



# ADVISORY COMMITTEE ON RELEASES TO THE ENVIRONMENT

## Report 1: Towards an evidence-based regulatory system for GMOs.

The Advisory Committee of Releases into the Environment (ACRE) is an independent advisory committee composed of leading scientists and technical experts. Our main function is to give statutory advice to UK ministers and ministers in the Devolved Administrations on the risks to human health and the environment posed by the release and marketing of genetically modified organisms (GMOs).

This report is one of three in which we consider the regulatory framework<sup>1</sup> in which we operate. We first registered concern about fundamental principles of the legislation in our 2007 report: *'Managing the Footprint of Agriculture: Towards a Comparative Assessment of Risks and Benefits for Novel Agricultural Systems'*<sup>2</sup>. This report was designed to place the advice we issued on the UK's farm-scale trials of herbicide-tolerant crops<sup>3</sup> into a wider context; it highlighted inconsistencies in the approach to GMO regulation. Our latest reports reflect our concern that the operation of this regulatory system is becoming increasingly untenable.

This first report considers the likely future limitations of the current regulatory framework and whether these can be addressed piecemeal or only via an entirely new framework. Report 2 discusses the scientific validity of adopting the current approach to regulation, which is to control organisms based on how they were produced rather than on their novel characteristics: *Why a modern understanding of genomes demonstrates the need for a new regulatory system for GMOs'*<sup>4</sup>. Report 3, considers a more effective approach to environmental risk assessment within the constraints of the principles set out in the current legislation: *'Towards a more effective approach to environmental risk assessment under current GMO legislation'*<sup>5</sup>.

### **Introduction**

In 2007, ACRE published a report outlining its views on how the results from the farm-scale trials of herbicide-tolerant crops impinged upon the current regulatory system for GM<sup>1</sup>. In this report, concerns were expressed about a number of aspects of the regulatory framework; in particular, the challenges

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<sup>1</sup>Directive 2001/18/EC.

<sup>2</sup><http://webarchive.nationalarchives.gov.uk/20080727101330/http://www.defra.gov.uk/environment/acre/fsewiderissues/pdf/acre-wi-final.pdf>

<sup>3</sup>Philosophical Transactions of the Royal Society B (Biological Sciences). **358**: 1819 – 1832.

<sup>4</sup> <http://www.defra.gov.uk/acre/files/Report-2.pdf>

<sup>5</sup> <http://www.defra.gov.uk/acre/files/Report-3.pdf>

posed by the ability to produce HT phenotypes<sup>6</sup> by conventional breeding that would have identical environmental impacts to GMHT varieties but that lie outside the scope of the regulations. Given that the comprehensive data from the farm-scale trials showed clearly that the environmental effects were due entirely to the effect of the novel herbicide regime on natural weed populations rather than the presence or absence of GM crops, ACRE suggested that regulation would be more logically applied to the novelty of the organism rather than to the use or otherwise of recombinant DNA technology in the process of producing that organism. The report generated a certain amount of discussion, both in the UK and elsewhere (EFSA scientific colloquium<sup>7</sup> and The Royal Society report (2009) on reaping the benefit<sup>8</sup>) but there have been no substantive changes in the European regulatory framework since that date and it would appear that, until recently, there has been no great political appetite for review. The current problems with operating the regulatory process have led to calls for more responsibility for final decisions on approvals (particularly for cultivation) to rest with individual Member States but even here progress has been slow and there have been no substantive suggestions that the regulatory process itself should be overhauled.

More recently, ACRE, as part of its ongoing work programme, has considered in more detail two elements of the current process. Firstly it has published a report on emerging technologies and their potential impact on the process for GM crops that might be the subject of future release applications<sup>9</sup> and secondly it has considered the detailed challenges involved in the mandatory process of post-market environmental monitoring of GM releases<sup>10</sup>. ACRE has also commented in detail on guidance from EFSA on environmental risk assessment and post-market environmental monitoring. In all these discussions, a number of broad concerns have emerged about the long-term effectiveness of the current regulatory system in terms of whether it can deliver a proportional, impartial and evidence-based process that covers the real challenges that face us associated with the introduction of novel phenotypes<sup>6</sup> into agriculture, medicine and the wider environment.

Accordingly, the current ACRE work programme will have three inter-related outputs, aimed principally at policy-makers in the UK and beyond. This report is the first of these and considers the likely future limitations of the current regulatory framework and whether these can be addressed piecemeal or only via an entirely new framework. ACRE accepts that reform of the current system in Europe is likely to be difficult, politically controversial and almost inevitably tortuous, but the challenges of meeting the basic needs of a population of 9bn by mid-century against a background of climate change, competition for resources and a growing need to protect non-market ecosystem services make it timely to consider future options for a time when the *status quo* becomes unacceptable.

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<sup>6</sup> An organism's phenotype refers to its biochemical and physical characteristics.

<sup>7</sup> <http://www.efsa.europa.eu/fr/search/doc/colloquiagmoera.pdf>

<sup>8</sup> Reaping the benefit: Science and the sustainable intensification of global agriculture (2009).

<sup>9</sup> [http://royalsociety.org/uploadedFiles/Royal\\_Society\\_Content/policy/publications/2009/4294967719.pdf](http://royalsociety.org/uploadedFiles/Royal_Society_Content/policy/publications/2009/4294967719.pdf)

<sup>9</sup> <http://www.defra.gov.uk/acre/files/20120710-FINAL-VERSION-ACRE-advice-on-new-techniques.pdf>

<sup>10</sup> <http://www.defra.gov.uk/acre/sub-groups/env-monitoring/>

This report builds upon the 2007 report, together with the outputs from the 2002 ACRE sub-group report on harm<sup>11</sup> and the 2012 publications on new plant breeding techniques<sup>9</sup> and on post-market environmental monitoring<sup>10</sup>. The report is organised around a series of key questions, listed below. It attempts to summarise briefly the current evidence relating to each question, including any significant uncertainties and to reach a conclusion before moving on to the next one. The report concludes by considering whether, *in toto*, this justifies the broad conclusions of the 2007 report in favour of a phenotype-based regulatory system.

### **Key Questions:**

1. Can a regulatory system that is triggered by the process by which new organisms are developed (i.e. recombinant DNA technology) rather than by their novelty or potential for harm (i.e. their phenotype), be scientifically justified?
2. Could a regulatory system that both takes account of potential benefits and includes potential compensatory measures, and thus allows a more explicit cost-benefit approach, result in greater potential benefits for the environment and human health and well-being than the existing system?
3. Can we develop a system that reduces administrative cost and decision times in order to ensure appropriate risk assessment without stifling technological innovation or encouraging technological approaches that are developed purely to evade evaluation?
4. Is general surveillance a scientifically justifiable and proportionate activity to require on a 'product-by-product' basis?

### **Key Question 1. Can a regulatory system that is triggered by the process by which new organisms are developed (i.e. recombinant DNA technology) rather than by their novelty or potential for harm, be scientifically justified?**

There is no doubt that the use of recombinant DNA technology enables the production of organisms with novel traits. To date, DNA sequences from elsewhere in the biosphere have been used as selectable markers, promoters, coding sequencers, terminators etc. Wholly synthetic sequences have also been used. Concerns have been expressed relating to the potential environmental impacts of these technologies in three main areas: (1) GMOs becoming more persistent, invasive or pathogenic as a result of the genetic modification; (2) gene flow (either via sexual recombination or by horizontal gene flow) altering the fitness or pathogenicity of organisms that were not the

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<sup>11</sup><http://webarchive.nationalarchives.gov.uk/20081107165902/http://www.defra.gov.uk/environment/acre/harm/index.htm>

intended recipients of the genetic modification and (3) GMOs or their use harming other organisms in the environment or ecosystem functioning. The ERA required from applicants for release of novel GMOs deals with each of these issues. However, similar issues involving conventional breeding or introduction of alien species are rarely subjected to the same analyses. Both horizontal and vertical gene flow between species is not restricted to products of recombinant DNA technology. There is good evidence of its occurrence between conventionally-bred crops and wild relatives (Small E. 1984<sup>12</sup>; Ellstrand *et al.* 1999<sup>13</sup> and Lutman P. 1999<sup>14</sup>) and between different phyla by horizontal gene transfer (Richards *et al.* 2006<sup>15</sup>; Boto L. 2010<sup>16</sup>). What is lacking is any convincing evidence that patterns of gene flow attributable to human activity have any greater likelihood of causing long-term significant alterations to fitness in wild populations than the natural processes that have been occurring throughout evolution. Whilst it is theoretically possible to conceive of traits that would not be desirable if transferred into wild populations, it is the trait that occasions the change in fitness, not the means by which it is bred into the donor plant that is of concern. The experience of the last 25 years tells us that (a) there is an increasing global history of safe use for GMOs in both organisms grown under containment and those released into the environment and (b) that all the major examples of damage to natural ecosystems caused by organisms with altered fitness in those ecosystems have been associated with invasive species not with modification of existing species. Changes in pathogen virulence or weed persistence in farmed environments have occurred as a result of enhanced selection pressure, but once again this has been occasioned from within the existing pool of variation and is associated with conventional means of pest and weed control as well as with the application of GM.

Accordingly it is difficult to find any compelling evidence that the techniques used for trait manipulation have any bearing on the environmental consequences of release. All the major negative consequences of human manipulation of the biosphere have resulted from novel selection pressures applied to existing populations of potential pests, pathogens or weeds; the introduction of "alien" species into novel receiving environments or the development of land management systems that perturb previously stable flows of material into the non-farmed environments. We have an increasing understanding of the ecological and evolutionary biological basis of sustainable management of the biosphere and it seems logical that this should be manifested via a case-by-case approach to the regulation of novel organisms and novel practices. The novelty of an organism's phenotype<sup>17</sup> should define its regulatory status; this contrasts with the existing system

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<sup>12</sup> Small E. (1984). Hybridisation in the domesticated-weed-wild complex. On: W.F. Grant (Ed) *Plant Biosystematics* 195-210. Academic Press. Toronto.

<sup>13</sup> Ellstrand NC, Prentice HC and Hancock J (1999) Gene flow and introgression from domesticated plants into their wild relatives. *Ann Rev Ecol and System* **30** 539-563.

<sup>14</sup> Lutman PJ (ed) (1999) *Gene flow and agriculture: relevance for transgenic crops* BCPC, London

<sup>15</sup> Richards, T.A., Dacks, J.B., Jenkinson, J.M., Thornton, C.R. & Talbot, N.J. (2006). Evolution of filamentous plant pathogens: gene exchange across eukaryotic kingdoms. *Current Biology* **16**, 1857-1864.

<sup>16</sup> Boto L. (2010). Horizontal gene transfer in evolution: facts and challenges. *Proceedings of the Royal Society B* **277**: 819 – 827.

<sup>17</sup> An organism's phenotype refers to its biochemical and physical characteristics.

which focuses on the genotype<sup>18</sup> of organisms and the technique(s) used to produce them. Traditionally, the language that has been used to debate these different regulatory approaches is 'product' versus 'process'<sup>19</sup>. ACRE uses the term phenotype-based regulation, rather than product-based regulation, to make it clear that this should be restricted to stable genetic or epigenetic changes in organisms.

**Key Question 2. Could a regulatory system that both takes account of potential benefits and includes potential compensatory measures, and thus allows a more explicit cost-benefit approach, result in greater potential benefits for the environment and human health and well-being than the existing system?**

ACRE has been considering the challenges associated with defining harm in a regulatory context since 2002<sup>11</sup>. It concluded then that harm was not the same as change, and that harm was essentially a relative concept which had a number of different strands, some capable of objective assessment, others less so. This report did not address issues of proportionality and resilience.

It is simple to frame the question in regulatory terms: "Does product A cause greater harm to human health or the environment than the product it is intended to replace?" It is, however, much more difficult to provide a clear answer without giving due consideration to context. All modifications will affect their receiving environment to a greater or lesser degree. Some effects will be positive, some negative; some significant in ecosystem terms, others much less so. There are likely to be confounding effects associated with other modifications elsewhere in the ecosystem coupled with the natural variations that occur in dynamic and complex systems. The current interpretation of the regulations (discussed in more detail in Report 3) does not, in ACRE's view, deal with these consequences in a proportionate way. Demonstration of the absence of harm seems to be viewed as a regulatory hurdle that has to be surmounted before an application can be considered further. This contrasts markedly with the way in which novel products not produced by recombinant DNA technology are introduced, where the emphasis is much more on the effective management of the altered range of impacts, both negative and positive.

This mismatch becomes even more acute when issues of benefit arise. The GM regulatory system does not explicitly take benefits into account. The need to consider benefit as well as risk has, however, been extensively discussed particularly with reference to GM mosquitoes designed to reduce the transmission of human diseases such as malaria and dengue fever. The regulations which apply to novel medicinal and veterinary products<sup>20</sup> (and

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<sup>18</sup> An organism's genotype refers to its genetic make-up.

<sup>19</sup> Tait, J. and Levidow, L. (1992) Proactive and Reactive Approaches to Risk Regulation: the Case of Biotechnology, *Futures*, April, 1992, 219-231.

<sup>20</sup> Recital 11 of the preamble to Directive 2004/28/EC establishes that the concepts of harmfulness and therapeutic efficacy can be examined only in relation to one another and have only a relative significance..'

indeed to chemicals<sup>21</sup>) are based clearly upon a consideration of benefit as well as harm. Implicit in this approach is the idea that a particular level of "harm" might be tolerated when the benefits were high, whereas they might not be if the product had much more restricted value. This "risk-benefit" analysis is seen particularly clearly in the consideration of the side-effects of novel bioactives for human prophylaxis. As the GM regulations are increasingly involved with applications that also impinge on other regulatory frameworks where benefit is an important element, this mismatch in approach will become increasingly difficult to manage. Accordingly ACRE believes that the current GM regulations will become more and more out of step with good regulatory practice elsewhere.

ACRE's concerns about the failure to consider benefits are exacerbated in the case of GM crops by the fact that application of the GM regulatory framework from the outset has had a very restricted and disproportionate approach to the use of managements that could compensate for any negative impacts. The BRIGHT trials of GMHT beet<sup>22</sup> showed clearly the potential benefits of in-field mitigation practices to maintain the yield advantage of HT whilst promoting the value of "non-competing" weeds as food sources for insects, birds and mammals. The scope for compensatory activities across the entire land use system where novel products are introduced is much higher, and this approach is already in use to maintain or extend populations of beneficial insects and other organisms around fields where intensive conventional practices are employed. Systems-based approaches to compensation are increasingly part of cultivation best practice for environmental stewardship schemes and have potential across a much wider range of environments. ACRE sees no reason not to consider GM products in this light.

In conclusion, ACRE considers that the current GM regulations are not being applied in a proportionate manner and that the way in which harm, benefit and compensation are dealt with is increasingly out of line with best practice elsewhere<sup>23</sup>.

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<sup>21</sup> Article 60.4 of Regulation (EC) No 1907/2006 establishes that a chemical that poses a risk to human health or the environment (after appropriate risk management measures are adopted) may only be authorised if the socio-economic benefits outweigh the risks (and if there are no suitable alternatives).

<sup>22</sup> Sweet J, Simpson E, Law J, Lutman P, Berry K, Payne R, Champion G, May M, Walker K, Wightman P, Lainsbury M (2004). Botanical and rotational implications of genetically modified herbicide tolerance in winter oilseed rape and sugar beet (BRIGHT Project). Project Report No. 353. HGCA.

<sup>23</sup> The RSPB-owned Hope Farm has increased its farmland bird numbers threefold over 10 years using a combination of in-field and field edge methods, without sacrificing profits:

<http://www.rspb.org.uk/ourwork/farming/hopefarm/index.aspx>

Baker, D. J., Freeman, S. N., Grice, P. V. & Siriwardena, G. M. 2012. Landscape-scale responses of birds to agri-environment management: a test of the English Environmental Stewardship scheme. *Journal of Applied Ecology*, 49, 871-882

**Key Question 3. Can we develop a system that reduces administrative cost and decision times in order to ensure appropriate risk assessment without stifling technological innovation or encouraging technological approaches that are developed purely to evade evaluation?**

Financial returns on regulatory investments for marketing GM crops in Europe are significantly lower than in North America or Australasia because of the time taken to make decisions on applications (if decisions are made in the EU). Additionally, in the EU permits to market are time-limited which adds further to compliance costs, as do the complex interactions between competent authorities in Member States and EFSA during the evaluation of dossiers<sup>24 25</sup>. *De facto* evidence for the complexities of the European system is that only one permit for cultivation of GM crops has been approved under the current regulatory framework which has been in place since 2001; there are 18 applications to cultivate GM crops in the regulatory pipeline, more than half of these were submitted at least 5 years ago. This contrasts markedly to the regulatory framework surrounding (e.g.) conventional crop varieties, where release is contingent only upon the demonstration of distinctiveness, uniformity and stability and for agricultural crops, value for cultivation and use. Companies submitting applications under this legislation can expect decisions to be made within 2.5 years of submission. The compliance costs for conventional varieties are also a fraction of those that apply to GMOs. These vary depending on the crop, but administration and testing fees amount to less than £5 000<sup>26</sup>. This compares to between £5-10 million for a GM crop<sup>27</sup>. A range of technologically advanced approaches to crop improvement, such as mutation breeding, marker assisted selection and chemically-stabilised wide crossing can be utilised to generate phenotypes that may be identical to those produced using recombinant DNA technology, but with none of the regulatory burden.

This situation has two significant negative consequences. The first is that only large companies can afford the investment needed to produce, characterise, test and register GMOs. This investment can only be justified if offset by increased income. Accordingly, traits that can be linked to sales of herbicides or that are expressed in hybrid crops are particularly financially attractive, even when other options might have greater agronomic, environmental or even consumer benefits.

Consequently over the last ten years, the larger seed companies have tended to concentrate on developing a restricted range of crop/traits (mainly insect resistance and herbicide tolerance in maize and cotton for example) where cultivation is on a large enough scale to justify the costs of development.

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<sup>24</sup> Raybould A. and Poppy G. (2012). Commercialising genetically modified crops under EU regulations, objectives and barriers. *GM Crops and Food: Biotechnology in Agriculture and the Food Chain* **3(1)**: 9 – 20.

<sup>25</sup> Evaluation of the EU legislative Framework in the field of cultivation of GMOs:

[http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo\\_cultivation\\_report\\_en.pdf](http://ec.europa.eu/food/food/biotechnology/evaluation/docs/gmo_cultivation_report_en.pdf)

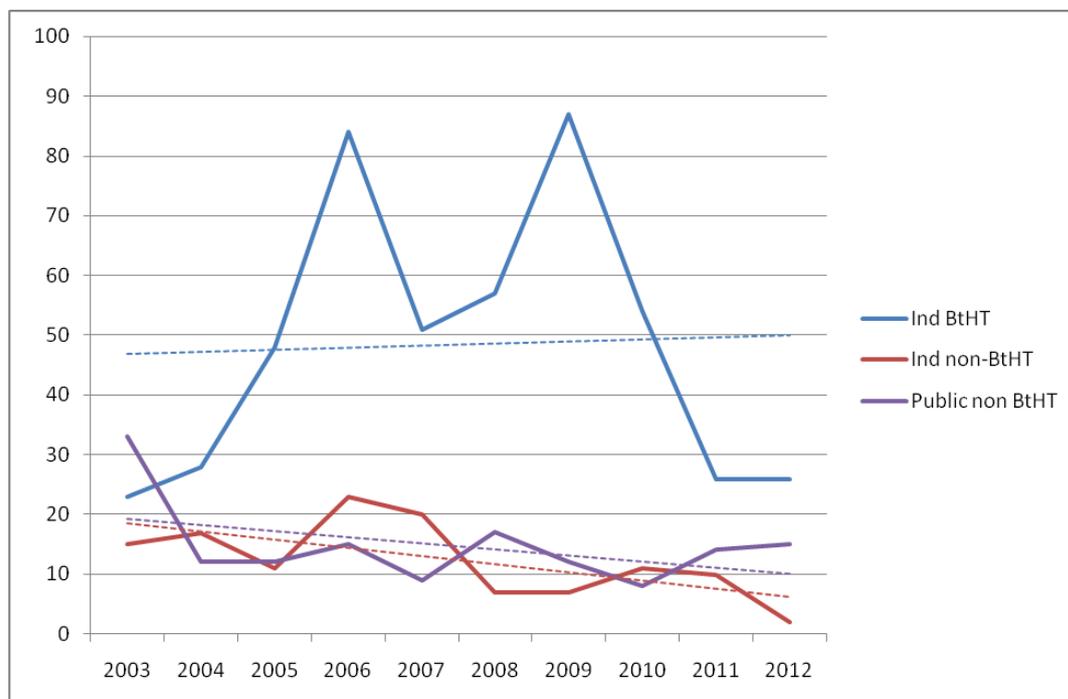
<sup>26</sup> <http://www.fera.defra.gov.uk/plants/plantVarieties/nationalListing/documents/feesAug2011.pdf>.

<sup>27</sup> <http://www.fera.defra.gov.uk/plants/plantVarieties/nationalListing/documents/fees2011.pdf>

<sup>27</sup> Kalaitzandonakes N., Alston J and Bradford K (2007). Compliance costs for regulatory approval of new biotech crops. Correspondence. *Nature Biotechnology* **25(5)** 509 -511.

These companies have also invested in the development of traits that have potentially wider utility for environmentally sustainable agriculture (such as abiotic stress tolerance, and improved nitrogen use efficiency etc), the scale of investment has been much smaller and has in fact declined steadily, supporting ACRE's concern that the complex, and seemingly obstructive regulatory framework in the EU is largely responsible. Publicly funded research towards developing these alternative traits has declined in parallel, suggesting i) a similar reluctance to invest in an area that is unlikely to provide a return and ii) a deterioration in the number of private/public collaborations that are often key for these more 'niche' areas.

The graph below illustrates these points by plotting the number of GM plant research applications received in the EU over the last ten years, divided into either industry funded containing Bt and/or HT traits, industry funded containing non Bt/HT traits and publicly funded containing non-Bt/HT traits. The data are from the European Commission's GMO register<sup>28</sup>.



Given the advantages that have accrued in the past from having a wide public-sector involvement in applied biological research, ACRE is concerned by the long term implications that these changes might have on our ability to address issues of sustainable practices and food security.

The second negative consequence is that the financial "rewards" for devising novel phenotypes not covered by the regulatory framework are potentially very large. A number of the scientific advances discussed in Report 2 may be considered recombinant DNA technologies (e.g. zinc finger nucleases) to generate organisms with novel traits that contain in the end product no

<sup>28</sup> [http://gmoinfo.jrc.ec.europa.eu/gmp\\_browser.aspx](http://gmoinfo.jrc.ec.europa.eu/gmp_browser.aspx)

sequences to allow them to be recognised as such. ACRE is concerned that the continuation of process-based regulation will divert attention away from novel material *per se* towards an increasingly small sub-set based on increasingly obsolete definitions. Given the current pressures on the global food system, it is increasingly anomalous that regulatory and compliance issues rather than agricultural opportunity should determine the patterns of intellectual and financial investment.

In conclusion, whilst ACRE accepts that streamlining the current system could speed up the regulatory process, and possibly reduce its cost, it remains concerned that it serves to stifle innovation, particularly from the public sector and that is not robust enough in its current form to cope easily with the range of new scientific approaches under development<sup>29</sup>.

#### **Key Question 4. Is general surveillance a scientifically justifiable and proportionate activity to require on a 'product-by-product' basis?'**

The current regulatory framework requires post-market monitoring to be carried out by the applicant as a condition of consents being issued. For "known unknowns" where there are specific hypotheses that can only be addressed during commercial cultivation, case-specific monitoring protocols can be devised to address them and the regulatory issues are fairly straightforward. This contrasts with the evaluation of "unknown unknowns" via general surveillance. Whilst the legislation is not explicit as to what this entails, applicants are expected to devise farm questionnaires and commit to annual literature reviews. EU regulators are also considering if, and how, existing wider ecological monitoring programmes may be useful. In its recent report on post-market environmental monitoring (PMEM)<sup>10</sup>, ACRE concluded that there are limits to the sensitivity of these three approaches and furthermore, we highlighted the difficulty in linking any detected change unambiguously to a specific cause. This is both because existing monitoring schemes do not necessarily align perfectly with the needs of PMEM programmes and because of the likelihood that the introduction of any novel organism will be restricted at first, and then expand as commercial success becomes established. It is worthy of note that the Australian regulatory system<sup>30</sup> does not have any requirement for general surveillance monitoring, only a duty on users to notify unanticipated adverse effects.

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<sup>29</sup> The latter is a consequence of the EU adopting a regulatory approach based on how novel organisms were produced rather than on their novel physical and biochemical characteristics (phenotype). As the definition of a GMO in the current legislation was adopted in 1990, it was designed to distinguish between techniques that were in use at that time. It is also based on a limited understanding about the plasticity of genomes. Technology in molecular genetics has developed rapidly since 1990 and a number of the techniques under development today were not foreseen at that time. It is unclear from the definition as to whether some of these techniques are captured by the GMO legislation or not. This includes recombinant technologies that cannot be distinguished from their non-GM counterparts. This is discussed in more detail in Report 2: *Why a modern understanding of genomics demonstrates the need for a new regulatory system for GMOs*.

<sup>30</sup> Australia's Gene Technology Act, 2000 (<http://www.comlaw.gov.au/Details/C2008C00198>)

ACRE is further concerned that more general cultivation of GM crops would lead to a proliferation of separate GS activities each using subsets of monitoring data to look for particular evidence of change. ACRE considers that this would not be an effective use of resources, given the findings of the PMEM working group, that it would divert effort away from more general analyses of the delivery of ecosystem services from farmland and that it will facilitate efforts to deliver "sustainable intensification".

Consideration of past changes in agricultural crops and managements suggests that negative environmental changes detected over a number of years will often be linked to a number of different drivers, given that novel organisms and managements are being introduced and developed all the time. In such circumstances, remedial activity is difficult to define and slow to have a measurable effect. Increasingly, such remedial activities are targeted at the ecosystem or catchment level, which wholly contradicts the approach taken with GM crops. ACRE concludes that "crop-by-crop" general surveillance activities that extend beyond simple dialogue with users and awareness of current relevant science is unlikely to be either proportionate or effective.

## **CONCLUDING REMARKS.**

Based on the arguments presented above, ACRE considers that the current EU regulatory system for GMOs will eventually need to be replaced. The current system is partial, in that it omits products that have identical environmental impacts to those that are included, it fails to give due regard to benefit and to compensatory options, which brings it into conflict with other regulatory procedures, and the approach to monitoring is very unlikely to produce the outcomes envisaged by regulators. In addition, the operation of the current system is slow, expensive and cumbersome, with very high compliance costs and it functions to stifle innovation, particularly in areas where regional rather than global challenges predominate. Increasingly the idea that effective risk management can be applied to some but not all novel components of agroecosystems runs contrary to concepts of effective protection of natural capital and will not facilitate the appropriate use of technology to sustain or increase outputs whilst minimising inputs and losses<sup>31</sup>.

ACRE accepts that there is little political appetite at present for recasting the regulatory system *de novo*. However, it argues that it would be prudent to start considering what a new regulatory system might look like. There are a number of issues that could cause the breakdown of the current system. First and foremost are the scientific advances (outlined in ACRE's new techniques report<sup>9</sup> and in Report 2) that will increasingly generate products with a wider range of novel functions, many of which will not fit in easily or at all into the current system. If a detailed reformulation of the criteria is necessary for

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<sup>31</sup> <http://www.official-documents.gov.uk/document/cm80/8082/8082.pdf>

deciding whether or not a product is “in scope”, then many of the other issues discussed above will come into play.

Secondly, the interfaces between the GMO regulations and other regulatory frameworks for medical and veterinary products and potentially for novel insects, fish, poultry and other animals are likely to increase in significance in the future. A significant part of ACRE’s current workload is in this area and it is already clear that issues relating to benefit and mitigation are problematic.

Finally, the costs to European economies of stifling innovation will increase markedly as the full range of biological technologies are employed by competitor countries to develop novel products in a more proportionate regulatory environment. Already, applied agricultural biotechnology is largely carried out beyond EU boundaries blocking access to a market with an annual value in excess of \$13bn<sup>32</sup>. Despite an excellent record of scientific innovation across bioscience, the increasingly pervasive use of recombinant DNA technologies in all types of novel product development means that UK universities, research institutes and small companies will increasingly be disadvantaged by a regulatory system that is expensive and ineffective. Given the importance attached by BIS and Defra to expanding wealth creation opportunities in this broad sector, ACRE recommends that Government departments should consider how the current system might best be recast in the short- to medium term.

ACRE does have some views on the essential characteristics of such a regulatory system. These are based upon some of the approaches outlined in the 2002 report, but are presented as high-level objectives rather than worked examples. They are listed below but not presented in any order of priority, since ACRE considers that an effective system should meet all of them<sup>33</sup>.

- The new system should be based on consideration of novel phenotypes, not of the technologies used to produce them.
- The overarching aim of the regulations should be the effective management of risk. Issues like adventitious presence that do not impact on harm to human health and the environment, should continue to be addressed via traceability and labelling regulations.
- Consumer awareness of novel products should be maintained via clear labelling.
- Decisions should be made on a case-by-case basis based upon objective assessment of risks, benefits and mitigation options and considering the full range of receiving environments
- Once there is a significant history of safe use (including mitigatory or compensatory actions), similar products would not require case-by-case assessment and thus would be exempt from regulation. This

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<sup>32</sup> James C. (2012). Brief 44. Global Status of Commercialised Biotech/ GM Crops: 2012. International Service for the Acquisition of Agri-biotech Applications (ISAAA).

<sup>33</sup> The Canadian Plant Biosafety Office (PBO) controls plants with novel traits (PNTs) regardless of the techniques used to produce them. This remains the best example of a regulatory approach that encompasses a number of the objectives listed above.  
<http://www.inspection.gc.ca/plants/plants-with-novel-traits/eng/13001378237/1300137939635>

would ensure that the overall regulatory system remained proportionate and that innovation was not stifled.

- The initial regulatory process of deciding whether or not any product fell within or outside scope should be a “single strike” and simple process with a minimal regulatory burden<sup>34</sup>.
- The current guidelines for the preparation of dossiers should be used as a pilot for full applications. ACRE fully supports EFSA’s proposals for a tiered approach to ERAs, with evidence of “no effect” at an early stage obviating the need for further evidence.
- In such a phenotype-based system, monitoring after release should be integrated with other analyses of the receiving environments for the sole purpose of detecting significant change, not attributing causality. Subsequent studies should be carried out to test hypotheses of causality and to determine options for risk management
- Consents should not be time-limited but revocation in the light of evidence would remain an option until the product moved “out of scope” through a history of safe use.
- The regulatory process should be reviewed regularly against metrics of success, to assess fitness for purpose, proportionality and efficiency.

Acknowledgement: ACRE thanks Professor Alan Gray for his constructive comments in reviewing this report.

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<sup>34</sup> The EU’s existing regulation on novel foods (Regulation (EC) 258/97) is an example of a legislative instrument that is operated in a way that allows for more pragmatic and proportionate control of novel products and processes. It adopts the concept of substantial equivalence such that new products can be dealt with using a simplified procedure as long as their principal characteristics – composition, nutritional value, metabolism and undesirable substances – are no different to those of other products on the market. New processes applied to foods are only covered if they result in a significant change to the end product. The assessment of novel foods also takes experience of prior use of a product/ process formally into account i.e. where the product has been marketed safely outside of the EU.

