

Misuse

As a probiotic bacterium that converts glucose into cellulose, this year's project is designed with the intention to provide holistic health benefits for the user. Of itself, our project has little opportunity to cause harm; since lactobacillus species are naturally found in the human gut, and the human body commonly processes both glucose and cellulose, it is unlikely that our product could be developed as a toxin. Unfortunately, it is always possible to misuse a product.

The greatest concern for misuse of our project is the false exaggeration of its effects. More specifically, it is possible that both marketers and consumers will consider the project as a weight loss scheme rather than a supplement to overall health. The bacterium will not convert glucose into cellulose at a rate fast enough to completely convert the sugar content of a candy bar or a can of soda; it is not a means of rapid weight loss, and should not be presented as such. Marketers of the product should not take advantage of consumers' ignorance by overselling the glucose-conversion capacity of the product. Likewise, consumers should not use the product as a means to "eliminate" the sugar they consume; if consumers use the product as an excuse to greatly increase their sugar intake, they will actually risk damaging their overall health rather than improving it. The bacterium is designed as supplement to a healthy lifestyle, not as a gimmick to lose weight, and should only be marketed and used for its intended purpose.

Improving Codes and Regulations on Genetic Engineering

Biosafety at the University of Ottawa:

We were not successful in meeting with the biosafety officer of our institution, but we know that our project does not violate the guidelines set by the University. http://www.uottawa.ca/services/ehss/biosafety.htm

Genetic engineering has the capacity to create genetically engineered machines that have a positive impact on the global community; however, the current technology could be abused to design organisms that do more harm than good. Genetic engineering can be viewed as threatening by the non-scientific community, and until codes adequately regulate the use of the current technology, it is possible that opposing public opinion will hinder the advancement of the science. It is therefore essential that extensive and widely accepted codes and regulations on genetic engineering be put in place as soon as possible.

International competitions like iGEM present an incredible opportunity for security collaborations among countries from around the world. The current concept of an iGEM code, to be followed by all members of the iGEM community, is a

great start, and could be a model for international codes in the future. iGEM should require that a security analysis of a project be submitted and approved prior to working on the project; this ensures transparency of the projects and also ensures that possible security threats are prevented rather than solved after the fact. The analysis should outline national regulations on genetic engineering, possible misuses of the project, the precautions that should be taken in the lab to ensure accordance with their national laws and to ensure the safety and security of the lab team, as well as measures to ensure that the project-in-progress remains safely within the lab environment and is not exposed to the outside world. The iGEM code should outline security requirements stating that projects should not be intended for harmful purposes, and that the risk of misuse of the project is minimal. It should also state that the laboratory techniques should minimize any risk to the researchers, and that measures of lab safety must be announced by the iGEM team in their initial report. The code should include provisions to prevent exposure of any untested genetically modified material to the outside world to prevent any unforeseeable interactions with the natural environment. Furthermore, the code should include a responsibility of iGEM team members to report any activity they find unsecure, and should clearly outline the measures to be taken both in reporting the incident and in eliminating the security risk. For example, iGEM could establish a Security Council which approves the security analyses and responds to any reports of misuse or neglect, and which has the power to punish teams for breaching the iGEM security code, such as lowering their scores or disqualifying them from the competition. Having a clear code, a governing body to review and enforce it, and a required analysis of security measures will help to ensure the safe use of current genetic engineering technology within the iGEM competition.

Having a clear code and governing security body at iGEM can act as a security model for other organizations, and since iGEM is internationally exposed, it could inspire better safety precautions in many areas around the world. As genetic engineering technologies become more common and widespread, it will be essential that regulations be put in place to ensure public safety. The transparency of genetic modification projects is key to prevent the development of harmful organisms. Regulations on the use of genetically modified organisms in foods and crops is also extremely important; these products should undergo rigorous testing to study their effects on natural populations before being exposed to the general public. As members of the iGEM community, we can develop a system to control iGEM projects and then use iGEM as a platform to advocate the use of the iGEM security model in our respective countries.

An iGEM security model should include:

- -A Security Council responsible for approving projects and addressing reported security issues
- -A requirement for all teams to submit a security report of their project that must be approved PRIOR to commencing lab work
- -A clear code that obliges teams to do no harm, to minimize possible risks and misuses, to follow their national safety legislation, to use safe laboratory techniques, to prevent exposure of projects to the outside world, and to report any security breaches

Security Provisions in Canada

In Canada, there are several governing bodies responsible for the regulation of biotechnology, each specializing in a different field or application of the technology. The Canadian Foods Inspection Agency is responsible for approving agricultural biotechnology, including genetically modified animals and animal feed, according to Health of Animals Act, the Food and Drugs Act, the Meat Inspection Act, and the *Feeds Act*. They also approve novel feeds according to the *Feeds Act*, novel fertilizers according to the Fertilizers Act, novel plants according to the Plant Protection Act and the Seeds Act, as well as veterinary biologics according to the *Veterinary Biologics Guideline 3.2E: Guideline for the Regulation of Veterinary* **Biologics** produced by Biotechnology. For more information. http://www.inspection.gc.ca/english/sci/biotech/bioteche.shtml

Health Canada and its many subdivisions regulate most other applications of biotechnology in Canada. For more information about Health Canada and its various roles in regulating biotechnology, see http://www.hc-sc.gc.ca/sr-sr/biotech/index-eng.php.

Specifically pertaining to our project, genetically modified foods are governed by Health Canada under the *Food and Drugs Act*. Genetically modified foods are submitted to Health Canada's Novel Foods Section, where a panel of scientific evaluators consider the submission according to guidelines regarding the development of the organism, the composition of the food, the food's potential to be toxic or to cause allergic reactions, the presence of any toxins, the food's potential for secondary health effects, and all constituents of the food. All criteria must be well documented by the creators and no judgment will be made if scientific documentation is not adequately presented. Once evaluated, a Health Canada Foods Ruling Proposal is submitted to the senior staff of the Food Directorate, who address any further issues before making a final acceptance or rejection. For more information, visit http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg-gen modeng.php.

In regards to the labeling of foods containing genetically modified organisms, according to *Voluntary Labelling and Advertising of Foods that Are and Are Not Products of Genetic Engineering* as developed by the Canadian General Standards Board, labels of genetically modified foods may, but are not required to, indicate that ingredients are genetically modified. However, regardless of if the label does

not state that an ingredient is genetically modified, the manufacturer is always required to make information available about the methods and origin of the genetically modified ingredients. To read *Voluntary Labelling and Advertising of Foods that Are and Are Not Products of Genetic Engineering*, visit http://www.tpsgc-pwgsc.gc.ca/cgsb/on-the-net/032-0315/standard-e.html.

Security Provisions at the University of Ottawa

At the University of Ottawa, biosafety is regulated by the Office of Risk Management. They are responsible for regulating laboratory safety and training procedures. Our team discussed our project with the office's Manager of Radiation and Biosafety, Lois Sowden-Plunket.