Appendix B

Concerns about Generic Quantitative Risk Assessment

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Member/Alternate Member of the UK Delegation to the EPC. (1998-2005)
Member of the British Pharmacopoeia Commission including Chairmanships of various Expert Advisory Groups. (1984-2005)
Member of the Committee on the Safety of Medicines (CSM). (1990-2002)
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Member of the Committee on Review of Medicines. (1984-1992)
Evaluator of over 5000 Marketing Authorisation Applications for Medicinal Products.
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Concerns about the Generic Quantitative Risk Assessment and the Environmental Statement within the Outline Planning Application for development of the former ROF site at Bishopton

1. **Nature of Site and its History**
   Appendix 11.1, Georgetown History describes the history of development and use of the site as an explosives and munitions factory from its commencement in 1915 to the late 1910s and early 1920s. Further information is given in Appendix 11.1 Preliminary Risk Assessment, Section 6.5.

   Its subsequent official history is much less well documented as stated in that and many of the other documents. In particular, the post WWII usage history appears largely to have been obtained from anecdotal statements by former employees of the ROF with very few reference sources being cited.

   The later uses appear to have included much disposal of many different types of munitions as well as continuing manufacture of several types of high explosives and filling of large munitions, work on a variety of rocket propellants, disposal of certain types of larger rockets.

   The importance of the apparently mixed work load of the ROF and of the seemingly very limited records is the uncertainty that results in knowing what sorts of potential contaminant there might be and so in what should be looked for.

   Do BAE Systems have a <u>full</u> audit, both type and quantity, of the chemical and biological hazards throughout the functional history of the site? If not then how can anyone be confident that all contamination can be removed?

   How many uncontrolled incidents have there been during the operation of the site, and do BAE Systems have a <u>full</u> audit, both type and quantity, of the various chemicals and biologicals in the case of such incidents? If not then how can anyone be confident that all contamination can be removed?

2. **Toxicological Points to Consider**
   The significance of the latter point is that the land, water and air sampling strategy adopted by BAE and the range of analyses done was largely defined by what was considered to have been the past uses and hence the likely sources of contamination of the various 'zones' into which the site was divided. Thus what is known about contamination and potential toxic risks has been constrained by the known history of the site and certain assumptions. How reasonable is this?

   It is noted in particular the firm statement in Appendix 11.1, Preliminary Risk Assessment, #7.3.4 that 'Depleted uranium munitions' were only handled in the 'Environmental Test Facility' but with no supporting reference source. Presumably on that basis no further information about testing for radioactivity elsewhere in the site is given. How confident is the exclusion of the presence of radioactive debris, even low level materials, elsewhere in the site and their possible contribution to health risks? Has the sampling strategy been adequate in this respect?

Has a sampling procedure been implemented, which is scientifically and statistically appropriate, for both soil and water (both ground water on the site and running water adjacent to the site)? What evidence is available to support this?

Will BAE Systems provide details of the sampling programme (in detail) so it can be subject to public scrutiny?

3. The adequacy of the BAE sampling and analytical strategy is so critical that it deserves close attention.

   The BAE sampling and analytical strategy has resulted in a very extensive body of information about a number of contaminants on the site in water, soil and air.

   As stated in the ‘Generic Quantitative Risk Assessment’ [Appendix 11.4; **GQRA**] and supporting documents, the initial, Stage I assessment of contamination is an early phase and more detailed and extensive investigations will be required of particular areas and substances.

   However, certain key points are made [*ibid* p5, #1.6]

   Certain areas could not be investigated yet because of the possible presence of explosives. This emphasises the preliminary nature of the present BAE Risk Assessment and emphasises the need for the Stage II investigation of contamination.

   And, the pattern and extent of contamination was broadly comparable across all the different zones investigated [GQRA, P8, #2..3.3], which may suggest that reliance on limited numbers of point analyses could be of limited reliability, i.e. basing sampling and analytical work and subsequent remediation on assumptions about past use and types of contamination at particular places may not be acceptable.

4. The GQRA has generally adopted standard approaches to indicate potential risks to humans from the pollutants detected.

   Where possible, recommended UK approaches and standards have been employed. These are sometimes supplemented by Dutch government standards when there was no recommended UK procedure. Use of a non-UK approach in the absence of a UK recommendation has not always been the case however, notably for dioxins and furans.

   Why have the assessments and standards employed in certain German Länder, for example, to evaluate soil contamination by dioxins and furans not been considered?

   Will a portion of each sample taken be made available for independent analysis by independent experts?

5. There has been reliance in the GQRA on standards produced by the ‘SNIFFER’ model for certain classes of substances. There is only a brief justification for this approach and its assumptions.

   The nature, workings and underlying assumptions of the SNIFFER approach to deriving tolerable concentrations [GSACs] in soil of, for example, Total Polycyclic Hydrocarbons, PAHs, Dioxins and Furans, and Explosives etc should be fully explained and justified. Comparison with the standards employed in other countries would show what confidence there could be in values obtained from the SNIFFER methodology.

6. Many different metallic contaminants have been identified on the site and it is possible that an even wider range has been handled at times because of the presence on site of explosive, incendiary and signalling munitions, the latter potentially containing a variety of metal compounds to produce colours.

   Why has barium been omitted from the risk assessment Table in #4.4?

7. Many of the chemical contaminants within the site are extremely toxic. Will BAE Systems conduct a full and complete analysis for <u>all</u> of the chemical and biological materials in <u>all</u> of the soil samples, taken according to the <u>very best</u> statistically acceptable sample procedures?

8. In many of the Risk Assessment sections for various materials and substances [#4’s] in the GQRA it is noted that ‘Statistical Outliers’ have been omitted, which has the result of lowering many mean values to below any action limit.

   Is this statistically reasonable?

9. The analyses appear to show significant amounts of contamination in Zone R, ‘Agricultural Land’, where there are many values for pollutants close to those in many of the former industrial areas. Has this any implication for the extent and nature of the Stage II sampling and analytical strategy required to properly define the risks? Has it any implication for the designation of areas as ‘Core Development’, ‘Recreational Land’ etc and for the tolerable levels of contaminants in the different areas?

10. There are contaminated waste dumps within the site. Is there a <u>full</u> audit/mapping of all these sites – their location, the nature of the materials contained and the effectiveness of the present containment?

11. Can BAE Systems provide assurance that they have a <u>full</u> understanding of the toxicities (both human and animal) and biological half-lives of <u>all</u> the chemical and biological materials involved?

12. Will the identities of the contracted laboratories involved, the analytes to be investigated, the methods to be used and the raw data generated, be made available for independent assessment?

13. **In the event that the site is developed and subsequently there are adverse events with regard to public health, which public office (as opposed to public officers) will be held publicly accountable?**