1. What institutional body enforces the laws regarding the use of GMMs?

European Union

European Commission is the institution responsible for proposing and implementing legislations applying to all member countries. Member countries may additionally restrict or prohibit the cultivation of GMMs in their territory. This possibility, however, is regulated by Directive (EU) 2015/412 adopted by the EU.

United States

Stemming from research from the University of Virginia and EMBO, the J. Craig Ventor Policy Center Team has concluded that the United States lack an agency that specifically focuses on enforcing laws regarding GMMs. Instead, legislation such as the Coordinated Framework for Regulation of Biotechnology and the President's Commission for studying Bio-ethical issues, which was established by Barack Obama. As of now, the regulatory agency with the most regulatory control on issues regarding synthetic biology is the United States Department of Agriculture (USDA).

Australia

In Australia, the use of GMMs is regulated under a nationwide legislative framework consisting of two main branches: the Gene Technology Regulator and Food Standards Australia New Zealand (FSANZ). Individual states and territories also have their own legislation in accordance with this framework.

Brazil

In Brazil, the Biosafety Law (Law 11105/05) sets the safety rules and fiscalisation of GMMs and its derivatives in the national territory. The National Technical Committee of Biosafety (CTNBio) is responsible for enforcing the laws and setting the rules for the construction, experimentation, cultivation, manipulation, transport, commercialization, consumption, release and discarding of GMMs and its derivatives.

Japan

In Japan, mainly Ministry of Agriculture, Forestry and Fisheries and Ministry of the Environment is responsible for the use of GMMs. With these ministries at the core, other institutions such as Ministry of Education, Culture, Sports, Science and Technology, Ministry of Health Labour and Welfare are also responsible for GMMs in each related field.

Chile

Chile doesn’t have a clear regulation for biotechnology. However, the Agricultural and Livestock Service is responsible for the importation, sowing and propagation of GMOs, also regulating the exportation of

seeds (Law N° 3.557/82 actualised Law N°1523/2001). The Ministry of Health, on the other hand, regulates the labelling of food made with the use of GMOs (Article 107).

Indonesia

The laws regarding the use of GMMs are regulated by 4 ministries: The Ministry of Agriculture, The Ministry of Forestry and Plantation, The Ministry of Health, and The Ministry of Food and Horticulture. They created the Government Regulation of the Republic of Indonesia Number 21 year of 2005 (PP No. 21/2005) on Biosafety of GMO.

Korea

The usage of the GMMs in Korea is strictly regulated by the *GMO Law,* established on Jan 28, 2001. The Ministry of Trade, Industry and Energy takes charge of this law.

India

India is currently undergoing a massive overhaul in their laws and regulations regarding GMOs. Currently, there is a proposed "Regulations and guidelines on biosafety of recombinant DNA research and biocontainment, 2017' draft that has been prepared and opened for comments. Currently, under the proposal, the following 6 bodies are in charge of enforcing laws regarding GMOs and GMMs -

1. Recombinant DNA Advisory Committee (RDAC) - Advisory
2. Institutional Biosafety Committee (IBSC) - Regulatory/ Approval
3. Review Committee on Genetic Manipulation (RCGM) - Regulatory/ Approval
4. Genetic Engineering Appraisal Committee (GEAC) - Regulatory/ Approval
5. State Biotechnology Coordination Committee (SBCC) - Regulatory/ Approval
6. Monitoring District Level Committee (DLC) - Monitoring

Canada:

In accordance with *Foods and Drugs Act*, Health Canada, the Canadian Food Inspection Agency (CFIA), Fisheries and Oceans Canada and Environment Canada are the administrative branches responsible for the regulation of products derived from biotechnology. Health Canada's role is to enforce standards for safety and nutritional quality of all foods sold in Canada. It works under the *Foods and Drugs Act.* The Canadian Food Inspection Agency (CFIA) role is to minimize diseases and other public health hazards that could potentially be caused by the food supply system. Fisheries and Oceans Canada role is to regulate Canadian fisheries, oceans and freshwater resources. This joint effort helps ensure that informed decisions regarding GMMs by pooling the expertise and considerations of each agency together.

2. Who regulates the use of GMMs on a case-by-case basis?

European Union

All member countries are obliged to establish 'competent authorities,' institutions responsible for overseeing the use of GMMs on a case-by-case basis.

United States

The US Food and Drug Administration regulates any GMMs that get used in consumer products, such as GMMs in food or cosmetics. The US Department of Agriculture regulates any genetic modification of plants. However, any GMMs that are to be released into the environment are regulated by the Environmental Protection Agency.

Australia

It is the role of the Gene Technology Regulator Advisory Committee to assess all data supplied by any applicant (who is intending to release GMMs into the environment) and perform a comprehensive literature review to determine whether or not it will be approved. FSANZ also regulates the use of GMMs in foods for human consumption on an individual case-by-case basis.

Brazil

The Brazilian Health Regulatory Agency (Anvisa) approves and inspects the use of GMMs and its derivatives in any products for human use (e.g., pharmaceuticals, biopharmaceuticals, cosmetics and food). The Ministry of Agriculture, Animal Husbandry and Supply (MAPA) is responsible for regulating the use of modified seeds and plants. All GMMs must be approved for release by CTNBio.

Japan

In Japan, Ministry of Education, Culture, Sports, Science, and Technology, and Ministry of the Environment regulate the use of GMMs on research and development. Ministry of Agriculture, Forestry and Fisheries and Ministry of the Environment regulate the use of GMMs that are agricultural produce. Ministry of Health, Labor and Welfare and Ministry of the Environment regulate the use of GMMs that are pharmaceuticals for human body.

Ministry of Education, Culture, Sports, Science, and Technology regulates the gene recombination experiments. Ministry of Economy, Trade and Industry regulates the use of GMMs on a production of enzymes for industrial use. Ministry of Agriculture, Forestry and Fisheries regulates the use of GMMs on a production or sale of experimental animals.

Chile

Environment Ministry regulates crops for production with environmental impact service (SEA) (Law N° 19.300/1994). The Health Ministry has a specific regulation for food and drinks. For the propagation of any GMO, the Agricultural and Livestock Service is in charge.

Indonesia

On a case-by-case basis, it is regulated by a specific non-ministry government institution *The Biosafety Commission and The Technical Team for Biosafety* on 5 different fields: foods, plants, animals, fishes, and microorganisms. They review all the required technical documents and inform whether or not it is needed to do a follow-up laboratory test and so on.

Korea

The committee of the Biosafety is the umbrella body for other GMO supervising ministries. With the help of the Korea Biosafety Clearing House (KBCH), which is the information center, each Ministry takes care of case falling under their supervision. For instance, the Ministry of Science, ICT and Future Planning is in charge of the academical usages of GMOs.

India

As per the proposed "Regulations and guidelines on biosafety of recombinant DNA research and biocontainment, 2017'', the following has been proposed -

Genetic Engineering Appraisal Committee (GEAC) [formerly known as Genetic Engineering Approval Committee (GEAC), has been established under the Ministry of Environment, Forest and Climate Change (MoEF&CC). The major functions of GEAC as prescribed in the Rules 1989 are:
i. To appraise activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from the environmental angle.
ii. To appraise proposals relating to release of genetically engineered organisms and products into the environment including experimental field trials.
iii. The committee or any persons authorized by it has powers to take punitive action under the Environment (Protection) Act, 1986.

The SBCC is a monitoring committee at State level and it shall have powers:
i. To inspect, investigate and to take punitive action in case of violations of statutory provisions through the State Pollution Control Board or the Directorate of Health etc.
ii. To review periodically the safety and control measures in various institutions handling GE Organisms.
iii. To act as nodal agency at State level to assess the damage, if any, due to release of GE Organisms and to take on site control measures.

There shall be a District Level Biotechnology Committee (DLC) in the districts wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous microorganisms and its applications in the environment.

The District Level Committee/or any other person/s authorized in this behalf shall visit the installation engaged in activity involving genetically engineered organisms, hazardous microorganisms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activities with a view to meeting any emergency. They shall also prepare an off-site emergency plan. The District Level Committee shall regularly submit its report to the SBCC/ GEAC.

Canada

Manufacturers wishing to make their products available in Canada are required to submit paperwork (including manufacturing and quality control methodologies, pre-clinical and clinical tests, side effects and limitation), as well multiple samples in the case of biologics, to Health Canada. Health Canada will then evaluate the product according to the regulations set out in the *Food and Drugs Act,* the *Food and Drugs Regulations,* and the *Medical Devices Regulations.*

3. What legal requirements do I have to fulfil in order to be able to use GMMs in my business?

European Union

A. If your business involves **contained use of GMMs**,

1. Run a risk assessment
2. Assign an appropriate risk class to your activity
3. Notify the competent authority about your planned use
4. Follow the safety measures which apply to the risk class identified

For more details, read Directive 2009/41/EC.

B. If your business involves **releasing GMOs into the environment**,

1. Run a risk assessment
2. Notify the competent authority about your planned use
3. After completion of a release, send to the competent authority the result of the release in respect of any risk to human health or the environment
4. Notify the competent authority about your product placement on the market
5. Following the placing on the market of a GMO as or in a product, ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent.

For more details, read Directive 2001/18/EC.

C. If your business involves selling or producing **genetically modified food or feed**,

1. Apply to a competent authority supplying them with relevant information
2. Follow appropriate labelling guidelines once you have received the authorisation

For more details, read Regulation (EC) 1829/2003.

D. If the product you want to sell inside the EU includes GMO,

1. Inform trade buyers in writing that a product contains GMOs (or provide a 'declaration of use' for products intended for food or animal feed).
2. Communicate the unique identifiers assigned to each GMO under the regulation.
3. Identify each ingredient produced from GMOs, if an ingredients list exists (for food and feed).

This information should be provided at every stage in the production and distribution chain and kept for 5 years.

For more details, read Regulation (EC) 1830/2003.

E. Finally, check if the country in which you plan to start your business, does not have additional restrictions. You should contact the competent authority operating in your country before you commit any capital.

United States

Under FDA regulations, most plant GMOs are considered equivalent to non-GMOs and do not require much further approval. However, if the modified plant expresses a protein that is significantly different from any protein it originally expressed, then the business must get approval from the FDA.

To receive EPA approval for GMOs with the Bt toxin, the business must conduct a food-safety analysis and verify that the toxin will be safe for the environment. GMOs without this toxin can be freely used.

Australia

Prior to any use of a GMM, a business must first obtain a licence from the Office of the Gene Technology Regulator. This process involves providing detailed information about the host, donor, transferred DNA, properties of the GMM and where it will be grown. A formal risk assessment is then carried out by the Office of the Gene Technology Regulator who then make a decision as to whether a licence will be granted.

Brazil

In order to use a GMM in your business, one needs to fulfill numerous requirements. The development of any GMM must be monitored by the CTNBio and the regulatory agencies. If your company is going to start working with GMM, the first step is getting the Certified of Biosafety by CTNBio and create an internal committee of biosafety. Then, you need the approval by the regulatory agency (e.g. Anvisa for

human purposes and the MAPA for agriculture purposes). You are going to need to fulfill a lot of requirements in order to get the registry and the permission to develop your research in your lab.
For **agriculture purposes**, once you have finished your research inside the lab, the CTNBio will evaluate it and emit a position paper that will allow you to do a planned and controlled release. To do that, you are going to need to fulfill the requirements of the Normative Resolution n. 6 of November 6th, 2008.
For **medical purposes,** once you finished your research inside the lab, you are going to need to ask Anvisa for a registry of biological medication and you are going to need to fulfill all of the requirements stared in the Resolution n. 55 of December 16th, 2010.
Once your product is registered and approved by CTNBio and MAPA or Anvisa, you will be able to release and/or commercialise it.

Japan

A. If you use GMMs in an open system (e.g. agriculture use, bioremediation use)

In the use of open system, first, you have to apply for the approval of use regulations with the evaluation sheet of biodiversity influence to Ministry of Agriculture, Forestry and Fisheries and Ministry of the Environment. Once you got approval, you can start using GMMs. At the same time, you have to report the results of the information collected after using GMMs. And you will also get site inspections by Ministries written above as well as independent administrative institutions (FAMIC, NARO, NLBC, FRA). As a result, you will get administrative orders and you have to follow these order by re-submitting information or change/annulment of the use regulations.

B. If you use GMMs in closed system (e.g. using GMMs for production of enzymes/catalysts, using GMMs for production of reagents/ industrial materials)

If you use GMMs inside faculties and prevent GMMs to diffuse, first you have to check if the GMM you're using is on the GILSP list. If it is on the list, you have to follow the steps to prevent diffusions that are prescribed and start using GMMs. Then, you have to report using situations and you will get inspections and orders. If the GMM is not on the GILSP list, you have to fill in a diffusion prevention measures sheet and send it to the Ministry of Agriculture, Forestry and Fisheries. Once those measures are approved, you will follow the same steps above.

Chile

It is forbidden to commercialise GMOs, the only way to establish a business with them is to export seeds. This is only allowed once an environmental impact study regulated by the National Service of Agriculture and Livestock (SAG) has been undertaken.

Indonesia

The certificate issued from the 4 ministries mentioned above after being assessed by The Biosafety Commission and The Technical Team for Biosafety as proof that the GMMs have fulfilled the main

requirements for biosafety which include Environmental Safety, Food Safety, and Feed Safety. To fulfill the Environmental Safety, the GMMs need to have clear information regarding the description and objective of use, the detected phenotypic and genotypic changes, the taxonomical identity, the physiology and reproduction, the inserted gene origin, the genetic engineering method adopted, the molecular characteristic, the product of gene expression, and the method to destruct the GMMs when any disruptions happen. To fulfill the Food and Feed Safety, the GMMs need to have clear information regarding the genetic engineering method adopted, the nutritional (includes the protein, carbohydrate, fat, amino acid, fatty acid, minerals, and vitamins) content of the GMMs have to be substantially similar with the non-GMMs, the content of any toxic substance and allergens have to be substantially similar with the non-GMMs, the protein product expressed by the gene need to be non-allergenic.

Korea

For the usage of the GMOs, an individual has to submit the examination application form for Biosafety, with 4000 dollars of examination fee, to the Ministry that is in charge of the usage. Which means, if you are willing to use the GMOs related to agriculture, it is the Ministry of Agriculture, Food, and Rural Affairs that you have to submit the application to. The examination of the GMO is done in two different aspects. One is the human body risks and the other is the environmental risks. The Ministry of Korea Centers for Disease Control and prevention proceeds the former test, and Three institutes, including The Ministry of Environment, Rural Development Administration, and National Fisheries Research & Development Institute proceeds the latter test. About 210 days are required for each of the examinations.

After all the processes, one can finally get the Biosafety report for the GMOs. the result is posted on the site (Korea Biosafety Clearing House) so that the data is available to not only the applicant, but also to anyone interested.

India

Approval process for commercial release of GMOs:

1.) Initially, the company developing the GMOs undertakes several biosafety assessments including, environmental, food, and feed safety assessments in containment.
2.) This is followed by Bio-safety Research Trials which require prior approval of the regulators, the GEAC and the RCGM.
3.) Approval for large scale Field Trials and evaluation protocol for environmental release is accorded by the GEAC after considering the findings of bio-safety studies.
4.) The Ministry of Agriculture(DAC/ICAR) would then provide approval for commercial release/notification/registration of variety(ies)/hybrid(s), which is followed by post-release monitoring by MInistry of Agriculture & State governments(DAC/ICAR).
5.) Finally, commercial release is permitted only for those GMOs found to be safe for humans and the environment.
6.) For the released GMO, the application data is prepared and then submitted to, Institutional Biosafety Committee (IBSC).

For Exchange/import/export of genetically engineered organism and products (following details are to be submitted to IBSC/RCGM):

1. General details and Agreements:
   Name of IBSC, Registration No. and date, Minutes and Date of IBSC Meeting, Consignor's Name & Address, Consignee's Name & Address, Activity for which approval is sought(Import/Export/Exchange), Material Transfer Agreement duly signed by both parties, Utilization certificate, Whether the GE organisms /LMO/toxin is belonging to SCOMET* list of DGFT *If yes, applicant has to apply to DGFT in cases of export
2. Scientific Information:
   Title of Proposal, Objectives of proposal, Material Transported, Quantity to be Exchanged/Imported/Exported , Biochemical Characterization, Information of GE Organisms/LMO, Certificate of analysis, if applicable, Containment facility, Summary of proposed activity.

Canada:

If it involves *Health Products* it must go through*:*

- Review and evaluation. (ie. pre-clinical trials in vitro, labelling of the product, etc).
- Compliance and Enforcement Activities which include fulfilling areas in Education, Consultation, and Information; Compliance Monitoring; Compliance Verifications and Investigation; and Enforcement.
- Monitoring and Tracking involves the process of continual monitoring after a product has been released to the market. This allows the public to interact with the product and provide valuable feedback.

If it involves *Food Products* it requires:

- Pre-market assessment is required under the *Food and Drug regulations* and is a science-based safety and nutritional assessment where the food product must fulfill a criteria.
- Letter of no Objection must be sent to the product developer and outlines that the product is able to be sold in Canada for a specific mentioned reason as well as include the limitations on the product as provided by *Health Canada.*
- Labelling of Foods Derived from Biotechnology is required to all foods whether created through genetic engineering or not. It is absolutely required if the food has any health or safety issues such as allergens.

If it involves *Environmental/Industrial Products* it requires:

- To follow the policies and regulations related to protecting the health and safety of Canadians and the environment. Health Canada has a system that outlines these obligations. This process occurs before manufacture or import and depending on the substance, at the research and development stage.
- Monitoring and Tracking requires the product to be assessed through collecting, integrating, analyzing, and interpreting data and finally to distribute this information.

4. As an employer who exposes their workers to biological agents, what safety measures am I obliged to adopt?

European Union

1. Risks
    a. Create a risk assessment
    b. Assign your activity an appropriate risk class (to Class 1 activities the rest does not apply)
    c. Eliminate any unnecessary risks
    d. Reduce any remaining risks to a minimum
    e. Renew the assessment regularly
2. Provide the competent authority with relevant information upon
    a. Any accident
    b. Request
    c. The first usage of group 2, 3 or 4 biological agents
    d. Identifying worker's disease/death as a result of work undertaken
3. Provide health surveillance to the exposed workers
    a. Provide vaccines when necessary
    b. Identify workers for whom special protective measures might be necessary
    c. Keep relevant medical records for at least 10 year following the end of exposure
    d. Keep a list of exposed workers to class 3 or class 4 risk usages
4. Keep good hygiene
    a. Provide workers with appropriate clothing
    b. Provide appropriate storage for the equipment
5. Provide workers with relevant training

For more details, read Directive 2000/54/EC.

United States

Employers are not required to adopt any specific safety measures just because their workers will be exposed to biological agents. Instead, under OSHA (Occupational Safety and Health Administration), they are only required to address any health concerns a specific organism might pose.

Australia

Currently there are no limits to worker exposure to biological agents. However, employers are required under the Occupational Health and Safety Act 2004 to provide a safe working environment that minimises health risks. This can include providing information, supervision, training and protective equipment (if necessary). A risk assessment must also be performed and the employer must take required measures to reduce these risks.

Brazil

There are no rules regarding specifically the exposure to biological agents; the employers must monitor the exposure levels under the same rules for other substances (Act 3214/1978).

Japan

In Japan, the Ministry of Health and Welfare established *The standard of manufacture management and quality management of biological agents* and *The standard of structure facility of manufacturing place of biological agents*. In this standard, there are several safety measures of workers.

- keep good hygiene of workers
  1. Don't let irrelevant people come inside the workplace.
  2. Make workers wear disinfected shoes, working clothings, working caps, and working masks.
  3. Make workers follow the rules when going in the workplaces that handles different microorganism or biological agents.
  4. Don't let workers who are engaged in manufacture step manage animals.
  5. Provide vaccines and other infection prevention measures when necessary, and make workers get medical check up on a regular basis.
  6. If making biological agents using people's blood or plasma, provide vaccine of Hepatitis B virus etc. to workers if necessary.
- Manage hygiene of workers in a sterilised zone or clean zone
  1. Check if workers are not in a dangerous condition by microorganism pollution or other reasons.
  2. Let workers get medical check ups every 6 months.

Indonesia

Mainly the general safety measures done on a genetic laboratory practice, which include the confinement procedure to not let any forms of genetic material (includes the seeds, spores, or any means of reproductive structure) to escape the laboratories used for the research and development of the GMMS.

Korea

Korean government assign different biosafety levels from 1 to 4, to each of the GMOs according to the safety examination. There are some differences between the GMOs with relatively lower risks (levels 1,2) and higher risks (levels 3,4)

1. Location of the facilities
    a. In common
        i. The facility has to be separated from general area.
        ii. Name of the person in charge, contact number, biosafety level, and license number should be on written on the main entrance.
    b. Levels 3 and 4
        i. Facility should be separated from the testing area.

ii. There should be an Inter- facility room between the general area and the facility.

2. Air conditioning

a. Levels 3 and 4
   i. Negative pressure must be maintained to prevent spill and recirculation
   ii. Ventilation must be done 10 times at least each hour
   iii. HEPA filter must be installed in any ducts and air conditioning systems
   iv. Preparatory HEPA filter box should be placed

3. Safety facility

a. Levels 3 and 4
   i. Hand and eye sterilizers must be installed
   ii. Emergency shower facility must be installed near the contaminated working clothes undressing room

4. Waste disposal facility

a. In common
   i. Waste : must be treated by chemicals or high pressure steam sterilization (autoclave method) in order to remove any of the biologic activity. (autoclave method is strictly required for level 3 and 4)
   ii. Waste water: must be treated by chemicals or high pressure steam sterilization (autoclave method) in order to remove any of the biologic activity. (autoclave method is strictly required for level 4)

5. Criteria of management

a. In common
   i. All entrance must always be closed unless they are used, and only authorised ones should enter the facility.
   ii. Working clothes must be equipped and used.
   iii. Immigration control ledger must be equipped and used.

India

1. For BSL-1 (level-1)

i. These microorganisms are unlikely to cause human disease or animal disease of veterinary importance. Ideally, however, staff members should be subjected to a pre-employment health surveillance procedure regarding past medical history.
ii.Prompt reporting of illness or laboratory accident is desirable and all staff members should be made

aware of the importance of maintaining good laboratory
safety practice.

2. For BSL- 2 (level-2)

i. Pre-employment or pre-placement health surveillance is necessary. This screening should include the past medical history. A clinical examination and the collection of a baseline serum sample would be advantageous and, in some cases, may be necessary.
ii. Records of illness and absence should be kept by the laboratory director and it is the responsibility of the laboratory worker and his own medical adviser to keep the director informed of all absences due to illness.

Monitoring should ensure that:

i. Only highly trained personnel are entering in the facility.
ii. Person working in the facility are not transporting the laboratory materials including hazardous organism outside the laboratory environment either without permission or without proper transport strategy with prior approval from competent authority.
iii. Person working in the laboratory are well aware about the microorganism(s) to be handled and its associated risks.
iv. Accidental spill or splashes are cleaned immediately, reported and recorded.

BSL-3

Protective solid-front laboratory clothing shall be worn by workers when in the laboratory and shall NOT be worn outside the laboratory.
ii. An eye protection policy should be in place. Eye protection devices must be worn when the chance of eye contamination exists.
iii. Respiratory protective equipment should be used if the microorganism has higher possibility of spread through aerosolization.
iv. Appropriate gloves must be worn. Frequent glove changing and handwashing is standard practice.
v. Cleaning and re-use conditions (if permitted) should be clearly defined.
vi Medical examination of all laboratory personnel working in the containment laboratory is mandatory. This examination should include a detailed past medical history and clinical examination.
iii. A baseline serum sample should be obtained and stored for future reference.
iv. Employees either immunocompromised or being treated with immunosuppressive drugs should not be employed in containment laboratories.

BSL-4

i.Personnel who enter the suit area are required to wear a one-piece, positively pressurized, HEPA filter-supplied air suit. Air to the suit must be provided by a system that has a 100% redundant capability

with an
independent source of air, for use in the event of an emergency.
ii.Worker must pass through a suit decontamination room before entering and leaving the working area.
Same as BSL-3 rules.

For women
Women of childbearing age should be made aware, in unequivocal terms, of the risks to the unborn child of occupational exposures to hazardous microorganisms, such as rubella and cytomegalovirus. The precise steps taken to protect the fetus will vary, depending on the microorganisms to which exposure may occur.
Same as men in all levels.

Canada

The specific guidelines facilities adopt depend on the risk group classification of the agents involved. For the handling of biological materials under Risk Group 1, the Public Health Agency of Canada (PHAC) and CFIA recommends containment level 1 (CL1) safety guidelines, however no requirements are specified. Risk group 1 includes any biological materials that are potentially pathogenic to humans or animals, but are very unlikely to be so, or are not pathogenic at all. Some recommendations for CL1 facilities outlined in the Canadian Biosafety Standard are as follows:

1. The designated areas for handling biological materials should be separated from public areas and administrative work areas.
2. There should be designated hand and eye wash stations appropriate for facility operations.
3. Appropriate personal protective equipment, such as safety glasses, lab coats and, footwear covering the feet, must be worn.
4. Only authorized personnel and visitors should be allowed in the facility.
5. Waste materials must be disposed in the proper containers and wastes that came into contact with biological materials must be decontaminated before disposal.
6. Proper hand washing techniques must be employed after coming into contact with biological materials.
7. Procedures must incorporate proper aseptic technique and minimizes contamination and the formation of aerosols.
8. Food and drinks should be prohibited from the lab.
9. Personnel must be trained for the safe handling and storing of biological materials to protect them.
10. Safety guidelines must be kept up-to-date.

To work with biological materials in higher risk groups (2, 3, and 4), in addition to adopting the appropriate containment level, a Pathogen and Toxin Licence must be obtained from PHAC. Although CL1 provides the foundational biosafety guidelines for these containment levels, further requirements must be followed to minimize contamination and hazards to personnel working with high risk group pathogens. Additional information for the operations of these controlled facilities are discussed in the Canadian Biosafety Standard Second Edition handbook.

Chile

Ministry of Health by the Public Health Institute (ISP) provides the following services:

1. Generation of protocols for risks and exposure evaluation.
2. Specific actions over biological agents and disinfection.
3. Elaboration of guides for reception, manipulation, transport and biological agents diffusion in the labour place.
4. Generation of new protocols associated with the area as elimination and disposal of dangerous biological residues.
5. Certification of bio-clean areas, biohazards control zones and sampling of viable bioparticules.

General requirements for biological agents manipulation:

1. Use of personal protection equipment (PPE) according to the activity (D.S. N°173/82 by Health Ministry).
2. The PPE must not hinder in the work done. Workers must be informed about the right use of PPE before to start working.
3. There are regulations for every biosafety level:

Level number	Activities and their risks	Laboratory techniques and practices	Primary barrier	Secondary barrier
1	Activities developed in a basic laboratory with trained staff. There's no proof that it produces diseases in healthy adults.	Standard written techniques. Lists of chemical substances with their safety forms.	Sink, procedure table, swinging door, basic equipment with safety devices, mandatory use of: non-slip closed footwear, closed apron, gloves, goggles resistant to chemicals.	Washable paint screened windows, non-slip washable floor, washable tables, extinguisher, eyes washer radioactive installation with authorized operator.

Level number	Activities and their risks	Laboratory techniques and practices	Primary barrier	Secondary barrier
2	Activities developed in a basic laboratory	Standard written practices and protocols about	Biological security cabinet with HEPA filters	All of level 1 plus autoclave available with

	with trained staff in moderated risks associated with human diseases. Percutaneous risks, ingestion, mucous membranes exposure.	microorganisms, sharpening elements, tables decontamination, autoclave, restricted access, warning of biological hazards, list of substances with their safety forms.	and ULPA (1 or 2 class), physical containment devices, safety equipment devices, mandatory use of non-slip closed footwear, closed apron, goggles resistant to chemicals, protective face mask, respirator with filter according what is handled, heat resistant gloves, PVC apron, laboratory cap.	installation permission and a licensed operator, radioactive installation with a licenced operator.

Level number	**Activities and their risks**	**Laboratory techniques and practices**	**Primary barrier**	**Secondary barrier**
3	Laboratory activities of containment. The staff must must be trained in specific operation of toxic agents with high risk of transmission with aerosol	Practices and protocols of level two plus: controlled access,decontamination of all the residues, decontamination of the work clothes	Biological security cabinet with HEPA filters and ULPA (1 or 2 class), physical containment devices, safety equipment devices used for all open manipulation of agents, mandatory use of non-slip closed footwear, closed apron, goggles resistant to chemicals, protective face mask, respirator with filter according what is	All of level 2 plus: separation of access corridors, access with automatic close in double door, the exhaust air is not recirculated, negative air flow inside the laboratory.

			handled, heat resistant gloves, PVC apron, laboratory cap.	

Level number	Activities and their risks	Laboratory techniques and practices	Primary barrier	Secondary barrier
4	Activities in a laboratory of maximum containment, that manipulate pathogens, dangerous and exotic agents of high risk for life. The staff is trained in the management of extremely infectious agents.	Standard written practices and protocols of level 3, plus: change of clothes before entering the lab, shower before leaving it, decontamination of materials at the exit of the facilities.	Biological security cabinet with HEPA filters and ULPA class 3, physical containment devices for open manipulation of agents, mandatory use of non-slip closed footwear, closed apron, goggles resistant to chemicals, protective face mask, respirator with filter according what is handled, heat resistant gloves, PVC apron, laboratory cap.	Remote building or isolated area, specialized vacuum and decontaminated power and exhaust system.

5. As a consumer, how do I know if a product I want to buy contains GMOs?

European Union

Final consumer packaging or pre-packaged products containing GMOs should be labelled: 'This product contains genetically modified organisms [or the names of the organisms]'. This does not apply to medical products.

United States

There are no requirements for labelling products that contain GMOs.

Australia

Under the Australia New Zealand Food Standards Code, it is a legal requirement for any food products derived from GMMs be labelled with the words "genetically modified" to ensure that consumers can make informed purchasing decisions. However, an exception to this is any foods produced by animals fed GM products which are not required to have this label.

Brazil

Currently, if the product is made of a GMMs plant/seed or if the final product contains any traces of a GMM used as an ingredient, the package must have a symbol "T" of transgenic (figure below) on its package and the words "This product contains [name of the organism] transgenic." However, the Congress and the Senate are currently voting on a project that modifies this law to remove the "T" symbol and leave the words "This product contains [name of the organism] transgenic" only if 1% or more of the final product has been genetically modified.

Japan

There are no requirements for labeling products that do not contain modified gene or products do not contain protein made by a modified gene. There are requirements for labeling products of which the modified gene constitutes more than 5% of its materials or if the genetically modified ingredient is within the top 3 ingredients.

Indonesia

The products must be clearly labeled they contain GMO if they do.

Korea

Any product containing more than 1% of genetically modified material, such as DNA and proteins, must be labeled as GM food.

India

India has supported the mandatory labeling of GM food by Codex.

Out of the two options under discussion by Codex i.e. Option 1 requires labeling when the products obtained through biotechnology differ significantly from the corresponding food as regards the composition, nutritional value or intended use.

Option 2 requires the declaration of the method of production for food and ingredients composed of or containing genetically modified/engineered organisms and food or food ingredients produced from, but

not containing, genetically modified/engineered organisms if they contain protein or DNA resulting from gene technology or differ significantly from the corresponding food.

The labeling of food derived from biotechnology is a major issue for India as its delegation at the CCFL has been seeking to achieve mandatory labeling as set out in Option 2. However, Option 2 has also raised a number of issues of concern including the enforcement, methodology, economic cost, consumer perception and difficulties likely to be faced.

Canada

In Canada, under the Canadian Food Inspection Agency and Health Canada. The Standards Council of Canada has taken in the *Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering.* This states a requirement to label food that may potentially cause health and safety risks and well as have any considerable changes in nutrition and composition. Thus, there are no policies put in place for the mandatory labelling of foods detailing if they're genetically modified unless there are reasons to do so such as a potential health and safety risks. Many food products might not be directly genetically modified but may contain ingredients such as corn or soy which have been genetically modified. To know if a food or its ingredients have been genetically modified, one would have to contact the manufacturer.

Chile

Any product made for human consumption that has different nutritional characteristics than conventional ones due to its genetic modifications must be clearly labeled as GM.

6. What are the most important documents related to GMMs?

European Union

1. Directive 2001/18/EC on the deliberate release of GMOs into the environment
2. Regulation (EC) 1829/2003 on genetically modified food and feed
3. Directive (EU) 2015/412 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory
4. Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms
5. Directive 2009/41/EC on contained use of genetically modified micro-organisms. Regulation (EC) 1946/2003 on transboundary movements of GMOs
6. Directive 2000/54/EC on the protection of workers from risks related to exposure to biological agents at work

7. Commission Regulation (EC) No 65/2004 on unique identifiers for genetically modified organisms

United States

1. Coordinated Framework for Regulation of Biotechnology (1986)
2. Plant Protection Act
3. Federal Food, Drug, and Cosmetics Act (1992)
4. New Animal Drug Application
5. Public Health Service Act
6. Toxic Substance Control Act
7. Federal Insecticide, Fungicide, and Rodenticide Act
8. National Environmental Policy Act

Australia

1. The Gene Technology Act 2000
2. The Gene Technology Regulations 2001
3. Occupational Health and Safety Act 2004

Brazil

1. Law 11105/2005 - Biosafety Law: creates the National Technical Committee of Biosafety (CTNBio)
2. Law 11460/2007 on planting GMMs in unities of conservation
3. Act 5591/2005 regulates the Biosafety Law
4. Normative Resolution 2, November 27th, 2006 on the classification of GMMs' risks and the biosafety levels
5. Normative Resolution 5, March 12th, 2008 on the commercial release of GMMs and its derivatives
6. RDC 55/2010 on the registry of biological products (e. g. biopharmaceuticals)

Japan

1. Act 18/06/2003 on the conservation and sustainable use of Biological diversity through regulations on the use of living modified organisms.
2. Law 18/06/2003 on sharing by competent minister concerning each measure.
3. Law 11/2003 - Cartagena Protocol on Biosafety
4. Directive 21/11/2003 – Type1 and Type2 use of living modified organisms in Japan.
5. 21/11/2003 Announce of submit Biological diversity risk assessment report.
6. 21/11/2003 Announce of Basic matter that have to be taken into account by a person who makes use of living modified organisms in order to undertake such acts properly.

7. 29/01/2004 Announce of diffusion containment measures in research and development , industrial use.

Indonesia

The Government Regulation of the Republic of Indonesia Number 21 year of 2005 (PP No. 21/2005) on Biosafety of GMO. Under this regulation, there are 17 minor supplementary documents for regulation of GMOs on specific aspects such as biological diversity, fishery industry, and plantation.

Korea

1. Sep 2000 Cartagena Protocol on Biosafety
2. Mar 2001 'The law about the transport of genetically modified organism between nations' (the LMO law)

India

1. Environmental (Protection) Act, 1986 - No. 29 OF 1986
2. "Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989"
3. 'Recombinant DNA Safety Guidelines, 1990'
4. 'Regulations and guidelines on biosafety of recombinant DNA research and biocontainment, 2017'
5. Seed Policy, 2002
6. THE FOOD SAFETY AND STANDARDS BILL, 2005

Canada

1. Voluntary labelling and advertising of foods that are and are not products of genetic engineering Canadian General Standards Board, 32.315- 2004 Reaffirmed May 2016
2. Foods and Drugs Act, R.S.C., 1985, c. F-27
3. Canadian Food Inspection Agency Act, S.C. 1997, c. 6
4. Consumer Packaging and Labelling Act, R.S.C., 1985, c. C-38
5. Canadian Environmental Protection Act, 1999, S.C. 1999, c. 33
6. Natural Health Products Regulation, SOR/2003-196

Chile

1. SAG Resolution 1523 of 2001 for Importation of Propagation Material (seeds).
2. Law 19.300 from Ministry of Environment for using GMOs in industries.
3. Decree 40 from Ministry of Environment for environmental impact study.

7. In what way is this document useful to my iGEM project?

European Union

Our project is tackling two environmental problems: eutrophication and phosphorus reserves depletion. iGEM Manchester is designing phosphorus-accumulating bacterium, thus killing two birds with one stone. As part of our Integrated Human Practices, we will be creating a potential business model for our bacterium. This GMM Legislation Doc will help us massively in deciding where our potential business could be most easily set up from a legal point of view.

Australia

The Macquarie University iGEM team is researching the use of genetically modified e-coli to produce hydrogen gas as a sustainable, zero-emission fuel source. Our prototype is an at-home refuelling station that utilises our technology to enable drivers of hydrogen-powered vehicles to refuel their vehicle at home. This document will be very helpful in developing our business plan as it will guide our decisions about consumer perceptions of GMO's, laws that we need to consider and authoritative bodies that we will need to approach should we decide to produce and sell our product in overseas markets.

United States

Our project focuses on improving the wastewater treatment process. As such, knowing what legislation within the United States regulates the use of GMOs within the environment and with products such as drinking water is important if we wanted to make our project usable outside the laboratory.

Japan

Our team is working on creating E.coli that can fix nitrogen. As our future vision, we are thinking of commercializing those GMMs by putting nitrogen-fixing GMMs into capsule. By taking this GMMs, we can help babies under 1000 days suffer from malnutrition comes from low intake of proteins. So, this GMM Legislation Doc will help us when thinking how we can actually commercialize.

Indonesia

ITB's iGem Project or Dewaruci is tackling the environment issue specifically the microplastic. We are designing a bacteria that could degrade micro-plastic on the open ocean. It means that we are going to release the GMO's to the environment. This document possibly could provide the regulation information for the future worldwide implementation of our project which may lead to more innovation and development of the project itself.

India

As a part of foundational advance, this year our team is working on a square wave generator with applications in varied fields. Seeing the potential it has to revolutionise the field of periodic drug delivery and biological clocks, the GMM regulations will be a great source of help to commercialise the iGEM project with the rules laid down for business across the globe, guiding through the best place for setup. Also, the import and export of GMMs across countries, for iGEM projects as well as business, would then be easily guided with minimised issues in the customs and thus their timely delivery.

Chile

As a team, we have realised that in comparison with other countries, ours stands out due to the lack of regulations for GMO and GMM. This situation, harm us as researchers, scientists and community, in two ways. Firstly, working with GMM might be dangerous as no safety guidelines have been established. Secondly, no research is done. Both options result in a danger to society, the lack of biosafety, and a delay in scientific research for biotechnology.

According to this analysis, we have thought of introducing a debate into the community about the implementation of regulations for GMM. We have also considered suggesting the creation of protocols and laws for the GMO and GMM to the institutions in charge of the GMO regulations, such as Agricultural and Livestock Service and Environment Ministry. This could imply an increase in area-related startups, along with scientific advancement and a more informed and conscious society about biotechnology in general.

Canada

UAlberta's outreach initiatives include education for the general public and establishing a Synthetic Biology student group at the University of Alberta.
For our education outreach, we are developing modules on scientific literacy and producing a video on the importance of Alberta's science curriculum in providing a foundation for the future. An element in our modules for high school students may introduce biotechnologies, including GMO's, and international legislations regulating the use of these biotechnologies. We are also starting an official student group at the University of Alberta dedicated to discussing and understanding the overarching reach of synthetic biology and biotechnology. Documents like these put to perspective the concerns associated with genetic modification of organisms.

Brazil

Our project is to develop a new treatment for type 1 diabetes using a genetically engineered probiotic bacteria, which means that to this project became a real product someday, it would have to go under several safety assessments and approved to be used in humans.
Over this year, as we worked in our project, we were always worried about the legal requirements for a GMO like ours become a real product and how biosafety laws affect and guide the development of new GMOs. This document was very useful to us to research and understand the laws of our country, and also

other countries, the steps that we would have to take if we wanted our project to became a product. It was also very important to know the laws of other countries and see how GMOs are seen around the world.

Korea

By chance, our project of this year is directly related to the regulation of the GMM since it would be the actual GMM product if we complete our project and try to materialize them. Our project this year was to make an edible probiotics, which is considerably regulated by the government's control for they directly interact with one's biosystem. Rather than simply considering the GMM regulation of Korea, proceeding a collaboration project with various other teams gave us the knowledge and insight about the biosafety which helped us a lot in many aspects while we proceeded our annual project. And it was pleasure to consider in what way can an iGEM project change the society.

The act of investigating also lead us to an unusual chance. A contact with a member of the GMM regulating-institution, in order to get informations required to fill in questions of this document, gave us a chance to meet the member of National Assembly, who mainly take charge of enacting GMM law.

European Union GMM legislations have been covered by **Manchester** Team.
United States GMM legislations have been covered by **Virginia** Team.
Australia GMM legislations have been covered by **Macquarie** Team.
Brazil GMM legislations have been covered by **AQA Unesp** Team.
Japan GMM legislations have been covered by **Botchan_Lab_Tokyo** Team.
Chile GMM legislations have been covered by **UChile_OpenBio-CeBiB** Team.
Indonesia GMM legislation have been covered by **ITB_Indonesia** Team.
Korea GMM legislation have been covered by **KUAS_Korea** Team.
India GMM legislations have been covered by **IIT_Delhi** Team.
Canada GMM legislations have been covered by **UAlberta** Team.