Department for Environment Food & Rural Affairs

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Chemicals and Emerging Technologies Evidence Plan

Policy portfolio: Food and Sustainable Economy

Policy area within portfolio: Chemicals and Emerging Technologies

Timeframe covered by Evidence Plan: 2013/14 - 2017/18

Date of Evidence Plan: March 2013

This evidence plan was correct at the time of publication (March 2013). However, Defra is currently undertaking a review of its policy priorities and in some areas the policy, and therefore evidence needs, will continue to develop and may change quite rapidly. If you have any queries about the evidence priorities covered in this plan, please contact StrategicEvidence@defra.gsi.gov.uk.

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1. Policy context

What are the key policy outcomes for the policy programme/area?

Chemicals and Emerging Technologies (CET) is responsible for chemicals management policy within Defra (this includes nanomaterials (NMs) and genetically modified organisms (GMOs). The UK has a large Chemicals Manufacturing Sector and we are also an extensive user of chemicals. Additionally, the UK has a strong-research base in genetics and is constantly looking at innovation in the agricultural sector which will enable production to become more sustainable. Consequently, the UK places a strong emphasis, both at EU level and globally, on developing appropriate agreements and proportionate regulatory frameworks for Chemicals and GM. CET key policy objectives are therefore to:

- promote in the EU a proportionate and science/risk-based approach for the development and implementation of chemicals, nanotechnologies, and GM policies, to help unlock the potential of emerging technologies, and to follow UK better regulation principles so as to minimise negative impacts on UK business while protecting human health and the environment;
- influence EU and international fora and ensure that comprehensive agreements, synergistic arrangements and achievable activities are agreed for multilateral agreements, international frameworks and treaties involving chemicals.

The principal regulatory framework for the sound management of chemicals, including NMs, is the EU REACH (Registration, Evaluation, Authorisation and restriction of Chemicals) Regulation. The REACH Regulation which manages the use of 100,000 chemicals in the EU will realise between £324m and £624m of net benefit to the UK (over 20 years) through environmental and human health protection. The deliberate release of GMOs into the environment is regulated under EU Directive 2001/18/EC. Full details are available at:
http://www.defra.gov.uk/environment/quality/chemicals/reach/
http://www.defra.gov.uk/environment/quality/gm/

Our ability to positive influence negotiations in these regulatory regimes and their associated European and international fora depends upon our having access to a comprehensive, robust and up-to-date evidence base

Chemicals
Some chemicals are known to have detrimental effects on the environment or human health. However, chemicals also form an essential part of the way we live and offer many benefits to society. CET policy objective is to manage the production and use of these substances so that the benefits associated with their use are maximised, and any detrimental impacts on the environment and human health are minimised. This means an emphasis on clear evidence for action and steering away from an over-precautionary approach.

The chemicals sector forms a significant part of the UK economy with 125,000 direct employees (supporting several hundred thousand jobs in other sectors) with total sales of ~£46.5bn p.a. and a Gross Value Added of £5.5bn p.a. The chemical industry has been identified as an important sector for UK growth in BIS' recently published Industrial Growth Strategy.

The UK Government takes a risk-based approach to chemicals management. This can mean, in some cases, continuing with the use of chemicals but identifying associated risks and acting proportionately to mitigate these. In other situations, restricting or even completely banning the use of a chemical may be more appropriate. Information is needed on the full costs and benefits of various strategies for chemical management, including those from the impacts of naturally-occurring chemicals, in order to take informed decisions. A recent example is the 2011 EU Export Prohibition of mercury. An Impact Assessment estimated the monetised benefits from adopting the prohibition to be at around £300m for the United Kingdom over 40 years, arising from reduced impacts on IQ development, together with lower cardiovascular damage and premature mortality. The likely costs to the United Kingdom were estimated to be £6m-£8m over the same period, through replacement of mercury technology and subsequent storage of the metal.

Nanotechnology

Nanotechnology is a rapidly growing area, with the novel properties exhibited by NMs driving their exploitation within diverse applications that may benefit the environment and society as a whole. Nanotechnology is important for UK growth and will help deliver BIS's Industrial Strategy and Defra's Sustainable Growth agenda. It also offers much potential to respond to global challenges, such as the need for low carbon energy production. Nanotechnology global revenues are expected to grow from $2bn in 2007 to $81bn in 2015. The UK, like many other countries, has invested heavily in nanotechnologies and we are considered to be world leaders in a number of areas, such as nano-medicines, sensors, engineering applications and coatings. While very rapid growth in the global market for nanotechnology-enabled products is predicted, there are concerns that UK ideas are not translating into products, with many start-up companies foundering before their ideas come to market. Much of this is believed to be due to the continuing knowledge gaps around the behaviour and toxicity of these novel materials, which is leading to regulatory uncertainty and prompting growing calls across Europe for ultra-precautionary regulatory responses.

Genetically Modified Organisms

Genetically modified organisms can be used in a wide range of different applications including medicines, food production and bioremediation. There is clear potential for technologies involving GMOs to offer benefits to the environment and society and contribute to the sustainable growth agenda. For Defra, GM technology has the potential to make a significant contribution to our long-term food security, sustainable intensification and climate change objectives.

The development and commercialisation of GM crops is hindered by adverse and uncertain EU market conditions both in terms of the way the current regulatory regime operates but also in terms of reported public opposition to the technology, which translates into anti-GM political stances adopted by many member states. This threatens to stymie research and investment in the technology and risks depriving EU farmers of tools which their competitors in non-EU countries are already using increasingly. GM has the potential to enhance our ability to develop and access tools which we may need in future to ensure a resilient, secure and sustainable food supply against the backdrop of climate change and global population rises. If the potential of GM technology is to be realised, issues with the slow functioning of the EU regulatory system will need to be resolved. Only one GM crop has been approved for commercial cultivation in the EU since 1998 whilst globally some 12% of arable land is now given over to GM crops.

2. Current and near-term evidence objectives

What are the current and near-term objectives for evidence and how do they align with policy outcomes?

The Defra CET Evidence Programme is formed of three sub-programmes: Chemicals (70% budget, high priority); Nanotechnology (25% budget, high priority); and Genetically Modified Organisms (5% budget, medium priority). Chemicals are attracting growing interest both within the EU and globally, and have several legislative obligations (see below). Research on nanotechnology and GMOs has strong ministerial and cross government (BIS) support, due to their growth potential and growing concerns around the trend across Europe towards ultra-precautionary, hazard driven regulatory responses, which could stifle innovation. However, while the EU regulatory pipeline remains blocked, the research needed to support risk assessment of GMOs is limited and the research portfolio is currently geared towards establishing an evidence base to support socio-economic analysis relating to choice, improved public engagement and communication.

The Defra CET Evidence Programme has the following principal aims:

Protect human health and the environment through science-based risk assessment of chemicals, NMs and GMOs by:

Primary and secondary evidence on the nature and properties of chemicals, NMs and GMOs; primary and secondary evidence on their fate and behaviour; assessment of the risks to human health and well-being from environmental exposure to these substances (individual chemicals, families or mixtures); investigation of the risks to human health and wildlife from exposure to chemicals through the environment, in particular impacts of endocrine (hormone) disrupters on the aquatic environment; sound understanding of how chemicals work in mixtures and of the risk they pose; assessment of priority chemicals to improve knowledge of their environmental effects as part of EU, Organization for Cooperation and Economic Development (OECD) and other international initiatives and

where necessary development of test methods that extend coverage to animal groups of intrinsic ecological and economic importance; getting new endpoints/tests accepted for present guideline species; investigation of innovative approaches on alternatives methods for testing chemicals – research focussed on developing appropriate test methods that do not use animals and agreeing their use at international level.

Evidence needs in this area are fulfilled through the Defra network; other Government agencies; EU partners; OECD partners; the Research Councils; the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs); international collaborations; externally commissioned research; and Defra Advisory Committees;

Enable informed risk management decisions and assess efficacy of existing control measures by:

Working with partners, in particular the Health and Safety Executive and the Environment Agency and with independent expert scientific committees, to gain an understanding of how REACH meets its objectives; assess the ongoing operation and real world impact of REACH on the environment, and build on these to develop an ongoing scheme for assessing (and monitoring, if necessary) the impacts of REACH against the aims of the Regulation;

Maintaining an emissions inventory for Persistent Organic Pollutants (POPs) identifying and quantifying sources of POPs releases into air, land and water; maintaining a monitoring network that is responsible for measuring UK air quality through the determination of POPs levels in rural and urban environments; and impact assessments to consider the socio-economic impacts to industry in addition to the environmental benefits; in support of UK obligations under the 1998 United Nations Economic Commission for Europe (UNECE) POPs Protocol made under the Convention on Long-Range Transboundary Air Pollution (LRTAP) and the 2001 Stockholm Convention on POPs; collaborating with the Environment Agency and other parties to contribute to the evidence underpinning the protocols and conventions;

Working with partners to maintain a strong UK evidence and skills base to enable the UK to be in a position to make evidence-based arguments on the interpretation and implementation of EU legislation; in particular, informing EU discussions on the combination effects of mixtures of chemicals and the management of substances with the potential to disrupt adversely endocrine systems; informing negotiations on the amendments to the EU Strategy on Endocrine Disruption and the development of criteria for the identification of such substances. Globally, these issues are attracting interest within the UNEP-led Strategic Approach to International Chemicals Management (SAICM);

Investigating the balance between the societal benefits offered by chemicals, NMs and GMOS and any negative impacts they may pose; economic analysis of the impacts on the UK of the EU regulatory system for GM crops; economic analysis of the costs and benefits of various strategies for chemical management, including those from the impacts of naturally-occurring chemicals; developing sound proposals and methods to counter the

ongoing shift towards hazard-based risk assessment and growing calls across Europe for ultra-precautionary regulatory responses; social science analysis to further understand what is driving policy positions in other EU Member States.

Unlock the potential of emerging technologies by:

Understanding the benefits that nanotechnologies and GMOs may bring to the environment and sustainability; developing the knowledge base around the use of nanotechnologies for environmental remediation; developing the knowledge base around the potential environmental and societal benefits of GMOs.

Reducing regulatory uncertainty to enable successful commercialisation of safe new materials by developing the evidence base on their fate, behaviour and properties; gaining a better understanding of those NMs to which humans and the environment are currently exposed thus providing reassurance that government has a firm grasp of the exact nature and provenance of NMs; supporting research on the methodologies required to enable effective risk management responses; collaborating with the Waste Strategy Team and EU partners to promote the safe design and use of nano products and applications and deliver risk assessment tools for future use by regulators (e.g. NANOREG, a €50m FP7 public/private partnership);

Enabling corporate social responsibility in the context of safeguarding the environment and human health; developing capability and a collaborative approach to future nano-risk governance (includes a high level policy officials group, which meets twice yearly, and the Nanotechnologies Strategy Forum, which is chaired by David Willetts and Lord de Mauley);

Undertaking social science analysis to engage and understand public concerns around the safety and societal aspects of nanotechnologies and GMOs; working with a range of stakeholders to explore new approaches to public and consumer engagement.

Enabling consumer and farmer choice on GM crops by:

Implementing effective coexistence measures to segregate GM and non-GM crops; secondary analysis of available data relevant to coexistence to update the evidence base since the 2006 Defra consultation on coexistence measures.

Improved public engagement and communication by:

Listening to public views and providing information on the development and use of emerging technologies by drawing on existing surveys such as the Eurobarometer and FSA biannual attitudes tracker; funding social research to further the understanding of public views and information needs to support Government policy; contributing to public engagement initiatives, as highlighted by the Green Food Project and the work of the Food Research Partnership; working with the Nanotechnology Strategy Forum and stakeholders to explore new approaches to public and consumer engagement on nanotechnologies;

working with the UK Chemicals Stakeholders Forum, the UK Reach Competent Authority, and Defra/BIS policy leads to evaluate the effectiveness and impact of REACH.

3. Future evidence needs

What are the longer-term evidence needs for the policy area/ programme?

Chemicals, nanotechnologies and GMOs are rising up the policy agenda in Europe and globally. The Presidency conclusions for the 7th Environment Action Plan highlighted a desire amongst EU Ministers for a beyond-REACH strategy addressing combination effects of chemicals and safety concerns related to endocrine disruptors and nanomaterials. There is growing concern over the lack of effective regulation of nano (e.g. via REACH) and this is leading to increasing pressure in Europe towards hazard, rather than risk-driven approaches. There is increasing recognition of the potential role of GM crops for sustainable agriculture, yet at the EU level there are similar pressures towards hazard rather than risk-driven approaches. The EU regulatory system is widely recognised as the most robust in the world and yet decisions on the authorisation of GM products are delayed for years. If unnecessary blockages to the progress of applications through the EU regulatory system were to be removed t, this could increase the relative priority for research to support the risk assessment of GMOs in the longer term.

For chemicals, EDCs are anticipated to remain priorities for the future, along with research on POPs substances (levels, fate and behaviour in the environment and emission inventory development), and the development of new non-vertebrate test methodologies for input into OECD test batteries to assist in the reduction of animals required in testing. New scientific issues recently arisen also include epigenetics and the development of Adverse Outcome Pathways, which link effects at the molecular level with resulting impacts for the organism as a whole or even for populations. These developments have important implications for the fundamental basis of the assessment of risks from chemicals (and nanomaterials). There are also rising concerns about the possible low-dose, long-term, chronic effects of pharmaceutical residues in the environment; and whether the low concentrations of antibiotics found in treated wastewater can promote natural selection of resistance genes in bacteria.

Evidence objectives specific to REACH will include: gaining an understanding of how REACH meets its objectives; assessing the ongoing operation and real world impact of REACH on the environment, to build on these to develop an ongoing scheme for assessing (and monitoring, if necessary) the impacts of REACH against the aims of the Regulation.

On nanotechnology, Defra and the EA have identified research priorities in the areas of environmental fate, behaviour and effects of NMs, covering a subset of ‘priority’ nanomaterials (e.g. nanosilver; metal oxides) which are already in production and use and for which there is already evidence of potential toxicity or pathogenic response. A strategic aim over the 3-5 year period will be to advance risk assessment methodologies to

a point where these can be implemented to ensure that potential risks of nanotechnologies are safeguarded against while the economic and societal benefits can be realised. A key element of our approach is the strengthening of our risk management capability, so that we are able to respond in the event of a 'risk incident'. We are addressing this in partnership with the Environment Agency and Health and Safety Executive, by gathering intelligence on which nanomaterials and nano-products are made and used in the UK. This information will enable us to focus our research effort on real world exposure.

CET Division's research budget has also contributed to several international nano-research initiatives which aim to develop underpinning knowledge on the nature and behaviour of NMs. It is expected that these programmes will deliver results over the 3-5 years period which will strengthen our understanding and ability to manage any potential risks. An early priority area will be to understand potential exposure and consequent risks arising from NMs arising in waste streams and we anticipate that the FP7 NANOREG project will provide valuable tools and insight in this area.

CET also aims to develop understanding of the implications of NMs throughout product life cycles, thereby contributing to principles of sustainability and safe design.

For GMOs, applications for environmental release for research or marketing purposes will be assessed on a case by case basis. Specific evidence needs therefore will arise with new developments. New types of GM crops, modified for a wider range of traits, are being developed; new sorts of breeding techniques are increasingly being implemented; and synthetic biology approaches are also being used to generate organisms with several targeted changes. Future developments of the technology may therefore present new challenges for the regulatory system and result in new evidence needs. GM crops are not currently grown in the UK however this may change in the coming years if unnecessary blockages to the progress of applications through the EU regulatory system were to be removed. This could result in new evidence needs, particularly relating to post market monitoring.

There will be a need to develop approaches to place economic values on the impacts of chemicals, nanotechnologies, and GMOs to changes in human health, productivity, amenity and natural resources.

In future we anticipate a need for closer links with the sustainable land management and biodiversity, soils and natural value programmes and the crops hub in order to ensure that the environmental impacts of GM crops are considered within the wider context of the impacts of agricultural systems more generally.

4. Meeting evidence needs

What approach(es) will be taken to meeting evidence needs?

Evidence needs are identified and prioritised through a process of consultation with policy leads and evidence specialists including: natural scientists, social scientists, economists, and statisticians.

Natural scientists are embedded within the team. These scientists have technical expertise in ecotoxicology, chemistry, genetics, biology and environmental science, and are responsible for maintaining the evidence base, procuring and managing evidence and providing technical advice to policy colleagues, as appropriate. CET specialists engage with a wide range of expert advice sources to identify early emerging topics of concern, and work collectively to promote a joined-up approach both across Government and on an international level. The CET specialists also undertake policy work in addition to their technical role. We also draw on the expertise of departmental economists, social scientists and statisticians for advice on monetary and non-monetary valuation approaches, evaluation of policy instruments, behavioural analysis, experimental design and also as a source of expert advice when we are assessing results from studies done elsewhere, including from the scientific literature.

A two-pronged approach is taken to plan for future requirements. Firstly, we ensure we are abreast of current research through horizon scanning and where necessary, through commissioning external reviews. We have systems in place to alert us to developments in relevant fields and CET members actively participate in a range of cutting-edge scientific conferences and workshops. The Division is a Global Partner of the Society of Environmental Toxicology and Chemistry (SETAC), a global professional organization comprised of some 6,000 individual members and institutions from academia, business and government. SETAC provides a forum where scientists, managers and other professionals exchange information and ideas on the study, analysis and solution of environmental problems, the management and regulation of natural resources, research and development, and environmental education. Secondly, research and policy developments (in for example the EU) are discussed with UK and international academics (e.g. via the UK-Japan research collaboration) and scientific advisory bodies (see below). We draw our priorities for future evidence requirements from these discussions.

Priorities are determined on the basis of:

- immediate evidence gaps to support risk assessment and risk management due to new technology or changes in regulatory requirements at the EU or international level;
- evidence needed to influence EU policy;
- evidence needed to develop domestic policy;

- extent to which CET is best placed to undertake the evidence activity or whether other sources of funding are more appropriate or other options for delivering the outcome exists;
- extent to which the project aligns with Ministerial priorities and support delivery of CET policy aims.

Wherever possible, projects are developed in a collaborative way. The CET evidence budget is small compared to national and international investment in chemicals, nanotechnology and GMOs research and so collaboration with other evidence providers is essential to address our evidence needs. Owing to the diversity of disciplines relevant to CET we are not dependent on a single agency or organisation. Key evidence providers and partners that we work with are:

Other Defra evidence programmes: we exchange specialist skills and knowledge with Atmosphere and Local Environment, Marine, Waste, Water Quality, Water Framework Directive, Pesticide, Sustainable Land and Soils, Biocide and Veterinary Medicines teams. We also have direct links with the Drinking Water Inspectorate team.

Defra network: Environment Agency; Food and Environment Research Agency; Centre for Fisheries and Aquatic Science. We collaborate with these agencies to meet evidence needs, whether via undertaking laboratory based research or helping us interpret results. The GM team has an MoU with FERA, who have a specialist GM team which is important for the supply of some of Defra's evidence needs on GM.

Other Government Departments, Agencies, and NDPBs: Business Innovation and Science; Department of Health; Home Office; Health and Protection Agency; Health and Safety Executive; Food Standards Agency; National Centre for the Replacement, Refinement and Reduction of Animals in Research.

The Devolved Administrations (DAs): we collaborate directly with DAs on a range of issues, such as endocrine disruption in the context of EU regulatory developments and negotiations on a global legally binding instrument on mercury. Following on from that, our research programme is aimed at producing results generally applicable across the UK and wider.

UK Research Councils: We have direct links with NERC, with one Divisional member who sits on the Peer Review Panel. CET also contributes to the Research Councils' programmes, e.g. Environmental Nanoscience Initiative, an US/UK consortium project that has brought together UK research councils (NERC, EPSRC, MRC) along with the Environment Agency and the Department of Health to address key questions relating to the environmental fate, behaviour and effects of manufactured nanomaterials; Environment Exposure Health Initiative, which aims to explore the impact of environmental pollutants (in water, air, soil, food) on human health.

EU Framework Programmes: Partnership working within EU partners is achieved by providing matched funding for FP7 projects (e.g. NANOREG).

International links: We have strong international links outside of the EU. This includes a partnership with Japan on endocrine disrupting chemicals, originally established in 1999 and recently extended until 2015. We are currently working with Australia and New Zealand to forge informal research links along similar lines. Our partnership work is also exemplified at an international level by our close collaboration with the Organization for Cooperation and Economic Development (OECD) partners on test method development (e.g. development of mollusc tests for EDCs with Germany, Denmark and France) and as part of the OECD's Nanosafety programme. We increasingly work in partnership with SETAC and since 2003, we have been collaborating with the International Council for Mining and Metals (ICMM) and Eurometaux to develop MERAG (Metals Environmental Risk Assessment Guidance).

Industry: A collaborative approach on NMs involving industry was recently called for by the Science Minister and CET has since been able to successfully engage with industry groups, which will provide information on what NMs are currently available and better understanding of those issues which drive (or impede) their responsible use.

The REACH process does not require significant data handling by Defra: this is undertaken by Health and Safety Executive (HSE) and Environment Agency (EA) which both have access to the European Chemicals Agency's (ECHA's) REACH-IT database system, and have both signed the terms required by ECHA to ensure appropriate levels of data protection. Evidence needs on REACH are therefore identified and met in close collaboration with the HSE and EA, who in addition to their regulatory functions, provide expert advice on evidence relating to (eco)toxicology, chemistry, monitoring, hazard and risk assessment, and economics. Applications for the deliberate release of GMOs to the environment are handled internally by Defra staff.

CET provides the secretariat to the Hazardous Substances Advisory Committee (HSAC) the UK Chemical Stakeholder Forum (UKCSF) and the Advisory Committee on Releases to the Environment (ACRE). HSAC gives advice, on request or otherwise, on matters relating to the protection of the environment, and human health via the environment, from potentially hazardous substances and articles, including nanomaterials. ACRE provides statutory advice to government on the release of GMOs to human health and the environment. Advice from HSAC and from ACRE is used to maintain awareness of future issues of concern, of research needs and other evidence gaps. UKCSF provides a ready-made process for a range of stakeholders to raise matters relating to the need for and impact of regulation, in an informed, balanced and non-polarised way.

5. Evaluating value for money and impact

What approach(es) will be taken to maximise and evaluate value for money and impact from evidence?

Evaluation of value for money and impact are addressed at two levels: individual projects; and the evidence programme.

Individual projects are evaluated at inception, during progress and on completion in line with the Evidence Handbook and the Government Social Research Code. Where ever possible research is procured through open competition. Proposals are evaluated in terms of added value through the establishment of co-funding and in-kind contributions. An assigned project officer monitors projects closely whilst research is ongoing and has responsibility for contributing to the review and impact evaluation of research outcomes. Impact is measured in terms of the extent of beneficiaries and the degree to which research has met objectives. We encourage publication in peer reviewed literature and final reports are peer reviewed before publishing to the Defra website. ACRE and HSAC are regularly consulted to comment on research proposals and results of individual projects.

Overall evidence needs and programme outputs are reviewed periodically as part of our evidence programme management cycle. We have a core of independent, external expert reviewers, who advise on the quality and robustness of our programme, value for money, and any additional needs to address gaps in knowledge and understanding. External experts are selected on the basis of their ability to contribute to the development of the programme by bringing appropriate knowledge and expertise. Effective use of independent expertise in ACRE, HSAC and within Defra also helps to ensure best use is made of available evidence. As part of our horizon scanning procedures, Members of the Committees are regularly invited to provide advice on the evidence gathering process.

We intend to use our external independent reviewers to conduct a preliminary review of the programme in the summer of 2013 and a more comprehensive review in 2015.