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## THE CASE FOR REGULATING INTRAGENIC GMOs

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**ABSTRACT.** This paper discusses the ethical and regulatory issues raised by “intra-genics” – organisms that have been genetically modified using gene technologies, but that do not contain DNA from another species. Considering the rapid development of knowledge about gene regulation and genomics, we anticipate rapid advances in intra-genic methods. Of regulatory systems developed to govern genetically modified organisms (GMOs) in North America, Europe, Australia, and New Zealand, the Australian system stands out in explicitly excluding intra-genics from regulation. European systems are also under pressure to exclude intra-genics from regulation. We evaluate recent arguments that intra-genics are safer and more morally acceptable than transgenic organisms, and more acceptable to the public, which might be thought to justify a lower standard of regulation. We argue that the exemption of intra-genics from regulation is not justified, and that there may be significant environmental risks associated with them. We conclude that intra-genics should be subject to the same standard of regulation as other GMOs.

**KEY WORDS:** consumers, environment, ethics, genetically modified organisms, intra-genics, nature, regulation, safety

### 1. INTRODUCTION

Modern gene technologies give scientists the power to move and/or modify specific genetic elements both within and between species.<sup>1</sup> “Transgenics” – organisms that contain genetic material from other species – represent the archetype of genetic modification; they reflect the power of modern scientists to re-engineer living organisms without regard for “natural” species boundaries. The violation of species boundaries has tended to feature prominently in public concern about genetically modified organisms (GMOs) (Brown and Michael, 2001; Cormick, 2003). An important recent response to this concern

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<sup>1</sup> By “modern gene technologies” here we mean both recombinant DNA and RNA technologies that allow the manipulation of specific sequences of an organism’s genetic material in the laboratory. Following others in this debate (Nielsen, 2003; Myskja, 2006; Schouten et al., 2006a, b), we have excluded techniques such as chemical and irradiative mutagenesis, cell-based techniques such as protoplast fusion, and traditional breeding from our definition of gene technology.

has been to advocate the use of recombinant DNA technology to produce genetic modifications without the transfer of DNA between species (Nielsen, 2003; Myskja, 2006; Jacobsen and Schouten, 2007). Organisms that have been genetically modified via modern gene technology using only endogenous genetic sequences or sequences from sexually compatible species are known as “intragenics.”<sup>2</sup> Nielsen (2003) and Myskja (2006) have argued that the development of intragenics represents an approach to genetic modification that is more “natural” than the creation of transgenic organisms and consequently involves lower levels of risk and uncertainty. Intragenic organisms may also be significantly more acceptable to the public. This promise and new developments in science, including genomics and interference RNA technology, may lead to intragenic modification becoming a widely used approach to creating new organisms (O’Neill, 2004; Rommens, 2004; Conner and Jacobs, 2006).

Over the last three decades, many nations have developed regulatory systems designed to manage the risks of GMOs and to respond to public concern about them. In this paper, we examine regulatory systems in the US, Canada, Europe, Australia, and New Zealand. New Zealand is the only jurisdiction that explicitly categorizes intragenics as GMOs. Canadian regulations, which focus on the products of gene technology and their characteristics, rather than the process whereby they have been created, capture intragenics in their regulation of GMOs. The United States has a similarly product-focused, but less precautionary approach wherein intragenics are treated in the same way as other GMOs – which is to say that they are not subject to any dedicated regulatory attention. In Australia, intragenics lie entirely outside the scope of GMO deliberate release regulations; research dealings with intragenics may also go unregulated. In Europe, intragenics are probably captured by GMO regulations, depending on their interpretation, but this may change as a result of industry pressure and arguments from scientists and philosophers.

If intragenics are the way of the future for genetic modification, it is timely to revisit the debate about the classification of novel organisms, to ensure that any decisions about the classification and regulation of intragenics are well-founded. We critically evaluate the arguments that have been made in favor of intragenics over transgenics and argue that these are insufficient to justify a lower standard of regulation of intragenics. There may be significant risks

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<sup>2</sup> Such organisms have also been described elsewhere as “cisgenics” (Schouten et al., 2006a; Jacobsen and Schouten, 2007) and “autotransgenics” (Nam et al., 2001). We have chosen to follow Nielsen (2003) in using the term, “intragenics,” which includes but is not restricted to these other categories where they are more strictly defined (for example, we do not use the restriction introduced by Jacobsen and Schouten (2007) that native DNA sequences are necessarily accompanied by their native promoters in intragenics).