EUROPEAN COMMISSION



HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate B - Consumer Affairs B3 - Product and service safety

> GPSD Committee meeting 7th June 2005 SANCO.B.3 – CB

Agenda Item 6

Presented for initial comments

SECOND CHAPTER OF THE GUIDANCE DOCUMENT ON THE RELATIONSHIP BETWEEN GPSD AND CERTAIN SECTORAL DIRECTIVES

The European Commission published in November 2003 a first guidance document covering the relationship between the GPSD and the Toys Directive, the Directive on Low Voltage Equipment, the Directive on Personal Protective Equipment (PPE), and the Directive on Cosmetic Products. It is available on the website of Health and Consumer Protection (SANCO) at the following address:

http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/revisedGPSD_en.htm.

At the request of several Member States, the services of the European Commission (DG SANCO and DG Enterprise and Industry) have drafted this second draft guidance document, which extends the analysis to additional sectoral directives that may cover specific consumer products. The second draft guidance document clarifies the relationship between the GPSD and the following sectoral directives: the Medical Devices Directive, the Construction Products Directive, the Machinery Directive, the Medicinal Products Directive and Motor Vehicles Directive.

This second document should be read together with the first. It has intentionally been made shorter since the basic principles for drawing the conclusions are already clarified in the first document. The document is intended as an informal guide to assist the public authorities of the Member States when applying the directives covered. It is also of practical use for stakeholders. It is not to be considered as a legal interpretation of the Directives covered.

The attached finalised draft version of the second guidance document and its annex are the result of work between the Product and Service Safety Unit of DG SANCO and the various sectoral Units of DG Enterprise and Industry. It may still be slightly modified in particular as regards the application of article 13 of the GSPD to medical devices. The draft guidance document has not yet been discussed with Member States in the different relevant Committees in place for the sectoral Directives concerned.

<u>Delegations are invited to comment on the draft either in the meeting or in writing before a</u> <u>date to be decided in the meeting.</u>