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 producyd 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 a 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 but rather supplement them. At the federal level, it is split into two major regulatory agencies: the Canada Food Inspection Agency (CFIA) and Health Canada, both of which have mandates to look over GMO biosafety. However, CFIA administers regulations prescribing the assessment of novel plants and farm inputs, while Health Canada assesses novel foods, a generic term encompassing foods derived from GMOs (Parliament of Canada, 1998).

Regardless of the agency, their jurisdiction falls under the directive of many legislations, including the Federal Regulatory Framework for Biotechnology, the Food and Drugs Act, and the Canadian Environmental Protection Act. Anything not covered under current federal statutes still fall under the 2000 Canadian Environmental Protection Act (CEPA), which acts as a safety net for novel technologies, among other things. 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 who have worked 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, the transgenic bees would be placed on the Domestic Substances List, an inventory of new substances produced in Canada. Currently, this list contains 35 living organisms (Environment Canada, 2013).

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 contained study prior to a second, larger 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 transgenic bees in Canadian farms. Most Canadian farmers hire beekeepers with "traveling beehives" to pollinate their crops and do not keep bees themselves. Thus, the risks associated with bees leaving the hive and flying to unwanted locations, such as into the US, due to these farms' geographic location is 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 about at various stages of the final product. Three layers can provide risk to both the environment and human health: the transformed imidacloprid-resistant bacteria, the transgenic bees, and the honey produced by these transgenic bees.

Transformation of bacteria is widely done around the world across various institutions and research centers. This is also the basis for many iGEM projects throughout the years. As such, many of these facilities have biosafety standards to prevent contamination and prevention of releasing unwanted transformed bacteria into the environment. At UBC, the iGEM team has ensured that all experiments are conducted in laboratories with the proper safety measures and biosafety certification, provided by the UBC 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 important, as it would be possible to bestow imidacloprid resistance in 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 metabolic pathway into these bacteria. The hope is that the product is only viable in the bee gut and cannot survive in both the environment and in the gut of pests. Of note, *Gilliamella apicola* is a microaerophilic bacteria 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 its relevant biological ecosystems. They are also pivotal in the production of numerous agricultural produce. These transgenic bees will thus interact heavily with its environment, escalating the risk of passing on the transformed genes it contains. Thus, major risk assessments mainly focus on methods to ensure that these bees, whether they are being studied in the laboratory or being used on farms by beekeepers, are housed safely to prevent unneeded exposure and activity. Through interviews with both bee researchers and beekeepers, the solution is to have the proper facilities and containment. The UBC iGEM team, under the advice of the Dr. Foster lab (http://www.chibi.ubc.ca/faculty/leonard-foster/foster-lab/), work with bees in containment vessels authorized and validated in preventing them from escaping. 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 transgenic bees.

Honey is produced when bees regurgitate collected nectar stored in their "honey stomachs" (U.S. Department of Agriculture, 1910). This process does not go through the normal bee gut, so the honey collected by bee farmers should not contain any of the project's transformed bacteria within it. In essence, ingesting honey from the transgenic bees should be no different than normal honey. Despite that, the UBC iGEM team would follow up on the concern of any unwanted contamination by assessing and experimenting on the transgenic bee honey. That way, it can be ensured that the general public is not consuming anything that may pose a health risk.

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