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DRAFT GUIDELINES ON THE RELATIONSHIP BETWEEN THE GENERAL PRODUCT SAFETY DIRECTIVE AND THE DIRECTIVES ON MEDICAL DEVICES, CONSTRUCTION PRODUCTS, MACHINERY, MEDICINAL PRODUCTS AND MOTOR VEHICLES

1. INTRODUCTION

The Commission's Directorate General Health and Consumer Protection (DG SANCO) in the autumn 2003 published an informal guidance document[1] (The Guideline), clarifying the relationship between the General Product Safety Directive 2001/95/EC (GPSD) and four key sectoral directives applying to certain consumer goods (the Toys Directive, the Directive on Low Voltage Equipment (LVD), the Directive on Personal Protective Equipment (PPE), and the Directive on Cosmetic Products). It is recalled that the general scope of the GPSD is limited to "consumer products". It should be emphasised that this is the general limitation of the scope of the GPSD defined in article 2 (a). "Consumer products" are products that are intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them. What are "reasonably foreseeable conditions" must be judged in the individual case and will change with market developments where consumers increasingly use complex products, for example medical devices and machinery. It should be noted that for the sector Directives covered by this document, the majority of products are not consumer products. For example, the Directive on Construction Products is to a large part focussed on the professional Construction sector. Still some Do-it-yourself products and other construction products migrate to the consumer market and are therefore relevant in this context.

There is no legal definition of a "consumer" in the GPSD or in the EC Treaty as such. The essential concept is however widely accepted to be individuals acting in a personal capacity in the market as opposed to individuals or legal persons acting in their professional capacity. In other pieces of consumer legislation the term has been defined. For example a "consumer" in the Directive on Consumer Credit (87/102/EC) and the Directive on Doorstep Selling (85/577/EC) means "a natural person who, in transactions covered by this Directive, is acting for purposes which can be regarded as outside his trade or profession". The definition is not directly applicable to the GPSD, but may be used as a basis for the interpretation.

The starting point for this assessment was article 1.2 of the GPSD which states that *'[t]his Directive shall apply to all products defined in article 2(a)* […] *in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned'.*

Also Recital 13 of the Preamble specifies that *'[t]he provisions of this Directive relating to the other obligations of producers and distributors, the obligations and powers of the Member States, the exchanges of information and rapid intervention situations and dissemination of information and confidentiality apply in the case of products covered by specific rules of Community law, if those rules do not already contain such obligations'.*

Several Member States have requested an extension of the analysis to several additional sectoral directives that may cover consumer goods: the Medical Devices Directive, the Construction Products Directive, the Machinery Directive, the Medicinal Products Directive and the Motor Vehicles Directive. Since the general principles on the relationship are already explained in the existing guidance document, they are not repeated here. Instead the analysis in the following is summarised and focuses on those articles of the GPSD that *apply* to consumer products falling under sector directives.

[1] http://europa.eu.int/comm/consumers/cons_safe/prod_safe/gpsd/guidance_en.pdf

This document [has been drafted in close contact with DG Enterprise, Member States' experts and stakeholders].

Only the text of the directives is authentic in law. The text of the directives is applicable where there are differences between the provisions of a directive and the contents of this Guide. The interpretation of Community law is ultimately the responsibility and privilege of the European Court of Justice. The analysis set out in this Guide does not in any way preclude a different interpretation by the ECJ in a particular case, and does not in any way commit the European Commission.

Annex I to this document gives an overview of the applicability in table format.

2. MEDICAL DEVICES[2]

2.1. Producers' obligations

2.1.1 General safety obligation

Article 2.1 GPSD states that the general safety requirements of the GPSD shall not apply to those products insofar as concerns the risks or categories of risks covered by the specific legislation.

This rule is clarified in recital 12 of the preamble:

"If specific Community legislation sets out safety requirements covering only certain risks or categories of risks, with regard to the products concerned the obligations of economic operators in respect of these risks are those determined by the provisions of the specific legislation, while the general safety requirement of this Directive should apply to the other risks."

Following the objectives of the GPSD it is unambiguous that the nature of the risks and categories of risks must relate to human health and safety. The Community Directives on medical devices set out safety requirements covering health and safety risks. These articles all refer to the Annexes of the respective Directive which use the notion "safety of patients", "the safety and health of users or other persons".

Therefore, the general rule applies: the general safety requirements of the GPSD are not relevant for medical devices as these requirements are set out in specific Community legislation on medical devices.

2.1.2 Other obligations for producers

The Community Directives on medical devices cover most of the obligations for producers set out in the GPSD. GPSD articles 5.1 and 5.3 may however apply in some particular situations

[2] The three main Directives in the regulatory framework for medical devices are: Council Directive 90/385/EEC of 20 June on the approximation of the laws of the Member States relating to active implantable medical devices, 20.07.1990, OJ L 189/17. Council Directive 93/42/EEC on medical devices of 14 June 1993, 12.07.1993, OJ L 169/1. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
They are referred to in the text as 'Community Directives on medical devices'. For the appropriate provisions see the annex.

since they contain general obligations for producers to follow up product safety after placing their products on the market and to inform public authorities of dangerous products and action to prevent risk. These aspects are partly covered by the Community Directives on medical devices for most medical devices, but not for custom made medical devices and devices for clinical investigation. If these products are consumer products, the GPSD applies in this respect

Furthermore the Community Directives on medical devices do not have a specific provision on the aspect in GPSD article 5.4 regarding co-operation between producers and the competent authorities, although co-operation is foreseen as a pre-condition for the functioning of the Directive. Thus the GPSD applies. Co-operation in line with this article will be established by sector authorities in view of the provisions applicable to medical devices.

2.2. Distributors' obligations

The Community Directives on medical devices has no provisions related to distributors' obligations. Therefore, all aspects of GPSD article 5 relevant for distributors apply to medical device consumer products.

2.3. Obligations and powers of Member States

Although it is not stated explicitly anywhere in the Community Directives on medical devices that competent authorities shall be organised and designated (GPSD article 6), some provisions envisage a national competent authority. These are specific provisions dealing with the market surveillance aspect and have the same objective. Because of the relatively limited scope of the sector directive provisions, the corresponding GPSD provisions should serve as an example and a model for market surveillance of medical devices.

Furthermore articles 7, 9 and 10 of the GPSD on the Member States' obligation to adopt rules on penalties and to follow-them up, to put in place a market surveillance strategy and to establish administrative co-operation between competent authorities apply since there are no specific provisions in the Community Directives on medical devices on these aspects. Administrative co-operation is carried out through the Administrative co-operation Group for medical devices already established.

The Community Directives on medical devices deal with powers of national authorities. These provisions cover several aspects contained in the GPSD article 8, but not the power to require recall of products. In this specific context the GPSD applies when the safety requirements of the Community Directives on medical devices are not fulfilled.

2.4. Notification, rapid intervention and administrative provisions

Community rapid intervention is covered by the Community Directives on medical devices. In combination with the vigilance procedure (i.e. information on incidents occurring following placing devices on the market) RAPEX notification (article 12) is not required since the existing "vigilance system" is equivalent to RAPEX.[3]

[3] See: Medical Devices: Guidance Documents: Guidelines on a medical device vigiliance system, MEDDEV 2.12-1 Rev 4., April 2001.

In addition, article 14b of the Medical Devices Directive provides for an intervention system by the Commission in cases of health and safety risks. It applies in most situations foreseen under article 13 of the GPSD [this paragraph may still be modified]

GPSD article 11 on notification of national measures is covered by the Community Directives on medical devices via safeguard clause procedures and mechanisms for invoking the particular health monitoring procedure. These procedures all include a notification procedure for measures taken. Consequently, this provision of the GPSD is not applicable.

3. CONSTRUCTION PRODUCTS[4]

3.1. Producers' obligations

3.1.1 General safety obligation

The general obligation in GPSD article 3.1 for producers to place only safe products on the market does not apply since article 2, ref Annex I, in particular paragraph 4, of the Directive on Construction Products (CPD) covers all risks.

3.1.2 Other obligations for producers

GPSD article 5.1, subparagraph 1 on producers' obligation to inform consumers on risks applies since there are no specific provisions in the CPD. Furthermore article 5.1, subparagraphs 3, 4 and 5 and article 5.3 relating to the follow-up of the safety of consumer construction products placed on the market [only factory control foreseen under Annex III.2 therefore not relevant] and the obligation to inform authorities on dangerous products and action taken to prevent risks apply because there are no provisions on these aspects in the CPD.

Finally, article 5.4 of the GPSD also applies because there is no specific provision in the CPD referring to the producers' obligation to co-operate with the competent authorities, although co-operation is foreseen as a pre-condition for the functioning of the Directive. Co-operation in line with this article will be established by sector authorities in view of the provisions applicable to construction products.

In those situations where there are no technical specifications for a consumer construction product and it therefore to be placed on the market without the CE-marking, the provisions in GPSD article 5.1 on identification of the producer and traceability of the product also apply.

3.2. Distributors' obligations

All provisions in article 5 of the GPSD relevant for distributors apply, because the CPD does not have specific provisions on this aspect.

3.3. Obligations and powers of Member States

Although it is not stated explicitly anywhere in the CPD that competent authorities shall be organised and designated (GPSD article 6), several articles and Annex IV, represent specific provisions that envisage a national competent authority. Because of the relatively limited

[4] Council Directive 89/106/EEC of 21 December 1988, amended by Council Directive 93/68/EEC OF 22 July 1993

scope of the sector directive provisions, the corresponding GPSD provisions should serve as an example and a model for market surveillance of construction products.

GPSD article 7 on an obligation to adopt and follow up rules on penalties, article 8.1 (a) – (f) on the power of Member States to make checks and take samples, to set conditions for marketing and to recall, article 9 on a market surveillance strategy and article 10 on co-operation between Member States' competent authorities also apply as there are no provisions in the CPD on these aspects. The CPD has some specific provisions on market surveillance in articles 15 and 21, but they do not deal with the overall approach. Administrative co-operation is carried out through the Administrative co-operation Group for construction products already established.

3.4. Notification, rapid intervention and administrative provisions

The CPD does not contain any provision related to rapid exchange of information (RAPEX) or on Community rapid intervention measures. Therefore, articles 12, 13, 14 and 15 of the GPSD apply.

GPSD article 11 on notification of national measures is covered in most cases by CPD article 21 on safeguard measures. In those cases where a measure concerning health and safety does not fall under CPD article 21 or under the RAPEX notification procedure, it should be notified under GPSD article 11.

In addition the administrative provisions in GPSD articles 16 and 18 apply.

4. MACHINERY[5]

4.1. Producers' obligations

4.1.1 General safety obligation

The general safety obligation in GPSD article 3.1 does not apply since article 2, ref. Annex I of the Machinery Directive (MD) covers all risks.

4.1.2 Other obligations for producers

The MD covers most of the obligations for producers set out in the GPSD. However, GPSD articles 5.1 and 5.3 contain obligations for producers to follow up product safety after placing their products on the market and to inform public authorities of dangerous products and action to prevent risk. These aspects are not covered by the MD so the GPSD will apply.

Furthermore the MD does not have a specific provision covering the aspect in GPSD article 5.4 on co-operation between producers and the competent authorities, although co-operation is foreseen as a pre-condition for the functioning of the MD. Thus the GPSD applies. Co-operation in line with this article will be established by sector authorities in view of the provisions applicable to machinery.

[5] Council and European Parliament Directive 98/37/EC of 22 June 1998, amended by Council and European Parliament Directive 98/79/EC

4.2. Distributors' obligations

The MD does not contain provisions on distributors' obligations, therefore the GPSD provision in article 5 on this aspect applies also to distributors of consumer machinery products.

4.3. Obligations and powers of Member States

Although it is not stated explicitly in the MD that competent authorities shall be organised and designated (GPSD article 6), several specific articles, including in particular Annex VII, point 7, foresee a national competent authority. Because of the relatively limited scope of the sector directive provisions, the corresponding GPSD provisions should serve as an example and a model for market surveillance of consumer machinery products.

GPSD article 7 on the obligation to adopt rules on penalties and to follow them up, article 9 on a Market Surveillance Strategy and the obligation to establish administrative co-operation between national authorities (GPSD article 10) apply to consumer machinery products since there are no provisions in the MD. Administrative co-operation is carried out through the Administrative co-operation Group for machinery already established.

Finally, with regard to GPSD article 8, as there is no provision in the MD on powers to make checks, take samples and require information, article 8.1 (a) of the GPSD would apply. The other aspects of GPSD article 8 are covered in the MD.

4.4. Notification, rapid intervention and administrative provisions

The MD does not contain any provision related to rapid exchange of information (RAPEX) or on Community rapid intervention measures. Therefore, articles 12, 13, 14 and 15 of the GPSD apply.

The obligation to notify national measures restricting the marketing of products in GPSD article 11 is in most cases covered by MD article 7 on safeguard measures for CE marked products. But in those cases where a measure concerning health and safety does not fall under the MD article 7 or under the RAPEX notification procedure, GPSD article 11 applies.
Finally GPSD articles 16 and 18 containing administrative provisions on access to information and motivation of decisions apply as far as MD article 11 and 7 do not cover this aspect.

5. MEDICINAL PRODUCTS[6]

The Directive on Medicinal products (MPD) sets out a detailed framework for the safe provision of medicinal products in the EU. The analysis shows that almost all aspects of the GPSD are covered by specific provisions in the MPD. However, the general safety obligation in GPSD article 3.1 applies to certain risks that are not covered by MPD article 6, ref articles 8,9 and 10, for example the risk of children getting access to medicinal products (child resistance of packaging).

[6] Council 2001/83/EC on the Community Code relating to medicinal products for human use, amended at the latest by Council Directive 2004/27/EC of 31 March 2004

6. MOTOR VEHICLES[7]

6.1. Producers' obligations

6.1.1 General safety obligation

The general safety obligation in GPSD article 3.1 does not apply since the Motor Vehicles Directive (MVD) article 7.1 on certificates of conformity and the relevant annexes of the Directive cover all risks relating to construction and functioning of motor vehicles.

6.1.2 Other obligations

The MVD covers most of the obligations for producers set out in the GPSD. However, GPSD articles 5.1 and 5.3 contain obligations for producers to follow up product safety after placing their products on the market and to inform public authorities of dangerous products and action to prevent risk. These aspects are not covered, so here the GPSD will apply.

Furthermore the MVD does not cover the aspect in GPSD article 5.4 of co-operation between producers and the competent authorities in a specific article, although co-operation is foreseen as a pre-condition for the functioning of the Directive. Co-operation in line with this article will be established by sector authorities in view of the provisions applicable to motor vehicles.

6.2. Distributors' obligations

The MVD has no provisions on distributors' obligations, thus the relevant provisions in article 5 of the GPSD applies to consumer products covered by the MVD.

6.3. Obligations and powers of Member States

There is no provision in the MVD dealing explicitly with the obligation to adopt rules on penalties and to follow them up or to establish a strategy for market surveillance although several specific provisions exist on elements of the market surveillance (such as the rules on type-approval and follow-up checks). Therefore GPSD articles 7 and 9 apply in a complementary way to the MVD.

Furthermore there is no provision in the MVD on the need for Member States to have the power to recall products in GPSD article 8.1 (f).

Apart from this, all aspects relevant for Member States authorities are covered by specific provisions in the MVD.

6.4. Notification, rapid intervention and administrative provisions

The MD does not contain any provision related to rapid exchange of information (RAPEX) or on Community rapid intervention measures. Therefore, articles 12, 13, 14 and 15 of the GPSD apply.

[7] Council Directive 70/156/EEC of 6 February 1970, amended, at the latest by Council regulation (EC) No 807/2003 of 14 April 2003

The obligation to notify national measures restricting the marketing of products in GPSD article 11 is in most cases covered by MVD article 4.2 on safeguard measures for type approved products. Vehicles already on the market are covered by MVD article 7.3. But in those rare cases where a measure concerning health and safety does not fall under these MVD articles or under the RAPEX notification procedure, GPSD article 11 applies.

Finally the MVD does not have any provisions governing access to information as set out in GPSD article 16, therefore this provision applies also to consumer products covered by the MVD.