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COUNCIL OF THE EUROPEAN UNION	Brussels, 16 November 2007 15127/07
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from :	General Secretariat
to	delegations, CATS, PSC
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No. Cion doc. :	11951/07 JAI 392 PROCIV 125 ENFOPOL 139 SAN 156 AGRI 241 AGRILEG 110 CODUN 23 COSDP 615 COTER 63 DENLEG 66 ENV 416 PHARM 2 RECH 213 VETER 12
Subject :	Draft Council Conclusions on addressing Chemical, Biological, Radiological and Nuclear Risks and on Bio-preparedness

<u>The Commission</u> submitted to the Council, on 11 July 2007, a Green Paper on bio-preparedness which aimed at protecting the populations, life and the environment against all biological hazards such as diseases, accidents, crimes and terrorism, in particular in case of multiple incidents.

This can be achieved by stimulating an active safety culture in a public-private partnership and using existing EU tools ¹.

This Green Paper was examined in multi-sectoral meetings of <u>Counsellors/Attachés on bio-</u> <u>preparedness</u> convened by the Presidency.

On the basis of several drafts submitted by <u>the Presidency</u>, the Counsellors/Attachés established, at their meeting on 5 November 2007 and following a subsequent silent approval procedure ², the draft Council conclusions contained in <u>the Annex</u>. This draft not only concerns bio-preparedness but also non-conventional (CBRN) risks in general.

The Counsellors/Attachés also took into account the first results deriving from the consultations undertaken by the Commission on the Green Paper and the lessons learned from a table-top exercise on a bio-terrorist scenario held within the EU-institutions in October 2007. In addition, the Counsellors/Attachés heard an exposé by the office of the SG/HR's personal representative for non-proliferation.

The draft conclusions are to be read together with the future Inventory of instruments on biopreparedness, a draft of which contained in doc. 14802/07.

These draft conclusions are/were submitted to other Council bodies (TWG, ProCiv...) for information and to <u>CATS</u> and <u>PSC</u> for endorsement as regards matters falling within their remits.

The draft conclusions will then be submitted to <u>the Permanent Representatives Committee</u> and <u>the Council</u> for approval/adoption under the I/A-items of their agendas.

¹ 11951/07

² <u>DK/DE/UK/Cion and the SG/HR's personal representative on non-proliferation</u> made suggestions on the text. Since they appeared to be technical or uncontroversial, it was not considered necessary to restart the silent approval procedure.

DRAFT ³ COUNCIL CONCLUSIONS ON ADDRESSING CHEMICAL, BIOLOGICAL, RADIOLOGICAL AND NUCLEAR RISKS AND ON BIO-PREPAREDNESS

THE COUNCIL OF THE EUROPEAN UNION :

- (a) <u>Considering</u> that the growing complexity of modern civilisation has created increased threats and risks of non-conventional chemical, biological radiological or nuclear (CBRN) disasters of an accidental, pandemic or intentional origin, including terrorism; <u>noting</u> that the Commission Green Paper on Bio-Preparedness of July 2007⁴, that was based on an allhazards approach, made a similar analysis of biological threats and risks;
- (b) <u>Recalling</u>, in particular, that tackling terrorist access to weapons and explosives, ranging from components for homemade explosives to CBRN material is a key priority under the European Union Counter-Terrorism Strategy adopted by Council on 1 December 2005 ⁵ and under the EU Strategy against proliferation of weapons of mass destruction (WMD) adopted by the European Council on 12 December 2003 ⁶; recalling the obligations under the Chemical Weapons Convention (CWC), the Biological and Toxin Weapons Convention (BTWC) and the Nuclear Non-Proliferation Treaty (NPT), as well as the need to work with partners and international organisations on the non-proliferation of CBRN materials, as highlighted by the abovementioned EU strategies;

³ Changes to 14744/07 are in bold.

⁴ 11951/07.

⁵ 14469/4/05, paras 20 and 31.

⁶ 15708/03 and SN 400/03, no 68.

- (c) <u>Recalling</u> that the EU Action Plan on Combating Terrorism establishes, in its latest revision of 29 March 2007,⁷ the importance of ensuring full implementation of the Programme of cooperation on preparedness and response to biological and chemical agent attacks (Health Security Programme) adopted by the Health Security Committee (HSC) on 17 December 2001 and of the EU Solidarity Programme on the consequences of terrorist threats and attacks (Solidarity Programme) adopted by the Council on 2 December 2004 ⁸, as well as the need to adapt the database of military assets and capabilities relevant to the protection of civilian populations against the effects of terrorist attacks, including CBRN ⁹, to reflect its expansion to all types of natural and man-made disasters; Recalling that the Council of 22 February 2007 temporarily prolonged the mandate in the areas of information, preparedness and coordination of response, that had been given to the HSC in 2001, extending it to cover also pandemic influenza and generic preparedness and response planning. ¹⁰
- (d) <u>Recalling</u> the two EU Radiological Risk Reduction seminars held on 23-24 November 2006 and on 21-22 June 2007 and the **keen** interest shown by the Member States in continuing and stepping up work in the radiological risk reduction field; recalling the two seminars on Biopreparedness of 24-25 July 2006 and of 15-16 November 2006, and the workshop on Transportation and Traceability of Bio-Materials of 7 November 2006, which led to the elaboration of the Commission Green Paper on Bio-Preparedness of 18 July 2007;

⁷ 7233/1/07 REV 1, actions 2.3.4, 4.1.12 and 4.2.1.

⁸ The Solidarity Programme (15480/04) was the successor to the Council and Commission Programme of 20 December 2002 to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats (CBRN Programme) (14627/02). The elements of the Solidarity Programme were included in the Action Plan on Combating Terrorism.

⁹ 6644/4/04 REV 4.

¹⁰ 5862/07.

- (e) <u>Noting</u> the existence of an extensive arsenal of instruments aiming at avoiding accidents in the handling of CBRN substances or technologies (CBRN-safety) and <u>convinced</u> of the need to use and, where necessary, develop those instruments with a view to preventing and responding to a voluntary abuse of those substances or technologies (CBRN-security); ¹¹
- (f) Noting the relevant work under way in the **subordinate bodies** of the Council with a view to strengthening the security of critical infrastructures in the EU;
- (g) <u>Recalling</u> the importance of further enhancing the quality of <u>risk assessment</u> and analysis by making better use of <u>threat assessments</u> and by improving the methodological quality and the information on cross-border risks as highlighted in the Solidarity Programme;
- (h) <u>Recalling</u> the importance of improving and interlinking the mechanisms for the <u>detection</u> and identification of terrorist threats and for alerting the professionals and the public, as also highlighted in the EU Solidarity Programme;
- (i) <u>Recalling</u> the importance given in the Solidarity Programme to strengthening the <u>preparedness</u> and capabilities for consequence management by improved mutual assistance, by increased learning, training and exercises and by better coordination;

http://www.biosecuritycodes.org/gloss.htm#biosec

WHO describes these terms as follows :

http://www.who.int/csr/resources/publications/biosafety/WHO CDS EPR 2006 6.pdf.

¹¹ <u>OECD</u> defines "Biosecurity" as "Measures to protect against the malicious use of pathogens, parts of them, or their toxins in direct or indirect acts against humans, livestock or crops."

OECDE also defines "Biosafety" as "The safe handling practices, procedures and proper use of containment facilities to prevent accidental harm caused by living organisms either directly or indirectly to individuals within laboratories or to the environment."

[&]quot;Laboratory biosecurity describes the protection, control and accountability for valuable biological materials within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release."

[&]quot;Laboratory biosafety describes the containment principles, technologies and practices that are implemented to prevent the unintentional exposure to pathogens and toxins, or their accidental release."

- Noting that that the EU Action Plan on Combating Terrorism identifies the need for the Civil (j) Protection assistance Mechanism to be able to respond in the event of major terrorist attack in the EU¹² and that the Mechanism includes the ability to pool and compile, in the event of a major emergency (such as a bio-terrorist attack), information on necessary medical resources and on the stocks thereof which might be available for intervention¹³:
- Recalling that the Council's conclusions of 12 June 2007 on preparedness for the (k) decontamination of casualties following chemical, biological, radiological and nuclear incidents (CBRN)¹⁴ advocate, in the framework of the Civil Protection Financial Instrument¹⁵ and of the Civil Protection Mechanism, precautionary measures to avoid primary or secondary contamination, exercises, training and the spread of best practices;
- Recalling the importance given by the EU Action Plan on Combating Terrorism to scientific (1) support to bio-security policies, including research on biological agents, risk assessment and on the modeling of the propagation of biological agents that could be used by terrorists ¹⁶,

¹² 7233/1/07 REV 1, actions 4.1.1, 4.1.3 and 4.1.6.

¹³ Council Decision 2007/.../EC, Euratom of 8 November 2007 establishing a Community Civil Protection Mechanism (Recast), 11163/1/07 REV 1 + COR 1 (ro); see Article 5, paragraph 6). 14 10015/07.

¹⁵ Council Decision 2007/162/EC, Euratom of 5 March 2007 establishing a Civil Protection Financial Instrument, OJ L 71, 10.3.2007, p. 9.

¹⁶ See actions 4.1.3. and 2.7.2.

ADOPTS THE FOLLOWING CONCLUSIONS :

A. Regarding Chemical, Biological, Radiological and Nuclear (CBRN) risks, the Council:

- 1. <u>Considers</u> that, as the Union **takes** forward its work on developing a comprehensive approach to the security enhancement of explosives, detonators, precursors and related technologies, it must **continue addressing** with equal determination the non-conventional risks, in particular those posed by Chemical, Biological, Radiological and Nuclear substances, including those related to their potential terrorist use, **as recognized and addressed by the EU Strategies on counter-terrorism and against the proliferation of WMD**;
- 2. <u>Considers</u> that it is first and foremost the responsibility of each Member State to protect its populations against such disasters and that the EU intervenes in this area mainly in a supportive role in accordance with the principles of subsidiarity and proportionality, giving preference where possible to non-legislative solutions;
- 3. <u>Considers</u> that effective policies to address CBRN risks should be **further** developed in close consultation with national authorities and, as appropriate, the industrial sectors concerned, academic institutions and other relevant stakeholders, notably with a view to ensuring the viability and proportionality of measures which may be required, and <u>welcomes</u> the increasing security awareness and commitment shown, notably during the consultation process on the Commission Green Paper on Bio-Preparedness of 18 July 2007¹⁷ and during the seminars referred to in Recital d), by private sector and civil society actors and their willingness to be actively involved;

¹⁷ 11951/07, COM (2007) 399 final.

- <u>Calls on the Commission and the Member States</u> to implement, each for the areas within their responsibility, the Health Security Programme, the Solidarity Programme and other relevant programmes such as the Framework Programme for Research ¹⁸, the Instrument for Stability¹⁹ and the relevant CFSP instruments and international obligations;
- 5. <u>Requests</u> the Commission and the Secretariat General of the Council to update by mid-April 2008 the CBRN inventory of 2002²⁰ which outlined the many EU instruments that can be used to counter CBRN risks and threats so that the Council can, on this basis, take stock of the capabilities and needs in this area in the course of 2008; <u>requests</u> the Commission and the Council Secretariat General to update this inventory biennially;
- 6. Notes that the Joint Situation Centre of the Council Secretariat and, as appropriate EUROPOL, continue assessing the threats of CBRN-terrorism and of the spread of WMD; also restates the importance of assessments and analyses of the risks caused by those threats to their possible targets such as persons, society, the economy and the environment; therefore calls upon the Commission and the Member States to reinforce work on risk assessment, notably looking into the mid-term future;
- <u>Invites</u> the Commission, in accordance with its competences, to continue its work in the CBRN field together with the Member States and relevant stakeholders, avoiding duplications and building on good practices across Member States, and <u>notes</u> the Commission's intention to propose relevant policy measures in 2009;

¹⁸ Seventh Framework Programme of the European Community for Research, Technological Development and Demonstration Activities (2007 to 2013), OJ L 54, 22.2.2007, p. 30, in particular the specific programme "Security", Council Decision 2006/971/EC of 19 December 2006 concerning the specific programme "Security" implementing the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007 to 2013), OJ L 54, 22.2.2007, p. 30.

¹⁹ Regulation (EC) No 1717/2006 of the European Parliament and of the Council of 15 November 2006 establishing an Instrument for Stability, OJ L 327, 24.11.2006, p. 1.

²⁰ Inventory of the EU instruments relevant for the Council and Commission Programme of 20 December 2002 to improve cooperation in the European Union for preventing and limiting the consequences of chemical, biological, radiological or nuclear terrorist threats (CBRN Programme), 15873/02.

- 8. <u>Invites the Counter-Terrorism Coordinator</u> and the <u>SG/HR's Personal Representative for non-</u> <u>proliferation</u> to work together and with Member States and the Commission, in accordance with their respective competences, with a view to identifying ways and means to mitigate the risk that terrorists might in the future obtain, directly or indirectly, CBRN materials;
- 9. <u>Considers</u> that regular training and exercises are of paramount importance in strengthening the <u>preparedness</u> and capability for consequence management; <u>calls for</u> due account to be taken of the lessons learned from several European exercises held in the CBRN-preparedness area such as EURATOX (France, October 2002), COMMON CAUSE (Denmark, October 2002), EU Response/FLORIVAL II (Belgium, February 2003), EUDREX (Austria, October 2004), EURATECH (France, June 2005), EUROSOT (Italy, October 2005), NEW WATCHMANN (SANCO, EU-wide, October 2007) and EULUX (Luxembourg, June 2007) and, most recently, CCAEX07 (EU Council September 2007) and invites the Commission and the Member States to continue to organise regular exercises addressing CBRN risks;

B. Regarding bio-preparedness in particular, the Council:

- 10. <u>Encourages</u> Member States and the Commission, without prejudice to and in parallel with the broader work on addressing non-conventional risks, to address as a matter of priority the area of bio-preparedness with a view to addressing biological risks and threats through appropriate actions and activities in the relevant policy areas;
- 11. <u>Welcomes</u> the Commission's Green Paper on Bio-Preparedness of 18 July 2007²¹ aimed at stimulating debate and at launching a process of consultation at European level on how to reduce biological risks and to enhance preparedness and response in the context of an all-hazards approach; <u>invites</u> the Commission to provide the Council with an analysis of the responses received to the Green Paper by mid-April 2008;

²¹ 11951/07, COM (2007) 399 final.

- 12. <u>Welcomes</u> the broad interest raised by the subject and the active participation of private sector, civil society, international bodies and third countries in the two European seminars on bio-preparedness held on 24-25 July and 15-16 November 2006, in the workshop on Transportation and Traceability of Bio-Materials of 7 November 2006 which led to the Green Paper and in the public consultations on the Green Paper;
- 13. <u>Notes</u> the inventory of **EU** instruments **in the area of bio-preparedness** relevant **to the present conclusions, which addresses** prevention, preparedness and response to biological risks existing in the areas of in human, animal and plant health, police, research, environment, civil protection, etc. **and which was** established on the basis of the relevant sections of the 2002 CBRN inventory;²²
- 14. <u>Notes</u> the existence of <u>many monitoring</u>, <u>notification and Rapid Alert Systems</u> which can provide early warnings in **the event** of pandemics or biological contamination, such as the Rapid Alert System for Biological **and** Chemical Agents and Threats (RAS-BICHAT) with a specific pillar on chemicals in development (RAS-CHEM), the Early Warning and Response System **for communicable diseases** (EWRS), the Medical Intelligence System (MEDISYS), the Rapid Alert System for Food and Feed (RASFF), the Animal Disease Notification System (ADNS), the Trade Control and Expert System (TRACES), the European Plant Health notification scheme (EUROPHYT), **the Customs Information System (CIS), the Community Customs Risk Management System (CRMS) with the RIF module for the rapid exchange of risk information and the Rapid Alert System for Non-Food Products** (**RAPEX**);
- 15. Notes the existence of several bodies which can provide <u>assistance and analysis</u> in **the event** of biological incidents, notably the European Centre **for** Disease Control (ECDC), the European Food Safety Agency (EFSA), the Civil Protection Monitoring and Information Centre (MIC), the Joint Research Centre (JRC), Europol, the Joint Situation Centre of the Council (Sitcen) etc.;

²² Present draft in 14802/07.

- 16. <u>Notes</u> the existence of <u>crisis response</u> systems and bodies in the EU such as the EU Crisis Coordination Arrangements (CCA), the Commission's overall alert network ARGUS ²³, the Civil Protection Mechanism, the Health Emergency Operations Facility (HEOF) with the Health Emergency & Disease Information System (HEDIS) as a situational awareness tool, the Health Security Committee, the Standing Committee on the Food Chain and Animal Health (SCOFCAH) and the Standing Committee on Plant Health (SCPH); with a view to testing and reinforcing their interoperability, <u>invites</u> the Commission and the Council Secretariat to check, each for the instruments within their competence, the adequacy of those systems for bio-risks;
- 17. Encourages the Commission, the Member States and the Council Secretariat to strengthen, within the framework of their respective competences, interoperability, and to improve the exchange of information between the systems and structures referred to in 14, 15 and 16 while taking due care to preserve their specificity and effectiveness;
- <u>Notes</u> the intention of the Commission, in the follow-up to the consultations on the Green Paper on bio-preparedness and in the work to be carried out in 2008, to continue to ensure the involvement of public and private stakeholders;

C. In conclusion, the Council :

- 19. Expresses its intention to remain seized of the matter;
- 20. <u>Considers</u> that the EU should carefully analyse the instruments that exist, make the best possible use of them -avoiding their duplication and seeking synergies with existing national, EU, regional and global mechanisms- and not create new instruments, systems or structures unless proven necessary;

²³ OJ L 19, 24.1.2006, p. 20.

- 21. <u>Calls upon</u> the Commission, the Member States and the Council Secretariat to implement the above conclusions, in accordance with their respective competences as laid down in the Treaties;
- 22. <u>Instructs</u> Coreper, supported by the competent Council Working Party/ies, to monitor the implementation of these conclusions.