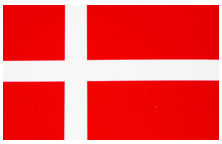


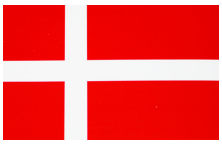



Country Policy Collaboration Notes

Questions each country can answer to compare policies around biotech/Syn bio:

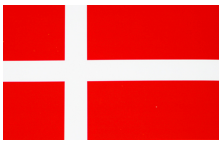
1. In general, what is your country willing to allow to the market?
    a. **US:** Product needs to be safe for human health and environment
    b. **India :** Products are approved in a case by case basis
2. What are some biotech examples of what your country has approved of?
    a. **US:** Plants that are tolerant to herbicides, plants that detoxify pollutants in soil, mosquito gene drive, Hawaiian papaya resistant to ringspot disease,
    b. **India** is the largest producer of Bt cotton which was approved in 2002.
3. Who approves of biotech products?
    a. US: So many government agencies, and some overlap depending on the product. The main ones are: EPA, USDA, FDA
    b. **India :** India has ratified the Cartagena Protocol in 2003 which requires a setting up of a regulatory body. Currently, the GEAC (Genetic Engineering Appraisal Committee) under the Ministry of Environment, Forests and Climate Change is responsible for approval of genetically modified products in India. Government of India is in the process of establishing Biotechnology Regulatory Authority of India (BRAI) for quicker realization of modern biotechnology products to Indian farmers (PIB, Government of India 2011).

4. When were the regulation/guidelines/policies created?
    a. US: Government developed a "Coordinated Framework" in 1986 (was updated in 2017: **Modernizing the Regulatory System for Biotechnology Products**) that decides which agency(ies) regulate which products
        i. But federal involvement of biotech originated when NIH published guidelines for recombinant DNA research in 1976
        ii. These have been updated and is still used today by controlling research that is funded by the NIH
    b. **India :** The Biotechnology Regulatory Authority of India (BRAI) bill was introduced in Lok Sabha in 2013 to set up an independent regulatory authority for regulation of organisms and products of modern biotechnology including GMOs (PRS Legislative Research 2013). This BRAI will regulate the research, transport, import, containment, environmental release, manufacture, and use of all biotechnology products and all the approval will be granted through a multi-level process of assessment undertaken by scientific experts (Lok Sabha 2013). Presently, the BRAI bill has been lapsed (PRS Legislative Research 2013) and expected to be produced again after substantial revisions under current government.

5. What biotech products could have a huge, positive impact if implemented in your country (list some examples)? What regulations/laws are holding these examples back from being used?
    a. Oxitec's GM mosquitoes that were just recently approved for release in Florida.
        i. Will look more into specific laws
    b. India :
        i. The most promising GM crop is a hybrid mustard that yields 25-30% more than the original seed. It was developed by a team of scientists of Delhi University. Mustard is used to make one of the most popular edible oils in India. The GM mustard seed could be a huge money saver and lower the country's dependence on edible oil imports: In 2014-15 India imported 14.5 million tonnes of it, worth over $10 billion. But the genetic engineering approval committee (GEAC), the Indian government agency responsible for approving the commercial release of GM crops, hasn't okayed the new seed as it is unsure about the possible public health and environmental impact of GM crops.
        ii. Current research and development in crop biotechnology in India is focused on the development of biotech food, feed and fiber crops that can contribute to higher and more stable yields and also enhanced nutrition. Rice being the major staple food, the research on genomics of rice is being pursued aggressively for conferring biotic and abiotic stress. Field trials with Bt rice are already underway

6. Is there currently a specific, easily accessible regulatory process for researchers to go through to get their product approved in your country? On a scale of 1-10, how easy is the regulatory process to navigate and understand?
    a. **The US** is all over the place with this. The regulatory process is extremely confusing for those who have never worked with the federal agencies before, and the confusion is enhanced by the fact that all three agencies work separately and together with different products. Having someone to walk people through the regulatory process would be much more effective.
    b. I would rate the US at a 6 because they have a lot of information and resources, but they would not be the easiest to understand if you do not have a scientific background. Also, it is hard to navigate the regulatory process because there is so much information required and because of agency collaborations.
    c. **India :** Although portals like GEAC, IGMORIS (Indian GMO Research Information System), Biosafety Clearing House are doing their role for assessing biosafety and their regulation of GM crops but there is an urgent need to build a single window system and online portal for assessment, control, regulations and approval of GM crops. Further India has way too many bureaucratic red tape to follow (things like state government issuing a No Objection certificate since

agriculture is a state matter) which politicises the whole procedure to a large extent

7. For a public outreach perspective, how many people in your country are aware of the current regulatory process and the safety measures taken to prevent adverse effects on public health and the environment? (There may be statistics for these somewhere).
    a. Not sure for the US yet, still looking into this.
    b. Not sure about formal statistics, will update once we find anything