

COLD STORES

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ORIGIN OF PROBLEM

- UK(NI), DE, HU

The background to the present situation is that due to food scandals being detected at cold stores in the United Kingdom (Northern Ireland), Hungary and Germany a survey of cold stores and activities was requested by the Commission in December 2005. The final report on the survey (mid-November 2006) revealed that a mixture of problems existed in most Member States (see Annex I for example).

Data on Problems

- RASFF Reports

RASFF notifications revealed that problems were not limited to meat but also involved fishery products, vegetables and herbs, fruit and bakery products, for example, notification 2006.0563 of 04.09.2006. This revealed that among the products concerned were meat; meat products, vegetables (e.g. carrots, peppers, mushrooms, cauliflower, spinach, broccoli), herbs (e.g. basil, dill), apfelstrudel, etc.

The meat-related incidents in Germany in 2005 and 2006 were due to fraudulent activities initiated by individuals. In a first case in **autumn 2005**, around 1800 tonnes of material (of poultry/ pork origin) unfit for human consumption were illegally channelled into the food chain in DE (from Bavaria), as well as delivered to FR, PL, IT, HU and NL, using forged documentation. The incident was detected by chance.

In a later series at the **end of 2005**, at least 500-600 tonnes of meat and meat products were detected in DE, in particular during official controls in cold stores storing both products fit and unfit for human consumption. The maximum durability date of the products had been changed.

Most recently, in **August/ September 2006**, in three cases in Bavaria, at least 120 tonnes (exact quantities unknown) of various meat and vegetable products were distributed to at least 9 other Member States with changed expiry dates.

In general, Community legislation offers adequate tools to prevent such contraventions. However, certain initiatives to review specific parts of the legislation are being considered.

- Community-Wide Survey of CS

The Member States' investigations revealed a catalogue of failures in connection with, but not exclusively confined to, foodstuffs of animal origin. The failures related in the main to labelling and marking, hygiene, traceability, cold store construction, records and documentation, and illegal practices such as date alteration.

- FVO Report

Among the investigations conducted by the FVO were on-the-spot visits to Ireland and the United Kingdom in December 2005 and to Germany in September 2006. The situations found there and in other Member States did not appear to be fully under control.

The German authorities took follow-up action after the incidents. However, results of an FVO inspection carried out in September 2006 suggest that improvements in official controls seem necessary in order to prevent similar shortcomings in the future. In particular, coordination between the central and regional authorities in DE should be improved so as to render official controls of the food and feed chain more effective.

- MS Presentation

DE made a presentation on the problems that it had experienced in the SCFCAH of September 2006.

Consultation of

- **MS in SCFCAH, CVOs and WGs**

Ireland made a suggestion in relation to facilitating traceability by implementing Article 18(5) of the General Food Law on 30.03.2006. This was discussed in a working group on 24.04.2006. Following further scandals in 2006, which culminated with the presentation of the problems that had arisen in Germany, France forwarded a suggestion in relation to cold store approval on 29.09.2006. The latter addressed in part the problem posed by the unclear situation in relation to wholesalers, due notably to the confusing definition of 'retailer' in the General Food Law. During an exchange of views on the investigations in cold stores in the SCFCAH of 18.10.2006 the Member States that had not forwarded the findings were strongly urged to send them to the Commission so that possible solutions could be discussed against a background of factual information.

A number of possible approaches were considered briefly at a working group meeting on food hygiene held on 06.11.2006. There was broad support for the Irish proposal. At the working group meeting on 11.12.2006 Ireland raised the matter under 'Miscellaneous'. FR pointed out that although the initial provision of additional information might create a burden, such a provision would benefit the food business operators further down stream by lessening the burden. In a working group on 29.01.2007 cold stores were discussed once more. Member States gave their first reactions to a table of possible actions and three texts relating to frozen foods (meat was not specified in the non-paper). The text on cold stores handling food of animal origin was considered to be superfluous. In relation to the text on information required for traceability purposes, Hungary, supported by several other Member States wanted the lot/batch number to be included in the accurate description of the foodstuff. It was agreed that the description of the container or vehicle could be dropped. The absence of an indication of maximum storage time, frozen foods and information for traceability were discussed in the working group on 05.03.2007. Further factual inputs from the Member States as well as cost-benefit analyses and the opinion of stakeholders are necessary prior to moving forward.

- **European Cold Storage and Logistics Association (ECSLA)**

Date of meeting(s) with stakeholder (Check with Willem and with Ron)

'Guidelines for the development of Community Guides to Good Practice" were published on the Commission website in late 2006. The ECSLA Guidance Note was distributed to Member States on 11.12.2006 and discussed briefly with the Member States at a working group on 31.01.2007. A restricted Group was formed (BE, DE, FR, HU, IE, NL & UK) and met on 06.03.2007. The draft remarks made at that meeting were circulated and were forwarded with a letter to ECSLA on 03.04.2007.

DEFINITION OF THE PROBLEMS

1. Approval-Definitions of 'Cold Store', 'Retail', 'Wholesale'

Explain the difficulties arising from the absence of definitions

'Retail' is defined in 178/2002 as follows:

'retail' means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and wholesale outlets.

This definition appears to be inadequate in relation to aspects of the hygiene Regulations

'Wholesale' is not defined in either the general food law or in the hygiene regulations and confusion is created by referring to 'wholesale outlets' (check) in the definition of 'retail' above.

'Cold Store' is not defined in the hygiene Regulations. Chapter IV and parts of Chapter XIV of Annex I to Council Directive 64/433/EEC provided a description of cold stores embracing chiller and freezer stores. (See Annex II)

2. Structures-Activities-Hygiene-Controls

Structures and Hygiene

Corrective actions should be put in place to overcome deficiencies of structures-installations, equipment, state of cleanliness-operational hygiene and to enforce EU requirements.

Activities

Cold stores are approved or registered for certain activities. If the food business operator excessively carries out activities for which he/she is not approved or registered, the activity is illegal and approval or registration should be suspended or withdrawn.

Controls

From the results of the survey conducted in 2006 it is obvious that the level of supervision of cold stores is insufficient to ensure general compliance in such establishments with EU requirements. It also appears obvious that the assumptions employed in the risk-based approach used by MS seriously underestimated the potential for non-compliance.

3. Information-Labelling/Marking-Traceability See Below

OPTIONS AND POSSIBLE SOLUTIONS (See Annex III)

In an answer given to an EP question it was stated that "...in light of the recent scandals the Commission continues to reflect on how to reinforce EU requirements. Possibilities include legislative amendments to improve traceability by listing minimal information to be provided in respect of consignments (subject to general considerations in relation to information obligations), to require food business operators to indicate at least the freezing date on packaging for wholesale and cold storage, to place a ban on repackaging in cold stores and to prohibit changing the dates at any step of the food chain. The EU Labelling Directive¹ already imposes the marking of the "best before" date for retail level."

The Labelling Directive does not, however, address the issue of the first freezing of a food or the raw material from which the food is made.

This statement was based upon an analysis of options that demonstrate the complexity of the situation. Part solutions, involving co-decision, comitology and guidance have been raised. It was evident from the survey carried out within the Member States during 2006 that a considerable number of problems in the running of cold stores have been revealed and that the level of control exerted by the competent authorities in cold stores was insufficient to ensure their functioning within the scope of the approval granted in relation to the activities carried out, to ensure their operation in accordance with the hygiene requirements, to respect traceability requirements, to ensure correct labelling and to prevent fraudulent activities, such as alteration of the best before date.

OPTIONS AVAILABLE

- (i) 'No Action'
- (ii) Actions/Measures
 - legislation
 - guidance
 - guides

POSSIBLE MEASURES

Preliminary questions in respect of each measure

- Is the measure needed at EU level?
- Would a national measure be sufficient?
- Is the measure needed to ensure food safety?
- Is the measure needed for the proper functioning of the market?

SOLUTION JUSTIFICATIONS

- Proof the measures are needed to change the law
 - Is inaction a real option?
 - Possible solutions suggested (see annexed table and following pages)
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COSTS AND BENEFITS OF SOLUTIONS

- If the measure is likely to be a burden on industry, then an impact assessment will be necessary.
- Costs, time, resources
 - How much for data?
 - How much for collection of the data?
 - How often are actions required (per week/month/year)?

See Annex IV for Member States' suggestions in relation to cold stores involving co-decision

ANNEX I

OUTCOME OF COLD STORE SURVEY

Some of the failures mentioned (e.g. freezing date of meat) relate to Council Directive 64/433

AT

- Looked at 1.370 CS with products of animal origin for human consumption between 01.11.2005 and 15.01.2006
- 624 inspections in 5.087 CS related to the veterinary services with hygiene failures, wrong labelling, records and own controls
- 637 inspections in 5.053 of food production establishments with labelling problems and construction deficiencies
- 109 inspections were in 424 cold stores for fish with mainly labelling problems

BE

- 334 of 426 annexed and independent cold stores visited
- Included all EU-approved and some nationally authorised CS
- Main non-conformities included activities for which an approval was required (18); labelling problems (e.g. non-adherence, absence of required data, labels from another establishment; absence of freezing date); and traceability (84 cases of lack of control at entry into establishments; insufficient links between 'in' and 'out' registers in 31; incomplete documentary data; registers not always on-site).

CY

- 28 of 30 approved CS inspected from 03. to 20.10.2006
- Some labelling problems, traceability deficiencies, commercial documents not properly marked although products were correctly marked
- Registered stock of products did not tally with actual quantities in 4 CS
- No products for human consumption unsuitable or exceeding expiry date.

CZ

- 337 controls in all 267 approved CS (142 stand alone + 125 annexed)
- Labelling, health mark, freezing date and documentation failures

- General hygiene problems e.g. packaged and exposed in the same rooms, exposed meat directly on wooden pallets, packages directly on the floor, condensation and ammonium.

DE

- 314 of a total of 317 EU cold stores inspected of which 61 are in Bavaria

- 4.500 small non-approved cold stores (butchers' premises) inspected in Bavaria – no significant problems

DK

- More than 50% inspected for shortcomings re storage of food products of animal origin; own checks for receiving/storing/shipping including wrapping/packaging and marking; checks on storage time and age of products

- Problems mostly re need to track storage time, age of products, some labels with shelf life for chilled product on frozen products

- Some admonishments, destruction of products, fining of establishments, restriction of raw materials to use in processed products

EE

- 18 formal instructions

- Minor prescriptions concerning labelling, inappropriate storage temperatures and, in relation to traceability, insufficient information on consignment documentation related to the products from other MS

ES

- 1.439 inspections of approved cold stores

- No anomalies in relation to meat or documents

- A small number of problems in relation to labelling, expiry date, traceability, health marking

- 1 incident of meat from PL notified to the Commission (News 2005/272)

FI

- In-depth inspections of 130 large/small, annexed/independent CS

- 'Illegal' meat not on the market

- Commercial document problems (traceability); deficiencies in compulsory beef labelling

- Salmonella guarantee deficiencies

FR

- 1060 of the 3.987 cold stores were visited were visited between 01.01.2006 and 01.04.2006
- 4 cases of illegal practices; 75 non-declarations of activity; 38 non-conformities linked to insufficient traceability; 89 other anomalies
- the infringements noted have led to 213 admonishments, 21 recalls from consumption and 13 *procès-verbaux*

GR

- 96 approved cold stores; + 165 low capacity cold stores
- Inspection by the prefectural veterinary services between 21.12.2005 and 24.01.2006
- No shortcomings in relation to changes of date, rewrapping or changes of country of origin

HU

- 74 approved cold stores and 478 wholesalers inspected involving 16.745 batches
- Problems with 475 batches included the following cases: food hygiene failure (391), traceability/comm. doc. (52), health/ID mark (38), best before date (62), other labelling (189) and illegal activities (13).
- 178 cases where foodstuffs were removed from the market and 181 cases where other measures (e.g. warnings, fines) were taken.

IE

- 291 premises inspected (148 stand-alone, 143 annexed to SH/CP and 93 to preparation/product establishments)
- 4,7% of 4.943 pallets; 2,8% of 3.268 cartons; and 10,9% of 1.576 documents had irregularities
- labelling, health/identification mark, freezing date, batch code, accompanying document deficiencies

IT

- Breakdown per region or autonomous province provided
- Approved CS, annexed CS and registered CS with wholesale activity checked
- Irregularities in 64 of 2.062 EU-approved CS (total 2.288) and in 125 of 1.640 nationally authorised CS (total 2.150) checked

- Irregularities relate to partial dates; absence of expiry date/expiry date exceeded; change of official name not communicated; absence of, or insufficient data on, labelling; packaging problems; some violations of hygiene rules.

LT

- 51 cold stores inspected by the State Food and Veterinary Service
- No shortcomings with respect to recent meat scandals in NI, DE and HU detected
- 16 hygiene shortcomings and 6 traceability deficiencies. 2 CS fined

LU

- Only annexed CS in LU
- Of the 12 approved establishments with CS, only 1 (No 24) had a problem: 2t of 'out-of-date' products

LV

- 55 approved and 111 registered wholesale cold stores
- 82 inspections in 66 cold stores from 01.01. – 01.07.2006
- Deficiencies included labelling problems (9), absence/exceeding of expiry date (2), packaging problems (4), violation of hygiene rules (15)

NL

- 377 inspections planned, 382 establishments inspected, of which 60 had no meat activity and 322 had meat activity.
- 111 with failings
- General inspection failures (1,2%), batch control problems (19,8%), documentary deficiencies (21,1%) and intake register problems (9,6%)
- 4 suspected of fraud, 4 subject to Agriculture police, 0 fraud confirmations

PL

- 01. to 08.01.2006: Checks in 50 cold stores with irregularities concerning exceeding expiry date (5), no freezing date (5) and some minor hygiene problems
- 15.01. to 31.03.2006: Inspection of all 95 cold stores with 68 defects in three main groups [47 deficiencies regarding hygiene, 14 irregularities relating to infrastructure and 7 infringements concerning Regulation (EC) No 1774/2002]
- 26 administrative decisions issued demanding elimination of shortcomings, 1 limiting production, 1 suspending production and 3 prohibiting production

PT

- In 2005, 85 official visits to some of the 58 independent and 135 annexed CS + 188 visits to some of the 13 independent and 222 annexed CS
- In 2006, so far, 121 official visits to some of the 49 independent and 136 annexed CS + 138 visits to the fish CS
- Problems included traceability, exceeded expiry date, lack of temperature records, hygiene deficiencies, icing up of evaporators, maintenance problems, improper dispatch and control of ABP, lack of storage facility for reusable 'boxes', layout & structural problems, simultaneous storage of exposed and packaged meat
- Corrective measures included rectifications, withdrawals/modification of approvals, admonishments, closures, calibration checks on scales and thermometers, cleaning and disinfection of surfaces, equipment and installations

SE

- 82 cold stores visited up to 15.03.2006
- No evidence of fraud observed
- Findings included identification marks not applied in such a way that they are destroyed when the packaging is opened (8 cases); identification-marked tape loose (6 cases); no or incorrect documentation for salmonella (10 cases)

SI

- No cases of illegal practices or fraud detected
- Inconsistencies between commercial documents (traceability) and health marking

Other problems related to hygiene (e.g. exposed and packaged fresh meat in the same rooms, condensation) and to own controls (e.g. temperature control, pest control)

SK

- Inspections conducted 03.01.06 to 23.01.2006
- 47 of 68 independent CS, 11 of 11 low-capacity CS, 51 of 65 integrated establishments and 101 low-capacity integrated establishments inspected
- No re-wrapping, re-packing or re-labelling activity shortcomings found

UK

- 230 premises audited with no evidence of illicit labelling
- 10 cases of suspect labelling (all investigated and appropriate action taken)

- Some hygiene issues in a minority of premises (5 mentioned in interim report)
- Approximately 150 in England, 20 in Scotland, 25 in Wales and 35 in Northern Ireland (final figures not supplied)

ANNEX II: Extracts from Directive 64/433/EEC

"CHAPTER IV

SPECIAL CONDITIONS FOR THE APPROVAL OF COLD STORES

16. In addition to the general requirements, stores in which fresh meat is stored in accordance with the first paragraph in point 66 of Chapter XIV must have at least:

(a) sufficiently large chilling and refrigeration rooms, which are easy to clean and in which fresh meat can be stored at the temperatures provided for under the first paragraph of point 66;

(b) a recording thermometer or recording telethermometer in or for each storage area.

17. In addition to the general requirements, stores in which fresh meat is stored in accordance with the fourth paragraph of point 66 of Chapter XIV must have at least:

(a) sufficiently large chilling and refrigeration rooms, which are easy to clean and in which fresh meat can be stored at the temperature provided for in the eighth paragraph of point 66;

(b) a recording thermometer or recording telethermometer in or for each storage area.

CHAPTER XIV

STORAGE

66. Fresh meat must be chilled immediately after the post-mortem inspection and kept at a constant internal temperature of not more than + 7°C for carcasses and cuts and + 3°C for offal. *(first paragraph)*

Derogations from this requirement may, for technical reasons relating to maturation of the meat, be granted by the competent authority on a case-by-case basis for the transportation of meat to cutting plants or butcher shops in the immediate vicinity of the slaughterhouse, provided that such transportation takes not more than two hours.

Fresh meat for freezing must come directly from an approved slaughterhouse or an approved cutting plant.

Freezing of fresh meat may be performed only in rooms of the same establishment where the meat has been obtained or cut or in an approved cold store, by means of appropriate equipment. *(fourth paragraph)*

When intended for freezing, cuts referred to in Article 3 (1) (A) of this Directive, the cuts referred to in point 53 of Chapter XI of this Annex and offal must be frozen without delay unless maturation is required for health reasons. In the latter case they must be frozen immediately after maturation.

Carcases, half carcasses, half carcasses cut into no more than three wholesale cuts, and quarters intended for freezing must be frozen without undue delay after a period of stabilisation.

Cut meat intended for freezing must be frozen without undue delay after cutting.

Frozen meat must reach an internal temperature of -12°C or lower and may not be stored at higher temperatures thereafter. (*eighth*)

Fresh meat which has undergone a freezing process must bear an indication of the month and year in which it was frozen."

* * * * *

There is confusion about the approval of cold stores due to the current definition of retail in the general food law and the absence of definitions of 'retail' for the purpose of the hygiene Regulations, 'wholesale' and 'cold store'.

Please see suggestions from 11 Member States (DE, EE, FI, FR, HU, IT, LT, LV, SE, SI, UK) in Annex IV.

ANNEX III: Possible actions at EU level

Table: Problems, possible solutions under the hygiene package and methods to resolve the problems

<i>Problems identified in cold stores</i>	<i>Possible solution</i>	<i>Method</i>
Absence of freezing date on food*	Introduction of requirement to indicate freezing date on food	Hygiene package Comitology
Absence of indication maximum storage time (use by date) of frozen food (wholesale level)	Introduction of “use by” date for frozen food	Amendment hygiene package Co-decision?
Changing labels containing “best before date” or “use by date”	Introduction of ban on changing labels	Amendment hygiene package/labelling Directive Co-decision?
Lack of traceability of food #	Introduction of requirement for information to contain mention of origin, destination, etc. of consignments	Hygiene package/General Food Law Comitology
Unclear situation with regard to approval of cold stores §	Introduction of clear requirement for approval of cold stores	Hygiene package Co-decision
Unauthorised activities in cold stores, in particular, re-wrapping	Withdrawal of approval of cold store	To be enforced by Member States

* RASFF notifications revealed that problems were not limited to meat but also involved fishery products, vegetables and herbs, fruit and bakery products

Alternative proposal by IE at CVO meeting on 11.01.2007

§ Proposal of 29.09.2006 by FR (General Food Law and Hygiene Regulations)

ABSENCE OF FREEZING DATE etc ON FOOD

Incorporating also 'absence of maximum storage time', 'alteration of labels'

(1) ABSENCE OF FREEZING DATE ON FOOD

Problem definition

The date of (first) freezing of food products should be known in order to help determine if the products are still suitable for human consumption or for further processing. Products should, preferably, not be frozen for excessively long periods.

Justification for the measure (see below)

- Data required from the MS

Costs and benefits

- Data required from the MS

(2) ABSENCE OF INDICATION OF MAXIMUM STORAGE TIME

Problem definition

Dates were not found on certain foodstuffs. The general approach is not to extend the date of minimum durability.

The labelling requirement under Directive 2000/13/EC is for pre-packaged foodstuffs to be delivered to, or, for presentation to, the ultimate consumer. Such information is not currently required for, for example, carcasses

The Labelling Directive

Directive of the European Parliament and of the Council 2000/13/EC of 20 March 2000 on the approximation of the laws of the Member States relating to labelling, presentation and advertising of foodstuffs

Terms used in the Labelling Directive

Article 3 states that an indication of certain "particulars alone shall be compulsory on the labelling of foodstuffs", including "(5) the date of minimum durability or, in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the 'use by' date".

Extract from Article 9:

Frozen food

1. Without prejudice to Directive 2000/13/EC, food which has undergone a freezing process must bear an indication of:
 - a) The month and the year in which it was frozen, and
 - b) The date of minimum durability
2. The dates referred to in paragraph 1 shall not be changed or removed from the food until the food is labelled in accordance with Directive 2000/13/EC or used for further processing.
3. By way of derogation from paragraph 2, the dates referred to in paragraph 1 may also be changed if the food business operators provide objective proof that the food is fit for human consumption and remains fit for human consumption until the new 'use by' date.

ANNEX IV:

Member State suggestions (involving co-decision) in relation to cold stores

FR 29.09.2006

OBJET : Question à la Commission relative à l'agrément des entrepôts frigorifiques.

Les autorités sanitaires françaises souhaitent attirer l'attention de la Commission sur la difficulté d'application des règlements du paquet hygiène au secteur de l'entreposage

La mise en œuvre des dispositions des règlements (CE) n°178/2002, 852/2004 et 853/2004 conduit en ce qui concerne l'agrément des entrepôts frigorifiques à des situations difficiles à justifier vis-à-vis des exploitants : un grossiste qui ne fait que stocker et transporter des produits d'origine animale dans un entrepôt frigorifique en vue de les vendre à des exploitants du secteur alimentaire n'est pas soumis à agrément (application de l'article 3 du règlement (CE) n° 178/2002 et de l'article 1 point 5 b i) du règlement (CE) n° 853/2004. Le même entrepôt frigorifique ayant la même activité (stockage et transport uniquement) mais géré par un prestataire de service, et donc n'entrant pas dans la définition du commerce de détail, est de fait soumis à agrément.

Dans un objectif de simplification, il serait souhaitable que ces dispositions puissent évoluer. Deux solutions sont envisageables qui nécessiteraient une modification du règlement (CE) n°853/2004:

- supprimer l'article 1 point 5 b i) du règlement (CE) n° 853/2004 : ce qui reviendra à agréer tous les entrepôts frigorifiques, qu'ils soient grossistes, plate-formes de distribution vers les grandes surfaces...
- modifier l'article 4.2.c du règlement (CE) n° 853/2004: remplacer "le stockage de produits qui ne nécessitent pas une régulation de la température" par " le stockage à l'exclusion de toute autre activité" : ce qui reviendra à ne pas agréer les entrepôts, quel que soit leur statut juridique (plate-forme, grossiste, prestataire...) dans la mesure où ils n'ont aucune autre activité que le stockage (congélation, conditionnement...)

Les autorités françaises souhaitent que ce sujet soit inscrit à l'ordre du jour du groupe de travail du CPCASA du 02/10/06 qui prévoit d'ores et déjà une discussion sur les mesures applicables aux entrepôts.

FR 15.02.2007

Article 1(5)(b)(i)	Amend this point by deleting "of storage or" and replacing it by:
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	<p>"..., unless: i) the operations consist only of transport, in which case the specific temperature requirements laid down in Annex III shall apply;"</p> <p>Approval will then become obligatory for all businesses, retail or otherwise, which are involved in storage.</p> <p>or delete this point.</p> <p>Approval will then become obligatory for all businesses, retail or otherwise, which are involved in storage or transport.</p> <p>This proposal supplements the proposed amendment of Article 4(2).</p> <p>Justification: As regards the approval of cold stores, the implementation of the provisions of Regulations (EC) Nos 178/2002, 852/2204 and 853/2004 leads to situations which are difficult to justify vis-à-vis operators: a wholesaler who only stores and transports products of animal origin in a cold store with a view to selling them to food business operators is not subject to approval (application of Article 1(5)(b)(i) of Regulation (EC) No 853/2004). The same cold store engaging in the same activity (storage and transport only) but managed by a service provider and therefore not covered by the definition of retail establishment is subject <i>de facto</i> to approval. France proposes making approval obligatory for the storage of the foodstuffs covered by Annex III to Regulation (EC) No 853/2204.</p>
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Article 4(2)	<p>Amend this Article, extending the scope of the approval requirement by listing another activity after the handling of products of animal origin.</p> <p>"Without prejudice to Article 6(3) of Regulation (EC) No 852/2004, establishments handling or storing without having handled those products of animal origin for which Annex III to this Regulation lays down requirements shall not operate unless the competent authority has approved them</p> <p>Justification: Supplements the previous proposal; controlled-temperature warehouses would therefore also need approval.</p>
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DE 21.11.2006

Hereby you receive our letter which has been sent already at the end of the last year. In No 1, we explained our attitude concerning the approval of cold stores. We think that approval of all cold stores would help to clarify many problems, but it would make necessary changes in Regulation 853/2004.

im Nachgang zur letzten Sitzung der Kommissionsarbeitsgruppe „Veterinary Legislation“ möchte ich Ihnen noch einige Bemerkungen übermitteln zu Sachverhalten, die uns wichtig erscheinen:

1. Vorschriften für Kühllhäuser:

Bei den Kühllhäusern gibt es zwei verschiedene Kategorien:

- **Betriebseigene Kühlhäuser:** Dabei handelt es sich um Kühlhäuser, die einem Produktionsbetrieb angeschlossen sind. In diesen Kühlhäusern wird nur betriebseigene Ware gelagert.
- **Gewerbliche Kühlhäuser:** Diese Kühlhäuser lagern Ware, die anderen Eigentümern gehört. Der Betreiber des Kühlhauses stellt somit nur die Kühllogistik zur Verfügung. Der sachgerechte Umgang mit der Ware obliegt dem Eigentümer der Ware. Bei diesen Kühlhäusern ist wiederum zu unterscheiden zwischen zwei Kategorien:
 - o **Eigenbewirtschaftete Kühlhäuser:** In diesen Kühlhäusern erfolgt die „physische Bewegung“ wie z.B. Einlagerung, Auslagerung und Umlagerung, durch betriebseigenes Personal des Kühlhausbetreibers. Diese Handlungen erfolgen aber ausschließlich auf Anweisung des Eigentümers der Ware.
 - o **Fremdbewirtschaftete Kühlhäuser:** In diesen Kühlhäusern ist Stellfläche bzw. Kühlzellen an andere vermietet, die auf der angemieteten Fläche bzw. in den angemieteten Kühlzellen ihre eigene Ware lagern und diese auch selbst „physisch bewegen“. Hier stellt der Kühlhausbetreiber ausschließlich die Kühllogistik (Räume und Kühlvorrichtung) zur Verfügung, hat aber mit der gelagerten Ware selbst physisch keinen Kontakt.

Die meisten gewerblichen Kühlhäuser werden jeweils teilweise in Eigenbewirtschaftung und in Fremdbewirtschaftung betrieben: Ein Teil der Stellfläche bzw. der Räumlichkeiten ist vermietet, der andere Teil wird mit eigenem Personal betrieben. In jedem Falle aber ist der Betreiber des Kühlhauses nicht der Eigentümer der gelagerten Ware.

Die Zulassung von Betrieben ist an die Betriebsstätte und an die Person des Betreibers gebunden. Daher hat der Betreiber eines Kühlhauses – nach den derzeitigen Vorschriften – die volle Verantwortung für den lebensmittelrechtlich korrekten Umgang mit den dort gelagerten Lebensmitteln. Dies erscheint uns aber nicht angemessen im Falle der gewerblichen Kühlhäuser. Wir schlagen daher folgende rechtliche Änderungen für Kühlhäuser vor:

1. Zulassungspflicht für alle Kühlhäuser einschließlich der in Artikel 1 Abs. 5 Buchstabe b Nr. i der Verordnung (EG) Nr. 853/2004 genannten.
2. Neuer Modus der Zulassung für gewerbliche Kühlhäuser: „Aufteilung“ der Zulassung in
 - Zulassung des Kühlhauses ausschließlich als „Kühllogistik“: Gebäude, Räume, funktionsfähige Kühleinrichtungen; der Kühlhausbetreiber hat nur die Verantwortung für die angemessene gebäudliche, räumliche und kühltechnische Ausstattung des Kühlhauses.
 - Zulassung des Einlagerers von Ware, d.h. von Lebensmittelunternehmern, die Ware im Kühlhaus lagern wollen, im Vorfeld der Aufnahme ihrer Tätigkeit:

Damit übernimmt der Eigentümer der eingelagerten Waren die volle Verantwortung für den lebensmittelhygienerechtlich korrekten Umgang mit der Ware. Bei dieser Zulassung wird die Zuverlässigkeit und die Sachkunde geprüft und der Unternehmer muss die Vorschriften bezüglich der Rückverfolgbarkeit einhalten. Damit würden auch die so genannten „Telefonmakler“ – anders als im Leitfaden zur VO (EG) Nr. 852/2004 unter Nr. 6.1 ausgeführt - zulassungspflichtig, die die Ware selbst nicht sehen, sondern sie telefonisch sowohl ein- als auch verkaufen.

Damit wird der in praxi bestehenden getrennten Verantwortung für Kühllogistik und für eingelagerte Ware Rechnung getragen. Eine an den Erfordernissen der Praxis orientierte getrennte Verantwortlichkeit besteht ja bereits bei der so genannten „Großmarktregelung“.

Rough Summary

1) Proposal for approval of cold stores

Three types: (i) approval of all cold stores attached to food establishments required
(ii) stand alone cold stores a) where foodstuffs are handled
b) rented out space

EE 26.01.2007

Cold store

There is no clear definition for “cold store”, which causes misunderstandings.

Regulation (EC) 853/2004 (Annex III) and the guidance document on the implementation of certain provisions of Regulation (EC) 853/2004 (paragraph 4.4 and Annex IV) make references to the term in several cases.

We understand that some legislative measures have been envisaged to regulate the activities of cold stores. Until the enforcement of these legal acts some more clarity on requirements (incl. traceability) and control measures could be provided by guidance documents.

LV 13.02.2007

Regulation (EC) No 853/2004:

1) To determine specific requirements to repacking establishments and cold stores of animal products for human consumption

2) To draw up the definitions for the cold store and wholesale warehouse.

It is not clear what temperature regime can be considered as the cold store. Whether it is premises where freezing equipment is used and any constant temperature regime is ensured or is the premises where the temperature minus18°C is ensured. Whether the wholesale warehouse can also be the cold store and whether it can operate a retail business. And how can the wholesale warehouse, which is also the cold store at the same time, be classified.

UK 14.02.2007

10. In addition, the UK would highlight a few issues which it would encourage the Commission to consider and discuss with Member States as part of its review and which might lead to proposals for resolution under co-decision. These are:

b) That the status of all types of cold stores be clarified (with regard to the need for approval – Article 4 of Regulation 853/2004) and that any hygiene requirements be contained in the hygiene legislation or guidance as necessary. The UK feels that a solution to this may lie in a specific definition of “retail” for the purposes of the hygiene legislation, which could then lead to greater clarity for other aspects of Regulation 853/2004.

HU 14.02.2007

1. It is necessary to clarify the difference between the cold store and the wholesaler, when these establishments have to be approved. The Commission guidance is not clear in this issue.
2. It is essential to ensure the traceability of food of animal and non animal origin, for this reason Hungary supports laying down the detailed requirements of the accompanying documents.

IT 14.02.2007

The Ministry has sent out a circular asking the Regions and the Autonomous Provinces to draw up a cold stores surveillance plan and carry it out in the course of 2007. In the light of the checks carried out in 2006, it was thought desirable to subject cold store operations to thorough scrutiny.

As regards the arrangements for licensing cold stores, we had provided the Regions and Autonomous Provinces (the competent authorities) with the following guidance by means of a circular:

"For establishments engaging in wholesale trade operations physically limited to controlled-temperature storage and transport of packaged foods of animal origin, registration as per Regulation (EC) No 852/2004 is sufficient, subject to compliance with the temperature requirements laid down by Regulation (EC) No 853/2004.

In both the above cases, if the establishments engage in marketing activity in EU countries and/or third countries, they require approval as per Regulation (EC) No 853/2004."

Italy agrees with Ireland's proposal, since for lack of information it can sometimes be difficult to exercise proper control over raw materials, intermediate products and non-finished products which do not fall within the scope of Directive 2000/13/EC.

Controls by the competent authority are sometimes made even more difficult in that the information accompanying raw materials and intermediate products (e.g. invoices and accompanying commercial documents) is very often given only in the language of the country of dispatch.

We believe the traceability labelling or identification mentioned in Article 18(4) of Regulation 178/2002 cannot be left to the sole discretion of the operator if it is to meet the planned objectives in full.

Consideration could therefore be given to the possibility of framing Ireland's proposal as an implementing provision for traceability identification and labelling as per Article 18(4) of Regulation 178/2002 for products not at present covered by Directive 2000/13/EC.

In this context, provision should therefore be made for compulsory labelling of raw materials and intermediate products (not covered by Directive 2000/13/EC) and the minimum information to be shown on such labelling (e.g. product name, batch, date of freezing, "use-by date").

There should also be a requirement that such compulsory minimum information must at least be provided also in the language of the country receiving the goods.

SE 14.02.2007

4. Cold stores.

We see a need for clarification concerning which cold stores should be registered according to 852/2004 and which need approval according to 853/2004.

LT 30.03.2007

State Food and veterinary Service of the Republic of Lithuania submits the following proposals on the development of the hygiene package:

1. In our opinion a clarification should be provided which cold stores should be registered according to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs and which cold stores need an approval according to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for food of animal origin.

SI 30.03.2007

Article 1(5)(b)(i) and Article 4(2): We see a need for clarification concerning which **cold stores** should be registered according to 852/2004 and which need approval according to 853/2004. It is necessary to clarify the difference between the **cold store** and the **wholesaler**, when these establishments have to be approved.

FI 02.04.2007

853/2004 Article 1 point 5 b (i):

The requirement for keeping specific temperatures for food of animal origin is very reasonable concerning the transport of merely foodstuffs of animal origin. However it causes difficulties concerning the transport of different kinds of foodstuffs in the same container. The temperature requirements should be clarified in these cases.

ANNEX V

Questions to the Member States

(For the purpose of initiating an impact assessment)

1) The questions will be used to initiate an impact assessment. It is very likely that at a later stage additional information will be required from the competent authorities and/or the industry.

2) We would appreciate receiving answers from the Member States to the fourteen questions by Wednesday 23.05.2007.

* * * * *

1. How many cold stores are approved in your country?
2. How many cold stores are registered approximately in your country?
3.
 - (i) What is the frequency of official visits for inspection purposes to the approved cold stores?
 - (ii) How many visits were performed in 2006 of approved cold stores?
 - (iii) How many inspections were performed in 2006 of approved cold stores?
 - (iv) Does the competent authority perform audits of cold stores?
 - (v) How many audits of approved cold stores were performed in 2006?
4.
 - (i) What is the frequency of official visits for inspection purposes to the registered cold stores?
 - (ii) How many visits were performed in 2006 of registered cold stores?
 - (iii) How many inspections were performed in 2006 of registered cold stores?
5. Does the competent authority have a risk based approach to establish the frequency of visits to cold stores? If this is the case, please attach.
6. Was any adjustment made to the risk based approach following the intensive round of inspections during 2006 of cold stores (see results in Annex I)? Indicate which changes were made.
7. Does the competent authority require a programme based on HACCP principles to be present in the approved cold stores or which other programme/requirements?
8. How many cold stores would need to be additionally approved in your country if the legislation were amended by co-decision as suggested by France on 15/2/2007 (see Annex IV)?

9. What would be the consequences of such additional work for the competent authority in terms of initial approval and regular inspections (in manpower/ man hours)?
10. (i) What would be the additional (administrative) burden for the food business operators of cold stores if "information required for traceability purposes" were implemented (see Annex III, p. 19)?
- (ii) Can this burden be expressed in man hours and/or in financial terms?
11. Undoubtedly, such additional traceability would be beneficial for food business operators further down the food chain. Can this advantage be expressed in savings in man hours and/or in financial terms?
12. (i) What would be the additional (administrative) burden for the food business operators of cold stores if the requirement of a freezing date were implemented (see Annex III, p. 16)?
- (ii) Can this burden be expressed in man hours and/or in financial terms?
13. Undoubtedly, the placement of a freezing date would be beneficial for food business operators further down the food chain. Can this advantage be expressed in savings in man hours and/or in financial terms?
14. (i) How many times was it necessary for the competent authority to take action in 2006 for unauthorised activities in cold stores?
- (ii) Is it possible to subdivide the actions, for example: seizure of goods, closing down (part of) the facility, legal action, fines, recalls, taking away approval status, etc?