Study on the Environmental Effects of Novel Materials and Applications – Questions for Written Evidence Exercise

Novel materials, along with new forms and applications of existing chemicals are continually being developed to help make technological advances and improve performance. An example of such a development is rhenium, which has previously been just a waste product from copper mining. It is now used in nickel alloys for jet engines, enabling them to fly at temperatures significantly higher than previously, so lowering fuel consumption. Nanotechnology and nanoscience are also developing at a rapid pace.

Although there is a large body of work which looks at the effects of the environment on novel materials, there are very few studies on the environmental impacts of novel materials. The study could therefore be usefully broken down into three broad themes:

- Scene-setting: what are novel materials and what developments are likely over the next 5-10 years? Which ones should be investigated for the purposes of the study?
- Environmental and health impacts of novel materials
- Governance and regulation issues

<u>Theme 1: Scene-setting: what are novel materials and what developments are likely over the next 5-10 years? Which ones should be investigated for the purposes of the study?</u>

1. What do you understand by the term novel material? How might novel materials best be classified? What novel materials should be included in the study?

   Novel materials can be wholly new chemicals, new forms of existing materials or may even be existing materials that are used in entirely new ways and applications. It would be best to consider only those materials that fall into the first two of these categories ie the wholly new chemicals and the new forms of existing chemicals. Nanomaterials could fall into either of these categories and certainly should be included in the study. It would also be valuable to consider novel organic and inorganic materials that are not nano since it would not be appropriate for the study to focus merely on nanomaterials.

2. At what point does a novel material cease to be novel?

   A novel material ceases to be novel when it is either a material of commerce or is recognised beyond a select band of scientists within the laboratory or company of origin.

3. What sort of materials and technologies are being developed – over the next 2, 5 and 10 years?

   Just as new or novel materials and technologies have emerged throughout history there will be new materials and technologies being developed over the next 2, 5 and 10 years largely in response to particular needs. These needs may be in many areas, but it is expected that given the current issues around alternative sources of energy and associated climate concerns, there is likely to be an acceleration in the development of materials and technologies to address issues and unmet needs in these areas. Thus, new materials are being and will be developed to meet the needs of inter alia solar power, hydrogen storage and use, wind power, low cost lighting, fuel cells, batteries and battery powered vehicles. These materials may include nanomaterials of a variety of different chemistries including metal oxides and doped metal oxides as well as more complex metal compounds such as those that might be required for low cost lighting. Technologies will most likely be required to combine these new materials with existing materials in forms suitable to

optimise their performance. This may require combinations of technologies that have not been used to date especially in the world of solar power and hydrogen storage and use.

4. What are the drivers for the development of novel materials? What are the potential benefits of novel materials and the drivers for these?

   The drivers are generally meeting unmet needs either those that are well understood and defined or those that the "customer didn't know he had" the latter because "the customer" hadn't access to the new material of technology now available.

5. Can the development of novel materials have an impact on resource depletion?

   As always if a new materials finds universal acceptance there is a danger that it my have an impact on resources. This would have to be managed to minimise the potential impact in the future as it is now.

6. Are issues of re-use and recycling considered when developing novel materials – e.g. could the phasing out of metals for composites make recycling difficult?

   Currently product development generally takes account of the disposal and potential for recycling that might be required at end of life for a material or range of materials within a product. This would be the case whether there is a new material present or not and indeed in certain industries is a prerequisite part of the product design.

7. Are novel materials likely to alter the amount of waste generated and the ways in which it has to be handled?

   Novel materials may reduce the amount of waste generated or at least change the form and type of waste. Plastic based composites for example will be used in ever increasing amounts in the future to replace metals and will utilise less material compared with metal. The handling criteria of composites will be very different, but nor necessarily more difficult compared with metal even where the composites contain nanomaterials since the nanomaterials will be embedded in the carrier plastic and would not require separate disposal.

<u>Theme 2: Environmental and health impacts of novel materials</u>

8. What are the most important impacts that novel materials could potentially have on the environment and human health? What are the main mechanisms and pathways for those impacts? How do we begin to conceptualise environmental impacts when we are in such unknown territory?

   The impacts that novel materials may make on human health and the environment are totally dependent on the exposure that either humans or their environment have to these materials. It is highly unlikely that novel materials in their own right will be exposed, but rather there will be some sort of composite or structure that contains the new material and it would be this composite or structure that would have to be considered. Since any risk is based on a combination of hazard and exposure it is the exposure that most often defines the extent of the risk. Where there is no or limited exposure risk can generally be contained and managed in an acceptable way. Alongside risk, benefit should also be considered since there are potentially occasions where there may be an acceptable risk provided the benefit is significant and measurable. For humans the most likely exposure route is via inhalation and so understanding the likely response to a new material in its native form or in its product form is fundamental to defining its "safe use". Similarly, the first

steps in understanding the potential environmental effects involve a full understanding of the chemistry of the material and its potential interactions in a water or soil. Primary tests need to be defined that allow comparison in each case to provide the "read across" capability that will mean that each new material does not have to be treated alone.

9. Do novel materials have the potential to help 'solve' environmental problems, e.g. land contamination, energy generation? If so, how and are there potential risks?

   There are novel materials currently being used and under development that are designed to "solve" environmental problems. Examples include nanoparticulate iron for land remediation, nanoparticulate cerium oxide as supplied by Oxonica for improved fuel combustion efficiency and hence lower fuel use and lower emissions. There also novel materials being developed to improve the performance and hence output of batteries that will result in more efficient electric vehicles. There are potential risks as there are with any new technology, but as indicated above risks are generally taken account of at an earlier stage of development than they were in the past. This allows more effective and generally more efficient products to be developed.

10. Do we have sufficient research and monitoring in terms of understanding toxicology and exposure in place in order to understand the effects of novel materials on the environment and human health?

    This is a question for HSE and the Environment Agency who can provide responses from direct experience.

11. Are current testing protocols 'fit for purpose' to test the potential environmental and health impacts of novel materials? If not, what needs to be developed or are there other strategies needed to address this issue?

    There are testing profiles for new materials that may also be applied to new nanomaterials and they have been tried and tested for a number of years, but should continue to be challenged as new knowledge comes along about the chemistry of new materials and the potential interactions between these new and existing materials. This applies to both environmental and human health.

12. Do we have adequate methodologies and instrumentation to detect and monitor engineered free nanoparticles in the environment?

    There are existing methodologies and instrumentation to detect and monitor such particles in the atmosphere, but new equipment is being developed and tested both in government laboratories and by companies. Generally equipment is non discriminatory in terms of combinations of particle size and also particle chemistry. However with new equipment being made available collection of specific particle size ranges allow detailed chemical analysis to be conducted to define the nature of particles collected. Oxonica is a member of a Framework 6 programme, Nanosafe 2, which has as one of its objectives the development of innovative detection, traceability and characterisation techniques for engineered nanoparticles.

13. Are the full life cycle impacts of novel materials being considered in terms of their potential effects on the environment and human health?

    Generally, companies would consider the full life cycle implications of novel materials, whether they be nano or not. Oxonica has certainly considered this with particular reference to its nano diesel fuel additive, Envirox, both in terms of preliminary ecotoxicology studies and an eco-

efficiency analysis. Alongside this, exposure during manufacture of Envirox and Optisol UV absorber has been considered with the manufacturers for these two products.

14. How can you look at the effects of novel materials as a coherent whole, if they are even more difficult to categorise than nanomaterials?

    The principles that might apply to nanomaterials can equally be applied to each of the categories that comprise novel materials. It is therefore acceptable to look at the effects in a consistent way across the categories. Processes such as Risk Assessment, for example, can be applied whatever the material or product whether it is old, novel or nanomaterialt. The principle remains the same - the process is material or product independent.

15. Are there lessons to be learned from 'green chemistry' – and ways that manufacturing could be made more benign?

    I am not quite sure what "green chemistry" covers, but lessons should be learned from any relevant source and manufacturing should be made as benign as possible consistent with balancing the economics of the processes involved.

Theme 3: how to manage novel materials in society: governance and regulation

16. Is REACH the right framework for regulating novel materials and nanotechnologies?

    REACH is not yet tested and so it is premature to say if it is the "right framework" for regulating novel materials and nanotechnologies. It does not discriminate on nanomaterial forms of existing materials, but will discriminate on novel materials whatever their form.

17. Are the regulations which affect novel materials fit for purpose? Is existing legislation sufficient to deal with potential problems that could arise during the different stages of the novel material's life cycle, i.e. manufacture, use and disposal?

    Existing regulations require novel materials to be registered on chemical databases in Europe and in the US and testing criteria have been long established for such materials. The tests are under continual review as knowledge on new tests grows. Test bodies are therefore able to add tests as appropriate to provide a broader basis for understanding the hazards associated with a novel material and an assessment of the potential risk.

18. Is the UK, EU and global science and knowledge base sufficient to support current legislation frameworks and any future regulation? Where are the gaps and what are the research priorities?

    It is impossible to say at any given time if the knowledge base is sufficient. Ongoing research and associated test development continue to fill any perceived gaps and to extend the test base to provide the expanded knowledge base that might be required in the future.

19. Is the UK's and EU's research funding sufficient in this area? Is it being delivered in the right way?

    More focussed funding by either or both the UK and EU would be preferable to the very large consortium based programmes currently funded especially by the EU. Funding focussed on the companies and organisations with recognised expertise with relatively short timelines would be

preferred over multi year programmes with many participants some of whom join a consortium to learn rather than contribute.

20. Can novel materials and technologies be effectively governed and regulated if it is not possible to obtain exposure data before products containing novel materials are produced and made available to consumers?

    While there is a paradox in not being able to obtain exposure data on novel materials, companies can conduct tests on the materials or read across to imply performance from exposure data on materials of similar chemistry, particle size or form. It is accepted that complications can arise with, for example, carbon nanotubes in all their various guises and this is an issue that manufacturers of such materials have to address preferably together notwithstanding intellectual property constraints. On the subject of the precautionary principle, it is very important that a full and proper risk assessment be conducted on the basis of hazard and exposure such that an appropriate conclusion can be drawn.

21. What is the role for engaging the range of different interests and perspectives, commercial, political, public and societal, on the development of novel materials in the context of global markets?

    While there can be considerable value in engaging a range of different interests and perspectives, uninformed opinions can be both dangerous and stifling of genuinely beneficial novel material developments. It is therefore the responsibility of the company or organisation involved to consider both the benefits and potential risks associated with novel materials and to publicise the conclusions from consideration of all available data.

22. Are there general lessons to be learned from the development and use of other novel technologies, e.g. the development of genetically modified organisms?

    There is a significant lesson to be learned and that is that each new development is unique in its own right and a direct comparison can not be made with any previous new technology introduction. However, let's not be afraid of nanomaterials nor more importantly let's not frighten the public about nanomaterials in the way the tabloids in particular were able to do with GMO. There are many benefits to be realised from novel materials including nanomaterials and it would be a significantly wasted opportunity if these benefits could not be realised because of allowing the tabloids to dictate the agenda.

23. How can an appropriate balance be achieved in the design of regulatory systems to effectively manage uncertainty?

    The risk-benefit review is paramount in effectively managing uncertainty and should be part of every product development process. This will provide the appropriate balanced perspective.

24. What are the implications for liability when problems arise even if procedures are properly followed in good faith: who should bear responsibility and what issues arise for insurance and redress?

    I have no opinion on insurance or liability issues.

25. How would you apply the precautionary principle to the management and regulation of novel materials?

If any doubt exists about the safety of a product then a conclusion can generally be drawn using risk and benefit analysis procedures without recourse to the precautionary principle which has its detractors.

26. In debate about new technologies, questions of need and control, as well as questions about consequences, have emerged as being important. To what extent should our study engage with questions about the need for novel and novel uses of materials; about who exercises control over such technologies; and about public trust in the institutions involved?

It is extremely difficult if not impossible to stifle or stop innovation and so applying controls over such technologies has to be managed carefully. The public expects and wants progress and is impatient for new materials and products especially in the medical world and authorities have to be mindful of this considering as before the risk-benefit balance for these new materials and products.

And finally:

27. Are there any other major questions or issues that the Commission should examine?