Critical evaluation of SCHER 2010

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Executive summary:

I have been invited to give an assessment of the scientific quality and therefore reliability, of the opinion provided by SCHER in their 2010 document entitled: "**Opinion on the Environmental and Health Risks Posed by Depleted Uranium**."

My expertise allows me to assess this document from the perspective of human health.

SCHER's opinion is essentially that the risks to human health are of very little or no consequence.

My assessment is that this opinion is not based on sound scientific grounds.

Questions SCHER was asked to address:

Q1) The SCHER is asked for an opinion building on an evaluation of available reports, including **but not restricted to those referenced above**, as to the environmental and **health risks** posed by DU.

Q2) In particular SCHER is asked to assess those **risks** that may arise from exposure to DU in contaminated areas following military activities with DU containing weapons.

Q3) SCHER is asked to take into account both the chemical and radiological toxicities of DU and, if appropriate, their possible synergistic relations.

Clarifications on terminology in the context of human health:

HAZARD: is an intrinsic property of an agent or substance that has the capability to cause HARM to human health.

HARM: is a detrimental effect, e.g., cancer, on the health of a person.

EXPOSURE: is the extent to which the HAZARD is present in the environment of persons

DOSE: the extent to which the HAZARD directly interacts with the tissues and organs of persons.

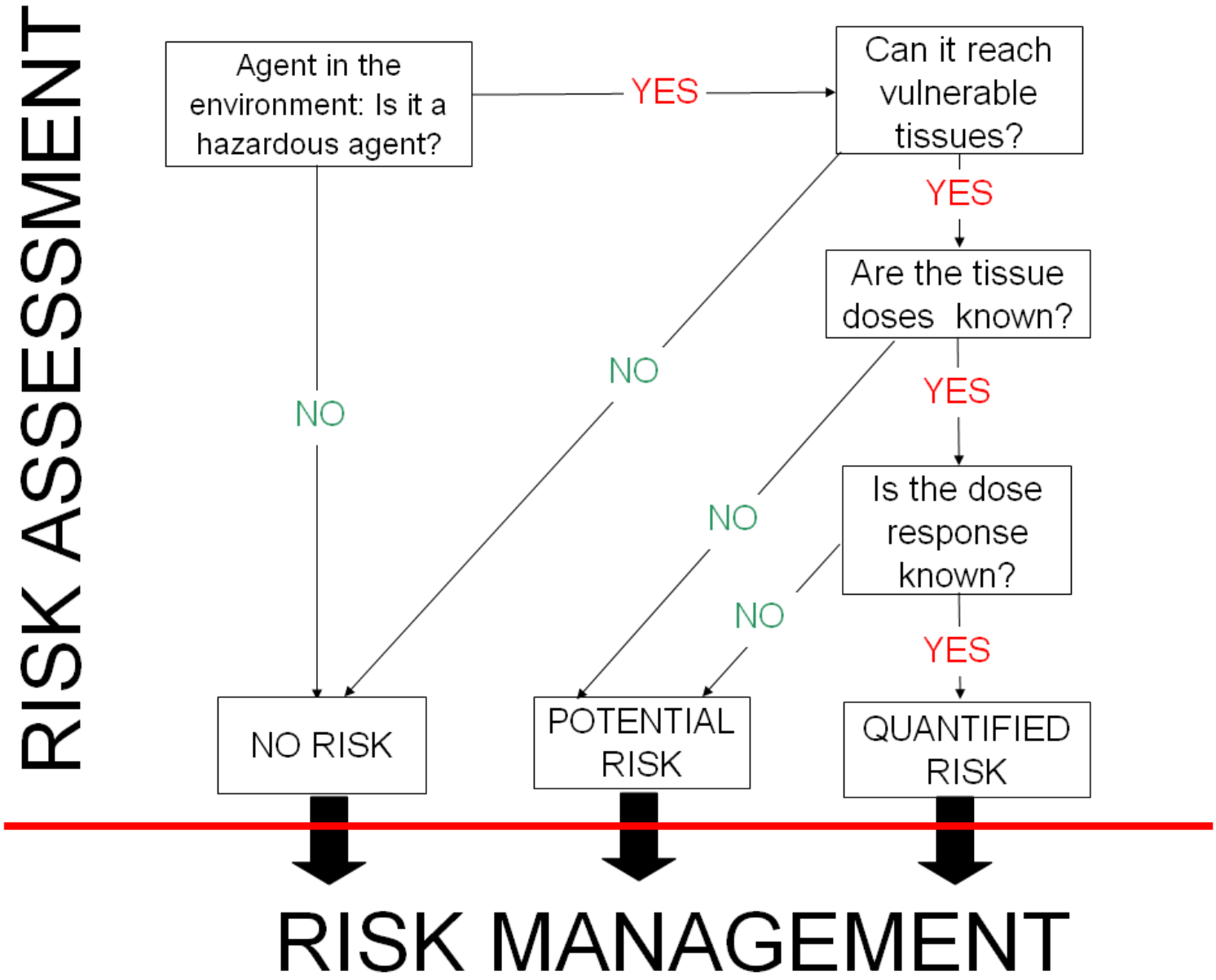
RISK: a quantitative statement of the relationship between DOSE and HARM in a given set of circumstances.

Questions SCHER might more logically have been asked to address:

Q1) The SCHER is asked for an opinion building on an evaluation of available reports, including but not restricted to those referenced above, as to the environmental and health **hazards** posed by DU.

Q2) In particular SCHER is asked to assess those **risks** that may arise from exposure to DU in contaminated areas following military activities with DU containing weapons.


RISK
ASSESSMENT
RISK
MANAGEMENT


RISK ASSESSMENT
Agent in the environment: Is it a hazardous agent?
YES
Can it reach vulnerable tissues?
YES
Are the tissue doses known?
YES
Is the dose response known?
YES
NO
NO
NO
NO
NO RISK
POTENTIAL RISK
QUANTIFIED RISK
RISK MANAGEMENT

Essentially SCHER is in agreement with strategy as they illustrate in their 2009 report entitled: “**Risk assessment methodologies and approaches for genotoxic and carcinogenic substances**.”

The HAZARDS of DU:

The WHO's International Agency for Research on Cancer (IARC) has designated uranium (inc. DU) as a Group I carcinogen (confirmed human carcinogen) due to its alpha emissions (Lancet Oncology; August 2009).

Extensive laboratory studies (*in vitro* and *in vivo*) show that DU (soluble and insoluble) is a genotoxin, that is, it damages in several ways the DNA in the genome and changes the properties (phenotypes) of affected cells.

The HARMS of DU:

Include, but are not necessarily limited to, cancer in any tissue that comes into contact (receives a DOSE from) with DU.

Key outstanding questions:

1) Which tissues can come into contact with DU and under what circumstances?

2) In relation to EXPOSURE what is the DOSE to those tissues?

3) What is the relationship between DOSE and HARM (health effect) for each tissue?

In the current state of knowledge:

1) Which tissues can come into contact with DU and under what circumstances?

   By inhalation, the lung, but due to the **partially soluble** nature of the dust produced in the military context DU can cross the air/blood barrier and become systemically distributed affecting many tissues including the germ cells.

2) In relation to EXPOSURE what is the DOSE to those tissues?

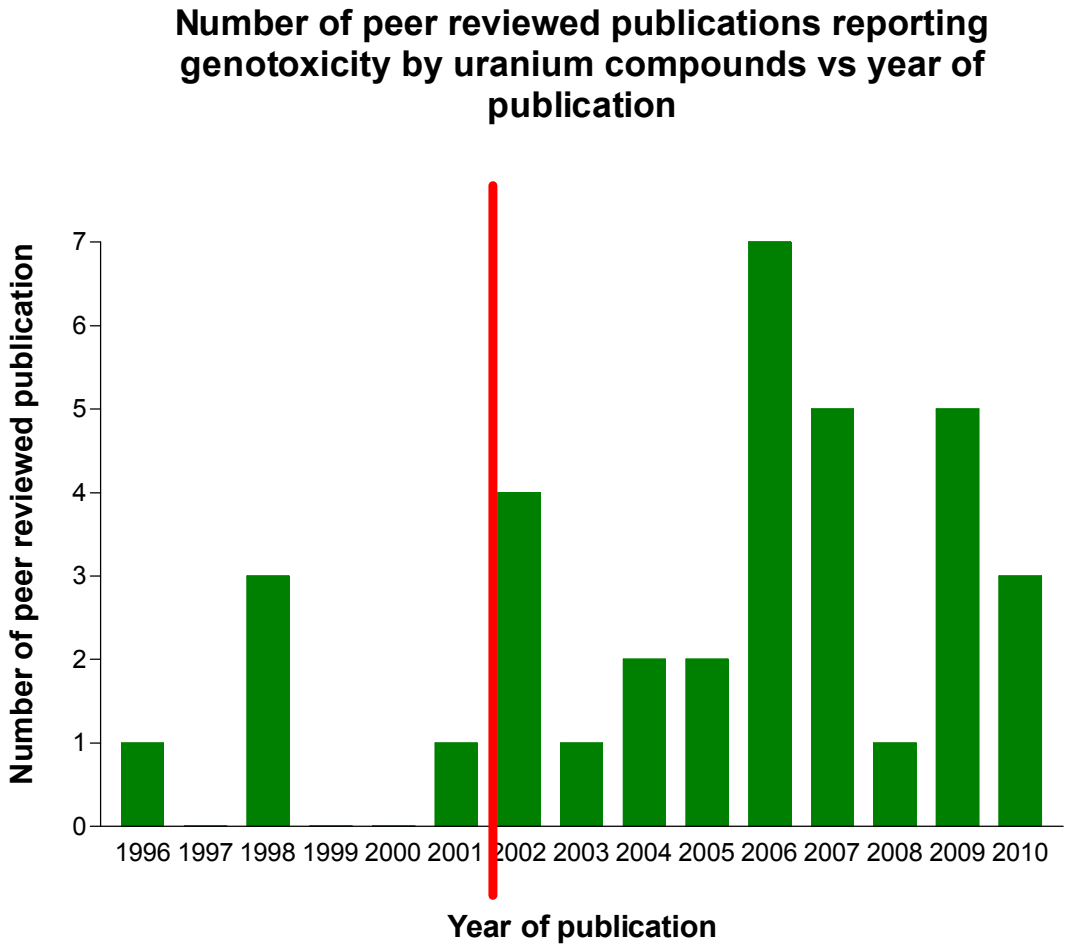
   This depends on the extent of re-suspension of environmental DU dust and the proportion of the soluble component at the time of inhalation; this declines with environmental weathering. In principle this question can be answered but only with further work.

3) What is the relationship between DOSE and HARM (health effect) (RISK) for each tissue?

   With the exception of the radiological risk to the lung; unknown at present.

The implications of genotoxicity:

The first indications that DU was genotoxic appeared in 1996 since then there have been several peer reviewed publications reporting it in many different forms and biological systems *in vitro* and *in vivo*.



The implications of genotoxicity:

In terms of the situation that existed in 2001/2 (red line) with respect to the toxicity of uranium, genotoxicity is a “game changer”.

At that time the radiological toxicity was **only** of concern in the case inhalation of insoluble U: soluble U, if it became systemic, was considered a **physiological toxic hazard** to the kidney.

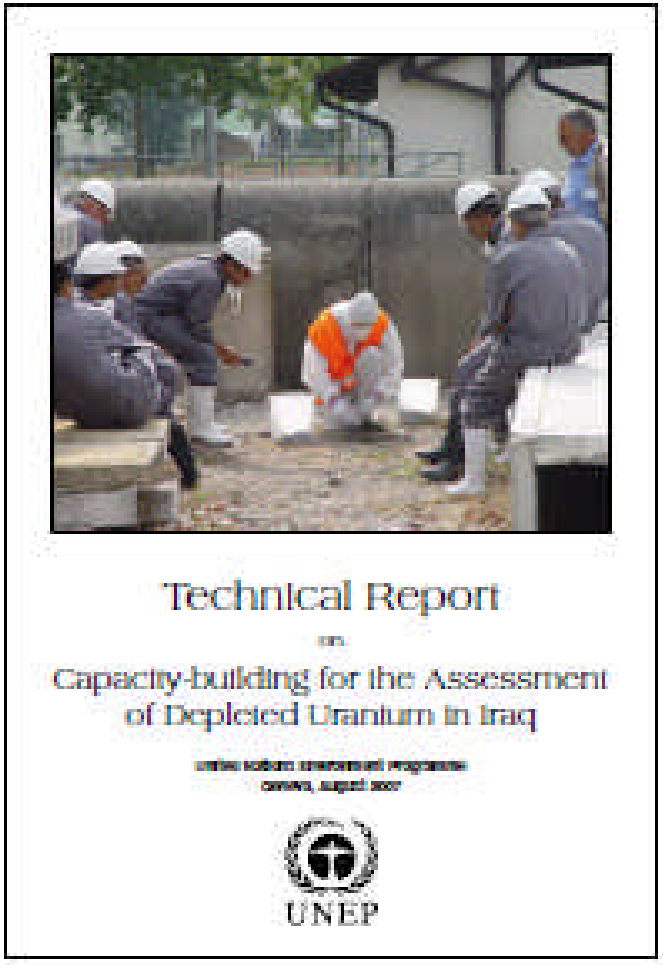
Natural U is ubiquitous in the environment but NOT in a soluble form that can be inhaled, so DU produced as a result of military activity **DOES NOT** have a natural analogue – it presents a unique **HAZARD**

SCHER's opinion (its risk assessment) in answer to question 1 relies almost exclusively on agreement with views expressed in publications (not peer reviewed) dating before 2004. None of these take into account genotoxicity as a HAZARD.

To take the an example from their opinion para 4.1:

"SCHER therefore **agrees with** the conclusion of UNEP, IAEA and others that environmental and human health risks due to a potential widespread distribution of DU are not expected due to the very limited exposure to DU as compared to background exposures to natural U (EU-EURATOM, 2001; UNEP, 2001, 2002, 2003, **2007**; UNEP/UNCHS, 1999; WHO, 2001, 2003b)."

However, UNEP 2007 says in its conclusions the following:



"The assessment also found that local people were being exposed to DU and other heavy metals in uncontrolled scrap yards and scrap metal processing areas, with potential consequences for their health. Indeed, it should be noted that the toxic effects of DU may be more serious for human health than its radiological effects"

In summary:

SCHER have performed a risk management exercise not a risk assessment.

SCHER have failed to take account of the unique properties of DU resulting from military activity and the substantial evidence of genotoxicity that has accrued since around 2001/2002.

They have dismissed RISK without the **necessary** knowledge of the relationships between EXPOSURE and DOSE and DOSE and HARM.

As a consequence SCHER's 2010 opinion cannot be considered to be a scientifically based risk assessment.

My written report provided to the Chair substantiates my opinion in more detail.

Postscript:

I would in fact go somewhat further than dismissing this report as simply "failing to answer the questions". There are two issues which profoundly disturb me as a scientist:

1) Given the 2009 SCHER report I referred to earlier it is difficult to attribute the failure of the 2010 report to do a proper risk assessment to lack of appropriate expertise; it seems to me that this must be to some extent deliberate.

2) Some of the statements in the report are highly misleading, for example, concerning assurances that can be drawn from the very limited "veterans study" in the USA. SCHER surely cannot have failed to understand the limitations, in the context of effects like cancer, of studying fewer than 80 individuals for however long.

Section 4.3 Question 2

"Further **support for an absence of health effects** of lower DU exposures can be derived from the medical monitoring of Gulf War veterans with embedded DU shrapnels and health monitoring of other veterans. Individuals with embedded DU shrapnel have much higher concentrations of total U in blood and urine as compared to the general population and to soldiers without direct DU exposure (Gwiazda et al. 2004). Sub-clinical effects have been observed in high-level DU concentrations (McDiarmid *et al.*, 2009), but overt health effects due to the release of DU from the embedded shrapnel were not observed (McDiarmid *et al.*, 2009) by health monitoring for more than 16 years."

Rate, molecular spectrum, and consequences of human mutation

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This contribution is part of the special series of Inaugural Articles by members of the National Academy of Sciences elected in 2009.

Contributed by Michael Lynch, December 3, 2009 (sent for review September 13, 2009)

Quoted from the Conclusion

Thus, the preceding observations paint a rather stark picture. At least in highly industrialized societies, the impact of deleterious mutations is accumulating on a time scale that is approximately the same as that for scenarios associated with global warming—perhaps not of great concern over a span of one or two generations, but with very considerable consequences on time scales of tens of generations. Without a reduction in the germ-line transmission of deleterious mutations, the mean phenotypes of the residents of industrialized nations are likely to be rather different in just two or three centuries, with significant incapacitation at the morphological, physiological, and neurobiological levels.