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HEALTH & CONSUMER DIRECTORATE-GENERAL

Directorate B - Consumer Affairs
B3 - Product and service safety

Brussels, 07/11/2008
DG SANCO B.3

SUMMARY RECORD OF THE MEETING OF THE COMMITTEE OF DIRECTIVE 2001/95/EC ON GENERAL PRODUCT SAFETY

BRUSSELS – 6&7 NOVEMBER 2008

Introduction

The meeting was chaired by Mr Stefano Soro, Head of Unit 'Product and Service Safety'.

1. Adoption of the Agenda

The draft agenda was adopted with an addition under "Any other business" of an information point on the issue of the reform of the comitology procedures, as requested by PL. The adopted agenda is attached as Annex 1.

The attendance list is attached as Annex 2.

2. Adoption of the minutes of the previous meetings

The draft minutes of meeting of 19 and 20 June 2008 were adopted without changes. The adopted minutes are attached as Annex 3.

Implementation and application of the General Product Safety Directive

3. Consumer market scoreboard.

The Commission reported on the results of the Interactive Policy Making (IPM) questionnaire on 2007 national market surveillance activities. 23 countries, including Norway and Iceland, replied to the questions. The Commission presented the two indicators which should be published for 2008: the national budget for Market Surveillance as a percentage of total national budgets and the number of inspectors involved in market surveillance activities and asked Member States' views regarding these indicators and the other indicators which can be proposed for the next years.

Most of the Member States agreed with the indicators proposed for 2008 but expressed their concerns regarding the difficulties to collect data and reliable figures at national level.

The Commission proposed a continuation of this exercise over the following years and invited the Member States to further discuss which other indicators could be useful to assess the effectiveness of market surveillance and whether it would be possible to develop a common template for collecting the data.

4. Complaints classification

The Commission informed the Member States of the results of a public consultation on consumer complaints. Over 100 responses from a wide group of stakeholders had been received. The majority of responses were in favour of introducing a voluntary (50%) or an obligatory (30%) methodology for classifying complaints. All responses to the consultation will be published on the DG SANCO website, accompanied by a synopsis

paper. An expert group will be set up to provide advice and assistance to the Commission on the development of a harmonised methodology for classifying consumer complaints addressed to third-parties.

GPSD members are invited to indicate which are the third-party bodies collecting consumer complaints related to safety in the Member States.

5. Report on the implementation of the GPSD

The Commission presented its Draft Report on the implementation of the GPSD, as required by Article 19(2) of the Directive 2001/95/EC, which is to be adopted in the form of a Communication from the Commission to the European Parliament and the Council. Member States were invited to comment on the document. Issues raised included the problem of traceability of products in some Member States, standardization work and the relationship between the GPSD and the New Approach Package. Overall, reactions from the Member States were very positive.

6. Application of the GPSD to subcutaneous implants and tattoo inks

The Commission presented its position on the applicability of the GPSD to subcutaneous implants and tattoo inks (that had been communicated to the members of the GPSD Committee in the note of 1 October 2008, reference number B3/SFS/AR/fm D(2008)230273). The Commission restated that the GPSD applies to subcutaneous implants which are inserted beneath the skin of consumers by surgeons only and which have exclusively a recreational function. Following the same approach, GPSD also applies to tattoo ink, if intended to be used on a consumer, irrespective of whether they can be purchased for self-application or purchased by a professional tattooist and are inserted by this service provider under the skin of a consumer.

7. Joint actions and exchange of officials

The Commission presented a final update on the results of the 2008 joint actions and exchange of officials programmes. For the Joint Actions four applications were received (EMARS 2; toys for children under three; sun beds and solarium services; cords and drawstrings on children's clothing) and all have been awarded financial support for a total of 2.6 M Euros. Regarding the exchange of officials, 8 applications were received and, after verification, the Commission has decided to award financial contributions to all requests.

From 2009, financial management of these joint actions will fall under the responsibility of the Executive Agency for Health & Consumers.

Following this update, the PROSAFE chairman was invited to speak about changes to be made to the structure of the PROSAFE organisation. The aim is to create a better link between the PROSAFE network and the foundation PROSAFE, which is the beneficiary for all the joint actions awarded in 2008.

Standardisation

8. Baby walkers

The Commission asked observers to leave the meeting room and invited Member States to vote on the Commission proposal to publish the reference of the standard EN 1273:2005 on baby walkers in the OJ. The Member States represented voted unanimously to support the Commission proposal (26 for, 0 against, 1 not represented – total weighted votes in favour 335).

FI asked to add the following statement to this summary record: "Due to the risks related to baby walkers, Finland would prefer a total ban of these products. However, as this is

not realistically possible at this time, Finland votes in favour of the Commission proposal".

9. RIP cigarettes mandate

The Commission informed the Committee that the mandate to develop a standard on Reduced Ignition Propensity (RIP) cigarettes was transmitted to CEN at the end of June 2008. CEN accepted the mandate at the end of August and transmitted it to ISO, since CEN does not have a relevant Technical Committee (TC) to work on the mandate. ISO will decide by end of November whether it accepts the mandate and which TC should work on it.

The CEN participant in the meeting reported that ISO indeed planned to accept the mandate and to constitute a joint TC, composed of members of ISO TC 92 "Fire safety" and ISO TC 126 "Tobacco and tobacco products", to develop the requested standard.

The Commission insisted that the standard should be developed in the shortest possible time, in order to make this life-saving measure available in the EU. CEN, respectively ISO, could take account of the existing ASTM standard on RIP cigarettes.

10. Child-resistant lighters mandate

The Commission presented the progress regarding the mandate to CEN to revise EN13869 regarding child resistant lighters. After the adoption of Decision 2008/357/EC laying down specific child safety requirements for lighters, the Commission issued a mandate to CEN in July 2008 based on the positive opinion of the GPSD and the 98/34 Committees. CEN presented the mandate to its members with a resolution to reject the mandate, due to a perceived lack of consensus on the text. At the end of August, of majority of CEN members did indeed refuse the mandate but Norway issued a fundamental objection to the resolution.

As a result, on 2 October the CEN Technical Board discussed the issue and decided to establish an ad-hoc expert group to further discuss the mandate with a view to come to a compromise that would allow CEN to still accept the (changed) mandate.

The Commission expressed its disappointment with the lack of progress with the mandate, which has the form of a Commission Decision backed by the vote of two Committees of the Member States (GPSD Committee and 98/34 Committee), especially in view of the fact that the temporary Decisions ex art. 13 GPSD cannot be renewed indefinitely, and presented the option to continue discussions with CEN but at the same time push for the publication of the reference of the existing EN 13869 in the Official Journal. Several Member States expressed their concern about this approach due to the uncertainty this would cause in the market place.

11. Chemicals in children's pyjamas

BE presented findings from the analysis of 20 samples of children's clothing for azodyes, formaldehyde and phthalates. BE considered that the result for azodyes, found in 1 sample, was by far above the legal limit and would indeed trigger a RAPEX notification. BE wondered, however, how to assess the formaldehyde finding (more than 100 mg/kg in one sample) since there was no legislation on formaldehyde, and how to interpret the phthalates findings (0.01 to >2% in 15 samples) since children's clothing was not covered by the ban established in the Chemicals Restrictions Directive 76/769/EEC.

Some Member States reported that they had a study ongoing. CEN reported that TC 148 was currently developing a method to determine phthalates in the textiles.

DE asked if the clothing containing formaldehyde and phthalates could be notified under the GPSD. The Commission explained that, to manage chemicals in consumer products in general, a temporary measure could be a first step, followed by legislation (as in the

case of phthalates) or a standard (as in the recent case of magnets). For phthalates in children's pyjamas, the amendment of the relevant Guidelines could indeed be an option. The Commission called upon all meeting participants to provide their studies, data or limits in national legislation, in order to put together a more comprehensive picture about the situation in the EU.

12. Hygienic masks

FR gave a presentation on the issue of confusion between "hygiene masks" and respiratory protective devices and suggested a standard to avoid confusion. A few Member States presented measures taken at a national level to inform consumers and manufacturers about the different kinds of mask in order to avoid misuse. FI was asked by the Commission to provide a copy of a press release they have issued on this subject. No Member States were against the drafting of a standard requiring positive warning on masks. The Commission invited the Personal Protective Equipment working group, represented by the French delegate, to submit further information to the GPSD Committee.

13. Children shoes

The Commission introduced a discussion on an issue that national authorities, the European Parliament and ANEC have brought to the Commission's attention regarding children's footwear. The discussion focused on the negative health effects posed by ill-fitting shoes as well as on the applicability of the GPSD to long-term health effects. The Commission informed that Hungary has notified in RAPEX dangerous children's footwear and Hungary explained in more details how these products on the basis of their risk assessment pose a serious risk. Some Member States expressed a wish that, in view of the different requirements existing at national level, a harmonized approach in this area is needed.

14. Ladders

A mandate for a standard has been pending for almost 10 years. The Commission recently met again with representatives from CEN /CMC and CEN/TC 93 who committed to submit to the Commission, by 30 November 2008, a roadmap with a timeline and milestones with the view to producing a revised version of EN 131-2 in 12 months. The roadmap will be assessed by the experts' group appointed by the Member States. In parallel, the experts' group is preparing a Report with recommendations. This report will be presented to the GPSD. If Member States agree with the recommendations, they will be sent to CEN.

International issues

15. Update on recent and forthcoming events

Joint EU-U.S.-China Initiative on Consumer Product Safety Compliance (September 2008)

The joint outreach and training seminar began with high-level talks on 19 September in Beijing. The European Commission was represented by Mr. Robert Madelin, Director-General for Health and Consumers, who together with members of his delegation, met with Vice Minister Wei Chuanzhong of the Chinese Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), and Chairman Nord of the U.S. Consumer Product Safety Commission (CPSC). The joint initiative continued with three one-day training seminars in Beijing, Guangzhou and Shanghai focusing respectively on textiles, toys and electrical appliances. The series of seminars brought together Chinese, EU and U.S. regulators, businesses, standard-makers and test laboratories.

Trilateral Summit (November 2008)

A trilateral summit on product safety between Commissioner Kuneva, Chairman Nord of the CPSC and Vice Minister Wei of AQSIQ will take place on 17 November in Brussels to discuss common challenges and future cooperation.

Upgrading of the Memorandum of Understanding (MoU) with AQSIQ

Revised annexes on non-food consumer product and food safety to the current MoU will be signed by Commissioner Kuneva and Vice Minister Wei on 17 November 2008 in Brussels during the International Product Safety Week with a view of strengthening cooperation and exchange of information.

Future Cooperation with Switzerland

The negotiations with Switzerland will start on 24 November 2008.

16. International Product Safety Week 17-21 November 2008

The Commission informed the Member States about the Product Safety Week taking place in Brussels in November and ran through the agenda.

17 November:	Trilateral Summit, ICPSC meeting and ICPHSO reception
18 and 19 November:	ICPHSO conference
20 November:	EMARS final conference; meeting of the EU-China Regulators RAPEX-China Working Group
21 November:	3 rd EC/China joint market surveillance seminar

Fire safety issues

17. Flame retardants

The Commission reported that a study was planned on the risks of available flame retardant substances and their alternatives, in order to submit such information to one of the Commission's Scientific Committees for evaluation and possible recommendations on which flame retardants are safe. In view of the large number of flame retardants and the ambitious objective, the study could last as long as two years.

18. Fire safety in hotels

The Commission reported on the current initiatives with regard to fire safety in hotels, including: the EuroSafe conference which took place in Paris on 9 & 10 October 2008 on injury prevention and safety promotion, the process launched by HOTREC, the hospitality industry European association, for the signature of a Charter on fire safety in hotels by the end of 2009 and the EP study on hotel safety to be presented in the IMCO committee in December 2008. The Commission also presented the state of play of the call for tenders on hotel safety launched on 15 July 2008 and which closed on 26 September 2009. Four proposals have been received and all are eligible. The final decision will be taken by the end of November and the contract should be signed in December.

Issues related to the operation of RAPEX

19. Revision of the RAPEX Guidelines

The Commission presented the state of play with regard to the new RAPEX Guidelines. The first version of the new RAPEX Guidelines will be sent for comments to members of the GPSD Committee and to the RAPEX Contact Points. Final adoption is planned for spring 2009.

20. New Risk Assessment Guidelines

The Commission explained that a public consultation on the draft RAPEX Risk Assessment Guidelines (RAGs) had been held from 15 July to 15 October 2008. 25 questions were asked and 68 replies were received, including replies from 17 Member States and U.S.A. 60-70 % of the respondents agreed or mostly agreed with the proposed new risk assessment methodology. The Commission will now evaluate these replies to include them in the draft version of a text for final discussion during the last IRAG Working Group on 9 December 2008, to which Member States are encouraged to participate. The draft guidelines, which will be a useful tool for enforcers, will then be submitted to Member States.

21. RAPEX-China

The Commission gave an update of the 6th Follow-up Report received from AQSIQ on their market surveillance and enforcement activities performed on the basis of RAPEX data and on the feedback provided by AQSIQ. The 7th report is currently being translated and will then be made available on Circa. The Commission invited the Member States to participate at the meeting of the RAPEX-China Working Group on 20 November during the International Product Safety Week. Ten Member States have already confirmed their participation at the meeting which will discuss operation of the RAPEX-China system, including certain EU legislation applicable to specific products and substances, obligations of different parties, classification of notifications and the different measures taken. A certain number of specific cases will also be discussed. Other suggestions for the agenda were requested.

22. RAPEX notifications: Food-imitating products and electrical child-appealing products.

The Commission presented the issue of the increasing number of RAPEX notifications on measures taken regarding food-imitating products, such as candles, cosmetics, decorative articles, stationery and child-appealing electrical appliances. The Commission also clarified the criteria to take restrictive measures on the basis of Directive 87/357/EEC on products which, appearing to be other than what they are, endanger the health or safety of consumers. The Commission reminded that detailed risk assessment and evidence of the existence of a serious risk is required to notify measures through the RAPEX system under of the GPSD. The Commission asked Member States to provide their views on this issue.

23. Personal music players

The Commission informed the Member States of the main findings of the Scientific Committee on the potential health risks of exposure to noise from personal music players and mobiles phones which include a music playing function. The Commission informed the Member States of a conference on this subject which is planned for early 2009 to discuss possible action, for example, finding technical solutions, revision of existing standards, etc. DG SANCO will reimburse the fees for one participant per Member State and DG ENTR will do the same. Other participants at the conference will be from the Scientific Committee, industry, EP, standardisation experts and consumer associations.

In order to prepare for the conference, Member States were invited to provide their views on this issue and the way forward and to submit information regarding any measures that have already been taken at a national level.

Miscellaneous

24. Business Application training sessions

The Commission informed that 28 Member States and EFTA/EEA (50 participants) participated in the trainings on the "Business Application". In total, 4 training sessions have been held in Brussels on 22, 23, 24 and 25 September. The feedback received from participants was positive and the Commission encourages Member States to carry out internal trainings and tests. The Commission will send a request to Member States asking for contact details of the authority responsible for treating notifications sent by businesses, so that this data can be published on the Commission's website.

25. Scientific Committee opinion on 'light sensitivity'

The Commission drew attention to the recent opinion of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR). According to the opinion, symptoms such as migraine or epilepsy encountered by light-sensitive people would not be significantly caused by the flicker or the electromagnetic fields from energy saving light bulbs. Only the increased UV/blue light radiation might cause a risk of aggravating certain diseases (such as chronic actinic dermatitis or solar urticaria) for around 250,000 individuals (0.05% of the EU population) in the worst case. Double envelope lamps could mitigate that risk.

26. Eurobarometer results

The Commission presented the main product safety-related results of the 2008 Eurobarometers on consumer protection in the internal market and on business attitudes towards cross-border sales and consumer protection.

27. Market surveillance

The Commission outlined developments under the New Legislative Framework relating to the GPSD and provided a brief summary of the SOGS-MSG meeting on 1 October 2008. Finland pointed out that the Consumer market scoreboard should be taken into account in the context of Article 18(6) of Regulation 765/2008.

With regard to the Community rapid information exchange mechanism under Article 22 of the new Regulation, the Commission stated that RAPEX under the GPSD was designed and established to exclusively cover all consumer products (regardless of whether they are in the so-called "harmonised area") posing a serious risk to the health and safety of consumers. The new system has a different scope as it will cover products in the harmonised area and different kinds of risks (including environmental and workplace risks) and it involves new legal requirements. Therefore, the currently operational RAPEX system, including guidelines, the IT application and the relative Network of authorities, cannot be used to cover the needs of the Regulation 765/2008. Rather, the RAPEX system should be used as a model and starting point by the responsible Commission services when establishing the mechanism under Article 22 but the accompanying guidelines, the IT application and the organisational arrangements must take into account these additional elements. As RAPEX has proved to be an effective and efficient tool in the consumer product safety area, its operation and the implementation of the GPSD should and will not be jeopardised by the changes planned.

Members of the GPSD Committee are encouraged to get involved in discussions that are currently ongoing at the European and national levels.

Any other business

28. Lighters – location of safety marking

Following a request from Poland, the Commission brought to the attention of the Member States the issue of safety warning messages on lighters and invited them to provide their views on where the messages should be located (display box, leaflet, on individual lighter, etc.), with regards to Article 2(b) of the GPSD and point 6 of ISO 9994:2005. The Commission will consult the Legal Service on that particular issue.

29. Polycyclic Aromatic Hydrocarbons (PAH) in bicycle grips of children's bicycles

The DE participant in the meeting reported that they would try to consolidate the data on PAHs in consumer products, including grips of children's bicycles, and prepare a summary report before the next meeting. She asked all participants to provide their data, if available, and to share information about their experiences with this substance. The Committee might then discuss the way forward at its next meeting, whether to submit the data to a Commission Scientific Committee or whether to prepare a proposal for restriction within the chemicals legislation.

The IT participant reported that an evaluation of PAHs in artificial lawns was currently ongoing.

The Commission reiterated the request to all meeting participants to provide data in order to develop a harmonised basis for dealing with this issue.

30. Miscellaneous

The Commission informed the Member States of a paper to be drafted to clarify the division of the GPSD Committee and the Consumer Safety Network (CSN).

The Commission indicated potential dates for the next GPSD Committee meeting: 29 and 30 January 2009 (1½ days).

Following a comment from PL, the Commission explained an error that had occurred regarding amendments to the GPSD due to changes in the comitology procedure. Member States were informed that only amendments to the annex of the GPSD Directive would fall under new scrutiny procedure. Nothing else changes.