EDITORIAL

GM crops—lessons from medicine

Earlier this year, the U.S. National Academy of Sciences released a report on genetically engineered crops that is comprehensive but offers few recommendations in terms of regulatory guidance. Although it acknowledges that a process-based regulatory system is becoming less technically feasible, the report suggests that regulators focus on safety aspects of technology when considering approval. We believe that products of new technologies should be regulated not only on the basis of their benefit-risk profiles, but also on their societal context and need.

Currently, a new crop variety is handled under European Union regulations dependent on the process used to generate it. A conventionally bred crop primarily has to show that the variety is uniform, distinct, and stable, whereas a genetically modified (GM) crop has to undergo an additional evidence-based risk assessment. With the advent of new technologies, such as genome editing with the clustered regularly interspaced short palindromic repeats (CRISPR)–Cas system, the boundaries between GM and non-GM techniques will become increasingly blurred, and in many cases there will be no way to tell whether a variety was arrived at by conventional breeding and/or use of new methods.

In Canada, a trait-based regulatory system is used in which the actual trait, such as drought or disease resistance, rather than the method used to derive it, is the basis for regulation. Such a trait-based system is analogous to the regulation of new agents in medicine, which takes into account the context in which the product will be applied. For example, therapeutic antibodies for diseases as diverse as cancer and arthritis are not regulated simply on the basis that they are antibodies—rather, they are assessed in terms of the proteins they target, the benefit to patients, and the risks of adverse events. The focus is on a benefit-to-risk ratio that is reassessed throughout the life cycle of the product (as evidence accumulates). With new medicines for life-threatening diseases, there will usually be a greater acceptance of risk in the absence of existing effective treatments—that is, the consequences of doing nothing are taken into account. Therefore, patients, as well as regulators, accept a lower benefit-to-risk ratio than would be considered appropriate for a disease that is self-limiting and rarely life-threatening, such as the common cold.

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The contextual notion used in regulating new medicines may also be helpful in debates around the assessment of new varieties of crops or other engineered products. It is important to consider their benefit-to-risk ratio in the context of the likely harm of making no intervention to combat the problem that the new product is aimed at solving, such as fungus resistance. Context might also change with time. For example, the risk posed by doing nothing in terms of the threat of swine fever, and therefore the acceptability of approving disease-resistant pig strains, might be very different if there were a low incidence of the disease and the existence of a vaccine to prevent it, versus a situation in which there was a high incidence of a virulent strain causing the disease and no vaccine.

Of course, in many cases, the evidence provided will not be complete because proving absence of adverse effects is subject to "real-life" data collection, as is the case in the postapproval surveillance process of new medicines. Indeed, absence of evidence is not evidence of absence. However, such a contextual framework will at least facilitate a more constructive debate that is more consistent with other forms of regulation in Europe and elsewhere and which should aid the translation of new research into application.

–Jackie Hunter and Gordon Duff

Jackie Hunter is the chief executive officer of Benevolentai Bio Ltd., London, UK, and is the former chief executive of the U.K. Biotechnology and Biological Sciences Research Council. Email: jackie.hunter@benevolent.ai

Sir Gordon Duff is principal of St Hilda's College, University of Oxford, UK; was formerly chair of the U.K. Medicines and Healthcare products Regulatory Agency; and is chair of the U.K. Biotechnology and Biological Sciences Research Council. Email: principal@st-hildas.ox.ac.uk

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