



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR AGRICULTURE AND RURAL DEVELOPMENT

WORKING DOCUMENT

GUIDANCE DOCUMENT OF THE COMMISSION SERVICES

on the hygiene provisions relevant for cross compliance

MANAGEMENT COMMITTEE FOR DIRECT PAYMENTS

This document gives the Commission services' view on the hygiene provisions relevant for cross compliance. It is intended for purposes of general guidance only and is not legally binding. It can in no way replace regulatory provisions, nor prejudice any ruling by the Court of Justice, which alone is competent to hand down legally binding rulings on the validity and interpretation of acts adopted by the Community institutions. Furthermore, it is emphasised that Member States have a responsibility to properly apply Community legislation.

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1. Introduction

Since the last quarter 2005, a number of Member States have raised questions about the application of the food law and so called “hygiene package” Regulations relevant for farmers in the context of cross compliance. The purpose of this document is to facilitate the implementation of cross-compliance as regards the requirements of the Food law which are listed in Annex III to Regulation (EC) n° 1782/2003¹. This document does not cover the other requirements mentioned in Annex III.

In fact at the level of the farm, compliance with the abovementioned provisions of the food law can only be ensured if, among others, the relevant hygiene requirements are fully respected. Therefore, cases of non-compliance with the requirements and obligations related to hygiene listed below should be considered as relevant for the application of cross-compliance penalties.

The list is limited to the requirements set out in Regulations (EC) No 852/2004, No 853/2004, and No 183/2005 insofar as they are relevant for the exercise of agricultural activities as defined in Article 2 (c) of Regulation (EC) No 1782/2003.

The document at hand is without prejudice to all other provisions of Food law which are applicable to farmers even though their violation does not result in the application of a cross-compliance penalty, and to the sanctions applied by the Member States to ensure correct enforcement of those provisions.

2. Cross compliance

Regulation (EC) No 1782/2003 establishes the concept of cross compliance. In its Annex III a list of statutory management requirements subject to cross compliance is given. Among them, Article 17 of Regulation (EC) No 178/2002 requires all food and feed business operators (including farmers) within the businesses under their control, to ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and to verify that such requirements are met.

As hygiene requirements form part of Food Law requirements, farmers who are found to infringe those requirements should be subject to reduction of direct aids in accordance with the principles of cross compliance.

3. The hygiene regulations

Regulation (EC) No 852/2004 on food hygiene,

Regulation (EC) No 853/2004 of hygiene of food of animal origin

¹ Articles 14, 15, 17(1), 18, 19, 20 of Regulation (EC) No 178/2002

Regulation (EC) No 183/2005 on feed hygiene,

address specific responsibilities of food/feed business operators along the food chain and have specific provisions addressing obligations at primary production level which are relevant for farmers.

Applying the flexibility that is embedded in the food hygiene Regulations, certain Member States may have adopted national measures to adapt the requirements in the Annexes of these Regulations² in order to enable the continued use of traditional production methods, to accommodate the needs of food businesses in regions to are subject to special geographical constraints, or in other cases with regard to the construction and layout of establishments. Where such adaptations have taken place, these should be taken into account in the context of cross compliance assessments.

4. Cross compliance and hygiene regulations applicable to primary production

In January 2006, several Member States have requested explanations on the hygiene obligations relevant for cross compliance.

In February 2006, the Commission made a statement in the Council where it was explained that the hygiene rules relevant for cross compliance are limited to those addressed to primary production and, that a guidance document on this subject will be presented in management committee for direct payments in March.

This guidance document deals with the minimum hygiene obligations that the farmers should respect in order to avoid triggering the reductions established by the cross compliance system as regards the hygiene Regulations.

The criteria for the selection of these obligations are:

- The obligations clearly target the farmer.
- The obligations are formulated in a clear and unequivocal way.

In no case should the above mentioned obligations established for cross compliance affect the obligations stipulated by food law.

5. Type of obligations

In certain cases, obligations stipulated in the hygiene regulations for primary production are formulated in a general way³. Given the specific characteristics of cross compliance, it can be difficult to measure them during on-the-spot checks on an objective basis and ensure their uniform application with due respect to the principle of proportionality. Therefore, such obligations should not trigger cross compliance penalties.

² See Article 13 of Regulation (EC) No 852/2004 and Article 10 of Regulation (EC) No 853/2004.

³ for example to “*protect primary products from contamination as far as possible*” or “*to comply with appropriate Community and national legislation to control hazards.*”

On the other hand, a large number of provisions are established in a clear way and may be subject to objective checks during on-the-spot controls⁴. Among this type of obligations are included those provisions related to temperature, storage and handling of hazardous substances and keeping records.

The annex to this guidance document lists the hygiene obligations which are relevant to cross compliance for the farmer. This list is based on the provisions applicable in respect of 2006. The list will be reviewed and up-dated in line with legislation.

⁴ However, farmers should be made aware that such control system includes the principle of “bottle neck” which means the possibility to conduct the checks at the most appropriate level such as testing at slaughterhouse or dairy plant level as well as making use for assessment when possible of existing quality assurance schemes. Nevertheless, the quality assurance schemes can not replace the cross compliance control system established by the competent authorities.

ANNEX

List of hygiene obligations which are relevant to cross compliance for the farmer

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004).
Extract from Article 4 (1) in connection with part A of Annex I as further specified below
<p>II. Hygiene provisions</p> <p>4. Food business operators rearing, harvesting animals or producing primary products of animal origin are to take adequate measures, as appropriate:</p> <ul style="list-style-type: none"> (g) to store and handle waste and hazardous substances so as to prevent contamination; (h) to prevent the introduction and spread of contagious diseases transmissible to humans through food, including by taking precautionary measures when introducing new animals and reporting suspected outbreaks of such diseases to the competent authority; (j) to use feed additives and veterinary medicinal products correctly, as required by the relevant legislation.
<p>5. Food business operators producing or harvesting plant products are to take adequate measures, as appropriate:</p> <ul style="list-style-type: none"> (f) to store and handle wastes and hazardous substances so as to prevent contamination; (h) to use plant protection products and biocides correctly, as required by the relevant legislation.
<p>6. Food business operators are to take appropriate remedial action when informed of problems identified during official controls.</p>
<p>III. Record-keeping</p> <p>8. Food business operators rearing animals or producing primary products of animal origin are, in particular, to keep records on:</p> <ul style="list-style-type: none"> (a) the nature and origin of feed fed to the animals⁵; (b) veterinary medicinal products or other treatments administered to the animals, dates of administration and withdrawal periods; (d) the results of any analyses carried out on samples taken from animals or other samples taken for diagnostic purposes, that have importance for human health; (e) any relevant reports on checks carried out on animals or products of animal origin. <p>9. Food business operators producing or harvesting plant products are, in particular, to keep records on:</p> <ul style="list-style-type: none"> (a) any use of plant protection products and biocides; (c) the results of any relevant analyses carried out on samples taken from plants or other samples that have importance to human health.

⁵ The Commission services' view is that farmers shall record the nature of the production on their farm and the total farm area where such feed is produced without having to make reference to the quantities or to the relevant parcel identification. Feed quantities arriving at or leaving the farm shall be recorded separately.

European Parliament and Council Regulation (EC) No 853/2004 of 29 April 2004 laying down specific hygiene rules for food of animal origin

Extracts from Article 3 (1) in connection with Annex III as further specified below:

Annex III Section IX: CHAPTER I: RAW MILK -

I. HEALTH REQUIREMENTS FOR RAW MILK PRODUCTION

1. Raw milk must come from animals:

(b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;

(c) that do not have any udder wound likely to affect the milk;

(d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC;

and

(e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.

2. (a) In particular, as regards brucellosis, raw milk must come from: ” (i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC(2), is free or officially free of brucellosis;

(ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC(3);

or

(iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.

(b) As regards tuberculosis, raw milk must come from:

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis;

or

(ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.

(c) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.

3. However, raw milk from animals that do not meet the requirements of point 2 may be used with the authorisation of the competent authority:

(a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the phosphatase test;

(b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, either:

(i) for the manufacture of cheese with a maturation period of at least two months;

or

(ii) after having undergone heat treatment such as to show a negative reaction to the phosphatase test;

and

(c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in point 2(a)(iii) or 2(b)(ii), if treated to ensure its safety.

4. Raw milk from any animal not complying with the requirements of points 1 to 3 - in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC - must not be used for human consumption.

5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk.

II. HYGIENE ON MILK PRODUCTION HOLDINGS

A. Requirements for premises and equipment

1. Milking equipment, and premises where milk is stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk.

2. Premises for the storage of milk must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.

3. Surfaces of equipment that are intended to come into contact with milk (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.

4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of raw milk must be cleaned and disinfected in an appropriate manner before re-use.

B. Hygiene during milking, collection and transport

1. Milking must be carried out hygienically, ensuring in particular:

- (a) that, before milking starts, the teats, udder and adjacent parts are clean;
- (d) the identification of animals undergoing medical treatment likely to transfer residues to the milk, and that milk obtained from such animals before the end of the prescribed withdrawal period is not used for human consumption;

2. Immediately after milking, milk must be held in a clean place designed and equipped to avoid contamination. It must be cooled immediately to not more than 8 °C in the case of daily collection, or not more than 6 °C if collection is not daily.

...

4. Food business operators need not comply with the temperature requirements laid down in points 2 ~~and 3~~ if the milk meets the criteria provided for in Part III and either:

- (a) the milk is processed within two hours of milking;
- or
- (b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.

ANNEX III SECTION X: EGGS AND EGG PRODUCTS

CHAPTER I: EGGS

1. At the producer's premises, ~~and until sale to the consumer,~~ eggs must be kept clean, dry, free of extraneous odour, effectively protected from shocks and out of direct sunshine.

European Parliament and Council Regulation (EC) No 183/2005 of 12 January 2005 laying down requirements for feed Hygiene

Extract from Article 5 (1) in connection with annex I as further specified below

ANNEX I PRIMARY PRODUCTION - PART A

I. Hygiene provisions

4. Where appropriate, feed business operators shall take adequate measures, in particular:

- (e) to store and handle wastes and hazardous substances, separately and securely, so as to prevent hazardous contamination;
- (g) to take account of the results of any relevant analyses carried out on samples taken from primary products or other samples relevant to feed safety.

II. Record-keeping

2. Feed business operators must, in particular, keep records on:

- (a) any use of plant protection products and biocides
- (b) use of genetically modified seeds;
- (e) the source and quantity of each input of feed and the destination and quantity for each output of feed.

Article 5 (5) in connection with annex III as further specified below

ANNEX III GOOD ANIMAL FEEDING PRACTICE – FEEDING

1. Storage

Feed shall be stored separately from chemicals and other products prohibited for animal feed.

Medicated feed and non-medicated feed intended for different categories or species of animals shall be stored such as to reduce the risk of feeding to non-target animals.

2. Distribution

Non-medicated feeds shall be handled separately from medicated feeds to prevent contamination

Article 5(6)

Feed business operators and farmers shall only source and use feed from establishments which are registered and/or approved in accordance with Regulation (EC) No 183/2005