Regulation of genetic engineering

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The regulation of genetic engineering begins before the experiment has started with approval processes, through to protocols that must be followed in the laboratory and finally the conditions under which the resultant product may be released. These regulations vary from country to country, particularly when it comes to the release of any genetically modified organism. Europe does not have a single policy but a patchwork of policies at international, Community, Member State and local levels.[1]

Contents

- 1 History
  - 1.1 Approval to conduct experiments
  - 1.2 In the laboratory
  - 1.3 Release
  - 1.4 Trade
  - 1.5 References

History

The development of a regulatory framework concerning genetic engineering began in 1975, at Asilomar, California. The first use of Recombinant DNA (rDNA) technology had just been successfully accomplished by Stanley Cohen and Herbert Boyer two years previously and the scientific community recognized that as well as benefits this technology could also pose some risks.[2] The Asilomar meeting recommended a set of guidelines regarding the cautious use of recombinant technology and any products resulting from that technology.[3] The Asilomar recommendations were voluntary, but in 1976 the US National Institute of Health (NIH) formed a rDNA advisory committee.[4] This was followed by other regulatory offices (the United States Department of Agriculture (USDA), Environmental Protection Agency (EPA) and Food and Drug Administration (FDA)), effectively making all rDNA research tightly regulated in the USA.[5] In 1982 the Organization for Economic Co-operation and Development (OECD) released a report into the potential hazards of releasing genetically modified organisms into the environment as the first transgenic plants were being developed.[6] As the technology improved and genetically organisms moved from model organisms to potential commercial products the USA established a committee at the Office of Science and Technology (OSTP) to develop mechanisms to regulate the developing technology.[5] In 1986 the OSTP assigned regulatory approval of genetically modified plants in the US to the USDA, FDA and EPA.[7]

The Cartagena Protocol on Biosafety was adopted on 29 January 2000 and entered into force on 11 September 2003.[8] It is an international treaty that governs the transfer, handling, and use of genetically modified (GM) organisms. It is focussed on movement of GMOs between countries and has been called a defacto trade agreement.[9] One hundred and fifty-seven countries are members of the Protocol and many use it as a reference point for their own regulations.[10] However Argentina, Australia, Canada, and the United States (major producers of genetically modified crops).

Approval to conduct experiments

Institutions that conduct certain types of scientific research must obtain permission from government authorities and ethical committees before they conduct any experiments. Universities and research institutes generally have a special committees that are responsible for approving any experiments that involve genetic engineering. Many experiments also need permission from a national regulatory group. Most countries have exempt dealings for genetically modified organisms (GMOs) that only pose a low risk. These include systems using standard laboratory strains as the hosts, recombinant DNA that does not code for a vertebrate toxin or is not derived from a micro-organism that can cause disease in humans. Exempt dealings usually do not require approval from the national regulator. GMOs that pose a low risk if certain management practices are complied with are classified as notifiable low risk dealings. The final classification is for any uses of GMOs that do not meet the previous criteria. These are known as licensed dealings and include cloning any genes that code for vertebrate toxins or using hosts that are capable of causing disease in humans. Licensed dealings require the approval of the national regulator.[11]

In the laboratory

Work with exempt GMOs do not need to be carried out in certified laboratories. All others must be contained in a Physical Containment level 1 (PC1) or Physical Containment level 2 (PC2) laboratories. GMOs classified as low risk include knockout mice as long as the modification does not confer an advantage to the animal or it does not secrete any infectious agents. If a laboratory strain is used that is not covered by exempt dealings or the inserted DNA could code for a pathogenic gene it must be carried out in a PC2 laboratory.[11]

Release

Main article: Regulation of the release of genetic modified organisms

The approaches taken by governments to assess and manage the risks associated with the use of genetic engineering technology and the development and release of genetically modified organisms (GMOs) vary from country to country, with some of the most marked differences occurring between the USA and Europe. The USAs regulatory policy is governed by the Coordinated Framework for Regulation of Biotechnology[12] The policy has three tenets: "(1) U.S. policy would focus on the product of genetic modification (GM) techniques, not the process itself, (2) only regulation grounded in verifiable scientific risks would be tolerated, and (3) GM products are on a continuum with existing products and, therefore, existing statutes are sufficient to review the products."[13] European Union by contrast enacted regulatory laws in 2003 that provided possibly the most stringent GMO regulations in the world.[14] All GMOs, along with irradiated food, are considered "new food" and subject to extensive, case-by-case, science based food evaluation by the European Food Safety Authority (EFSA). The criteria for authorization fall in four broad categories: "safety," "freedom of choice," "labelling," and "traceability."[15]

For a genetically modified organism to be approved for release in the USA, it must be assessed by the Animal and Plant Health Inspection Service (APHIS) agency within the US Department of Agriculture (USDA) and may also be assessed by the Food and Drug Administration (FDA) and the Environmental protection agency (EPA), depending on the intended use of the organism. The USDA evaluate the plants potential to become weeds, the FDA reviews plants that could enter or alter the food supply,[16] and the EPA regulates genetically modified plants with pesticide properties, as well as agrochemical residues.[17] In Europe the EFSA reports to the European Commission who then draft a proposal for granting or refusing the authorisation. This proposal is submitted to the Section on GM Food and Feed of the Standing Committee on the Food Chain and Animal Health and if accepted it will be adopted by the EC or passed on to the Council of Agricultural Ministers. Once in the Council it has three months to reach a qualified majority for or against the proposal, if no majority is reached the proposal is passed back to the EC who will then adopt the proposal.[14] However, even after authorization, individual EU member states can ban individual varieties under a 'safeguard clause' if there are "justifiable reasons" that the variety may cause harm to humans or the environment. The member state must then supply sufficient evidence that this is the case.[18] The Commission is obliged to investigate these cases and either overturn the original registrations or request the country to withdraw its temporary restriction.

The level of regulation in other countries lies in between Europe and the USA. Common Market for Eastern and Southern Africa (COMASA) is responsible for assessing the safety of GMOs in most of Africa, although the final decision lies with each individual country.[19] India and China are the two largest producers of genetically modified products in Asia.[20] The Office of Agricultural Genetic Engineering Biosafety Administration (OAGEBA) is responsible for regulation in China,[21] while in India it is the Institutional Biosafety Committee (IBSC), Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Approval Committee (GEAC).[22] Brazil and Argentina are the 2nd and 3rd largest producers of GM food.[23] In Argentine assessment of GM products for release is provided by the National Agricultural Biotechnology Advisory Committee (environmental impact), the National Service of Health and Agrifood Quality (food safety) and the National Agribusiness Direction (effect on trade), with the final decision made by the Secretariat of Agriculture, Livestock, Fishery and Food.[24] In Brazil the National Biosafety Technical Commission is responsible for assessing environmental and food safety and prepares guidelines for transport, importation and field experiments involving GM products, while the Council of Ministers evaluates the commercial and economical issues with release.[24] Health Canada and the Canadian Food Inspection Agency[25] are responsible for evaluating the safety and nutritional value of genetically modified foods released in Canada.[26] License applications for the release of all genetically modified organisms in Australia is overseen by the Office of the Gene Technology Regulator, while regulation is provided by the Therapeutic Goods Administration for GM medicines or Food Standards Australia New Zealand for GM food. The individual state governments can then assess the impact of release on markets and trade and apply further legislation to control approved genetically modified products.[27][28][27]

One of the key issues concerning regulators is whether GM products should be labeled. Labeling can be mandatory up to a threshold GM content level (which varies between countries) or voluntary. A study investigating voluntary labeling in South Africa found that 31% of products labeled as GMO-free had a GM content above 1.0%.[29] In Canada and the USA labeling of GM food is voluntary,[30] while in Europe all food (including processed food) or feed

which contains greater than 0.9% of approved GMOs must be labelled.[14] Japan, Malaysia, New Zealand, and Australia require labeling so consumers can exercise choice between foods that have genetically modified, conventional or organic origins.[31]

Trade

Main article: International trade of genetically modified foods

The Cartagena Protocol sets the requirements for the international trade of GMO's between countries that are signatories to it. Any shipments contain geneticially modified organisms that are intended to be used as feed, food or for processing must be identified and a list of the transgenic events be available.

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