

Royal Commission on Environmental Pollution

Submission of Written Evidence to the Study on Novel Materials

1. Introduction

The Health & Safety Executive (HSE) welcomes the opportunity to submit written evidence to the study on Novel Materials, which is being conducted by the Royal Commission on Environmental Pollution. In responding to the request for input, consideration has been given to those aspects of the study, that relate to HSE's:

- mission of “protecting people’s health and safety by ensuring risks in the changing workplace are properly controlled”,
- role as the responsible regulatory authority for various aspects of legislation covering industrial chemicals and biocides
and
- responsibilities as the Competent Authority for REACH.

The comments in the following section relate specifically to the human health rather than environmental impacts of novel materials and focus mainly on the questions concerning the definition, detection, monitoring and regulation of such materials.

2. Response to Individual Questions

Q1. 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?

HSE agrees with the proposal by the RCEP, that the term “novel material” should extend to compounds other than nanomaterials and should encompass in addition new uses for existing materials, as this provides a useful and practical working definition. Limiting the scope of the study to those materials, which are not the subject of effective control through other highly regulated and specialist sectors such as the pharmaceutical and biocide industries would also seem to be a sensible approach.

Q3. What sort of materials and technologies are being developed – over the next 2, 5 and 10 years?

Through its Horizon Scanning system, HSE aims to “systematically anticipate, identify and prepare for new or changing risks in the workplace”. Among the current issues highlighted by this process, there are a number, which are likely to involve the development and use of novel materials as defined by RCEP.¹

New materials and technologies are expected to appear in support of areas as diverse as energy generation, nanotechnology and sustainable development, as well

¹ <http://www.hse.gov.uk/horizons/library.htm>

as in response to environmental and other legislation such as RoHS (Restriction of Hazardous Substances Directive), the Solvent Emissions Regulations and REACH.

Some specific examples of materials and technologies, which HSE believes are likely to grow in importance over perhaps the next 2-10 years, are:

- Energy generation – carbon capture technology, the hydrogen economy (including storage systems, possibly based on hydrides), components for fuel cells and photovoltaics and alternative fuels such as biodiesel.
- Nanotechnology – continued rapid growth in the development and use of a wide range of nanomaterials, principally nanoparticulate metals and metal salts (oxides, sulphides, selenides) and carbon nanotubes.
- Sustainability – various Green Chemistry and other initiatives based on more efficient process design, industrial biotechnology and novel materials as described e.g. in the plans of the European Technology Platform for Sustainable Chemistry.² The use of process intensification, possibly based on novel ionic solvents or supercritical fluids is foreseen here, together with the development of feedstocks derived from renewable sources as opposed to fossil fuels. The development of the concept of the biorefinery is predicted, with an associated increase in the use of biological as opposed to chemical processing, involving technologies such as enzymatic catalysis and anaerobic digestion.
- Environmental – substitution of chemicals of high concern is expected to continue, with e.g. the removal of persistent organic pollutants and the replacement of high VOC solvents by a variety of alternative systems (aqueous-based, radiation- curable and other solvents with high boiling points).
- Advanced Materials – e.g. the OSI's study into the Wider Implications of Science and Technology (WIST)³ points to developments in electronic and intelligent polymers and "Smart" materials.

Q4. *What are the drivers for the development of novel materials? What are the potential benefits of novel materials and the drivers for these?*

Key drivers for the development of novel materials, in addition to commercial considerations, include changes to environmental and other legislation, the need to ensure the security of supply of energy and concerns around climate change and the reduction of green house gas emissions. As well as raising concerns over energy supplies, uncertainty over the future availability of oil is a driver in the development of alternative sources of feedstocks for the chemical industry. HSE supports any developments that are potentially less harmful to human health and which reduce the incidence of occupational ill health or allow for greater substitution of hazardous materials, providing there are no significant deleterious impacts of such developments on the economy, the environment or society in general.

² <http://www.suschem.org/>

³ http://www.foresight.gov.uk/HORIZON_SCANNING_CENTRE/WIST/Index.html

Q8. *What are the most important impacts that novel materials could potentially have on human health? What are the main mechanisms and pathways for those impacts?*

Novel materials clearly have the potential for both beneficial and harmful impacts on human health. Nanomaterials for example are promoted as offering a range of potential benefits in terms of drug delivery, diagnostics and therapeutics. However there is a need to develop an improved understanding of the hazardous properties of engineered nanomaterials and the possible risks associated with their use resulting e.g., from exposure through inhalation, ingestion and dermal contact and also from potential fire and explosion hazards. At present it is the potential extent and consequences of inhalation exposure, which are of particular concern. HSE believes that it is important to take a holistic view of the impacts of novel materials, positive and negative, in relation to the protection of both human health and the environment.

Q10. *Do we have sufficient research and monitoring in terms of understanding toxicity and exposure in place in order to understand the effects of novel materials on human health?*

In a broader context it is perhaps worth noting that it should not be assumed that we have “sufficient” knowledge of the toxicity, exposure and risks to human health of materials in general, hence the introduction of REACH. For novel materials, the assessment of what is a “sufficient” level of understanding needs to take account of the likely availability of these materials and the extent to which their use is controlled.

There is currently considerable research being done internationally to examine the potential toxicity of nanoparticles and nanomaterials, much of this using laboratory-based systems. Although this is making good progress, in many cases, with the exception perhaps of carbon black and titanium dioxide, we still do not fully understand the effects of nanomaterials on human health. There are major knowledge gaps relating to levels of human and environmental exposure. These data are urgently needed to inform experimental and regulatory toxicology.

HSE has taken an oversight on nanotechnology in relation to workplace health and safety over the last four years. It has critically reviewed the available information on physicochemical and toxicological hazards of nanomaterials of relevance to the workplace and the occupational exposure situation. Investigations are on-going as part of EU and multi-national/multi-industry activities and include e.g. studies into potential exposure levels during nanotechnology research at UK universities. It is likely that each nanomaterial will need to be assessed on a case-by-case basis and knowledge of potential or actual exposure will be crucial to the prioritisation of effort in the field.

In response to the Royal Society and Royal Academy of Engineering report, a cross-Government group (Nanotechnology Research Co-ordination Group - NRCG) to co-ordinate research efforts in nanotechnology has been formed and HSE is a key contributor to this group. As well as contributing knowledge and experience to the NRCG, HSE is taking a lead on research efforts on occupational exposure control and fire and explosion hazards, which are issues of particular relevance to HSE's remit. HSE will also contribute to discussions on the strategic direction of other

research areas covered by the NRCG as well as maintaining an oversight on further developments in nanotechnology of relevance to the workplace.⁴

The current status in terms of progress on the Government's policy commitments in the area of the health, safety and environmental impacts of nanosciences and nanotechnology was reviewed in a recent report from the Council for Science and Technology,⁵ to which the Government response has now been published.⁶

Q11. *Are current testing protocols “fit for purpose” to test the potential health impacts of novel materials? If not, what needs to be developed or are there other strategies needed to address this issue?*

OECD guidelines for toxicity testing broadly speaking provide adequate protocols for evaluating new materials but are under review with relation to nanomaterials. However, there is growing momentum to develop and validate alternative approaches that do not use large numbers of animals, at least to gain preliminary information on the potential toxicity of novel materials, to compare them with existing materials of known toxicity, and to determine the factors that influence toxicity. A coherent strategy is needed internationally to move this area forward, with a strong input from regulatory toxicologists about which tests would be most informative. A particular area of focus needs to be improving the ability of laboratory tests to predict both human and animal health effects.

It is important to maintain an awareness of the development and introduction of novel materials as the potential health impacts and appropriate monitoring and control strategies are likely to vary on a case-by-case basis. Effective risk assessment and implementation of control measures, supported by appropriate testing protocols, is key to preventing / controlling exposure and any potential health impacts. Improved systems for the monitoring and recording of occupational exposure and improved modelling and prediction of exposure patterns would be beneficial, while the use of biological monitoring could be valuable e.g. for novel metal compounds.

Q12. *Do we have adequate methodologies and instrumentation to detect and monitor engineered free nanoparticles in the environment?*

As highlighted in the recent CST report⁵ a significant amount of effort is being expended on improving capabilities in terms of nanometrology. The limitations of current methodologies and instrumentation relate to difficulties in specifying which metrics and instrumentation are most appropriate for detecting and monitoring nanoparticles and how to relate these to potential health effects. In the case of engineered free nanoparticles in the environment, the situation is further complicated by the difficulty in detecting such materials against an existing background level of ambient combustion-derived or natural nanoparticles.

⁴ <http://www.hse.gov.uk/horizons/nanotech.htm>

⁵ http://www.cst.gov.uk/cst/news/Files/nano_review.pdf

⁶ <http://www.cst.gov.uk/cst/news/Files/response.pdf>

Q13. *Are the full life cycle impacts of novel materials being considered in terms of their potentials effects on human health?*

The REACH regulations require that a full life cycle approach is taken to risk assessment and this is embodied in the Chemical Safety Assessment and report.⁷

Q16. *Is REACH the right framework for regulating novel materials and nanotechnologies?*

The REACH principles, that those who supply materials are responsible for developing an understanding of the properties of the products they supply and for instructing recipients on appropriate risk management, are felt to be appropriate in a modern-day regulatory framework. These principles are not new but REACH strengthens their application. The impact of the 1 tonne per annum per company threshold for REACH registration needs to be kept under review as it relates to nanomaterials.

However, it should be noted that In addition to REACH there is other important legislation that impacts on novel materials and nanotechnologies, including the COSHH regulations (EU Chemical Agents Directive and Carcinogens Directive) and the Classification & Labeling/CHIP legislation.

Q17. *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?*

The HSE reviews of the impacts of nanotechnology on workplace health and safety were submitted to the Royal Society and Royal Academy of Engineering for their report "Nanoscience and nanotechnologies: opportunities and uncertainties"⁸ and HSE has contributed to the Government response to this report. In this context HSE has reviewed the adequacy of the regulatory framework in relation to potential concerns for health and safety in the workplace arising from supply, use and production of nanomaterials.⁹ The conclusions from this study were incorporated into the report issued to the DTI, which provides "An Overview of the Framework of Current Regulation affecting the Development and Marketing of Nanomaterials".¹⁰

Q18. *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?*

⁷ <http://www.hse.gov.uk/reach/definitions.htm> - actor

⁸ <http://www.nanotec.org.uk/finalReport.htm>

⁹ <http://www.hse.gov.uk/horizons/nanotech/regulatoryreview.pdf>

¹⁰ <http://www.berr.gov.uk/files/file36167.pdf>

There are various problems for nanomaterials for example in terms of which tests are most appropriate and how the results of particle inhalation in rodent lungs should be interpreted. Inhalation tests are generally seen as being too costly and there is currently a lack of simple screening tests for low-tonnage/low profit chemicals. Uncertainty about appropriate exposure metrics and measurement techniques for airborne nanomaterials also presents a problem. All of these point to a precautionary approach to regulation and control.

Q20. *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?*

This will be possible, providing exposure patterns can be effectively modelled and predicted. It should be noted that in general, the exposure of workers to novel materials and technologies is potentially much higher than that of the consumer.

Q22. *Are there general lessons to be learned from the development and use of other novel technologies, e.g. the development of genetically modified organisms?*

Protocols are in place to ensure that genetically modified organisms are handled safely within the laboratory and that escape into the environment is prevented. However, the use of genetically modified viruses beyond the laboratory in clinical trials and industrial applications appears to be increasing. Currently the materials involved tend to present a low level of hazard and to date the biological containment of the organisms is considered to be sufficient to prevent release. This could change however if there is a move to using less biologically contained organisms and developments in the field are being constantly scrutinised and controlled through a series of Advisory Committees (SACGM, GTAC, ACRE).

In terms of lessons to be learned, the maintenance of public confidence is crucial and any regulatory system needs to be flexible enough to be able to react to new knowledge and accrued experience. Ensuring that Government has access to the best independent scientific advice available is important in implementing an appropriate system of regulation and maintaining public confidence and support. Taking a precautionary approach is sensible but the system should be able to relax the level of control once sufficient data has been obtained to warrant this.

Q23. *How can an appropriate balance be achieved in the design of regulatory systems to effectively manage uncertainty?*

The risk based approach adopted for most modern legislation is sufficiently flexible to effectively manage uncertainty.

Q25. *How would you apply the precautionary principle to the management and regulation of novel materials?*

The challenge is to ensure effective protection of workers, the environment and the public whilst limiting any detrimental impact on the commercial development of novel materials. The approach adopted by HSE is to demand a graduated response depending on the degree of uncertainty. Where the uncertainty is greatest we require duty holders to apply stringent levels of control over exposure only relaxing those controls when the knowledge of the risks improves. For those who might argue that REACH requirements (and their like) stifle innovation, REACH does have the PPORD (Product and Process-Orientated Research & Development) concept for softening the regulatory burden during R&D.

Q26. *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?*

The issue of public understanding of developments in science and technology and the associated questions as to perception of risk and acceptance of novel technologies are of great importance and HSE would be happy for these to be a part of the RCEP study.
