

09.04.2007

CATALOGUE OF MEMBER STATES'
GENERAL COMMENTS &
CO-DECISION PROPOSALS

(with certain editorial changes)

COMMENTS

1. GENERAL

NO COMMENTS RECEIVED

DK	AT	DE	HU	MT	SE
FI	BE	EE	IE	NL	SI
LU	BG	EL	IT	PL	SK
UK	CY	ES	LT	PT	
x	CZ	FR	LV	RO	

2. NO RADICAL OVERHAUL

DK	AT	DE	HU	LV	RO
FI	BE	EE	IE	MT	SI
SE	BG	EL	IT	NL	SK
UK	CY	ES	LT	PL	
x	CZ	FR	LU	PT	

3. EXPERIENCE GAINED

BE	SK	AT	EE	IE	NL
DK	UK	BG	EL	IT	PL
FI		CY	ES	LT	PT
LU		CZ	FR	LV	RO
SE		DE	HU	MT	SI

4. EXTENSION OF HACCP TO FOOD BUSINESS OPERATORS CARRYING OUT PRIMARY PRODUCTION

BE	LU	AT	EE	IT	PT
DK	SE	BG	EL	LV	RO
FI	UK	CY	ES	MT	SI
FR		CZ	HU	NL	SK
LT		DE	IE	PL	

5. COLD STORES (See also MS' proposals)

DE	IT	UK	AT	DK	MT	SK
EE	LT		BE	EL	NL	
FI	LV		BG	ES	PL	
FR	SE		CY	IE	PT	
HU	SI		CZ	LU	RO	

6. TRANSITIONAL ARRANGEMENTS TO BE MADE PERMANENT NO COMMENTS RECEIVED

AT	IE	BG	EL	MT	SI
BE	IT	CY	ES	NL	SK
DK	LV	CZ	HU	PL	
FI	SE	DE	LT	PT	
FR	UK	EE	LU	RO	

7. COMPOSITE PRODUCTS

BE	SE	AT	EE	IE	PL	UK
DK		BG	EL	IT	PT	
FI		CY	ES	LT	RO	
LU		CZ	FR	LV	SI	
NL		DE	HU	MT	SK	

PROPOSALS REQUIRING CO-DECISION

Regulation (EC) No 852/2004

Articles

1(3)	LU
1(4)(a)	FR
2(1)	EE
2(1)(f)	IE
5	NL
5(2)(e)	NL
13(4)(a)	FR

Regulation (EC) No 853/2004

Articles

1(2)	FI, LU, NL, SE
1(3)(d)	AT, BE, EE, FR, SE
1(4)	LU
1(5)(b)(i)	FR, LU
1(5)(b)(ii)	LU
3(2)	FI, FR
4(2)	FR, LT
10(3)	LU

Annex I

1.1	LV		
1.2	FI, FR		
1.3	FR		
1.4	ES, FR, NL, SK		
1.5	FR		
1.9	FR		
1.14	NL		
1.15	CZ, FI		
1.16	FR		
(1)(19?)	ES	'rodents'	
(3)(5)	ES		
(4)(1)	NL		
(7)(1)	FI		
(7)(2)	BE		
(8)(3?)	DE, SE	'cold stores'	
(8)(4?)	LT	'wholesale'	'wholesale outlet'
(8)(5?)	ES	'invertebrates'	

Regulation (EC) No 854/2004

Articles

4(4)	NL
5(2)	NL

5(3)(e)	NL
5(5)(b)	FR
5(6)	FI
5(6)(a)	FI, FR

MS' COMMENTS

1. GENERAL

FI 26.01.2007

As a comment on the manner of proceeding in further working with the hygiene Regulations Finland is in favour of option 2, i.e. the report to the Parliament and the Council would be accompanied by necessary proposals to amend the Articles only.

DK 13.02.2007

Denmark does not have any wishes for amendments of the Articles of Regulations (EC) 852/2004, 853/2004 and 854/2004, or of Annex I to Regulation (EC) 853/2004.

UK 14.02.2007

9. In considering whether to identify issues to be resolved as part of the Commission's review, the UK has considered the commitments contained within the legislation, the commitments given at the time of the legislation's adoption, the transition arrangements and (for the sake of completeness) the issues which the UK would like to see the Commission address (but which can be dealt with under comitology or in guidance). These are listed in the enclosed Annex, which the UK hopes will allow for their systematic consideration.

A. COMMISSION DECLARATIONS IN RELATION TO THE REPORT TO COUNCIL AND THE PARLIAMENT CONTAINED IN STATEMENTS FOR ENTRY IN THE COUNCIL MINUTES ON ADOPTION OF THE LEGISLATION (DOC 8066/04 ADD 1 REV 2 AND DOC 8066/04 ADD 1 REV 3 COR 2)

Regulation 853/2004

Annex III, Section I – Emergency slaughter

“The Commission declares that when it reports to the European Parliament and to the Council to review the experience gained from the implementation of the Regulation as

provided for in Article 14, it will discuss in particular the issue of emergency slaughter. If appropriate, it will accompany the report with relevant proposals.”

Annex III, Section VII – Fishery products

“The Commission declares that when it reports to the European Parliament and to the Council to review the experience gained from the implementation of the Regulation as provided for in Article 14, it will discuss in particular the issue of exemptions from the requirement to freeze certain fishery products in accordance with Annex III, Section VIII, Chapter III, Part D. If appropriate, it will accompany the report with relevant proposals.”

Regulation 854/2004

Article 21 – Reviews

“The Commission declares that when it reports to the European Parliament and to the Council to review the experience gained from the implementation of the Regulation as provided for in Article 21, it will discuss in particular whether:

- (a) different national approaches to staffing levels create problems for food safety;
- (b) it would be opportune to increase the minimum training requirements for official auxiliaries;
- (c) it would be appropriate to widen the scope of the rules permitting the slaughter of farmed game at the place of production.

If appropriate, it will accompany the report with relevant proposals.”

B. OTHER DECLARATIONS CONTAINED IN STATEMENTS FOR ENTRY IN THE COUNCIL MINUTES ON ADOPTION OF THE LEGISLATION WHICH COMMIT THE COMMISSION TO REVIEW ISSUES AND IF APPROPRIATE BRING FORWARD PROPOSALS (POSSIBLY UNDER COMITOLGY)

Regulation 853/2004

Annex III, Section IV – Wild game

“In order to ensure that the Regulation achieves the objective of enhancing food safety and consumer protection, the Commission will review the new rules concerning the responsibilities of trained hunters as a matter of priority. In particular, the Commission will examine the rules allowing trained hunters to decide, in certain circumstances, that certain viscera need not accompany wild game to the game handling establishment for post-mortem inspection, and will consider whether more stringent control requirements

are necessary depending on the scale of the hunting operation. It will, if appropriate, propose amendments to these rules.”.

Annex III, Section IV – Fishery products

“The Commission will review the rules on the storage and transport of fishery products in cooled water and, if appropriate, make relevant proposals.”

Annex III, Section X – Eggs and egg products

“The Commission confirms that, pursuant to Regulation (EEC) No 1907/1990 as amended by Regulation (EC) No 5/2001, it will submit a report to the Council by 30 June 2003, together with appropriate proposals. The report will discuss, in particular, the relationship between hygiene legislation and legislation on the marketing of eggs, including as regards identification marking; the approval of establishments; and the washing of eggs. The Commission will also submit a report to the Council (together, if appropriate, with proposals) discussing the introduction of flexibility regarding the time limit for the delivery of eggs to consumers and the possibility of linking the time limit to storage temperatures. The Commission will, if appropriate, seek scientific advice on these issues.

The Commission will review the analytical specifications for egg products contained in Annex III, Section X, Chapter II, Part IV, and make appropriate proposals.”.

Regulation 854/2004

Article 3(7)

“The Council regrets that the European Parliament has not accepted the balanced package of amendments it proposed to it in the light of the informal contacts between the Institutions. In a spirit of compromise, it is however ready to accept the Parliament amendments. The Council invites the Commission to study the practical application of the provisions of Article 5(6) and Annex I, Section III, Chapter III A and come forward as soon as possible with any appropriate proposal to apply the same provision to other species and to clarify the notion of internationally recognised certification.

With regard to Article 5(6) and Annex I, Section III, Chapter III, the Commission will, as soon as possible after the entry into force of the Regulation, produce a report on slaughterhouse staff assisting in meat inspection, with a view to examining whether and under what conditions the system in force at present for poultry meat and rabbit meat can be extended to other species, such as fattening pigs and veal calves and to clarifying the notion of internationally recognised certification. The report will be accompanied by a legislative proposal as appropriate.”

Annex I, Section III, Chapter IV, Part B

“The Commission will consider whether it would be feasible and desirable to extend Annex I, Section III, Chapter IV, Part B, paragraph 8, to cases where official auxiliaries carry out other sampling and analysis tasks and, if appropriate, make relevant proposals.”

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:

a) The need to clarify the egg processing activities that fall within the scope of 853/2004. The definitions in Annex I as read with Article 1(2) of Regulation 853/2004 mean that the manufacture of finished foods such as bakery products or pasta requires the approval of establishments and the application of an identification mark. The definitions in Annex I Regulation 853/2004 also mean that the manufacture of (for example) boiled eggs for sale to food service providers is also covered. The UK considers that the hazards associated with producing such finished foods are adequately controlled under Regulation 852/2004 alone. This was the sense also of the discussions in Council. We believe there is an inconsistency between the regulations and Annex III of the Commission’s guidance (which mentions bakery products as an example of a food benefiting from the exemption in Article 1(2)). We suggest the whole issue needs further discussion with a view to amending Article 1(2) and the definition of an egg product.

c) The reference to primary production at Art 4.2 (a) of Regulation 853/2004 embraces milk production holdings. Under the previous dairy hygiene rules (Directive 92/46) the registration requirement for milk production holdings was effectively akin to the approach to approvals under the current legislation. Given the relatively high risks associated with primary milk production, as evinced by the full suite of detailed controls set out in the legislation, the UK would welcome discussion of whether primary milk production holdings should fall to be approved rather than registered. More generally, the UK would welcome discussion of whether there should be a specific provision in the legislation permitting (for those businesses required to be registered) registration to be removed in the event of sub substantial non-compliance. This would parallel the approach to premises requiring approval, and increase enforcement flexibility.

d) That the Commission should review all instances in the hygiene legislation where food business operators are required to notify the competent authority. The aim would be to establish the value of the requirement to notify and the extent to which it is clear what action the competent authority is to take. The UK considers that this would give useful reassurance about the administrative burdens of the hygiene legislation and might identify requirements that could be dropped without compromising public health protection.

LU 08.03.2007

Législation hygiène des denrées alimentaires

La nouvelle réglementation en matière d'hygiène alimentaire vise un niveau élevé de la protection de la vie et de, la santé humaine. A cet effet, il y a mise en application de principes communs, notamment concernant la responsabilité des fabricants et des autorités compétentes, des exigences en matière de structure, d'organisation et d'hygiène pour les établissements, des procédures d'agrément, des exigences en matière d'entreposage et de transport, des marques d'identification etc. Bref, toute une série de modifications qu'il fallait transposer en réglementation nationale et appliquer sur le terrain, démarches pour lesquelles le délai de mise en œuvre est jugé trop court. S'y ajoute la lenteur des procédures de la mise en place des lignes directrices ce qui n'aide pas à faciliter les mises en application de la nouvelle réglementation. Le secteur a besoin de consignes techniques claires, dotées d'une certaine souplesse qui cependant ne doit pas être à l'origine de distorsions dans la compétitivité des établissements des différents états membres.

2. NO RADICAL OVERHAUL

DK 13.02.2007

Denmark does not have any wishes for amendments of the Articles of Regulations (EC) 852/2004, 853/2004 and 854/2004, or of Annex I to Regulation (EC) 853/2004.

UK 14.02.2007

- The UK has not identified that the hygiene legislation needs a fundamental overhaul as part of the planned review.

3. The UK considers that the hygiene legislation met these objectives to a significant degree. For this reason, the UK has not identified that the legislation needs a fundamental overhaul as part of the planned review.

FI 02.04.2007

We thank the Commission for the possibility to communicate our experiences in implementing the hygiene package and to make suggestions for amending it. On the whole we can say that according our knowledge there have been fewer problems in

implementing the legislation than could have been anticipated. Our new Food Safety Authority (Evira), the competent authority with operational duties, has informed us that most queries have concerned either individual details of the legislation or interpretations of the legislation. These questions cannot be seen as problems to do with the legislation itself.

SE 30.03.2007

Summary

We are positive to the ideas in the new Regulations. No fundamental changes are needed.

3. EXPERIENCE GAINED

SK 14.02.2007

Experience with the new hygiene package:

The industrial establishments, in particular, do not like the flexibility of the new hygiene package because before the accession of the Slovak Republic to the EU they had to fulfil all the detailed hygiene requirements laid down in the Directives and this upgrading process required big financial investments.

UK 14.02.2007

THE UK EXPERIENCE OF THE HYGIENE LEGISLATION

1. The UK's objectives for the negotiation of the hygiene legislation and its application were that the resultant legislation should be:
 - risk-based,
 - proportionate,
 - flexible,
 - outcome-focussed,
 - apply throughout the food chain and
 - clarify the obligation of food business operators to produce safe food.
2. Achievement of these objectives contributes to significant policy objectives for the Food Standards Agency (FSA) including
 - contributing to a continuing decline in the burden of foodborne illness in the UK;

- developing approaches to enforcement which focus on securing compliance and thus improved consumer protection; and
- looking for ways to minimise the regulatory and administrative burden on food businesses without compromising consumer protection.

3. The UK considers that the hygiene legislation met these objectives to a significant degree. For this reason, the UK has not identified that the legislation needs a fundamental overhaul as part of the planned review. The UK also considers that the objectives outlined at 1 above continue to be relevant and will therefore review any proposals for amending the legislation in the light of how they support the original negotiating objectives.

4. The Commission has invited Member States to comment on their experience of applying the hygiene legislation. The UK would like to offer the following general observations at this stage and can expand further on these as necessary.

5. The flexibility inherent in the legislation (and amplified in the Commission guidance material) about the application of food safety management procedures based on HACCP principles is greatly welcomed. For the UK, our most significant challenge has been the application of this requirement to the catering sector. Working with the flexible legislation and building on national initiatives to improve basic hygiene knowledge has enabled the FSA to develop a toolkit of materials for this sector, including the innovative approach of *Safer Food, Better Business*. These approaches will be evaluated over the coming year and the UK would be happy to report further in due course.

6. The application of the legislation to primary production is welcomed, as is the approach that acknowledges that other legislation requires that hazards to food safety at this level are controlled.

7. In relation to the experience of applying the new legislation to the fresh meat sector, the UK believes the Regulations have had a very positive effect in clarifying the responsibility of the operator. The exercise to re-approve meat premises, in which the food business operator has had to demonstrate responsibility for the hygienic production of meat, appears to have elevated standards in establishments to levels that were not achieved when there was lack of clarity between the roles of the operator and the official veterinarian.

8. There is one issue that the UK has identified in relation to working with the new legislation that needs further consideration. That is that the outcome-focussed approach and removal of prescription puts a greater onus on those auditing compliance (both of food business operators and of enforcement by competent authorities) to be able to interpret the legislation in a risk based fashion. The UK in no way wishes to see the reintroduction of prescriptive requirements, but the legislation must be clear and unambiguous as to its desired outcomes. If there are sound risk based reasons why, for example, flexibility for food business operators as to how those outcomes may be

achieved in practice needs to be constrained, then that needs to be clear in the legislation. Those auditing compliance must be able to reach judgements on the effectiveness of the combination of controls in place that achieve the outcome objectives.

BE 29.03.2007

Belgian experience gained from the application of the Hygiene Regulations and the difficulties encountered by them

REGULATION (EC) No 852/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 29 APRIL 2004 ON THE HYGIENE OF FOODSTUFFS

No wishes for amendments of the Articles of Regulation (EC) No 852/2004...

DK 30.03.2007

Experience regarding application of the Regulations

What is food – how far back must raw materials be food?

According to Article 2 of Regulation (EC) No 178/2002, food means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Further it is explained, that food includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment.

This definition must mean, that additives are also food, even though according to the definition of “food additive” in Directive 89/197/EEC food additive means “any substance not normally consumed as a food in itself ...”. Food additives also include processing aids like enzymes.

The general principle is that raw materials for food must in itself be food or be sourced from a food business – raw vegetables must be sourced by a primary producer, the fish used for production of fish oil must be sourced by a primary producer, who is a food business operator, etc.

Certain qualities of calcium hydroxide (CaOH) (E 526) are additives. The production of this CaOH must take place in a food business – but do the raw materials have to be sourced by a food business operator?

For the production of certain cheeses, rennet is used. Does the raw material for the production of this rennet have to be a food? Below is a quotation from a Danish producer of cheese rennet, which explains the problems of sourcing the rennet from food grade raw materials:

“We are producers of cheese rennet, which is an aqueous extract of stomachs primarily of calves (abomasum). Ox stomachs serve as a supplement. Especially calf stomachs are in very short supply globally and need to be sourced also from slaughterhouses in third countries, such as USA or New Zealand. It is impossible to clean such stomachs without destroying the enzyme, which is located in the mucosa on the inside, ie stomachs are trimmed and emptied of their contents but not rinsed or washed, and of course not heat treated. They are frozen in large blocks as soon as possible after they are trimmed and emptied. The rennet is an extract of minced stomachs, which is sterile filtered and preserved by means of salt and a permitted preservative. The hygienic quality of cheese rennet is excellent.

When a shipment of stomachs enters the EU, it may not be in compliance with food hygiene rules in two respects, namely 1) the stomachs cannot be "treated" (salted, heated or dried) as outlined in Reg. 853/2004 Annex II Section XIII and they cannot be of quite the hygienic standard you would require if they were destined for a butcher's shop; 2) they come from animals fit for human consumption but not necessarily from slaughterhouses which are authorized to deliver meat to the EU (because the sourcing of stomachs is global, much more than the sourcing of veal and beef, and it is not realistic to expect that all abattoirs delivering stomachs to EU are also prepared to go through an authorization as meat suppliers to EU).

Earlier on, the importation was administered as "raw materials for technical purposes", but I understand that is no longer correct. I understand that the former practice is actually still continued on a provisional basis, both in Denmark and in certain other EU countries where importation takes place.

If all importation of stomachs for this purpose were to be administered strictly as food, I believe the supplies from third countries would cease to exist, and the EU rennet producers would experience severe shortages, perhaps leading to a drastic reduction in the production of rennet. There are alternatives, eg chymosin produced by means of a GMO, but part of the EU cheese industry can only use animal derived rennet because of cheese regulations (standards of identity, DOC, AOC etc.), and the continued existence of animal rennet is also adding to the competition in the market.

We would therefore suggest that it is in the best interest of the EU that this problem is permanently solved by modification of the legislation so that the importation may continue in a regular manner, of course with due regard to relevant hygienic considerations, as always.”

There is a need to clarify the requirement for the quality of raw materials for these special types of food.

Regulation (EC) No 852/2004

1) The term “food premises”

In Annex II, Chapter I, point 1, there is a general requirement to keep “food premises” clean and maintained in good repair and condition.

During negotiations in the Council Working group the understanding was, that “food premises” means all parts of a food establishment, including the outside facilities like the surface for trucks at in- and out-loading facilities. However, the translation into Danish, and a number of other languages, e.g. Swedish, German, Dutch, French, Italian, Spanish and Portuguese, restricts the requirement to rooms, in which food is handled.

This gives some problems for enforcing a requirement of keeping all parts of food establishments in good repair and condition. It should be considered to change the wording, so it covers all parts of establishments.

2) Use of parts of dwelling-houses as part of an establishment

Chapter III of Annex II set up the requirements for, among others, premises used primarily as a private dwelling-house, but where foods are regularly prepared for placing on the market.

These requirements are a continuation of similar requirements in the former hygiene Directive. The Directive however, allowed for stricter national requirements. Based on that, Denmark has had a rather strict interpretation of the use of parts of dwelling-houses as parts of food businesses, e.g. only allowing the use of kitchens in very specific circumstances:

- Day-care of a few children (up to 5) in private homes.
- Bed & breakfast and farmhouse holidays, where the only meal served is breakfast and the number of guests does not surpass 12.

The wording of Chapter III opens up a wider range of establishments, e.g. catering establishments, which may use the private kitchen as part of the establishment.

Not all parts of the private dwelling-house is part of the establishment, and the rest of the household (spouse, children, pets) are not part of the establishment and not covered of requirements for hygiene, health etc. When the consumer is in the private dwelling (parents of children in day-care, costumers of bed & breakfast or farmhouse holidays, the consumer can decide for himself, whether the conditions are satisfactory or not, whereas when the food is served in another place, e.g. as would be the case for catering establishments, the consumer has no chance to make an informed choice.

The extent of the possibilities to use private dwelling-houses should be discussed and clarified. A possibility could be to allow national restrictions on the use of dwelling-houses.

Regulation (EC) No 853/2004

- 1) Are all types of ice cream produced from processed milk and vegetable ingredients considered products covered by Article 1, paragraph 2, of Regulation (EC) No 853/2004, i.e. exempt from the Regulation?

According to Article 1, paragraph 2, the Regulation does not apply to food containing both products of plant origin and processed products of animal origin, unless expressly indicated. The processed products of animal origin must be obtained and handled in accordance with the Regulation.

Based on this, ice cream produced from processed milk could be considered exempt from Regulation (EC) No 853/2004 and only covered by Regulation (EC) No 852/2004. Certain ice creams are mentioned in point 3.4 of the Guidance Document on implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin as examples of products manufactured under Regulation (EC) No 852/2004.

However, in the definition of processed products in Regulation (EC) No 852/2004, Article 2, paragraph 1, point o, it is mentioned, that processed products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

Based on this, the Danish Veterinary and Food Administration has resolved, that ice cream where processed milk constitutes a major part, while vegetable ingredients constitute a smaller part, are to be considered food of animal origin and produced in accordance with Regulation (EC) No 853/2004 (i.e. the establishment must be approved according to the Regulation and the products marked with identification mark), while ice cream where processed milk constitutes a smaller part may be exempt from Regulation (EC) No 853/2004 and produced under Regulation (EC) No 852/2004.

A common approach to this question is needed.

- 2) Identification marking

The requirements in Annex II, Section I, on identification marking needs clarification.

In point 8 there is a requirement for establishments located within the Community to include an abbreviation indicating the Community, e.g. EC, in the identification mark. However, establishments in countries outside the Community in some cases also use such an abbreviation, e.g. stating "EC number XXX". It should be clarified, that products

imported into the Community from third countries may not be marked using these abbreviations.

According to point 9 the mark may be applied to the product, the wrapping or packaging or a label, depending on the presentation of the product. However, there is no explanation of what influence the presentation makes, e.g. it is not clear, whether the mark must always be visible. E.g. point 13 is quite ambiguous. It is not clear, whether the mark may be on the wrapping, which can only be seen when the consumer-package is opened, or the mark must be on the package, so it can be seen directly.

Annex III, Section IX, Chapter V, includes a derogation regarding identification marking for milk: rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated. Other food business operators have expressed a wish for a similar derogation.

3) Slaughtering outside slaughterhouses

In Annex III, Sections I and II, the main principle is that animals must be slaughtered at the slaughterhouse. For domestic ungulates there is a possibility to perform emergency slaughter outside the slaughterhouse (Chapter VI in Section I), and for poultry there is a possibility to perform the slaughter on the farm for special products (Chapter VI in Section II).

Section III opens up for slaughter on the farm of farmed game, and in exceptional circumstances of bison.

There is a growing interest from the public to slaughter animals at the farm for animal welfare and ethical reasons. It should be discussed to allow slaughtering and bleeding of all types of animals at the farm. It should be a requirement, that the slaughtering and bleeding can take place under hygienic conditions, and that the carcasses can be transported hygienically to a slaughterhouse for further dressing.

4) Slaughter animals must be clean

Annex III, Section I, Chapter IV, point 4, states that animals (domestic ungulates) must be clean. In practise, this is not feasible. The text could include a more risk-based approach, like: "Animals must be clean enough so as not to present an unacceptable risk of contaminating meat during slaughter and dressing."

5) Bleeding of domestic ungulates and farmed game

According to Annex III, Section I, Chapter IV, point 7, a, the trachea and oesophagus must remain intact during bleeding, except in the case of slaughter according to a religious custom.

According to the TSE-Regulation ((EC) No 999/2001), the laceration, after stunning, of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity shall not be used on bovine, ovine or caprine animals whose meat is destined for human or animal consumption.

In some small slaughterhouses no other means of protecting the staff has been possible, so Denmark allow a cut traversing the throat for bleeding, although this means severing the trachea and oesophagus.

For ovine and caprine animals the same happens for practical reasons.

It should be discussed, if this procedure should be allowed generally. The food business operator must of course then cut away any meat that has been contaminated as a result of the use of the procedure.

6) Cleaning of stomachs at a different establishment

According to Annex III, Section I, Chapter IV, point 18, a, stomachs must be scalded or cleaned when destined for further handling.

It should be made clear, if this processing must take place at the slaughterhouse, or it can take place at another establishment.

7) Temperatures

The Regulation states a number of temperature requirements for different products, especially meat, fishery products and milk. E.g. for meat in Annex III, Section V, Chapter III: 4 °C for poultry, 3 °C for offal, 7 °C for other meat, 2 °C for minced meat and 4 °C for meat preparations. Frozen minced meat and meat preparations must be frozen to an internal temperature of not more than –18 °C. For fresh meat no freezing temperature is given.

It would be desirable to have a discussion of the relevance of these different temperatures, i.e. whether the decision on temperatures could be left to a risk-based approach and decided by the food business operators, or the temperature requirements should be maintained in the Regulation but based on a scientific evaluation, e.g. performed by EFSA. If the temperature requirements are maintained it should also be considered, whether they should be extended to retail.

8) Freezing and re-freezing of meat.

According to Annex III, Section I, Chapter VII, point 4, meat from domestic ungulates intended for freezing must be frozen without undue delay, taking into account where necessary a stabilisation period before freezing.

According to Section III, point 1, of Annex III, the provisions of Section I apply to the production and placing on the market of meat from even-toed farmed game.

Should there be a similar requirement for freezing of meat without undue delay for other types of animals (poultry etc.)?

Does this requirement preclude freezing of meat, thawing, cutting and re-freezing of the cut meat?

The Regulation does not seem to preclude re-freezing of meat in general. It is mentioned specifically in Section V, Chapter III, point 5, of Annex III, that minced meat, meat preparations and MSM must not be re-frozen after thawing.

It could be argued, that the requirement to freeze the meat without undue delay does not only apply to the meat right after slaughtering and cutting just after slaughtering or stabilisation, but would equally well apply to meat, that has been frozen, thawed, cut and then re-frozen, i.e. the meat must be re-frozen without undue delay after the cutting operation. Thawing must of course fulfil the requirements of Regulation (EC) No. 852/2004, Annex II, Chapter IX, point 7.

9) Use of clean water in establishments on land handling fishery products.

The transitional measure in Article 11 of Regulation (EC) 2076/2005, which is a derogation to Annex III, Section VIII of Regulation (EC) No 853/2004, and allows the use of clean water in land based establishments handling fishery products, should be made permanent. The use of clean water has not given rise to any adverse effects on hygiene.

Regulation (EC) No 854/2004

1) Training of plant staff for assisting with official controls

Annex I, Section III, Chapter III, Part A, allows plant staff to assist the official veterinarian under certain conditions, including that the plant staff has been trained in the same way as official assistants. The competent authority should be allowed to require training for just the specific tasks the plant staff is to perform.

SE 30.03.2007

General Comments

Are the rules easy to read and understand?

Regulations 852/2004, 853/2004 and 854/2004 are not always easy to read or understand. Earlier, when Directives were transformed into national legislation, it was possible to change the language (make long complicated sentences shorter, delete unnecessary words

and so on). It was also possible to change the whole layout. The layout of the Regulations, 853/2004 in particular, with all its Annexes, Sections and Chapters, and its mixture of Roman figures, Arabic figures and letters makes it extremely difficult to follow.

Although some of the rules have been changed, there is still no consolidated version available, including all amendments up to November 2006.

For which activities should the Regulations be applied?

Since the hygienic rules are applicable only for food business operators, it is crucial to understand that term. However, it is not always quite obvious if a certain activity should be considered as a food business operator or not, for instance “Bed and breakfast”.

What do we think about flexibility?

We are positive to the concept of flexibility. However, it has sometimes been difficult for inspectors and food business operators to make use of this flexibility in practice. Further discussions would be helpful in order to harmonise the interpretation.

The procedure for national adaptations of requirements in Annex II of 852, II and III of 853/2003 and Annex I of 854/2004

Perhaps Directive 98/34 should be mentioned, in order to avoid more unintentional mistakes.

Guidance document to Regulation 852/2004 and 853/2004

These guidance documents were not foreseen in the Regulations. They have been a good help. However, when they were developed, the experience of the new regulations was very limited. Furthermore, the guidance documents were available only in English. Since questions of how the rules are understood in other countries are often raised, there is perhaps a need for both a revision of existing guidance document and a need for discussion of other questions as well.

Several Swedish Food Business operators stress that the rules should be implemented in the same way in all countries and in different parts of Sweden. Therefore they wish more guidance from the Commission and from the National Food Administration

Comments on Regulation 852/2004

Definitions

Some words are used without being defined. We have some problems with the word “handle” and the words “prepare and reparation”.

National guides

The role of the competent authority is not quite clear. Article 7- 9 can be understood as follows: Member States shall only assess guidelines, not take part in the development of the guides.

We have noticed that other Member States assess guides that we would not have accepted.

Comments on Regulation 853/2004

Borderline between 852/2004 and 853/2004

The borderline is not clear. The problem relates to composite products, see document SE request. The problems also relates to definitions of egg products and milk products, see below.

Definitions

The definitions of egg products and milk products have caused some questions. One way to handle it might be to give some examples of milk products or egg products in the guidelines.

The term “rewrapping” is used in the guideline to Regulation 853/2004 and in the technical list. Since the term it is not defined anywhere, it has caused some confusion.

Comments on Regulation 854/2004

There must be a mistake in Article 4(8)(a). There is a reference to “Regulations referred to in paragraph 1(a) and 1(b)”. However, there is no paragraph 1(a) or (b) in Article 4, so we guess that it should be paragraph 2(a) and 2(b) instead.

Information about work in Sweden in order to reduce the administrative costs for businesses

Only some weeks ago, a report of a study of the administrative cost for Swedish food business operators was presented. The study has been carried out by the Swedish Agency for Economic and Regional Growth (Nutek). The report is one of many steps in order to achieve a national goal of reducing the administrative costs for all types of businesses with 25% by the autumn 2010. An English summary of the report from Nutek is available, se enclosure.

The report indicates that the main area for reducing administrative costs for food business operators is within the area of implementation of legislation. Examples: How the flexibility in the regulations can be used, the need for more and better guidelines for food inspectors and also more guidance to food business operators.

The Swedish National Food Administration now has to examine the report and to decide what can be done.

English summary of a report from the Swedish Agency for Economic and Regional Growth (Nutek).

This report concerns the results of a study of the administrative costs for Swedish businesses of fulfilling regulations related to food, including drinking-water. The study has been conducted using the Standard Cost Model (SCM). The SCM is the most widely applied methodology for measuring administrative costs throughout Europe. The SCM methodology is an activity-based measurement of businesses' administrative costs over time. The SCM has been developed to provide a simplified, consistent method for estimating the administrative costs imposed on business by central government. This baseline measurement takes its starting point from regulations that had the force of law March 1, 2006. A detailed analysis of 148 relevant pieces of legislation led to the identification of 369 so called information obligations for Swedish businesses.

The results of the study can be used to identify areas of legislation where there is a possibility to reduce the administrative costs for businesses. The possibilities for simplification should always be weighed against the societal benefits of regulations.

This study shows that administrative costs are primarily found in the following areas; hygiene, HACCP¹, public surveillance and consumer information through labelling. In order to reduce administrative costs the main area of simplification is implementation of legislation. The study further shows that there is a discrepancy in how smaller and larger businesses perceive the legislation. While larger businesses regard great parts of the legislation as an integrated part of their quality procedures, smaller businesses find that the implementation of the legislation often is too detailed and does not fit the needs and purposes of their activities. These are important points to consider when assessing the total cost of regulations for Swedish businesses relevant to this study, which is just over 8,4 billion Swedish crowns (approximately 1 billion euro).

LU 08.03.2007

(See 1. GENERAL)

FI 02.04.2007

We thank the Commission for the possibility to communicate our experiences in implementing the hygiene package and to make suggestions for amending it. On the whole we can say that according our knowledge there have been fewer problems in implementing the legislation than could have been anticipated. Our new Food Safety

¹ Hazard Analysis Critical Control Points

Authority (Evira), the competent authority with operational duties, has informed us that most queries have concerned either individual details of the legislation or interpretations of the legislation. These questions cannot be seen as problems to do with the legislation itself.

However, there are some points which have been found problematic because of the wording of the Regulation. These items have been indicated to the Commission in our letters of January 26th and February 14th, 2007. As the legislation is extensive, we would like to present additional comments, which have been set out in the annex to this letter.

4. EXTENSION OF HACCP TO FBO IN PRIMARY PRODUCTION

DK 13.02.2007

Danish remarks concerning amendments to Regulations (EC) 852/2004, 853/2004 and 854/2004

In particular, we find it too early to extend the requirements of Article 5 of Regulation (EC) 852/2004 regarding procedures based on the HACCP principles to cover also primary producers.

DK 30.03.2007

HACCP based procedures for primary producers

As stated in letter of 13.02.2007 (file 2007-20-221-02245), Denmark does not consider it practicable to extend the requirement for HACCP based procedures to food business operators carrying out primary production at the present time. The implementation of good hygiene practices as required in Regulation (EC) No 852/2004, gives a sufficient protection of consumers.

FI 02.04.2007

As regards Finland's position on the application of HACCP-principles in primary production we feel that it is too early to consider it. There is a large number of new requirements currently to be implemented in primary production and this has taken resources and is still taking up. Nevertheless, we would see many positive aspects in applying HACCP to primary production. The advantage of the HACCP system is that HACCP is a clear, well-defined, universally known and accepted concept. The application of HACCP in primary production could in the long run be a more economic way to assure all operators along the chain, as well as our export partners, than resorting

to the various quality systems which undoubtedly will arise in the near future. However, our position is negative for the application of HACCP-principles at this stage.

UK 14.02.2007

The UK considers that there is insufficient evidence to support the extension of HACCP-based procedures to the generality of primary production (an issue on which the Commission has to report). It should continue to be an option for Member States to encourage this approach, rather than a legislative requirement.

LU 08.03.2007

HACCP – secteur primaire

L'extension du secteur primaire de la mise en application des procédures du principe HACCP, telles que disposées à l'article 5 du Règlement (ECE) No 852/2004, nous semble prématurée.

FR 08.03.2007

De plus, en réponse au courrier adressé aux états membres par la DG SANCO le 16 février 2007, j'ai l'honneur de vous informer que la France considère que l'application d'un système de type HACCP au stade de la production primaire doit rester facultative et au libre choix du producteur concerné. Parallèlement la France continue toutefois de promouvoir l'utilisation de cette approche puisque des guides de bonnes pratiques sanitaires (GBPS) dans les filières animales y compris en élevage sont en cours de rédaction par les organisations professionnelles et intègrent l'identification des dangers et les points critiques pour les maîtriser.

FR 06.04.2007

Moreover, in response to the letter addressed to the Member States by DG SANCO on 16 February 2007, France wishes to specify that the application of HACCP at the stage of primary production has to remain optional and to the free choice of the producer concerned. At the same time France continues however promoting the use of this approach since guides to good practice in the animal channels including in livestock-farming are being drafted by the professional organizations and incorporate the identification of the dangers and the critical points to control them. Therefore, these guides already constitute an appropriation of the HACCP method by the stock breeders through a collective step.

BE 29.03.2007

Belgian position concerning the desirability and practicability of providing for the extension of HACCP to food business operators carrying out primary production and associated operations

The extension of HACCP to food business operators carrying out primary production and associated operations, at this time is neither advisable nor practicable

The requirements of the general food law (The responsibility of the food business operator, traceability, notification, withdrawal from the market) and compliance with the general hygiene provisions of part A of Annex I of Regulation 852/2004 (Hygiene provisions and record keeping) should ensure food safety.

LT 30.03.2007

In our opinion it is too early to apply the requirements of Article 5 of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 regarding the procedures based on the HACCP principles, to primary producers.

SE 30.03.2007

Should HACCP- principles be introduced for primary production?

It is too early to introduce HACCP principles in primary production.

However, we wish to stress that in some cases the first step (hazard analysis) may be needed. Example: Annex I, Part A.II.5(c) states “to use potable water, or clean water, whenever it is necessary to prevent contamination”. A producer of lettuce and similar products must be aware of the hazards that may be introduced if he uses water from ponds or brooks.

5. COLD STORES (See also MS' proposals)

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, 852/2204 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)	<p>Amend this point by deleting "of storage or" and replacing it by:</p> <p>"..., unless:</p> <p>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>
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	<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 Kühllhäuser:** Dabei handelt es sich um Kühllhäuser, die einem Produktionsbetrieb angeschlossen sind. In diesen Kühllhäusern wird nur betriebseigene Ware gelagert.
- **Gewerbliche Kühllhäuser:** Diese Kühllhäuser 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 Kühllhäusern ist wiederum zu unterscheiden zwischen zwei Kategorien:

- Eigenbewirtschaftete Kühllhäuser: In diesen Kühllhäusern 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.
- Fremdbewirtschaftete Kühllhäuser: In diesen Kühllhäusern 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 Kühllhäuser 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 Kühllhäuser. Wir schlagen daher folgende rechtliche Änderungen für Kühllhäuser vor:

1. Zulassungspflicht für alle Kühllhäuser 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 Kühllhäuser: „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.

6. TRANSITIONAL ARRANGEMENTS TO BE MADE PERMANENT

AT 19.01.2007

Austria requests a discussion in the course of the review of the following problem areas, which have been temporarily solved in Regulation (EC) 2076/2005, in order to find a definitive solution.

1. Article 3

It should continue to be possible for small quantities of directly marketed poultry

and rabbit meat in processed form to be supplied to the final consumer, as is currently possible for game from open hunting grounds.

2. Article 8(2)

The requirement to provide food chain information 24 hours ahead of animals arriving in the slaughterhouse should be abandoned. It is enough for the documents to accompany the animals, as has so far been the case.

FI 26.01.2007

We would like to know if the Commission finds it possible to continue the derogation of accreditation of laboratories according the Regulation of transitional arrangements at least for the Trichinella laboratories in small slaughterhouses. Otherwise it is soon time to arrange the Trichinella inspection in a new way. Those decisions of arrangements are very difficult to the small producers so the information should be early available.

FI 02.04.2007

854/2004 Article 5 point 6 and Annex I, section III, chapter III, A:

The requirements for training of official auxiliaries in poultry slaughterhouses are too demanding compared to the extent of their tasks in poultry meat inspection. We hope that the derogation in the regulation 2076/2005 Article 14 could be made permanent.

NO 27.01.2007

Suggestions from Norway on points that should be considered during the process of reviewing the Regulations of the Hygiene Package:

1. Permanent rules allowing the use of clean seawater in establishments (including factory vessels) handling fish and fishery products.

(Reference: (EC) 852/2004 Annex II, Chapter VII, no. 1, (EC) 853/2004 Annex III, Section VIII, Chapter III letter A and Chapter IV no.1, and Regulation (EC) 2076/2005 Article 11)

LV 13.02.2007

It is necessary to specify Annex II, Section III of that Regulation on food chain information. Point 4(a)(ii) of this Section provides:

"4. (a) However, it is not necessary for the slaughterhouse operator to be provided with:

(ii) the information referred to in point 3(a), (b), (f) and (g), if the producer declares that there is no relevant information to report."

How the text "no relevant information to report" in point 4(a)(ii) be understood?

We consider that the indicated derogation is too flexible and it allows different interpretations, and such information, particularly if it refers to animal health status, status of the holding of provenance or the regional animal health status, is always a "relevant information to report".

SE 14.02.2007

1. Direct supply of small quantities of meat from poultry and lagomorphs.

We would like a permanent change in 853/2004 Article 1.3 d), cf. 2076/2005 Article 3.

2. Direct supply of small quantities of meat from ostriches.

We think this should be possible. The establishments are very small and the quantities of meat produced are very small. The hygienic risks are not higher than for poultry meat.

SK 14.02.2007

Regulation (EC) No 2076/2005

To delete Article 10: Composition criteria and labelling requirements for minced meat, because they are the parameters of quality, not food safety

UK 14.02.2006

D TRANSITION MEASURES IN REGULATION 2076/2005 WHICH APPLY UNTIL 31 DECEMBER 2009 WHICH THE UK WOULD LIKE TO SEE RESOLVED PERMANENTLY

Depending on the steps necessary to give permanent effect to the following, these might be achieved by amendments under comitology or may need amendments to the Articles (or Annex I of Regulation 853/2004) under co-decision.

Issue	Reference	Request	Justification
2. Health import	Article 7	Transitional	Under Article 7(2)

<p>conditions on food containing both products of plant origin and processed products of animal origin.</p>		<p>measures should <u>not</u> be made permanent. As set out in Article 7(2), a risk-based approach to implement harmonised health import conditions and checks for such products should be developed. Pending the adoption of these harmonised measures, guidance should be issued to clarify the import conditions that currently apply.</p>	<p>imports shall comply with the harmonised Community rules in force before 1 January 2006 where applicable and with national rules implemented before that date in other cases. Many EU and UK provisions that applied before 1 January 2006 have been revoked, leaving the import provisions that apply to such products unclear. Also, SCoFCAH has recently agreed significant changes to the animal health and veterinary controls that apply to the import of such foods.</p>
<p>5. Training of plant staff for assisting with official controls</p>	<p>Article 14</p>	<p>As agreed at restricted Commission working group on 14 June transitional measure to allow plant staff only to be trained for the tasks they perform should be made permanent.</p>	<p>Requiring plant staff to be trained for tasks they do not carry out is unnecessary for the protection of public health.</p>
<p>7. Cracked eggs</p>	<p>Article 13.2</p>	<p>Transitional measure should be made permanent</p>	<p>Consistency with new Codex Code of Hygienic Practice for eggs and egg products.</p>

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IT 14.02.2007

TEMPORARY DEROGATION FOR POULTRY AND LAGOMORPHS

Italy would like the temporary derogation under Article 3 of Regulation 2076/2005 concerning the direct supply of small quantities of meat from poultry and lagomorphs slaughtered on the farm to be made permanent.

This mode of production and distribution was already covered by the previous Community legislation and has not to date given rise to trade or food safety problems.

Moreover, direct supply of small quantities of meat from poultry and lagomorphs slaughtered on the farm is a way of safeguarding a marginal economic activity linked to the countryside and maintaining and preserving a type of production and distribution which may be regarded as traditional, especially in some rural areas.

We believe this practice does not affect the dynamics of the common market or compromise attainment of the common objective of food safety.

However, if this temporary derogation were made permanent, it would be desirable, precisely in order to avoid trade distortions, to provide a clear, harmonised definition of the "small quantities" referred to in Article 3 of Regulation (EC) No 2076/2005. We propose a limit of 10 000 head per year.

FR 15.02.2007

Request to prolong transitional measures (2076/2005)

Regulation (EC) No 853/2004	
Passage in question	Problem raised and proposal
Article 3(2)	<p>Prolong the transitional measure permanently.</p> <p>A derogation from the obligation to use only drinking water is provided for in Article 11 of Regulation (EC) No 2076/2005 for:</p> <ul style="list-style-type: none"> - the chilling of fresh fishery products in establishments on land; - the handling of fishery products, irrespective of the type of establishment; - the cooling of cooked crustaceans and molluscs. <p>The French authorities would like this derogation to be prolonged, and would like clean seawater to be authorised again for all these activities. They have asked the AFSSA, the French food safety agency, to try to establish objective criteria for the definition of clean seawater (result expected in one month). The French authorities would like to know whether other MS have taken similar action with regard to this issue,</p>

which they consider to be crucial.

IE 01.03.2007

REGULATION (EC) No 853/2004

Annex II, Section III Food Chain Information:

Regulation (EC) No. 2076/2005 states:

“By way of derogation from the requirements laid down in ...Regulation (EC) No 853/2004, ...the competent authority may permit such information to be sent to the slaughterhouse operator with animals of all species, to which it relates and in all circumstances where this does not jeopardize the objectives of Regulation 853/2004”.

This provision should be made permanent by incorporating it into Annex II, Section III.

Point 7 of Section III says that “slaughter house operators must evaluate the relevant information.”

It is not within the competence of the slaughterhouse operator to evaluate FCI and it is required in Reg. 854/2004 that this evaluation be undertaken by the official veterinarian. The sentence relating to evaluating of FCI should be deleted from Point 7.

BE 29.03.2007

Transitional measures in regulation 2076/2005 *Article 14, Article 15.*

Article 14

Training of slaughterhouse staff assisting with official controls.

By way of derogation from Article 5(6)(a)(i) to Regulation (EC) No 854/2004 and Chapter III(A)(a) of Section III of Annex I to that Regulation, slaughterhouse staff authorised by the competent authority to carry out specific tasks of official auxiliaries shall be trained in the same way as official auxiliaries only with regard to the specific tasks they are authorised to perform and shall not be required to have passed the same examination as official auxiliaries.

As agreed at the restricted Commission working group on 14 June 2006 this transitional measure should be made permanent.

Common position at Council:

The designated slaughterhouse staff may only carry out specific tasks if they have received appropriate training and passed an appropriate test, and if the official veterinarian supervises these tasks. Training and tests are to be at least equivalent to those required for official auxiliaries in respect of the specific tasks carried out.

Article 15

Certification of establishments using staff assisting with official controls in slaughterhouses.

By way of derogation from the second subparagraph of Chapter III (A)(a) of Section III of Annex I to Regulation (EC) No 854/2004, establishments wishing to use their staff assisting with official controls shall, during the transitional period, be exempted from the requirement to possess an internationally recognised certification, provided that the establishment demonstrates that it has initiated and is pursuing certification in accordance with international standards, such as relevant EN ISO standards on quality management or food safety.

**Article 15 should not be made permanent
and the requirement in Regulation 854/2004 Annex I section III Chapter III A.
a :**

**“and any establishment wishing to use the establishment's own inspectors must
possess internationally recognised certification”
should be deleted.**

Common position at Council :

To receive the authorisation referred to in ...

The slaughterhouse must have been operating in full compliance with hygiene requirements, particularly good hygiene practices and HACCP-based procedures, for at least 12 months.

DK 30.03.2007

Training of plant staff for assisting with official controls

Annex I, Section III, Chapter III, Part A, allows plant staff to assist the official veterinarian under certain conditions, including that the plant staff has been trained in the same way as official assistants. The competent authority should be allowed to require training for just the specific tasks the plant staff is to perform.

Use of clean water in establishments on land handling fishery products

The transitional measure in Article 11 of Regulation (EC) 2076/2005, which is a derogation to Annex III, Section VIII of Regulation (EC) No 853/2004, and allows the

use of clean water in land based establishments handling fishery products, should be made permanent. The use of clean water has not given rise to any adverse effects on hygiene.

7. COMPOSITE PRODUCTS

FI 14.02.2007

According to Article 1 (2), Regulation (EC) No 853/2004 shall not apply to food containing both products of plant origin and processed products of animal origin. We propose that meat preparations would be exception to this general rule.

Some of the meat preparations can be classified as processed products and some as unprocessed products. However, there is not any significant difference in the microbiological risks between processed and unprocessed meat preparations. For example curing or marinating does not reduce the risk of salmonella. Also, it is not always clear which type of processing makes meat preparation a processed product. For example marinating can cause problems because there is no definition for “marinating” today. Cut meat in sauce can be regarded as non-marinated or marinated product depending on the time the meat is kept in the sauce before further processing or cooking at home.

Hence, we feel that Regulation (EC) No 853/2004 should apply to all foodstuffs containing meat preparations, and the establishment preparing these kinds of foodstuffs should be approved according to this Regulation.

LU 14.02.2007

Another point to clarify is the fact that now composite products of plant and animal origin may be placed on the Community market without an identification mark as foreseen in Annex I Section I Ch.III of 854 depending whether they are issued by a premises that only handle processed meat products or performs itself the processing of the meat products. Some operators and control authorities consider that for international trade of food containing products of animal origin a “health mark” is required as by the old regulation.

LU 08.03.2007

- La réglementation actuelle, prévue à l'**article 1, point 2** du Règlement (CE) No 853/2004 relative aux denrées alimentaires contenant à la fois des produits d'origine végétale et des produits d'origine animale transformés, est à préciser.

NL 14.02.2007

Article 1.2: Mixed products. Especially in the field of dairy it is still a problem to define what mixed products are. Example: ice cream with a small portion of plant fat; is this a mixed product or not. Therefore, the approval for mixed products is still a discussion. This should be clarified in this Article.

SE 25.01.2007 as revised 14.02.2007

A clarification is needed regarding composite products. According to Article 1.2 in Regulation 853/2004, composite products containing both products of plant origin and unprocessed products of animal origin are within the scope of that Regulation. In the Guidance document (see Annex III, Page 18- 19 in the English version), the following activity is described: *Assembly of food of plant origin with unprocessed food of animal origin further processed together*. Two examples of that activity are: *Canning products made from vegetables and raw meat and ice cream*.

We are not quite sure how to deal with bakery products and ready to eat food such as meatballs, potatoes and sauce. We guess that these products are within the scope of Regulation 853/2004, if they are processed from raw eggs, raw meat or raw fish. The Regulation does not lay down any specific rules for bakery products or for ready to eat food, so we guess that the establishments need not to be approved and need not an identification mark. Besides we don't see any need for approval and identification mark for such products.

However, Annex III of the Guidance document says that approval **is** required.

BE 29.03.2007

1. Annex III of the guidance document to H2 lists activities where food of plant origin is assembled with food of animal origin (= composite products).

- assembly of food of plant origin with **processed** food of animal origin and placed on the market as such:
 - e.g. manufacturing of certain edible ices made from processed milk (heat treated milk, milk powder)
 - e.g. making bakery products

The manufacturing of these products should comply with H1.

- assembly of food of plant origin with **unprocessed** food of animal origin further processed together
 - ice cream from raw milk

The manufacturing of these products should comply with H2 (approval of establishments and application of identification mark).

This includes that all manufacturing of composite products with raw milk should comply with H2. e.g.: pancakes with raw milk, flan with raw milk, mix of fruit juice and raw milk ...

Proposal: Since the wording “dairy products” reflects the classical products such as consumption milk, butter, cheese, yoghurt, **the wording “dairy products” should be changed into “milk products” or “products with milk”**

DK 30.03.2007

Are all types of ice cream produced from processed milk and vegetable ingredients considered products covered by Article 1, paragraph 2, of Regulation (EC) No 853/2004, i.e. exempt from the Regulation?

According to Article 1, paragraph 2, the Regulation does not apply to food containing both products of plant origin and processed products of animal origin, unless expressly indicated. The processed products of animal origin must be obtained and handled in accordance with the Regulation.

Based on this, ice cream produced from processed milk could be considered exempt from Regulation (EC) No 853/2004 and only covered by Regulation (EC) No 852/2004. Certain ice creams are mentioned in point 3.4 of the Guidance Document on implementation of certain provisions of Regulation (EC) No 853/2004 on the hygiene of food of animal origin as examples of products manufactured under Regulation (EC) No 852/2004.

However, in the definition of processed products in Regulation (EC) No 852/2004, Article 2, paragraph 1, point o, it is mentioned, that processed products may contain ingredients that are necessary for their manufacture or to give them specific characteristics.

Based on this, the Danish Veterinary and Food Administration has resolved, that ice cream where processed milk constitutes a major part, while vegetable ingredients constitute a smaller part, are to be considered food of animal origin and produced in accordance with Regulation (EC) No 853/2004 (i.e. the establishment must be approved according to the Regulation and the products marked with identification mark), while ice cream where processed milk constitutes a smaller part may be exempt from Regulation (EC) No 853/2004 and produced under Regulation (EC) No 852/2004.

A common approach to this question is needed.

Also relevant for Article 1(2) of Regulation (EC) No 853/2004

MS' PROPOSALS

REGULATION (EC) No 852/2004

ARTICLES

1(3)

LU 14.02.2007

- 1) In relation to paragraph 3 of Article 1 of 852, to paragraph 4 of Article 1 of 853 and to paragraph 3 of Article 10 of 853 where Member States adopt national measures, it should be clarified whether those products can be placed on the national or the Community market.

Luxemburg suggests that these products can be placed on the Community market but the products and the operator have to comply with the national rules of the destination Member State.

1(4)(a)

FR 06.03.2007

<i>Article 1, point 4 a)</i>	<p>Ajouter un iii) à ce point 4 qui devient</p> <p>4. a) Les mesures nationales visées au paragraphe 3 ont pour objet :</p> <p>i) de permettre de poursuivre l'utilisation des méthodes traditionnelles à toute étape de la production, de la transformation ou de la distribution des denrées alimentaires ;</p> <p>ou</p> <p>ii) de répondre aux besoins des établissements du secteur alimentaire situées dans des régions soumises à des contraintes géographiques particulières.</p> <p>ou</p> <p><u>iii) de répondre aux spécificités des associations caritatives</u></p>
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distribuant des denrées alimentaires.

Motivation : Il serait souhaitable de prévoir la possibilité pour les autorités nationales d'adopter des mesures spécifiques pour les associations caritatives qui manipulent des denrées alimentaires.

2(1)

EE 26.01.2007

Small quantities, marginal and local

In order to avoid the distortion of market due to the inequitable terms the more harmonised approach to the definitions “small quantities”, “marginal” and “local” should be considered.

2(1)(f)

IE 01.03.2007

The definition of “contamination” as “the presence or introduction of a hazard” should be changed. Something that is naturally present in a food (e.g. bones in a fish or the stone in a peach) could be considered a hazard, but not be a contaminant.

Consider the Codex definition of a contaminant:

“Any biological or chemical agent, foreign matter or other substance not intentionally added to food, which may compromise food safety or suitability”.

5

NL 14.02.2007

Article 5: the first 5 steps which are mentioned in the Codex Alimentarius document (Assemble HACCP team, description product, identification of intended use, construct flow diagram and on site confirmation of flow diagram) are not mentioned in this Article. This causes problems in the field of auditing the HACCP implementation, because the enforcement by the government cannot be followed when the HACCP system of an establishment does not correspond with these five Codex steps. Therefore the five Codex steps should be mentioned in this Article.

5(2)(e)

NL 14.02.2007

Article 5(2)(e): corrective measures are mentioned in this Article. The corrective actions should not only be described, but they also have to be implemented. The fact that corrective actions also should be implemented is not mentioned in this Article. Therefore, this Article has to be changed in this way.

13(4)(a)

FR 06.04.2007

<i>Article 13, point 4 a)</i>	<p>Add a iii) at this point 4 that becomes</p> <p>4. a) national measures referred to in paragraph 3 shall have the aim of :</p> <ul style="list-style-type: none">(i) enabling the continued use of traditional methods, at any of the stages of production, processing or distribution of food;or(ii) accommodating the needs of food businesses situated in regions that are subject to special geographical constraints ;or <p><u>iii) satisfying the specific characters of the charities distributing food.</u></p> <p>Justification: It would be desirable to envisage the possibility for the national authorities of taking specific measures for the charities that handle food.</p>
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REGULATION (EC) No 853/2004

ARTICLES

1(2) (See also **7. COMPOSITE PRODUCTS**)

FI 14.02.2007

According to Article 1 (2), Regulation (EC) No 853/2004 shall not apply to food containing both products of plant origin and processed products of animal origin. We propose that meat preparations would be exception to this general rule.

Some of the meat preparations can be classified as processed products and some as unprocessed products. However, there is not any significant difference in the microbiological risks between processed and unprocessed meat preparations. For example curing or marinating does not reduce the risk of salmonella. Also, it is not always clear which type of processing makes meat preparation a processed product. For example marinating can cause problems because there is no definition for “marinating” today. Cut meat in sauce can be regarded as non-marinated or marinated product depending on the time the meat is kept in the sauce before further processing or cooking at home.

Hence, we feel that Regulation (EC) No 853/2004 should apply to all foodstuffs containing meat preparations, and the establishment preparing these kinds of foodstuffs should be approved according to this Regulation.

LU 14.02.2007

Another point to clarify is the fact that now composite products of plant and animal origin may be placed on the Community market without an identification mark as foreseen in Annex I Section I Ch.III of 854 depending whether they are issued by a premises that only handle processed meat products or performs itself the processing of the meat products. Some operators and control authorities consider that for international trade of food containing products of animal origin a “health mark” is required as by the old regulation.

LU 08.03.2007

- La réglementation actuelle, prévue à l'**article 1, point 2** du Règlement (CE) No 853/2004 relative aux denrées alimentaires contenant à la fois des produits d'origine végétale et des produits d'origine animale transformés, est à préciser.

NL 14.02.2007

Article 1.2: Mixed products. Especially in the field of dairy it is still a problem to define what mixed products are. Example: ice cream with a small portion of plant fat; is this a mixed product or not. Therefore, the approval for mixed products is still a discussion. This should be clarified in this Article.

SE 25.01.2007 as revised 14.02.2007

A clarification is needed regarding composite products. According to Article 1.2 in Regulation 853/2004, composite products containing both products of plant origin and unprocessed products of animal origin are within the scope of that Regulation. In the Guidance document (see Annex III, Page 18- 19 in the English version), the following activity is described: *Assembly of food of plant origin with unprocessed food of animal origin further processed together*. Two examples of that activity are: *Canning products made from vegetables and raw meat and ice cream*.

We are not quite sure how to deal with bakery products and ready to eat food such as meatballs, potatoes and sauce. We guess that these products are within the scope of Regulation 853/2004, if they are processed from raw eggs, raw meat or raw fish. The Regulation does not lay down any specific rules for bakery products or for ready to eat food, so we guess that the establishments need not to be approved and need not an identification mark. Besides we don't see any need for approval and identification mark for such products.

However, Annex III of the Guidance document says that approval **is** required.

1(3)(c) & (e)

EE 26.01.2007 See also 1(3)(d)

Small quantities, marginal and local

In order to avoid the distortion of market due to the inequitable terms the more harmonised approach to the definitions “small quantities”, “marginal” and “local” should be considered.

1(3)(d)

AT 19.01.2007

It should continue to be possible for small quantities of directly marketed poultry and rabbit meat in processed form to be supplied to the final consumer, as is currently possible for game from open hunting grounds.

BE 26.01.2007

This Regulation shall not apply in relation to:

(d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs **and ostriches** slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat;

Text proposal:

"3. This Regulation shall not apply in relation to:

(d) the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs **and ostriches** slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer as fresh meat."

Motivation:

The direct supply by the producer to the final consumer of small quantities of meat from ostriches slaughtered on the farm was allowed by Dir. 91/495/EEC Article 10.

There was no intention to change existing practices.

Regulation (EC) No 853/2004 allows slaughtering of farmed ratites at the place of origin if the animals cannot be transported, to avoid any risk for the handler or to protect the welfare of the animals.

EE 26.01.2007

Small quantities, marginal and local

In order to avoid the distortion of market due to the inequitable terms the more harmonised approach to the definitions "small quantities", "marginal" and "local" should be considered.

IT 14.02.2007

Italy would like the temporary derogation under Article 3 of Regulation 2076/2005 concerning the direct supply of small quantities of meat from poultry and lagomorphs slaughtered on the farm to be made permanent.

This mode of production and distribution was already covered by the previous Community legislation and has not to date given rise to trade or food safety problems.

Moreover, direct supply of small quantities of meat from poultry and lagomorphs slaughtered on the farm is a way of safeguarding a marginal economic activity linked to the countryside and maintaining and preserving a type of production and distribution which may be regarded as traditional, especially in some rural areas.

We believe this practice does not affect the dynamics of the common market or compromise attainment of the common objective of food safety.

However, if this temporary derogation were made permanent, it would be desirable, precisely in order to avoid trade distortions, to provide a clear, harmonised definition of the "small quantities" referred to in Article 3 of Regulation (EC) No 2076/2005. We propose a limit of 10 000 head per year.

FR 15.02.2007

Article 1(3)(d)	Prolong the transitional measure permanently. Amend the body of the text to create a version drafted in the same way as in Article 3 of Regulation (EC) No 2076/2005 (deletion of "as fresh meat").
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SE 14.02.2007

Direct supply of small quantities of meat from poultry and lagomorphs - Article 1(3)(d)

We would like a permanent change in 853/2004 Article 1.3 d), cf. 2076/2005 Article 3.

Direct supply of small quantities of meat from ostriches.

We think this should be possible. The establishments are very small and the quantities of meat produced are very small. The hygienic risks are not higher than for poultry meat.

1(4)

LU 14.02.2007

In relation to paragraph 3 of Article 1 of 852, to *paragraph 4 of Article 1 of 853* and to paragraph 3 of Article 10 of 853 where Member States adopt national measures, it should be clarified whether those products can be placed on the national or the Community market.

1(5)(b)(i)

FR 15.02.2007

Article 1(5)(b)(i)	Amend this point by deleting "of storage or" and replacing it by: "... , unless: i) the operations consist only of transport , in which case the specific temperature requirements laid down in Annex III shall apply;" Approval will then become obligatory for all businesses, retail or otherwise, which are involved in storage. or delete this point. Approval will then become obligatory for all businesses, retail or otherwise, which are
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	<p>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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LU 08.03.2007

Les dispositions sur le stockage des denrées alimentaires dans les entrepôts à température contrôlée sont à reconsidérer, respectivement à préciser (**article 1, point 5 sous b)i**) du Règlement (CE) No 853/2004.

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.

1(5)(b)(ii)

LU 08.03.2007

Il y a de nettes différences d'interprétation entre les états membres concernant les notions d'activité marginale, localisée et retrainte. (**art.1, point 5 sous b) ii**) du Règlement.

3(2)

FI 26.01.2007

We would like it to be clarified that any substance and pasteurization with hot steam is forbidden to remove surface contamination from products of animal origin without the special permission granted through the comitology procedure.

FR 15.02.2007

Article 3(2)	<p>Prolong the transitional measure permanently.</p> <p>A derogation from the obligation to use only drinking water is provided for in Article 11 of Regulation (EC) No 2076/2005 for:</p> <ul style="list-style-type: none">- the chilling of fresh fishery products in establishments on land;- the handling of fishery products, irrespective of the type of establishment;- the cooling of cooked crustaceans and molluscs. <p>The French authorities would like this derogation to be prolonged, and would like clean seawater to be authorised again for all these activities. They have asked the AFSSA, the French food safety agency, to try to establish objective criteria for the definition of clean seawater (result expected in one month). The French authorities would like to know whether other MS have taken similar action with regard to this issue, which they consider to be crucial.</p>
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4(2)

FR 15.02.2007

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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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.

10(3)

LU 08.03.2007

In relation to paragraph 3 of Article 1 of 852, to paragraph 4 of Article 1 of 853 and to paragraph 3 of *Article 10 of 853* where Member States adopt national measures, it should be clarified whether those products can be placed on the national or the Community market.

ANNEX I

1.1

LV 13.02.2007 (See also 1.11)

5) The definition “meat” given in Annex I subparagraph 1.1. contains also blood and in the definition “offal” given in subparagraph 1.11. blood is also mentioned. In our opinion blood should be considered as offal therefore we suggest to delete the words “including blood” in the definition “meat”.

1.2

FR 15.02.2007

List other species under "bovine": bison, buffalo, yak and zebu.

1.3

FR 15.02.2007

List bird species which are considered to be domestic + harmonise the definition with the animal health texts (in particular for ratites);

- Provide for a decision listing the authorised poultry species and lagomorphs. The current definitions are too broad. Furthermore, anatomically speaking, rodents are not lagomorphs: for example, could rodents such as rats or gerbils be consumed? Or link with novel foods?

1.4

ES 28.07.2007

Clarification and delimitation of the definition of lagomorphs in Regulation (EC) No 853/2004

Annex I to Regulation (EC) No 853/2004, includes the definition:

'Lagomorphs' means rabbits, hares and rodents.

First: We have received questions on the possibility to breed in Spain, for later slaughtering and commercializing in all the European Union, rodents of the species *Cavia porcellus* (cuyes, cobayas, small rabbits of Indies or guinea pig). This species has a lot of acceptance in populations of South America, especially in Ecuador and Peru.

Second: Rodents' species included in lagomorph's definition should be delimited, otherwise any sort of rodents, like black rat (*Rattus rattus*) or grey rat (*Rattus norvegicus*). could be located in the community market.

ES 14.02.2007

Definition of lagomorphs (Annex I, 1.4.) Given the wide range of species covered by the term "rodents" which comes within the definition of lagomorphs, the species of rodents included in this definition should be limited. We propose that this term be limited to the species *Cavia porcellus* (*cuys*, *cobayas*, *conejillos de indias* or guinea pigs). This species is quite popular among South American peoples (principally in Ecuador and Peru), and we have received numerous enquiries about the possibility of breeding these animals, slaughtering them and placing them on the market for consumption in the EU.

NL 14.02.2007

Annex I, point 1.4: Definition of lagomorphs. Rodents do not belong to lagomorphs, but to rodentia. Beside rabbits and hares also pica's (hamsterlike animals) belong to lagomorphs. This definition should be changed.

SK 14.02.2007

Regulation (EC) No 853/2004, Annex I definitions, point 1.4.”: to delete “and rodents” or to name the rodents which can be eaten, e.g. nutrias, because it cause the disgust of the consumers.

FR 15.02.2007

Provide for a decision listing the authorised poultry species and lagomorphs. The current definitions are too broad. Furthermore, anatomically speaking, rodents are not lagomorphs: for example, could rodents such as rats or gerbils be consumed? Or link with novel foods?

1.5

IT 14.02.2007

We have the following comments on the problems of distinguishing between farmed and wild game meat throughout all the production and marketing stages.

Under the previous EU directives, it was possible to distinguish wild game meat from farmed game meat since the former bore a pentagonal health stamp and the latter an oval stamp.

With the entry into force of the hygiene regulations, this distinction has disappeared, since both types of game meat are to receive an oval health stamp or identification mark, as the case may be.

At present, this information should thus be supplied in transactions as commercial information only.

Our department has been informed that an Italian firm found itself obliged to seek information on whether the original game was farmed or wild by means of commercial agreements with suppliers in other Community countries, since such information was not provided for the first deliveries received under the new regulations, the goods being described in general terms as "game meat".

There should therefore be a binding requirement for identification of game meat always to be supplemented by an indication of how the product was originally obtained, as "farmed game meat" or "wild game meat".

FR 15.02.2007

Definition of wild game: include trapped game in addition to hunted game.

1.9

FR 15.02.2007

The current definition of a carcass as "the body of an animal after slaughter and dressing" should be amended to include poultry carcasses.

1.11

LV 13.02.2007

The definition “meat” given in Annex I subparagraph 1.1. contains also blood and in the definition “offal” given in subparagraph 1.11. blood is also mentioned. In our opinion blood should be considered as offal therefore we suggest to delete the words “including blood” in the definition “meat”;

1.14

NL 14.02.2007

Annex I, point 1.14: Definition of mechanically separated meat (MSM). There are different kinds of this type of product. It would better if this type of different kinds of MSM were mentioned in this definition and that this definitions were also mentioned in the Directive for labeling (Directive 2000/13/EC). The reason is that some kinds of MSM have the same appearance as minced meat, which causes problems in the enforcement by the government in relation to the labelling.

FI 02.04.2007

853/2004 Annex I, point 1.14:

The definition of mechanically separated meat, MSM, is complicated due to the requirement 'resulting in the loss or modification of the muscle fibre structure'. In practice most problems arise when the muscle fibre structure is compared to that of minced meat. Changing the definition to refer e.g. to the calcium content of the product would be helpful.

1.15

CZ 25.01.2007

1.15. "Meat preparations" means fresh meat, including meat that has been reduced to fragments **or minced meat** which has had foodstuffs, seasonings or additives added to it.

FI 25.01.2007 (See also point 7.1 – meat products)

We feel that the difference between definition of meat preparation and meat product is not clear enough. According to the definitions a product is not a meat preparation if the internal muscle fibre structure has been modified, and a product is not a meat product if the cut surface shows the characteristics of fresh meat. In some cases there is a gap between these definitions. The internal muscle fibre structure might be modified but still

the cut surface shows the characteristics of fresh meat. For example some cured or marinated meat preparations are these kinds of products. Also it is not always easy to determine if the internal muscle structure has been modified or not.

We propose that the definition of meat preparation would be changed so that it would not include the sentence "insufficient to modify the internal muscle fibre structure". In Finland, the old national legislation defined meat preparation as "products that has been prepared wholly or partially of fresh meat or minced meat, and that has not been processed by heating, cooking, drying or smoking or by any combination of these. Meat preparation has salt, seasonings, additives or foodstuffs added to it". This definition could be a base for a new EU definition.

In practice, the old national definition was much easier to apply than the EU definition, because there was no need to determine if the internal muscle fibre structure has been modified.

1.16

FR 15.02.2007

Slaughterhouse: definition unsuitable for birds. In addition to dressing, provision should be made for plucking, for example.

1.19 (?) 'rodents'

ES

Annex I to Regulations 853/2004, include the definition: 'Lagomorphs' means rabbits, hares and rodents.

[First: We have received questions on the possibility to breed in Spain, for later slaughtering and commercializing in all the European Union, rodents of the species *Cavia porcellus* (cuyes, cobayas, small rabbits of Indies or guinea pig). This species has a lot of acceptance in populations of South America, especially in Ecuador and Peru.]

Second: Rodents' species included in lagomorph's definition should be delimited, otherwise any sort of rodents, like black rat (*Rattus rattus*) or grey rat (*Rattus norvegicus*). could be located in the Community market

3.5

ES

Frozen fish. Currently, frozen fishery products cannot be included in the definition of “fresh fishery products” (Annex I, 3.5), since this definition covers only those fishery products “that have not undergone any treatment to ensure preservation other than chilling”; nor can they be defined as “processed fishery products” (Annex I, 7.4), since freezing is not included in the definition of “processing” [Reg. 852/ 2004, Article 2(1)m)].

We therefore consider that the current definition of “fresh fishery product” should be amended to read as follows:

“<Fresh fishery products>: unprocessed fishery products, whether whole or prepared, including products packaged vacuum or in a modified atmosphere, that have not undergone any treatment to ensure preservation other than chilling, freezing or quick-freezing.”

4.1

NL 14.02.2007

Annex I, point 4.1: Definition of raw milk. It is not clear that raw milk from species like dromedary’s can be seen as raw milk. This type of raw milk is marketed more and more. The definition should be clear and clarified in this point.

7.1 (See also 1.15)

FI 14.02.2007

We feel that the difference between definition of meat preparation and meat product is not clear enough.

7.2

BE 26.01.2007

Annex I Definitions: 4.1 'Raw milk' and 7.2. 'Dairy products'

2. Annex III of the guidance document to H2 lists activities where food of plant origin is assembled with food of animal origin (= composite products).

- assembly of food of plant origin with **processed** food of animal origin and placed on the market as such:
 - e.g. manufacturing of certain edible ices made from processed milk (heat treated milk, milk powder)
 - e.g. making bakery products

The manufacturing of these products should comply with H1.

- assembly of food of plant origin with **unprocessed** food of animal origin further processed together
 - ice cream from raw milk

The manufacturing of these products should comply with H2 (approval of establishments and application of identification mark).

This includes that all manufacturing of composite products with raw milk should comply with H2. e.g.: pancakes with raw milk, flan with raw milk, mix of fruit juice and raw milk ...

Proposal: Since the wording “dairy products” reflects the classical products such as consumption milk, butter, cheese, yoghurt, **the wording “dairy products” should be changed into “milk products” or “products with milk”**

3. The definition of raw milk in H2 sounds as follows:

“Raw milk means milk produced by the secretion of the mammary gland of farmed animals that has not been heated to more than 40 °C or undergone any treatment that has an equivalent effect.”

If the reasoning of point 1 is being applied, H2 does not apply to composite products made with milk treated at temperatures higher than 40 °C, since such milk is not considered any more as raw milk (cfr. definition), although not all microbiological dangers are eliminated in a temperature range of 40 °C to temperature of pasteurization.

Proposal: Since there are still some remarkable microbiological dangers linked with milk in a temperature range of 40 °C to temperature of pasteurization, the definition of raw milk should be changed.

“Raw milk means milk produced by the secretion of the mammary gland of farmed animals that has not been pasteurized or undergone any treatment that has an equivalent effect.”

8.3 (?) 'cold stores' (See also **5. COLD STORES**)

8.4 (?) 'wholesale'

EE 26.01.2007

Wholesale outlet

Paragraph 7 of Article 3 from Regulation (EC) 178/2002 defines “retail” as handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes inter alia “wholesale outlets”. Paragraph 3.5 of the guidance document on the implementation of the certain provisions of Regulation (EC) 853/2004 on hygiene of food of animal origin gives an additional explanation to this definition and mentions “wholesale operations”.

Wholesale

The term 'wholesale' has not been defined properly and has been therefore freely and not always equivalently interpreted.

The most direct explanation for 'wholesale' seems to be given in the paragraph 3.5 of the guidance document on the implementation of the certain provisions of Regulation (EC) 853/2004 as the “operations with the view to supplying food of animal origin to another establishment”. In Article 3 of Regulation (EC) 854/2004 certain provisions for approval of 'wholesale markets' are provided without explaining the term (see also paragraph 1 of the Chapter I in the Annex III for the inspection requirements for wholesale markets).

'Wholesale' should be defined in the Regulation or clarified in a guidance document.

8.5 (?) 'invertebrates'

ES 28.07.2006

Trading of invertebrates intended for human consumption.

The same as it happens with crocodile meat, we understand that the invertebrates have the same need of regulation, since nowadays a great variety of foodstuffs constituted by invertebrates or containing them like ingredient are being placed in the European Union market for example::

Liquors with worms (maguey’s worm of Mexico),

Lollipops with ants, worms or crickets

Snacks toasted or seasoned: Colombia’s big bottom ants, Chapulin or Mexico's grasshopper, Escamoles or Mexico's egg of ants, crickets, scorpions, chrysalides, etc.

In due time, Spain transferred a question to the Commission on this subject and its possible inclusion in the ambit of application of Regulations (CE) n 258/97, of the Parliament and of the Council, relative to new foodstuff and food additives.

This subject was studied and discussed in the meeting of the Working Group on New Foodstuff the December 10, 2004. The general commentary from the Commission and from the delegations of the States members was that, this category of products does not go into the ambit of application of Regulations (CE) n 258/97 above-mentioned. Besides, no delegation did express declaration that they commercialize this type of products within its territory neither an answer was given about the possible legal normative that should regulate them.

In Spain, as at the present, this trade is not allowed. However, we are receiving petitions of authorization supported in that such products whit invertebrates are commercialized in other States members.

We request throughout the above that this matter will be examined in the working group of hygiene, to harmonize the commercialization of these products.

ES 14.02.2007

3. Invertebrates. We consider that rules need to be laid down in respect of invertebrates for human consumption, since at present a wide variety of food products made from or containing invertebrates as an ingredient are being marketed in the European Union. We therefore propose that a definition of “invertebrates” be included in Annex I of Regulation 853/2004, and that rules governing these be laid down in the subsequent annexes, in order to harmonise the marketing of these products.

REGULATION (EC) No 854/2004

ARTICLES

4(4)

NL 14.02.2007

Article 4, point 4: this Article says that audits have to be done on procedures in relation to the points of a) till I). These points are related to the basic conditions of establishments (Annex II of Regulation 852/2004) and can be verified with an inspection and not by an audit. This should be changed in this Article.

5(2)

NL 14.02.2007

Article 5.2 and 5.3.e: Health mark. It is not described how carcasses/organs have to be marked when they are declared unfit for human consumption. This should be mentioned also in this Article.

5(3)(e)

NL 14.02.2007

Article 5.2 and 5.3.e: Health mark. It is not described how carcasses/organs have to be marked when they are declared unfit for human consumption. This should be mentioned also in this Article.

5(5)(b)

FR 15.02.2007

Article 5(5)(b)	<p><u>Replace</u> "A risk-based approach shall be followed to assess the number of official staff that need to be present on the slaughter line in any given slaughterhouse. The number of official staff involved shall be decided by the competent authority and shall be such that all the requirements of this Regulation can be met."</p> <p>with "A risk-based approach shall be followed to assess the number of official staff that need to be present on the slaughter line in any given slaughterhouse. The number of official staff involved shall be decided by the competent authority and shall be such that a high level of consumer protection is ensured".</p> <p>Justification: This change would make it possible to adapt the requirement for an official veterinarian to be present in the slaughterhouse according to the risk level. Knowledge of this risk level is linked in particular to the inspection record of the establishment and the slaughter volume. This wording gives flexibility which we consider as equivalent to that proposed in the wording of the amendments to Regulation (EC) No 2074/2006 on visual inspection.</p>
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5(6)

FI 26.01.2007

The status of the slaughterhouse staff in official controls is a complicated question but it is necessary to improve their role at least with some conditions also in other slaughter procedures than those of poultry and lagomorphs. There should be emphasis on the availability of official control personnel and costs of the employee especially in small slaughterhouses in remote areas. In general, we are of the opinion that the resources of official control staff should be targeted to auditing and documentary checks (e.g. food chain information) and physical inspection of carcasses with non-conformities.

FI 02.04.2007

854/2004 Article 5(6) and Annex I, section III, chapter III, A:

The requirements for training of official auxiliaries in poultry slaughterhouses are too demanding compared to the extent of their tasks in poultry meat inspection. We hope that the derogation in the regulation 2076/2005 Article 14 could be made permanent.

5(6)(a)

FI 14.02.2007

Reindeer meat

Regulation (EC) No 854/2004

According to **Article 5 (6a)** Member States may allow slaughterhouse staff to assist with official controls by carrying out specific tasks, under the supervision of the official veterinarian, in relation to the production of meat from poultry and lagomorphs. Finland wishes to extend this possibility also to reindeer in addition to poultry and lagomorphs. Reindeer (*Rangifer tarandus tarandus*) belong to the group farmed game in the food hygiene legislation, although they are semi-wild and live freely in the nature like wild game. Reindeer exist only in two Member States of the European Union; Finland and Sweden. Our intention would be to allow the possibility of the inspection of the intestines of reindeer performed by the slaughterhouse staff, and during that inspection of intestines the official veterinarian need not be present at all times, if the slaughterhouse staff would put aside the intestines with abnormalities. In wild game the post mortem inspection does

not usually include the inspection of intestines, and the hygienic risks related to this could be considered equal to reindeer.

Therefore we suggest the inclusion of reindeer in Article 5 (6a) and Annex I, Section III, Chapter III, point A of Regulation 854/2004.

FR 15.02.2007 – up-dated 06.04.2007

<p>Article 5(6)(a)</p>	<p>Replace "A. If they do so, they shall ensure that staff carrying out such tasks: i) are qualified and undergo training in accordance with those provisions; ii) act independently from production staff, and iii) report any deficiency to the official veterinarian." <u>with</u> "A. If they do so, they shall ensure that staff carrying out such tasks: i) are qualified and undergo appropriate training; ii) are placed under the control of the competent authority when executing these tasks; and iii) report any deficiency to the competent authority." Justification: The training provided for official auxiliaries in France by far exceeds the skills required for slaughterhouse staff to participate in the official control of poultry. A comparable level of training should therefore not be required (link with Annex I, Section III, Chapter III), but rather appropriate training. The proposed wording provides a clearer explanation of the concept of independent work carried out by production staff.</p>
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<p>Article 5(6)(a)</p>	<p>Replace "A. If they do so, they shall ensure that staff carrying out such tasks: i) are qualified and undergo training in accordance with those provisions; ii) act independently from production staff, and iii) report any deficiency to the official veterinarian." <u>with</u> "A. If they do so, they shall ensure that staff carrying out such tasks: i) are qualified and undergo appropriate training; ii) are placed under the control of the competent authority when executing these tasks; and iii) report any deficiency to the competent authority." Justification: The training provided for official auxiliaries in France by far exceeds the skills required for slaughterhouse staff to participate in the official control of poultry. A comparable level of training should therefore not be required (link with Annex I, Section III, Chapter III), but rather appropriate training. The proposed wording provides a clearer explanation of the concept of independent work carried out by production staff.</p>
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<p>article 5, point 6 a)</p>	<p>Replace</p> <p>a) Member States may allow slaughterhouse staff to assist with official controls by carrying out certain specific tasks, under the supervision of the official veterinarian, in relation to the production of meat from poultry and lagomorphs in accordance with Annex I, Section III, Chapter III, part A. If they do so, they shall ensure that staff carrying out such tasks:</p> <ul style="list-style-type: none"> (i) are qualified and undergo training in accordance with those provisions; (ii) act independently from production staff; <p>and</p> <ul style="list-style-type: none"> (iii) report any deficiency to the official veterinarian. <p>By</p> <p>a) Member States may allow slaughterhouse staff to assist with official controls by carrying out certain specific tasks, under the supervision of the official veterinarian, in relation to the production of meat from poultry and lagomorphs in accordance with Annex I, Section III, Chapter III, part A. If they do so, they shall ensure that staff carrying out such tasks::</p> <ul style="list-style-type: none"> i) are qualified and undergo appropriate training; ii) are placed under the control of the competent authority when executing these tasks; and iii) report any deficiency to the competent authority." <p>Justification: From i to iii The training provided for official auxiliaries in France by far exceeds the skills required for slaughterhouse staff to participate in the official control of poultry. A comparable level of training should therefore not be required (link with Annex I, Section III, Chapter III), but rather appropriate training. The proposed wording provides a clearer explanation of the concept of independent work carried out by production staff.</p> <p>Moreover, France also wishes new discussions on the possible extension of the participation of slaughterhouse staff with official controls in relation to the production of meat from other species than poultry and lagomorphs, particularly pigs and calves.</p>