Recommendations for the layout of monographs on substances of human and animal origin

(November 2010)

1. SCOPE

This set of recommendations covers the elaboration of monographs on substances of human and animal origin and their layout. Substances for homoeopathic use and blood products are excluded.

2. ANALYTICAL METHODS: GENERAL PRINCIPLES

Analytical methods included in monographs must have been validated according to the principles set out in Chapter 3 of the *Technical guide for the elaboration of monographs* and to those in ICH guidelines Q2A *Validation of analytical procedures: definitions and terminology* and Q2B *Validation of analytical procedures: methodology*, taking into account specific issues concerning the unique tests used for analysing biological products.

3. GENERAL CONSIDERATIONS AND MONOGRAPH LAYOUT

Products of human and animal origin form a heterogeneous group of substances, it is therefore not possible to apply a single set of criteria in this guideline.

Where relevant, some of the principles defined in the *Technical guide for the elaboration of monographs on synthetic peptides and recombinant DNA proteins* for recombinant DNA proteins may apply to pure proteins derived from material of human or animal origin.

Specific provisions applicable to monographs on oils, fats and waxes of animal origin are given in chapter 4 of the *Technical guide for the elaboration of monographs on fatty oils and derivatives*.

3.1. Definition

The definition states the source species and where applicable, the organs or tissues from which the substance is derived.

3.2. Production

For substances of animal origin, a statement is included concerning, as appropriate:

- the health of animals used for production of the substance ("the animals from which [the substance] is derived must fulfil the requirements for the health of animals suitable for human consumption");
- the quality of the feeding stuff given to the animals used for production of the substance ("the animals shall only be given feed with a composition that is in accordance with the relevant European Union or other applicable regulations");

– the control of levels of contaminants (e.g. “the content of dioxins and dioxin-like PCBs[1] is controlled using methods and limits in accordance with the requirements set in the European Union or other applicable regulations”), where applicable through the manufacturing process (e.g. “[the substance] is produced by methods of manufacturing designed to minimise or eliminate hypotensive substances”).

The issue of infectious agents needs not be addressed in individual monographs as it is covered by general texts such as general chapter *5.1.7. Viral safety*, which applies through the relevant general monographs.

3.3. Labelling

As mentioned in the *General notices*, a statement relative to the origin of the substance is only added to the Labelling section where this is necessary to demonstrate compliance or non-compliance with the monograph requirements.

[1] Polychlorinated biphenyls