How are Genetically Engineered Organisms Regulated in Canada?

Canada is the fifth largest producer of genetically modified (GM) organisms in the world. With the majority of genetically modified products hailing from the agriculture industry, such as maize, soybean, and beets, the Canadian government has updated its regulations and policies in response to the rapidly growing GM industry (ISAAA, 2010).

The first major policy relevant to GMOs in Canada was established in 1993 with the Federal Regulatory Framework for Biotechnology. This framework stated that new biotechnologies would be regulated under existing regulations that cover more traditional products, avoiding the need to create a separate agency with its own legal frameworks, preventing increased redundancy among regulatory agencies. In contrast, GMO regulation and assessment in the United States of America (U.S.A) is overseen by multiple agencies. These include the Environmental Protection Agency (EPA), Food and Drug Administration (FDA), the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS), as well as by smaller regulatory units within these agencies specifically focused on GM projects (MacLaughlin, 2004).

Canada's regulatory approach focuses on the review of novel products rather than processes used in their making. Unlike other countries, Canada relies on the idea of novelty to trigger regulatory oversight, allowing the regulation of a wider array of novel technologies (Montpetit, 2005). In essence, the regulation of GM projects allows for free innovation and the faster creations of solutions using synthetic biology, as long as they do not infringe upon existing regulations. As a result, Canada is considered to adopt an exceptionally permissive attitude towards GMOs and takes a far less precautionary approach than European countries and the US.

Regulatory Assessment Considerations

In Canada, GMOs are assessed at both the federal and provincial level, with regulation that may or may not overlap between the two. Generally, provinces do not impede on federal policies and often choose to supplement them. At the federal level, regulatory authority is split between the Canada Food Inspection Agency (CFIA) and Environment Canada, with both organizations mandated to look over GMO biosafety. The CFIA and Environment Canada have distinct duties with respect to the nature of the genetically modified product: the CFIA administers regulations prescribing the assessment of novel plants and farm inputs, while Environment Canada assesses novel foods, a generic term encompassing foods derived from GMOs (Parliament of Canada, 1998).

At the end of the day, the jurisdiction of both organizations falls under the directive of many legislations, such as the Federal Regulatory Framework for Biotechnology, the Food and Drugs Act, and the Canadian Environmental Protection Act. Anything not covered under current federal statutes would fall under the 2000 Canadian Environmental Protection Act (CEPA), which acts as a safety net for novel technologies. CEPA establishes a process of assessing and regulating new living products derived from biotechnology, which includes the release of

transgenic animals into the environment. As of right now, there are no other regulations that apply to them specifically (Parliament of Canada, 2004).

The UBC iGEM team approached multiple experts with experience in government biotechnology regulation to determine the appropriate avenues for the downstream assessment of their project. Collectively, these experts agreed that due to the nature of the project, it would fall under CEPA. Current GMO regulation standards mainly pertain to the agriculture industry, specifically for crop plants and additives to animal feeds or fertilizers. On the other hand, CEPA regulation of “animate products of biotechnology” (living organisms) is done by CEPA enforcement officers as a part of Environment Canada (Environment Canada, 2013). The UBC iGEM team, in assessing the project in this manner, would need to provide reports that state all environmental and human health risks.

Once all concerns have been addressed, both the transformed bacteria and the bees carrying them be placed on the Domestic Substances List, an inventory of new substances produced in Canada. Currently, this list contains 35 living organisms.

Upon approval, CFIA would oversee the production and dispersal of the GMO into the environment. Regulatory analysis and evaluation are done in a preliminary, small-scale, and contained study, followed by a second, large-scale screening under application settings. It is at this step that certain risks are tested to deem the product viable for consumer usage. In this context, approval from the CFIA would allow for the use of the probeeotics in Canadian farms. Most Canadian farmers hire beekeepers with "traveling beehives" to pollinate their crops and do not keep bees themselves. Thus, risks associated with bees leaving the hive and flying to unwanted locations, such as into the US, due to these farms' geographic location are very limited.

Specifically in British Columbia, a third and final assessment would need to be done so that local farmers and beekeepers can access the product. Through interviews and independent research, the UBC iGEM team determined that approval of the project in B.C. would fall under the Ministry of Environment. Currently, the Ministry does not have regulations on GMOs and as such would require the team to individually talk to provincial officials for further feedback.

Risk Assessment Considerations

Due to the complex nature of this project, different risks come into play at various stages of the final product. Three facets of the project can be identified as risks to both the environment and human health: the transformed imidacloprid-resistant bacteria, the probeeotic bees, and the honey produced by these bees.

Transformation of bacteria is a common procedure around the world across various institutions and research centers. This process is the bread and butter for not only iGEM projects throughout the years, but the entire field of molecular biology. As such, many facilities geared towards molecular biology have biosafety standards to prevent the contamination and release of unwanted transformed bacteria into the environment. At UBC, the iGEM team has ensured that all experiments are conducted in laboratories with the appropriate safety measures and certifications, provided by the UBC Biosafety Risk Management Services (RMS). From

interviews with veteran geneticists, feedback on the project focused primarily on the bacteria's ability to exit the bee and/or the possibility of horizontal transfer into other organisms. This risk is especially pertinent, enabling the transfer of imidacloprid resistance to pests meant to be killed by the pesticide. To address this issue, the UBC iGEM team investigated the transformation of bee gut-specific bacteria, such as *Gilliamella apicola* and *Snodgrassella alvi*, to eventually add the imidacloprid degradation pathway into these bacteria. With difficulty in culturing the bacteria in environments varying from the native environment of the bee gut, there is evidence to believe that a modified bacterium would only be viable within the bee gut and cannot survive in both the environment and guts of other pests. Of note, *Gilliamella apicola* is a microaerophilic bacterium that would not be expected to survive under environmental oxygen concentrations. To learn more about this investigation, look in the "Screening" section on the UBC IGEM website.

Unlike other insects, bees are unique in that they are highly social and integral to the biological ecosystems they participate in. They are also pivotal in the production of numerous agricultural produce. Bees inoculated with transformed bacteria could thus interact adversely with the environment, escalating the risk of transgene transmission. Due to this, major risk assessments mainly focus on methods that ensure safe containment of bees

The UBC iGEM team, under the advice of the Foster lab, worked with bees in containment vessels designed to prevent the event of a breakout. Further progress would involve consultation with beekeepers in seeing what their current technology is for holding their bee hives. Based on those assessments, the UBC iGEM team would help implement structural changes to those enclosures to ensure proper housing for probeeotic bees.

Honey is produced when bees regurgitate collected nectar stored in their "honey stomachs" (U.S. Department of Agriculture, 1910). This process is not mediated by the normal bee gut, preventing the spread of transformed bacteria in honey, building a case for the thought that the ingestion of honey from bees inoculated with transformed bacteria should be no different than normal honey. Given that the systems are so closely intertwined, however, there is no reasonable way to provide reassurances of safety on this front, highlighting the need to address the concern of honey containing GMOs in the interest of general public and environmental health.

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