



Brussels, 18 May 2007
FVE/07/corr/037

Advisory Group on the food chain, animal health and plant health
Directorate General SANCO
European Commission
B-1049 Brussels

Subject: FVE answers to questionnaire for stakeholders with regard to the "Food Hygiene Package"

Regulation (EC) No 852/2004

1. Article 5 (HACCP)

Q: What is your experience of the application of HACCP in particular with regard to
- small businesses?

A: HACCP is not always necessary, often not suitable and can be disproportional complicated for small businesses. For many of these businesses prerequisites are sufficient, sometimes in combination with different kinds of guidelines, e.g. guides for good practice.

- the assessment by the competent authorities?

A: Experience from our members shows, that there is a tendency to demand too much unnecessary documentation, and therefore the process becomes more complex.

Q: Is it desirable and practicable to extend HACCP requirements to primary production?

A: FVE sees a problem in an extension of the requirements of Article 5 (EC) 852/2004 (Hazard Analysis and Critical Control Points [HACCP] principles) to food business operators carrying out primary production. Due to limited resources and abilities in many primary production facilities it is not clear how HACCP could be implemented effectively in such places. Therefore we would recommend using guidelines for food safety in primary productions. The basic principles of HACCP could be applied for these guidelines.

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2. Article 6 (registration and approval of food businesses)

Q: What is your experience of registration with regard to up-date information to be supplied to the competent authority and notification of significant change in activities?

A: *Businesses are not always aware of their duty to inform. However, improvement is to be expected in the future when they get used to the new system.*

Q: What is your experience of approval with regard to establishments that have to be approved?

A: *The approval process is seen as a very useful procedure, but being approved does not in anyway assure that forward production and operation will be satisfactory. The approval process, despite best efforts, results in a single structural assessment. Ideally this process should be annual and should be linked to the Competent Authority's findings throughout the course of the preceding year.*

3. Article 8 (National guides to good practice)

Q: Has your food business sector developed national guides to good practice?

A: *It depends on the Member State:*

- ***Sweden:*** *several sectors have developed such guides. These guides are also published on the website of the central Competent Authority (CA).*

- ***UK:*** *the CA has developed guides to good practice on behalf and with involvement of the industry. If the CA had not taken the lead then the industry would not have prepared such guides. Confusion does still exist as to the usefulness and application of such guides versus legislative practice: industry still rely on the CA for supervision and the CA still uses a non-risk based approach to enforcement and supervision.*

- ***The Netherlands:*** *several national guides were developed*

Q: Have member states encouraged the development of such guides for (i) hygiene and (ii) for the application of the HACCP principles?

A: *Yes to both*

Q: Do you intend to develop EU guides to good practice?

A: *Not applicable*

4. Article 9 (community guides)

Q: Discussions have commenced on developing Community guides, based on food business sector submissions, in the sectors on wholesale markets and cold stores, and will shortly commence on egg products.

Has your food business sector a draft pan-European guide that you consider may be submitted as a potential Community guide?

A: *Not applicable*

5. Annex I (Primary production)

Q: What is your experience with regard to the application of Annex I?

A: UK: Annex I has made little impact; those businesses that had good systems prior to 1/1/2006 continue to have good systems and those that didn't remain poor. The application of food chain information is limited adding little value to the food production process at this stage of implementation.

Regulation (EC) No 853/2004

6. Article 1(5)(c) (Scope – national measures)

Q: What is your experience of national measures adopted in relation to marginal, localised and restricted activities?

A: This expression must be defined at European level. At present there is a lot of confusion and it is not implemented in real life because of the confusion over what it really means. National measures have been used as a means of removing as much as possible from the auspices of the Regulations. The terms marginal, localised and restricted have been defined using definitions that are so wide they undermine the spirit of the law. As a concept they are potentially useful in protecting niche operations – their use thus far is limited and unless the EU were to set clear definitions they will continue to be used out with the original intentions of the law.

7. Annex I (Definitions)

Q: Have you comments on any of the definitions?

A: No

8. Annexes II (Requirements concerning several products of animal origin) and III (Specific requirements)

Q: Have you comments on technical requirements for meat, fishery products, dairy products, etc?

Have you particular comments regarding any of the following:

- Food chain information

A: No special comments.

- Minced meat

A: No special comments

- MSM

A: No special comments

Regulation (EC) No 854/2004

9. Article 4 (General principles for official controls in respect of all products of animal origin falling within the scope of the Regulation)

Q: What is your experience with regard to:

- (i) Provision of assistance to ensure official controls can be performed effectively?

- (ii) Making documentation and records available?

A: There seems to be little change from the requirements under the previous legislation. FBOs have not changed their attitude, nor their approach, in relation to their responsibilities and assistance. Those FBOs who were co-operative previously remain so; those that weren't have not changed accordingly.

10. Annex I, Section III, Chapter III (Involvement of slaughterhouse staff)

Q: What is your experience regarding involvement of slaughterhouse staff?

A: The use of trained plant-based staff continues to be popular amongst the better operators and works extremely well. The continued presence of the OV ensures that control is maintained. The system is not being used differently from under previous legislative requirements and the same numbers of FBOs continue to use the facility.

11. Have you any other remark/observation on the hygiene package?

1.: Concerning post mortem inspection (854/2004), there is a need to define discontinuous slaughter. FVE is not content with the definition of "discontinuous slaughtering" as discussed in SANCO/2696/2006 (amending Commission Regulation (EC) No 2074/2005), and the Annex VIb does not meet the intention of Regulation (EC) 854/2004 for visual inspections. We consider that "discontinuous slaughter" does not fulfil the intention of the derogation regarding "small, local and remote" areas and that the proposed risk analysis does not provide sufficient reassurance that standards will be maintained in all cases where it is proposed that the official veterinarian does not need to be present at all times during slaughter activities.

2.: The hygiene package as a legislative tool is excellent and makes provision for a number of matters that can only be considered ideal viz. FBO responsibility, food chain information and risk based approach to enforcement. However, CA application remains focussed on zero-tolerance, precautionary principles and difficulty with a risk based approach to enforcement; furthermore, FBO mind-set has changed little and more effort is required to assist FBOs to take-over responsibility for production of a safe food product. Unfortunately, the FVO has not assisted the implementation of the Hygiene Package as they do not reflect a risk based approach and have not taken on the full-impact of modern legislative requirements.

3. Regulation (EC) 854/2004 Annex I, Section II, Chapter I para 4 and Chapter V (e) both mention the OIE List A and B. The OIE established a new list in 2004 and List A and B don't exist anymore since the beginning of 2005. The section needs to be adjusted according to the new OIE list, in order to prevent that meat has falsely to be declared unfit for human consumption.

4. Regulation (EC) 853/2004 Annex II, Section III para 3 lays down the details of the Food Chain Information (FCI) to be provided by the Food Business Operator. 3(h): the name and address of the private veterinarian **normally attending** the holding of provenance

In Regulation (EC) 854/2004 Annex I, Section II para 2 (b) it is laid down that: When the problem arose during primary production, the official veterinarian is to inform the **veterinarian attending** the holding of provenance.....

Regarding this two Regulations, FVE is of the opinion that

- a) the terms "**normally attending**" or "**attending**" should be defined, in order to make sure that the veterinarian who is examining, diagnosing and treating the food producing animals on a regular basis is the veterinarian whose name is laid down in the FCI, and that this is also the person that has to be contacted by the OV in the above mentioned case (854/2004). There is a need for regular veterinary supervision of food producing animals in order to assure consumer safety on a high level. One way to prove the accuracy of the data would be to make it mandatory for the FBO to develop the herd health plan together with the private veterinarian who then should have to sign the document.
- b) the official veterinarian should need to verify, that the name of the veterinarian laid down in the FCI is the name of the veterinarian who is regularly visiting the farm and treating the animals.

We thank you for your time and consideration and ask you not to hesitate to contact us in case further information would be required. We will be happy to answer your questions.

Yours sincerely,

Jan Vaarten
Executive Director

<p>FVE is the umbrella body for veterinary organizations from 37 European countries, including all EU and EFTA countries and most of the Eastern and Central European countries. FVE represents approximately 200.000 veterinarians throughout Europe.</p>
