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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

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?

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?

We have deliberately framed our inquiry to extend beyond nanotechnology per se. However, we do not intend to address all innovation and in particular, do not feel that it would be appropriate to cover the large number of organic molecules introduced each year particularly those produced in small quantities in highly regulated and specialists sectors. This includes the pharmaceutical and biocide industries where the biological activity, at least (though not the full spectrum of potential environmental effects) is characterised as part of the product development and approval process. In our view the study should be based on a working definition of novel materials which would encompass:

- *New uses for existing materials where the new usage may lead to substantially different exposures and hazards than current uses so that experience based on the current usage may not be a good indication of potential problems.*

- *New forms of existing materials: this is intended to include nanomaterials where significantly different functionalities are developed as a result of changing the scale and shape and arrangement of the particles at the nanolevel, e.g. the expression of significant chemical activity at the nanoscale of materials such as noble metals which may exhibit significant chemical reactivity or biocidal effects which are not manifested in the bulk form.*
- *Use of new materials such as metallic elements (Rhodium, Yttrium etc) and compounds derived from them. There is likely to be some interplay between all these categories, for example some nanotechnology products will include not only new forms of existing materials, but also other new substances, either as adjuncts, dopants or ligands and both new materials and nanoproducts may both be ultimately incorporated in new devices such as ICT equipment.*

A1. All materials in their nanoform should be included. Functionalised (i.e. surface modified) materials should be tested with and without the surface modifying substances and the longevity of the surface modification should be assessed.

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

What lies behind this question is to some extent an exploration of the degree to which unexpected environmental consequences may not emerge until some considerable time after the material has been in widespread use. The effect of refrigerant gases on the ozone layer is clearly one example but the developing evidence about the long term effects of non-degradable plastics particularly in marine and aquatic environments may well be another. The issue also relates to questions of what mechanisms might be set in place to monitor environmental impacts to give warning (even if not always early warning) of potential difficulties as materials enter the environment and, even if they do not degrade, change in form through weathering and mechanical break up into smaller particles over time.

A2. Engineered nanoparticles released in the environment will undergo transformations through physical/chemical degradation, agglomeration, interaction with organic matter, aging, and other such processes. This is likely to have an impact on their potency as pollutants, as well as on our ability to trace their fate.

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

A3. Self assembling nanomaterials.

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

What we have in mind here is essentially to try to tease out the underlying functionalities and products or improved performance which the use of new materials is seeking to deliver for society. Therefore it is part of the process of trying to identify the potential benefits which are discussed in more detail in Theme 2 below.

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

A4. Could be a positive impact due to reduced quantities needed if materials are in their nanoform.

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

Theme 2: Environmental and health impacts of novel materials

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?

Embedded in this question are several issues. On the one hand there are fairly straightforward issues related to potential negative impacts through the biological effects of new materials on organisms (plants, animals and micro organisms) in soil and water. Beyond this there is also the question of chemical and other interactions with parts of the environment such as the depletion of the ozone layer. There are also potential positive impacts where the use of the new material may allow the replacement of existing technologies which have significant negative impact on the environment. In addition potential uses also exist for new materials in remediation and improvement of water and soil quality and improvements in the efficiency of processes such as energy generation and power transmission. New materials may also have indirect effects on the environment. For example, certain materials may be able mobilise substances in soil in advantageous ways, but they could also lead to the mobilisation of hazardous material. These are intended only as examples and we would be very grateful for further thoughts on these issues.

A8. This theme has been explored in several recent review papers (e.g. Nel A, Xia T, Madler L, et al. 2006. *Science* 311 (5761): 622-627; Tsuji JS, Maynard AD, Howard PC, et al., 2006. *Toxicological Sciences*, 89,42-50; Guzman KAD, Taylor MR, Banfield JF, 2006. *Environmental Science & Technology* 40, 1401-1407; Hardman, R, 2006. *Environmental Health Perspectives*, 114,165-172.). However, conceptual models can only go so far; it is important that the scientific community working in this area is given appropriate support to generate good quality **experimental** data.

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?

A9. Very likely, by showing greater reactivity in the presence of pollutants (e.g. zero valent Fe nanoparticles). However, potential risks are largely unknown (see also reply to Q.8).

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?

A10. Clearly not. Existing studies to date are small, fragmented and contradicting.

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?

A11. Existing toxicity protocols were not designed with nanomaterials in mind and fail to assess the toxicity of such materials at the most fundamental level. Ideally new tests should be devised specifically tailored for engineered nanomaterials and their special properties. If existing tests are used, they should, at the very least, account for potential transformations of the nanomaterial when introduced in the test media and should monitor the fate of the nanomaterial in the media for the duration of the tests.

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

A12. Clearly not and this is a major concern. My research group is working towards developing a method of tracing isotopically modified 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?

We are particularly concerned here about potential exposures through manufacture, use and disposal both in relation to the regulated official disposal routes (for instance for electronic products) and illegal or accidental losses e.g. leakage from accidents, disposal direct to land/water. There are also issues about products which constantly abrade during use, creating dust or other mobile forms of release into the environment, even for products which are manufactured to be essentially fixed but may wear away in use.

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?

A14. In my opinion, it is too early to answer this question with current level of knowledge.

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

A15. Biomimetic approaches.

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

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

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?

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?

A18. Many existing toxicology studies are very small in scale and therefore isolated; furthermore, there are a lot of contradictions in the literature. A major gap is the lack of a link between nanomaterial physicochemical properties (i.e. what is it that makes them toxic) to their impact on the environment and/or human health.

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

A19. It is important that some large scale studies are funded for the reasons explained above.

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?

We have been made aware that even within carbon nanotubes there are potentially at least 10,000 possible formulations due to variations in substances added to the tubes and the actual physical size of the tubes themselves: all of these can affect functionality and potentially their environmental and biological behaviours. It is clearly not possible to apply conventional testing protocols because of the sheer numbers of formulations involved. If the industry is to develop it is inevitable that there will be a degree of uncertainty. Although research can seek, and is seeking, to derive certain basic parameters to help identify and predict which materials may be problematic, some degree of uncertainty and ignorance is likely to remain. The social need is to develop regulatory mechanisms which reduce the risk of deleterious outcomes, while permitting the process of innovation to develop new materials for social benefit. The precautionary principle in its various formulations has been seen as one possible approach; would it be appropriate in this case or are there other approaches which would be preferable.

A20. Yes, because although exposure levels may currently be unknown, actual exposure is inevitable. However applying the precautionary principle may be unnecessarily draconian. Clearly new funding at an appropriate level, made available immediately, is the best way forward to avoid both late discovery of potential deleterious effects but also extreme measures that ultimately prove to be unnecessary.

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?
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?
23. How can an appropriate balance be achieved in the design of regulatory systems to effectively manage uncertainty?
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?
25. How would you apply the precautionary principle to the management and regulation of novel materials?
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?

And finally:

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