disproportionate. We consulted the small Business Service, who agreed with our approach.

7. Administrative costs of Information Obligations

7.1 The Information Obligations required by the recommended options 2 and 3 are near identical to those associated with the 1990 QFF Regulations (as amended). The new EC rules additionally require businesses to keep evidence demonstrating that their temperature monitoring equipment is CEN compliant. This additional requirement should not place a significant cost on businesses as it is likely to only involve storage of documentation supplied by TME manufacturers. The estimated additional industry and enforcement burdens imposed by the reading, familiarisation and dissemination of the new Regulation are discussed at paras 5.19 and 5.24 and are not considered to be significant.

7.2 The new EC rules apply to all forms of transport of QFF, including rail which was previously exempted. Therefore businesses who transport QFF by rail will now be required to meet the CEN standards and the associated information obligations. Information from stakeholders suggests that there is little transport by rail of QFF, and we therefore consider this to be an insignificant administrative burden.

8. Sustainability Assessment

8.1 The economic, social and environmental costs and benefits associated with the three options were all considered.

Option 1 – This option is not sustainable as it would leave the UK open to infraction proceedings by the EU.

Option 2 – Environmental and social costs are not significant. There will be economic costs falling on industry and enforcers.

Option 3 – Costs are as outlined for Option 2, but are offset against the benefits offered by consolidating the regulations. This is the most sustainable option.

9. Competition Assessment

9.1 A competition filter assessment has been carried out and the results indicate that the proposed Regulation is unlikely to have any significant effects on competition in the UK marketplace.

9.2 The recommended options 2 and 3 will not have any significant differential impact on businesses already active in the market as there is already a high level of awareness of the new temperature monitoring requirements given that businesses and relevant trade associations have been fully consulted during negotiations on the new EC Regulations and development of the CEN standards over the past 3-5 years and given cyclical commercial capital replacement/updating. Our research suggests that most businesses affected are already either partly or wholly compliant with the European standards, and that there are minimal costs associated with compliance.

9.3 In summary, it can be concluded that the new Regulation is unlikely to impose a significant negative impact on competition, and indeed harmonisation of standards across Europe will serve to remove an existing trade barrier thereby increasing the competitiveness of the market as a whole. This increased competitiveness may induce more efficient practices by firms in the EU. Entry barriers will not be significantly affected as the new temperature monitoring provisions involve minimal expense and apply consistently to all new and existing businesses (e.g. manufacturers (food and equipment), cold storers, distributors, retailers, etc.) and are unlikely to fall disproportionately on any individual company. Our research suggests that there is no evidence that conforming to the CEN standards will significantly stifle technological innovation in the field and stakeholders did not provide any information to the contrary in response to the public consultation.

10. Enforcement Sanctions and Monitoring

10.1 Enforcement of the England Regulations will be the responsibility of Local Authority Trading Standards or Environmental Health Departments.

10.2 The effectiveness and impact of the new Regulations will be monitored via feedback from stakeholders, as part of the ongoing policy process.

11. Implementation and Delivery Plan

11.1 At the start of 2006, an 'interim position' letter was sent to stakeholders advising them of the new requirements of Commission Regulation 37/2005. It was highlighted that whilst Regulation 37/2005 is directly applicable in all Member States, national regulations would be needed to give effect to related administration and enforcement provisions and that these would be made at the earliest opportunity.

11.2 The publication of the new, consolidated Regulations will be communicated to stakeholders through the Agency's website, FSA News, etc. The Agency is also updating the relevant sections of the statutory food law Code of Practice, subject to a separate consultation in due course, to reflect changes to the QFF legislation. In addition, it is expected that a short factsheet to accompany the new, consolidated QFF Regulations will be produced for all stakeholders, including small businesses.

12. Post-implementation Review

12.1 The Agency will consider proposals from stakeholders for any further changes to the Regulations that they may consider necessary in the light of experience and the effectiveness of the new legislation. Agency mechanisms for review include: open fora, stakeholder meetings, and general enquiries from the public / industry.

13. Summary and Recommendation

13.1 Summary costs and benefits table

Option	Total cost[(a)] per annum: - economic, environmental, social - policy and administrative	Total benefit per annum: - economic, environmental, social
1. Do nothing	- Restrictions to trade if there is no accurate and consistent means of monitoring air temperature to which QFF are subject. - Risks infraction proceedings against the UK.	- None.
2. Legislative change to amend the existing 1990 Regs	- As for option 3 below but likely to be increased costs in terms of time and resources in referring to several sets of regulations; cannot be quantified but may be	As for option 3 below.

	significant.	
3. Legislative change to re-make the QFF Regs 1990 into a new, single SI	- One-off administrative costs to enforcement authorities and industry of up to £60k. - One-off costs to industry of up to £207,500 (including one-off costs to: distribution, warehousing and storage businesses of £195,000 over 4 years (£48,750 per year); and manufacturers and retailers of £12,500 over 4 years (£3,125 per year)). (a) – a proportion of these additional costs are likely to be passed on downstream. To that extent, whilst we present a full monetisation of costs to businesses, we recognise that some of these costs may already have been accounted for by the TME manufacturers at manufacturing level.	- Accurate, uniform TME will further ensure the quality of QFF in the cold chain. - Removal of barrier to trade will increase competitiveness of the market and may help drive down equipment costs.

13.2 The recommended option is option 3 – Re-making and consolidating the QFF 1990 Regulations into a new, single SI. As well as being the most sustainable option, it also appears to be the most cost effective.

14. Declaration and Publication

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

Signed……Caroline Flint……

Date 20th January 2007

Caroline Flint, Minister of State for Public Health

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Annex 1

Small Firms Impact Test – detailed costs to businesses

1. In general, while storers and distributors of QFF may require at least one temperature probe per cold store, only one central logger and set of soft ware is necessary. Discussions with a small supplier of TME indicate that temperature monitoring units can cost from £44 up to around £300-400 and the software required to log and store the data on computer costs in the region of £60. Companies routinely service and calibrate the equipment (annually at a minimum), at a cost of £28 for a single point calibration and £38 for a 2 point calibration).

2. The blast freezing and storage company contacted estimated that it had cost them in the region of £2000 to update their temperature probes (one per store room) and loggers to meet the new standards. They had been fully compliant for 2 years and considered the financial cost a "small investment".

3. A transport and distribution company with 13 vehicles estimated that it cost them a total of £10,000 to fully comply, although this cost included 6 high tech temperature monitoring units which incorporate satellite navigation (the remainder of the vehicles were fitted with basic equipment). It would therefore be expected that this cost would be at the higher end of expected compliance costs. Although the company considered this to be a significant financial outlay they felt that early compliance offered benefits to the company in terms of reputation and marketing advantage. They also felt that it would offer some protection against customer complaints.

4. The TME manufacturer contacted was unable to quantify the benefit to their company of the new regulations, although they confidently expected sales of equipment to increase during the transition period as transport and storage businesses gradually replace their equipment. These increased sales will lead to increased turnover for the company.

5. The manufacturer also estimated that only 80% of their current temperature loggers and 50% of probes currently comply with the new standards. However they did not see this as a potential cost to the firm as once the transition period had expired, non-compliant equipment could be sold to companies who are exempt from the QFF regulations but who may wish to still monitor air temperatures.