



Brussels,
SANCO.C7

EXPLANATORY NOTE FOR THE MODIFICATIONS OF THE SCHER OPINION ON THE ENVIRONMENTAL AND HEALTH RISKS POSED BY DEPLETED URANIUM FOLLOWING THE PUBLIC CONSULTATION ON THE DRAFT FINAL OPINION

This note sets out the rationale for the modifications made to the opinion of the European Commission Scientific Committee on Health and Environmental Risks (SCHER) on the environmental and health risks posed by depleted uranium (DU) following a public consultation conducted between 4 March 2010 and 12 April 2010.

Introduction

In May 2009, the European Commission requested the Scientific Committee on Health and Environmental Risks (SCHER) to assess the effects of depleted uranium on the environment and human health. A SCHER Working Group (WG) was formed comprising of members of SCHER, and experts from the Scientific Committee on Emerging and Newly Identified Risks (SCENIHR), and from academia with experience on the subject. The WG produced a draft opinion which was discussed and adopted by the SCHER plenary on 1 March 2010 as a preliminary opinion suitable for public consultation.

In line with its procedures for stakeholder dialogue, implemented in the Rules of Procedures of the new Scientific Committees set up by Commission Decision 2008/721/EC of 5 September 2008, the European Commission Health and Consumers Directorate General (DG SANCO) conducted a public consultation on the preliminary opinion of SCHER between 4 March and 12 April 2010.

Results/participation

By the deadline of 12 April 2010, DG SANCO received a total of six contributions. All of them were reviewed by the SCHER Working Group during its meeting on 26 April 2010 and introduced appropriate modifications into the opinion which was then discussed and adopted as the final opinion by SCHER at its plenary of 18 May 2010.

Modifications to the opinion

The opinion has been modified to take into account those submitted comments which were assessed by SCHER to be pertinent and relevant for the subject matter and which were within the competences of the Scientific Committees and respected the clear separation between risk assessment and risk management that underpins the Scientific Advisory Structure of the European Commission. Comments on policy, risk

management, legal clarification, ethics, the precautionary principle, were not considered as although pertinent to the subject matter are outside the competences of the Scientific Committees.

Detailed explanations of the way the comments received were treated by the SCHER are provided below. The numbering of paragraphs and lines correspond to the sections of the final opinion adopted by the SCHER on the 18 May 2010 and published together with this document.

Changes to the opinion

1. Table 1 (section 3.2.1, page 6) was modified to correct mistakes (inverted radioactivity between DU and U-234) and all figures were checked for consistency and adjusted accordingly following comments to the effect that the specific activity of DU after one year is lower than fresh DU due to ingrowth of intermediate decay products and removal of U-234 and U-235.
2. A sentence and a reference (Bleise *et al.*, 2003) clarifying the scientific basis for the statement that DU is 60% less radioactive than natural uranium was added (just below Table 1, section 3.2.1, page 6) following comments questioning its scientific validity.
3. The potential occurrence of the so-called bystander effect was missing from the discussion and has now been included (section 3.2.2, third paragraph, pages 7-8).
4. The state of the art of the scientific knowledge in response to comments received on the possibility that respirable nano DU particles are being formed which may cross the blood brain barrier are summarised in the opinion (bottom of page 8 and in section 3.4, page 13 (Cheng *et al.*, 2009; Parkhurst and Guilmette, 2009b, a). In the opinion of SCHER although in theory that possibility exists, to date there is no confirmatory evidence in the scientific literature.
5. In response to comments on the units of measurement expressing the concentration of DU in soil (page 12 of the report) and the difficulty in comparing the different units used, the final version of the opinion has been modified to use the same unit of measurements and the significance of those findings has been further elaborated (bottom of page 13 and top of page 14).
6. In response to comments that scientific publications by Alexandra C. Miller *et al.* were not cited in the preliminary opinion, the report has been modified to include a reference to these publications and their validity for the risk assessment of DU was discussed (section 3.2.3, pages 8-9).
7. In examining these publications and the entire body of scientific evidence, SCHER concluded that positive *in vitro* tests and studies involving cellular models are not predictive of causal carcinogenicity *in vivo* since carcinogenic effects have not been observed in animals ingesting soluble or insoluble uranium compounds (ATSDR, 1999). (section 3.5.1, page 16).
8. Comments received on the potential significance of low levels alpha radiation particles for human health have been evaluated by SCHER and are discussed in section 3.2.2, page 7 of the report.
9. The issue of the DU-particles re-suspension in the air was further elaborated (section 3.2.4, page 13) and the role of the desert climatic conditions was commented (Environment modelling indicates that in a desert DU movement is minimal - Appendix II, page 36) in response to comments received on those issues.

10. Table-6 was corrected to include the missing line “0.56 – 1.8 micrometers” of particle aerodynamic equivalent diameter following comments pointing to this omission.
11. The testing techniques for DU used are cited in the opinion (section 3.4, pages 14-15) in response to comments to this effect.
12. Regarding human exposure to DU, the results of measured DU excretion in urine in soldiers (Gwiazda *et al.* 2004) and residents (Oeh *et al.* 2007) have now been included (section 4.2, page 19) following comments suggesting their inclusion.
13. The indications "na" and "nd" in Table 8, page 15 and its content overall was verified for accuracy and clarity as suggested by the comments received.
14. The concentration of DU in areas with intensive use of DU ammunition was further clarified and explained (bottom of page 13) following comments on this subject.
15. The SCHER agrees with the comment received that since some level of natural uranium in urine is a given, all DU-containing samples will be mixtures (bottom of page 14).
16. The recent references about human toxicology were placed in a more appropriate place in the text (section 3.2, pages 9-10) to clarify what they actually support in response to comments received requesting a more structured presentation. In addition, some more comments were added to strengthen the evaluation and rationale of the significance of those studies.
17. The SCHER agrees with the view expressed in comments received arguing that when DU particles lodge in the lung, they may remain there for considerable time. This has been cited in section 3.2.3 page 8 and the scientific data for their potential effects are discussed in the same section of the opinion.
18. Although the SCHER agrees with the notion expressed in comments received that a 16 year period since the use of DU ammunition in the Gulf war may not be enough for showing all possible health effects of DU, the evidence in the scientific literature, so far, shows absence of health effects (section 4.2, page 19).

Comments for which no changes could be made

In addition to the comments received which resulted in the above-listed changes, the following comments were received and were evaluated by the SCHER but no changes were introduced in the opinion. The main reasons for this are :

- 1) comments were outside the scope of the terms of reference for this opinion;
- 2) comments were outside the competences of the Scientific Committees (and SCHER in this case) as they concerned policy, risk management, on field use of DU ammunition and on site sampling and surveillance;
- 3) in the scientific judgement of the SCHER, the submitted scientific evidence and argumentation were not of sufficient quality and strength to support changes and modifications in the opinion and its conclusions.

For reasons of clarity, a brief SCHER rationale underpinning its evaluation of each comment is provided for each comment.

1. Chemical properties of DU: By definition, the chemical properties of an element are determined by the number of protons in its nucleus. Hence the SCHER sees no reason as to why a comment to that effect should be particularly highlighted in the opinion since

the very essence of the terms of reference requested the SCHER to examine exactly those particular aspects of DU as they relate to its inherent toxicity and potential risks to human health and the environment.

2. Health effects of heavy metal fumes formed as the result of DU use: Comments on the potential health effects of the heavy metal fumes formed as a result of the DU use were not examined by SCHER and not included in the opinion as this issue is outside the terms of reference for this opinion

3. Potential exposure to DU material spewed to the air outside a target vehicle: Published exposure data (section 3.4) indicate that even though material may be spewed to the air outside of the targeted vehicle, the assumption that most of the debris would be kept within the target vehicle is still valid.

4. Mixtures or oxides of other metals: Although SCHER agrees with the comment that the DU particles produced at a hard target are a mixture of oxides of other metals, SCHER concluded that the contribution of these materials to the toxicity of DU to humans would be negligible as they are only present in trace amounts and hence considered that no further evaluation of the potential risks that may be associated with exposure to these trace amounts is necessary.

5. Precautionary principle and DU: The risk assessment aspects of DU weapons cannot be discussed based on the 'precautionary principle', as suggested, because the 'precautionary principle' is a matter of risk management, not risk assessment.

6. Values in table 8: The Committee considers the values shown in table 8 to be meaningful because these data are based on state-of-art methodology.

7. Role of DU trade: The opinion of SCHER does not neglect the widespread trade – and therefore transports - of DU metals scrap after the 2003 invasion in Iraq. In section 4.1, page 18, it is specifically stated that “vehicles hit by DU should be made inaccessible to the general public and be properly disposed. Used DU ammunition should also be collected and properly disposed.”

8. High levels of ionizing radiation in Iraq that were found around Iraq were the result of the use of DU weapons. As no published scientific evidence is provided to support this comments, SCHER considers that this seems unlikely from the scientific point of view given the fact that the radioactivity of DU is rather low.

9. Values in table 7: Table 7 reports data assuming the worst-case scenario in terms of DU contamination. Representative values are not available and these values would have been lower.

10. Value of DU urine testing and ceramic nano DU particles: SCHER agrees with the possibility that small DU particles might be in the body but not in the urine sample (section 3.4, page 14). However, the urinary excretion of DU in soldiers involved in “friendly fire” incidents without retained shrapnel shows that the DU-particles formed are soluble and that urinary measurements are useful for exposure estimation. Furthermore, the fact that “if highly insoluble uranium is inhaled, urinary DU concentration could not be used to assess the exposures to DU” is implied in the relevant section of the opinion (page 14) and hence considered that the discussion of the section adequately covered the issue.

11. Exposure data for residents in areas where DU ammunition has been used: The issue is covered by Oeh *et al.* and quoted in the opinion (Table 8, page 15).

12. The DU incident in Colonie, NY, USA: In the view of SCHER, the development of high-sensitivity testing procedures for *detection* of small amounts of DU 20 years after

exposure (as presented in Parrish *et al.* 2008) is a different issue from *contamination* of the environment with DU and its risk assessment.

13. DU levels in urine of US, UK, and Canadian veterans: SCHER did not find any scientific references showing high “DU levels in urine for many U.S., Canadian and U.K. veterans”.

14. Use of ICRP modelling not applicable to DU: The SCHER disagrees with the notion that the use of ICRP modelling of natural uranium dust cannot be applied to DU because there is no other modelling available in the scientific literature. The health effects of ceramic nanosized DU dust may be detrimental but they are not well-documented in the scientific literature to allow for a proper risk assessment.

15. Consideration of non-scientific evidence: The comments concerning the use of evidence outside the scientific literature like policy decisions or interviews with physicians and scientists from Iraq and Kuwait as well as the references to the clean-up and collateral damage to civilians and military personnel are indeed related to the issue under discussion; however, these comments and references are not relevant to the risk assessment analysis performed by SCHER which is based solely on the available data in the scientific literature.

16. Suitability of exposure scenarios for DU: The SCHER considered that the use of exposure scenarios and the assessment based on environmental monitoring can be reliably used in the risk assessment of DU. This was confirmed by measured evidence of low or non-detectable contamination of DU in areas of general contamination with DU, including those where heavy fighting took place with documented intensive use of DU ammunition.

17. Questions on non-exposure of soldiers, disposal of DU hit vehicles, visits to sites in the Balkans where DU ammunition was used, information of risks of DU to the general public were outside the competences of the SCHER as they concern policy, risk management and risk communication and were therefore not addressed in the opinion.

18. Subtle effects observed in Gulf war veterans: The SCHER agrees that studies of Gulf War veterans done by Dr. M. A. McDiarmid and co-workers do state that there are some subtle effects in the veterans they have monitored for 16 years. However, overt health effects due to the release of DU from the embedded shrapnel were not observed.

19. Synergism between DU radioactive and chemical toxicity: In the view of SCHER, the weight of the available scientific evidence does not show synergism between DU’s radioactive and chemical toxicity. This may be theoretically possible but it has not been demonstrated experimentally to date. Articles in the scientific literature like the one by Miller *et al.* (2002) only speculate about that possibility. Furthermore, a confounding issue is that it is practically impossible to demonstrate synergism since all uranium isotopes are radioactive and one cannot study U toxicity without having some potential effects of radioactivity. Thus, the synergism maybe de facto present in all studies on uranium effects.