Guidance document agreed between the Commission services and the competent authorities of Member States for the Directive on Biocidal Products 98/8/EC

BORDERLINE BETWEEN DIRECTIVE 98/8/EC CONCERNING THE PLACING ON THE MARKET OF BIOCIDAL PRODUCTS AND DIRECTIVE 92/46/EEC CONCERNING RAW MILK, HEATED MILK, AND MILK PRODUCTS

Introduction

The determination of a clear borderline between the Biocidal Products Directive 98/8/EC[1] (BPD), and a number of other Directives mentioned in Article 1 (2) of Directive 98/8/EC is crucial for the proper implementation of the Biocidal Products Directive.

In the framework of the borderline discussion between the Biocidal Products Directive and the Directive 2001/83/EC on medicinal products for human use[2] (which has replaced Directive 65/65/EEC[3]) and Directive 2001/82/EC on veterinary medicinal products[4] (which has replaced Directive 81/851/EEC[5]) disinfectants applied on human and animal skin have been identified as products necessitating particular attention. Among these teat dips and udder cleaning products have been singled out as they are not necessarily veterinary medicinal products (in particular in the absence of a therapeutic claim), but could still be exempted from the provisions of Directive 98/8/EC, as Article 1 (2) excludes products covered by Directive 92/46/EEC laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products.

This document attempts to provide guidance to Member States on borderline cases between these two Directives. It will be submitted to the meetings of competent authorities of the Directives involved for endorsement.

It has been conceived as an opinion of the Commission Services involved, but it does not oblige Member States to adopt the same attitude and it is not legally binding since only the Court of Justice can give an authoritative interpretation of existing Community law.

A proposal for amendments to the BPD (notably to the description of Product types in Annex V) is under discussion to introduce in the legal text the agreed adjustments on scope.

General principles

Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based

[1] OJ L 123, 24.4.98. p. 1

[2] OJ L 311, 28.11.2001, p. 67.

[3] OJ 22, 9.2.1965, p. 369 as last amended by Directive 2000/38/EC, OJ L 139, 10.6.2000, p. 28.

[4] OJ L 311, 28.11.2001, p. 1.

[5] OJ L 317, 6.11.1981, p. 1 as last amended by Directive 2000/37/EC, OJ L 139, 10.6.2000, p. 25.

products is contained in Article 1(2) of Directive 98/8/EC. Article 1(2) excludes from the scope of Directive 98/8/EC products that are defined in or within the scope of the listed instruments for the purposes of those instruments.

In the view of the Commission services "Products within the scope of the Directives listed in Art 1(2) are excluded from Directive 98/8/EC irrespective as to whether or not the relevant Directive provides for an authorisation scheme or an evaluation of risks. Products covered by a Directive listed in Art. 1(2) can only be authorised according to the rules of this Directive[6]". Directive 92/46/EEC is mentioned in Article 1(2) of the BPD. Therefore products within the scope of the milk Directive should be excluded from the BPD.

Annex B, Chapter II of Directive 92/46 lays down the "*General conditions of hygiene in treatment establishments and processing establishments*."

Point A.5 states: "*Disinfectants and similar substances must be approved by the competent authority and used in such a way that they do not have adverse effects on the machinery, equipment, raw materials and products covered by this Directive. Their containers must be clearly identifiable and must bear labels with instructions for their use. Their use must be followed by thorough rinsing of such instruments and working equipment with potable water."*

Since these disinfectants are within the scope of Directive 92/46/EEC for the purpose of this Directive, they are outside of the scope of the BPD.

Furthermore, according to Art. 13 of the Directive, production holdings (i.e. farms, where milk is produced) shall undergo regular checks to ensure that hygiene requirements are being complied with. Article 29 of the Directive establishes that Commission Directive 89/362/EEC of 26 May 1989 on general conditions of hygiene in milk production holdings[7] shall continue to apply for the purposes of Directive 92/46/EEC.

In Directive 89/362/EEC the text relevant to this issue is the following:

"ANNEX: GENERAL CODE OF HYGIENE TO BE COMPLIED WITH IN PRODUCTION HOLDINGS

CHAPTER III

General hygiene conditions relating to milking operations

5. Teat dips or sprays for lactating cows must only be used immediately after milking unless otherwise authorized by the official authorities. Components in teat dips or sprays must be acceptable to the official authorities."

Point 5 thus states that any "teat dips or sprays for lactating cow" products should be used only after the milking operation unless otherwise authorized by the authorities. An authorization is not explicitly required, but the components of these products must be acceptable to the official authorities.

These disinfecting products are therefore within the scope of Directive 92/46/EEC and they are excluded from the BPD.

---

6 Doc.Biocides/50/99, 9 November 1999, p.1, 3rd paragraph.

7 OJ L 156 , 08/06/1989 p. 3

Conclusion

In conclusion, disinfectants for machinery and equipment used in treatment and processing establishments and teats dip and udder cleaning products (with disinfecting activity) used on production holdings are excluded from the BPD since they are within the scope of Directive 92/46/EEC for the purpose of this Directive. Directive 92/46/EEC does not have any Community authorisation procedure, but it states that before being used, these products must be *approved by the competent authority* (disinfectants for machinery / equipment) or *acceptable to the official authorities* (components in teat dips or sprays). Since 1 January 1994, the deadline for the implementation of the Directive in national law, each Member States should have appointed these authorities and established the criteria for the proper use of these products.

However, disinfectants for machinery and equipment at farm level do not seem to be covered by either of these Directives. This is a very unsatisfactory situation as the same products can be used in processing establishments and at farm level. The industry sector concerned has informed the Commission and the Member States that it is prepared to accept that all food and feed area disinfectants will be under the scope of the Biocides Directive.

According to the Commission's proposal[8] regarding new legislation concerning the hygiene of foodstuffs, which, when adopted, will replace the current legislation, primary production operators (i.e. farmers) will have to refer to Good Farming Practices Guidelines. When these Guidelines are established, industry, operators, the Commission and the Member States should work towards the objective that the Guidelines foresee that only authorised products can be used for all hygiene purposes including those related to machinery and equipment.

Awaiting the future adoption of the new legislation on hygiene of foodstuffs, and taking into account the provisions of Article 16(1) of Directive 98/8/EC, during the transitional period Member States may continue to apply their current practices for authorisation of teat dips.

Nevertheless, in the future, when the review process of active substances under Directive 98/8/EC for those active substances contained in "Teat dips and/or udder cleaning products" will be finalised, authorisation of such products would generally take place under Directive 98/8/EC, in accordance with the procedures foreseen in that Directive.

However, if a particular teat dip product falls under the scope of Directive 2001/82/EC – in particular if a therapeutic indication is being claimed – in compliance with this Directive, an application will have to be submitted to the responsible competent authorities. This application will have to prove that compliance with all the requirements of Directive 2001/82/EC regarding quality, safety and efficacy are met; and finally that could lead to the granting of a marketing authorisation as veterinary medicinal product in accordance with the procedures foreseen in Directive 2001/82/EC.

8 COM (2000) 438 final, OJ *C 365 E , 19/12/2000 P. 43.*