



EUROPEAN COMMISSION  
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: production and distribution chain

Brussels,  
ACR D(2005)

**Subject: Harmonisation of microbiological criteria – Maintenance of national criteria**

Your Excellency,

The services of the Commission presented the interpretation of Article 17.3 of Regulation (EC) No 852/2004 and of the level of harmonisation of microbiological criteria during the working group meeting of 11 November.

The question is whether harmonisation in the area under consideration is total, or whether the Member States still have a residual competence based on subsidiarity, and therefore to what extent the Member States would remain free to adopt microbiological criteria in the areas covered historically by Directive 93/43 on the hygiene of foodstuffs and as from 1 January 2006 by Regulation (EEC) No 852/2004 on the same subject.

Before 31/12/2005:

1. Directive 93/43 (Article 4) stipulates that the microbiological criteria applicable to the hygiene of foodstuffs may be adopted by the comitology procedure after consulting the Scientific Committee. It also lays down (Article 7.1 and 7.2) that the national criteria adopted prior to its application (1 January 1996) and not replaced by a Community criterion may remain applicable provided that **they do not constitute a restriction, hindrance or barrier to trade in foodstuffs** that comply with the Community rules of hygiene. Article 7.3 sets out the procedure to be followed when new national criteria are deemed necessary by adoption of new legislation or amendment of existing legislation: in such cases, the Member State must submit a reasoned notification of its intention to the Commission and the other Member States, and it may formally adopt the new criteria only three months after such communication and provided that it has not received an opinion to the contrary from the Commission in the meantime. In the event of an objection, it is stipulated either that an appropriate Community criterion be adopted on a proposal from the Commission or that the national measures proposed by the Member State shall remain inapplicable (Article 7.3, last indent).

After 01/01/2006:

2. Under Regulation 852/2004, it is also stipulated that the Community microbiological criteria shall be adopted in accordance with the comitology procedure (Article 4.4). Article 17.3 provides also that transitionally, “pending the setting of the (Community) criteria... Member States may maintain any national rules establishing such criteria ... that they had adopted in accordance with Directive 93/43/EEC”<sup>1</sup>. However, it should be stressed above all that Article 4 of the Regulation provides in substance that “food business operators ... (shall comply with) the microbiological criteria ... adopted in accordance with the (comitology) procedure”. It can be deduced from this that the other criteria which do not fulfil this condition will cease to be enforceable against operators and that the wish for total harmonisation is thus clearly expressed by the legislator, subject only to the transitional provision laid down by Article 17.3.

3. Consequently, on first analysis, the only national criteria that are currently enforceable against operators and could, in accordance with this transitional provision, remain applicable from 1 January 2006 until they are replaced by a Community criterion would be the criteria adopted by the Member States before 1 January 1996 and which do not constitute a restriction, hindrance or barrier to trade in foodstuffs that comply with the Community rules of hygiene, and the criteria effectively and formally adopted or amended by the Member States after 1 January 1996 in accordance with the reasoned notification procedure established by Article 7.3 of Directive 93/43, when this procedure has not given rise either to objections or to the adoption of a Community criterion.

4. Under the new arrangements instituted by Regulation 852/2004, there is therefore **no provision for the Member States to be able to continue, beyond 31 December 2005, to adopt microbiological criteria applicable to the hygiene of foodstuffs** that are enforceable against food business operators. This conclusion is all the more logical because for other types of rules<sup>2</sup> this Regulation lays down explicitly the conditions under which variations or derogations from the Community standards may be stipulated by such national rules.

Emergency situation:

5. However, in case of emergency, or if official control analysis reveals that a foodstuff is likely to constitute a serious risk to human health, the procedure set down in Article 54 of Regulation 178/2002 applies and national measures could be adopted on an interim basis. Such measures are unlikely to be in the form of standing criteria. The Commission and the Member States shall be immediately informed of these measures, the future of which the SCOFCAH shall decide.

To summarize:

6. Article 17.3 of Regulation (EC) No 852/2004 provides that national microbiological criteria adopted according to the procedure laid down in Directive 93/43/EEC on the

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<sup>1</sup> The first sentence of Article 17.3 concerns measures other than the microbiological criteria (derogations from the rules of hygiene referred to in Article 3.3 and safeguard measures under Article 10 of Directive 93/43).

<sup>2</sup> National rules governing supply to local establishments as referred to in Article 1.3; derogations from Annexes I and II for the application of HACCP procedures in small businesses under Article 13.2; adaptation of the provisions of Annex II by national measures in accordance with Article 13.3 to 7.

hygiene of foodstuffs and which do not constitute a barrier to trade may be maintained after 1 January 2006. For that purpose, a table is attached, which deals with the necessary information to provide the Commission with in order to maintain national criteria. Other national criteria will cease to be applicable to operators as of 1 January 2006.

Yours faithfully,

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Annex: Table of information the Commission needs

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