DOWNLOAD PDF BIOTECHNOLOGY REGULATIONS

Chapter 1 : biotechnology regulations â€“ SEARCA Biotechnology Information Center

Biotechnology Regulatory Services (BRS) In order to protect plant health, Biotechnology Regulatory Services (BRS) implements APHIS regulations for certain genetically engineered (GE) organisms that may pose a risk to plant health.

Genetically engineered crops and animals GMOs have been a controversial public issue since the first products were introduced in the s. They have posed unique challenges for governments to regulate. GMOs have become a symbol of the battle over what our global, regional and local food systems should look like going forward. The clout of the food movement that vocally rejects many aspects of conventional farming has exponentially increased since then, promoted by mainstream journalists, scientists and non-profit groups from Michael Pollan to Consumers Union to the Environmental Working Group. Organic leaders and lobbyists, such as Gary Hirshberg , founder of Stonyfield Organics and Just Label It, openly demonize conventional food and farming in defiance of their commitments agreed to in the s that organic food would not be promoted at the expense of conventional agriculture. Partly in response to the prevailing winds, the USDA has evolved increasingly byzantine regulatory structures when it comes to new GE products. Leading scientists, journalists and social scientists explore the ramifications of genetic engineering and so-called new breeding technologies NBTs , specifically gene-editing technologies such as CRISPR. We will post two articles each week, on Tuesday and Wednesday, over the next 5 weeks. Regulation is at the heart of this ongoing debate. No wonder the agricultural sector is consolidating, and most new products are innovated by larger corporations. The regulatory climate may be changing, perhaps radically, in the United States and possibly in the United Kingdom, as the result of recent elections. Many of the old rules and regulations regulating GE crops were set up in the s and early s. They are arguably creaky, overly-restrictive and do not account for dramatic increases in our understanding of how genetic engineering works and the now clear consensus on their safety. Now with NBTs, which are largely unregulated since the techniques were not foreseen 30 years ago when regulations were first formulated, agricultural genetic research is at an inflection point: Will governments make the same mistake that they did previously and regulate innovation almost out of existence, or will they incorporate reasonable risk-risk and risk-benefit calculations in evaluating which technological advances should proceed with limited regulations? Decisions on these issues will shape not only food and farming in Europe, North America and the industrialized nations, but the food insecure developing world, which looks to the West for regulatory guidance. Gene Editing and Animals The second article in our series, by University of California animal geneticist Alison Van Eenennaam, addresses the challenges of regulating genetically engineered animals. She focuses on dehorned cows, which have been developed without gene editing over many years with, at times, less than optimal results. Should gene editing be evaluated on a case-by-case basis triggered by the novelty of the traits, or should the entire process be heavily regulated â€” the general approach favored by the European Union in regulating more conventional genetic engineering? Dave Walton, an Iowa farmer, discusses the brouhaha that has erupted in recent years over the use of glyphosate, the active ingredient in the weed killer originally developed under patent by Monsanto. Many GMO critics are now expressing concerns over pesticide use in conventional agriculture, using glyphosate as a proxy for attacking the technology. Are their concerns appropriate? Walton, who grows both GE and non-GE crops and is director of the Iowa Soybean Association, has used glyphosate on his farm since the introduction of herbicide resistant crops in He uses on average a soda-sized cup of glyphosate per acre, and the use of the herbicide has allowed him to switch from more toxic chemicals. Most strikingly he discusses the sustainability impact if a glyphosate ban is imposed, as many activists are calling for. Monsanto glyphosate lobbyists barred from EU parliament Plant pathologist Steve Savage challenges us to think in a more nuanced way about a popular belief that organic farming is ecologically superior to conventional agriculture. The Agricultural Department has been a fractious mess in recent years in its efforts to oversee and encourage new breeding technologies. When the Clinton administration oversaw the founding of the National Organics Standards Board in , USDA officials extracted the commitment from organic industry that the alternative farming system would not be promoted at the expense of conventional agriculture. After all, study after study, then and now, has established that organic

farming offers no safety nor clear ecological benefits. Africa and poorer sections of Asia. Ma- haletchumy Arujanan, executive director of Malaysian Biotechnology Information Centre and editor-in-chief of The Petri Dish, the first science newspaper in Malaysia, takes on the emerging Asian food security crisis posed by a parallel rise in population and living and food consumption standards. She reviews the successes and failures in various countries, and the effective campaigns by anti-GMO NGOs, mostly European funded, to block further biotech innovation. Cracks are beginning to form in the anti-GMO wall erected across the continent and there are hopes that young people will be attracted to farming, lured by the introduction of GE crops and other innovations. The public has a widely distorted perception of what genetic engineering entails, which helps explain why consumers remain so skeptical about technological innovation in farming. Is the celebrity-backed science misinformation campaign working? By law, land grant university scientists are required to work with all stakeholders, particularly corporations who are developing the products used by farmers, including organic farmers. Finally, risk expert David Ropeik has an optimistic take on the future. He believes may have been a turning point in the debate over GE foods. Technology rejectionists, from Greenpeace to labeling activists, are sounding increasingly shrill and less scientific. Gene editing, he believes, could undercut claims that GE foods are unsafe because they are unnatural. The Genetic Literacy Project is a c 3 non profit dedicated to helping the public, journalists, policy makers and scientists better communicate the advances and ethical and technological challenges ushered in by the biotechnology and genetics revolution, addressing both human genetics and food and farming. We are one of two websites overseen by the Science Literacy Project; our sister site, the Epigenetics Literacy Project , addresses the challenges surrounding emerging data-rich technologies.

Chapter 2 : Biotechnology & the Law

All formal Federal regulations are published in the Federal Register and also in the Code of Federal Regulations, a large multivolume series. Those regulations for Agriculture and the USDA comprise fifteen volumes and those governing biotechnology as overseen by APHIS-BRS are found in Volume 7, Section

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Chapter 3 : STATES WITH BIOTECH LAWS AND REGULATIONS | The Scientist MagazineÂ®

Regulation of Biotech Plants How the Federal Government Regulates Biotech Plants The Federal government has a coordinated, risk-based system to ensure that new biotechnology products are safe for the environment and human and animal health.

This includes a description of the source of the pesticidal gene promoters, enhancers, open reading frame and termination signals for the pesticidal trait and identifies the source of any other traits introduced such as selection markers herbicide resistance, antibiotic resistance or a visual trait such as cells turning blue when introduced beta-glucuronidase is present. This information is given as a plasmid map of the vector DNA and includes the exact DNA sequence for the introduced traits. The discussion also includes the biology of the source organism s and describes any hazards associated with source organism s such as pathogenicity or toxin production. Rationale is also given as to why this trait was selected and any changes to the actual DNA sequence of the introduced gene s are described. A description of the recipient plant is provided including the general biology and use as a crop. The details expected to be covered would include the possible production of toxins or anti-nutrients by the plant, major insect pests, weeds and diseases of the crop, reproductive biology, and presence of wild or weedy relatives of the crop in the United States. A description of the recipient plant is provided, including the general biology and use as a crop. Confirmatory data show what part of the vector DNA is actually incorporated into the plant genome. A southern blot analysis is a DNA detection assay based on the high binding affinity of the two complimentary strands of DNA for each other. Using a radioactive or other labeled form of one of the complimentary strands and restriction endonuclease enzymes which cut the DNA at specific locations, information about the status and insertion of the introduced traits in the transformed plant can be surmised. The stability and inheritance of trait is examined to determine any linkage of the introduced trait s and if there is more than one site of incorporation for the trait s. The presence and performance of the trait over several plant generations is examined for determining stability of trait expression. Protein characterization and expression data provide biochemical information about the actual expressed protein in the plant and its concentration in various tissues. This includes the amino acid sequence, the activity of the protein usually information about the range of susceptible species and identification of the expressed protein. Expression data are provided to determine maximum exposure levels for the PIP in several plant tissue stem, leaf, root, flower, pollen, etc. Expression levels are cogent for human health and environmental hazard assessment as well as insect resistance management. Mammalian Toxicity The mammalian toxicity data examined is guided by the fact that most PIPs seen to date are proteins. Given this fact a special set of data is generally considered to affirm the assumption that the introduced protein behaves like other dietary proteins. In vitro digestibility data is often considered part of the biochemical characterization of the expressed protein but may also address toxicity issues. The rationale behind its use is to determine if the expressed protein degrades in the presence of acid, heat or simulated gastric and intestinal digestive fluids as would be expected of a normal dietary protein. The stability to digestive fluids, acid or heat also is one of the complex of characteristics that is examined to determine if a protein with no dietary history has potential to be a food allergen. If a protein is not rapidly broken down by digestive fluids, it may have a longer time period to interact with the gastrointestinal mucosa and possibly induce an allergic reaction in susceptible individuals. Acute oral toxicity is examined since the primary route of exposure is dietary for PIPs. At the end of 14 days the animals are sacrificed and the internal organs are examined by gross necropsy. This time period can be extended to 21 days if appropriate. The test substance used is the protein expressed from the gene introduced into the plant or the same protein produced from an alternate source. If the protein has no unusual persistence in digestive fluids and shows no toxicity in the acute oral toxicity tests, there is no reason to believe that the introduced protein would behave any differently than any other dietary protein and longer term toxicity testing would not be justified. Test substance equivalence may be required if an alternate source for the producing test material has been employed. In all the PIPs examined to date, there has never been sufficient expression of the protein PIP in the plant itself to provide adequate purified material to supply an

acute oral toxicity test. Therefore, to provide adequate protein test material for the study, an alternate production system for the protein is employed. This has been either the original source bacterium Bacillus thuringiensis or an industrial fermentation strain like a laboratory strain of Escherichia coli. In order to be able to utilize this alternate source, however, a series of tests similar to those done for product characterization need to be performed using both the plant expressed protein and the bacterial protein to insure these two are equivalent. Amino acid sequence homology is examined for the introduced protein to determine if there are any similarities between the introduced protein and known protein toxins or allergens. This analysis is done by both a whole sequence homology comparison and also a stepwise eight contiguous amino acid sequence comparison. The eight amino acid fragment analysis is done for comparison to known allergens since this is believed to be the smallest stretch of amino acids that can be recognized by an antibody. Since antibodies are intimately involved in the aberrant response causing food allergies, this analysis is critical for examining proteins with no previous dietary exposure for their potential to be related to a food allergen. Top of Page Gene Flow Assessment for Plant-Incorporated Protectants The movement of transgenes from the host plant into weeds and other crops has been a significant concern for EPA due to the possibility of novel exposures to the pesticidal substance. This concern has been considered for each of the Bt plant-incorporated protectants PIPs currently registered. EPA to examine all potentially adverse environmental impacts, including those which may arise from gene flow of PIPs to wild or feral populations of sexually compatible plants. In addition to this mandate, the Federal Food, Drug, and Cosmetic Act requires the issuance of a food tolerance or exemption from the requirement of a tolerance for all pesticidal substances that may enter the food supply whether through seed mixing or cross pollination. To date, PIPs in three crop species have been registered by the Agency and all have received exemptions from the requirement of a tolerance. Bt Corn, cotton and potato were reviewed for their potential to hybridize with wild and feral relatives of sexually compatible plants in the U. EPA has determined that with the conditions of registration in place there is no significant risk of gene capture and expression of any Bt endotoxin by wild or weedy relatives of corn, or potato in the United States, its possessions or territories. The Bt corn and potato PIPs that have been registered to date have been expressed in agronomic plant species that, for the most part, do not have a reasonable possibility of passing their traits to wild native plants. Wild plant species in the United States cannot be pollinated by these crops corn and potato due to differences in chromosome number, phenology and habitat. There is a possibility, however, of gene transfer from Bt cotton to wild or feral cotton relatives in Hawaii, Florida, Puerto Rico and the U. Where feral populations of cotton species similar to cultivated cotton exist, EPA has prohibited the sale or distribution of Bt cotton in these areas. These containment measures prevent the movement of the registered Bt endotoxin from Bt cotton to wild or feral cotton relatives. Potato Solanum tuberosum EPA has reviewed the potential for gene capture and expression of Bt plant-incorporated protectants only Cry3A has been introduced into potato by wild or weedy relatives of cultivated potato in the United States, its possessions or territories. Based on data submitted by the registrant and a review of the scientific literature, EPA concluded that there is no foreseeable risk of unplanned pesticide production through gene capture and expression of the Colorado potato beetle control protein Cry3A in wild potato relatives in the United States. Tuber-bearing Solanum species, including S. Three species of tuber-bearing wild species of Solanum occur in the United States: Solanum fendleri, Solanum jamesii, and Solanum pinnatisectum. But, successful gene introgression into these tuber-bearing Solanum species is virtually excluded due to constraints of geographical isolation and other biological barriers to natural hybridization. These barriers include incompatible unequal endosperm balance numbers that lead to endosperm failure and embryo abortion, multiple ploidy levels, and incompatibility mechanisms that do not express reciprocal genes to allow fertilization to proceed. No natural hybrids have been observed between these species and cultivated potatoes in the U. EPA believes there is no significant risk of gene capture and expression of any of the Cry endotoxins by wild or weedy relatives of maize in the United States because extant populations of sexually compatible species related to Zea mays are not present in the continental United States or its territories and possessions. Zea mays is a wind-pollinated species, and the presence of spatially separate tassels male flowers and silks female flowers encourages outcrossing among nearby plants. Maize cultivars and landraces are known to be interfertile to a large degree. Recent studies have

indicated that cross-pollination at ft. For production of Foundation Seed, a distance of ft has been required to ensure separation of pollen types. Additionally, the relatively large size of corn pollen as compared to other grass species and the short time span that corn pollen remains viable i. Under conditions of high temperature and desiccation, corn pollen longevity is measured in minutes. These conditions may even destroy the anthers before any viable pollen is shed. More moderate conditions can extend the field life to hours. For transformed plants to become weedy escapes as a result of the genetic modification i. These traits do not exist within the corn complement of genetic characters, a species that has been selected for domestication and cultivation under conditions not normally found in natural settings. The presence of a large cob or ear that does not shatter as the bearer of seeds severely limits the dispersing abilities of corn and it has been theorized that in the species as we know it would die out in a few generations due to competition amongst seedlings germinating from the cob. Transformation of corn to express Bt endotoxin does not alter the ability of corn to outcross with teosintes Zea mays ssp. Teosintes exist as special plantings e. Many native teosintes in Mexico, El Salvador, Guatemala, Nicaragua and Honduras are interfertile with corn to varying degrees and have been known to produce viable seedlings. Despite having coexisted and co-evolved in close proximity to corn in the Americas over thousands of years, however, corn and teosintes maintain distinct genetic constitutions even with this sporadic introgression. Given the cultural and biological relationships of various teosinte species and cultivated corn over the previous millennia, it appears that gene exchange has occurred based largely upon morphological characters between these two groups of plants and that no weedy types have successfully evolved as a result. More recent cytogenetic, biochemical and molecular analysis has indicated that the degree of gene exchange is far less than previously thought and evidence for gene introgression into teosinte from corn may be considered as circumstantial at present. Hence, the dispersal of large numbers of seeds, as is typical of weeds, is not characteristic of teosintes or corn. In their native habitat, some teosintes have been observed to be spread by animals feeding on the plants. Teosintes and teosinte-corn hybrids do not survive even mild winters and would not propagate in the U. Additionally, some types have strict day length requirements that preclude flowering within a normal season i. Based on the ability of corn to hybridize with teosintes, the results of previous genetic exchange amongst these species over millennia, and their general growth habits, any introgression of genes into wild teosinte from Zea mays is not considered to be a significant agricultural or environmental risk. The growth habits of teosintes are such that the potential for serious weedy propagation and development is not biologically plausible in the United States. Sixteen species of Tripsacum are known worldwide. Most of the 16 different Tripsacum species recognized are native to Mexico, Central and South America, but three occur within the United States. It is commonly grown as a forage grass and has been the subject of some agronomic improvement i. For the species occurring in the United States, T. Eastern Gama Grass T. Many species of Tripsacum can cross with Zea, or at least some accessions of each species can cross, but only with difficulty and the resulting hybrids are primarily male and female sterile. Albeit with some difficulty, hybrids between the two species have been made. Relatively few accessions of T. In controlled crosses, if the female parent is corn, there is a greater likelihood of obtaining viable seed. When these hybrids have been backcrossed to corn in attempts to introgress Tripsacum genes for quality enhancement or disease resistance, the Tripsacum chromosomes are typically lost in successive generations. Even though some Tripsacum species occur in areas where corn is cultivated, gene introgression from corn under natural conditions is highly unlikely, if not impossible. Hybrids of Tripsacum species with Zea mays are difficult to obtain outside of the controlled conditions of laboratory and greenhouse. Seed obtained from such crosses are often sterile or progeny have greatly reduced fertility. The only known case of a naturally occurring Zea - Tripsacum hybrid is a species native to Guatemala known as Tripsacum andersonii. Tripsacum species are perennials and seem more closely related to the genus Manisurus than either to corn or teosinte. Since both teosinte and Tripsacum are included in botanical gardens in the United States, the possibility exists although unlikely that exchange of genes could occur between corn and its wild relatives. EPA is not aware, however, of any such case being reported in the United States. Gene exchange between cultivated corn and transformed corn would be similar to what naturally occurs at the present time within cultivated corn hybrids and landraces. Plant architecture and reproductive capacity of the intercrossed plants

will be similar to normal corn, and the chance that a weedy type of corn will result from outcrossing with cultivated corn is extremely remote.

Chapter 4 : PPT â€“ BIOTECHNOLOGY REGULATIONS PowerPoint presentation | free to view - id: 70ae

FDA Biotechnology regulations training through webinars and seminars. This section includes training on FDA biotech regulations and compliance, biosimilars development, Part , biologics, bioassays, blood & blood products, tissue & tissue products, cellular & gene therapy and more.

Indeed, the cultivation of plants may be viewed as the earliest biotechnological enterprise. Agriculture has been theorized to have become the dominant way of producing food since the Neolithic Revolution. Through early biotechnology, the earliest farmers selected and bred the best suited crops, having the highest yields, to produce enough food to support a growing population. As crops and fields became increasingly large and difficult to maintain, it was discovered that specific organisms and their by-products could effectively fertilize , restore nitrogen , and control pests. Throughout the history of agriculture, farmers have inadvertently altered the genetics of their crops through introducing them to new environments and breeding them with other plants â€” one of the first forms of biotechnology. These processes also were included in early fermentation of beer. In brewing , malted grains containing enzymes convert starch from grains into sugar and then adding specific yeasts to produce beer. In this process, carbohydrates in the grains broke down into alcohols, such as ethanol. Later, other cultures produced the process of lactic acid fermentation , which produced other preserved foods, such as soy sauce. Fermentation was also used in this time period to produce leavened bread. Darwin added to that body of work with his scientific observations about the ability of science to change species. In selective breeding, organisms with desirable characteristics are mated to produce offspring with the same characteristics. For example, this technique was used with corn to produce the largest and sweetest crops. In , Chaim Weizmann first used a pure microbiological culture in an industrial process, that of manufacturing corn starch using Clostridium acetobutylicum , to produce acetone , which the United Kingdom desperately needed to manufacture explosives during World War I. In , Alexander Fleming discovered the mold Penicillium. His work led to the purification of the antibiotic compound formed by the mold by Howard Florey, Ernst Boris Chain and Norman Heatley â€” to form what we today know as penicillin. In , penicillin became available for medicinal use to treat bacterial infections in humans. Cohen Stanford significantly advanced the new technology in by transferring genetic material into a bacterium, such that the imported material would be reproduced. The commercial viability of a biotechnology industry was significantly expanded on June 16, , when the United States Supreme Court ruled that a genetically modified microorganism could be patented in the case of Diamond v. Revenue in the industry is expected to grow by This section needs to be updated. Please update this article to reflect recent events or newly available information. The biotechnology sector has allowed the U. By increasing farm productivity, biotechnology boosts biofuel production. For example, one application of biotechnology is the directed use of organisms for the manufacture of organic products examples include beer and milk products. Another example is using naturally present bacteria by the mining industry in bioleaching. Biotechnology is also used to recycle, treat waste, clean up sites contaminated by industrial activities bioremediation , and also to produce biological weapons. A series of derived terms have been coined to identify several branches of biotechnology, for example: Bioinformatics also called "gold biotechnology is an interdisciplinary field that addresses biological problems using computational techniques, and makes the rapid organization as well as analysis of biological data possible. The field may also be referred to as computational biology, and can be defined as, "conceptualizing biology in terms of molecules and then applying informatics techniques to understand and organize the information associated with these molecules, on a large scale. An example would be the selection and domestication of plants via micropropagation. Another example is the designing of transgenic plants to grow under specific environments in the presence or absence of chemicals. One hope is that green biotechnology might produce more environmentally friendly solutions than traditional industrial agriculture. An example of this is the engineering of a plant to express a pesticide , thereby ending the need of external application of pesticides. An example of this would be Bt corn. Whether or not green biotechnology products such as this are ultimately more environmentally friendly is a topic of considerable debate. An example is the designing of an organism to produce a useful chemical. White

biotechnology tends to consume less in resources than traditional processes used to produce industrial goods. This includes biotechnology-based approaches for the control of harmful insects, the characterisation and utilisation of active ingredients or genes of insects for research, or application in agriculture and medicine and various other approaches. One application is the creation of enhanced seeds that resist extreme environmental conditions of arid regions, which is related to the innovation, creation of agriculture techniques and management of resources. Biotechnology has contributed to the discovery and manufacturing of traditional small molecule pharmaceutical drugs as well as drugs that are the product of biotechnology â€" biopharmaceutics. Modern biotechnology can be used to manufacture existing medicines relatively easily and cheaply. The first genetically engineered products were medicines designed to treat human diseases. To cite one example, in Genentech developed synthetic humanized insulin by joining its gene with a plasmid vector inserted into the bacterium Escherichia coli. Insulin, widely used for the treatment of diabetes, was previously extracted from the pancreas of abattoir animals cattle or pigs. The resulting genetically engineered bacterium enabled the production of vast quantities of synthetic human insulin at relatively low cost. The application of biotechnology to basic science for example through the Human Genome Project has also dramatically improved our understanding of biology and as our scientific knowledge of normal and disease biology has increased, our ability to develop new medicines to treat previously untreatable diseases has increased as well. In addition to studying chromosomes to the level of individual genes, genetic testing in a broader sense includes biochemical tests for the possible presence of genetic diseases, or mutant forms of genes associated with increased risk of developing genetic disorders. Genetic testing identifies changes in chromosomes , genes, or proteins. As of several hundred genetic tests were in use. Agriculture[edit] Genetically modified crops "GM crops", or "biotech crops" are plants used in agriculture , the DNA of which has been modified with genetic engineering techniques. In most cases, the main aim is to introduce a new trait that does not occur naturally in the species. Examples in food crops include resistance to certain pests, [36] diseases, [37] stressful environmental conditions, [38] resistance to chemical treatments e. These have been engineered for resistance to pathogens and herbicides and better nutrient profiles. GM livestock have also been experimentally developed; in November none were available on the market, [50] but in the FDA approved the first GM salmon for commercial production and consumption. Industrial[edit] Industrial biotechnology known mainly in Europe as white biotechnology is the application of biotechnology for industrial purposes, including industrial fermentation. It includes the practice of using cells such as micro-organisms , or components of cells like enzymes , to generate industrially useful products in sectors such as chemicals, food and feed, detergents, paper and pulp, textiles and biofuels. By using renewable raw materials to produce a variety of chemicals and fuels, industrial biotechnology is actively advancing towards lowering greenhouse gas emissions and moving away from a petrochemical-based economy. Vallero and others have argued that the difference between beneficial biotechnology e. Regulation of genetic engineering and Regulation of the release of genetic modified organisms The regulation of genetic engineering concerns 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 GMO , including genetically modified crops and genetically modified fish. There are differences in the regulation of GMOs between countries, with some of the most marked differences occurring between the USA and Europe. For example, a crop not intended for food use is generally not reviewed by authorities responsible for food safety. Depending on the coexistence regulations, incentives for cultivation of GM crops differ. Each successful application is generally funded for five years then must be competitively renewed. Graduate students in turn compete for acceptance into a BTP; if accepted, then stipend, tuition and health insurance support is provided for two or three years during the course of their Ph.

Chapter 5 : Biotechnology - Wikipedia

Links to biotechnology guidance documents & regulatory information. Draft Guidance for Industry: Voluntary Labeling Indicating Whether Food Has or Has Not Been Derived From Genetically Engineered.

Testing Requirements to Assess Risks to Human Health and the Environment Before making a regulatory decision about a pesticide, EPA requires data on a range of subjects to ensure that the product meets Federal safety standards. For all pesticide products, including genetically engineered pesticides, EPA requires testing of product composition and chemical properties, human health effects, environmental effects on non-target pests, and the fate of the pesticide in the environment. Specifically for genetically engineered pesticides, EPA routinely examines the following types of information and data: Identification of new genetic material and all new proteins. Mammalian toxicity testing of all new proteins. Comparison of new proteins to known toxins and allergens. Toxicity testing on birds, fish, earthworms, and representative insects such as bees, ladybird beetles, and lacewings. Toxicity testing on insects related to target insect pests. Length of time required for the new proteins to degrade in the environment. Toxicity testing will be conducted with a range of doses and concentrations 10 to times higher than those expected in environmental conditions. EPA also consults literature and other sources of supporting information related to any aspect of the proteins and the organisms from which they are derived. Insect resistance could affect the long-term viability of the PIP itself and also that of related conventional biopesticides like microbial Bt sprays. Thus, the Agency has looked for methods to minimize the likelihood that an insect will develop resistance to the Bacillus thuringiensis Bt PIPs. The strategy of the program focuses on the level of the PIP produced and the planting of refuges areas set within or close to a field of the genetically modified crop where unmodified versions of the same crops are planted. By setting these crops close to each other, the refuge encourages the interbreeding of resistant and nonresistant insects, reducing the likelihood of pesticide-resistant offspring. Evaluating Potential of Genes Moving to Other Plants EPA closely evaluates the potential transfer of a new pesticidal trait to wild relatives and weeds. Known as gene flow, cross-pollination of wild relatives can disrupt a local ecosystem by changing the makeup of local plants, crowding out related species, and changing the local habitat. Less risk of cross-pollination exists in the United States than in tropical countries where the wild relatives of most of these crops are found. In the case of genetically modified Bacillus thuringiensis Bt cotton, where the potential for gene flow did exist, EPA restricted the planting of this crop in order to reduce the risk. A crop plant that is resistant to an herbicide. The herbicide tolerant trait occurs naturally in some plants, while others have this trait introduced through conventional breeding or through the use of modern biotechnology. A plant on which an insect pest lives or by which it is nourished. A scheme for managing plants expressing insect control proteins that will provide economically important control of the pest and insure that the target insect pest remains susceptible to the trait. The IRM plan often includes growing plants that are not insect resistant in close enough proximity to provide susceptible insects. These susceptible insects will mate with any rare resistant pests, dilute out the resistance gene and prevent the selection of significant resistant populations. Microbial Pest Control Agent: A microorganism that is usually used to infect and kill a target pest or to compete with undesirable microbial pests in the environment. A pesticidal substance that is intended to be produced and used in living plants, or in the produce thereof, and the genetic material necessary for the production of such a pesticidal substance. A plant-incorporated protectant also includes any inert ingredient contained in the plant or produce thereof. A portion of cropland devoted to harboring susceptible pest insects. These susceptible insects can reduce the appearance of resistant pest insects by diluting out the resistance gene in the pest population. The maximum permissible levels for pesticide residues allowed in or on commodities for human and animal consumption.

Chapter 6 : Biotechnology Case Law and Regulation

The state of biotech regulations in â€" an ag policy expert's perspective. By Drew L. Kershen. Professor Emeritus University of Oklahoma College of Law.

But what about a potentially damaging biotech creation made the same way? Still, genetic technology exists on a continuum, and the regulatory conundrum the mushroom raises is relevant to any organism tweaked in a lab. Over the past two years, policymakers had a fleeting chance to improve biotech lawsâ€"and they missed it. Advertisement To understand biotech regulations, we have to go back in time to , when the cool kids were pegging their jeans , Top Gun was in the theaters, and Lionel Richie and Bananarama dominated the airwaves. Another trend back then: Scientists discovered this genetic engineering tool in the early s , when they first swapped genes from one species into another using the bacteria E. The discovery was a landmark for biotechnology. The first is to advise the president on matters of science, tech, and engineering. The second is to help coordinate multiple agencies on scientific policy. Rather than writing a new law, the OSTP decided to fit genetically engineered products into existing laws. The result, called the Coordinated Framework for the Regulation of Biotechnology, published in June Under the coordinated framework, regulation falls to the Environmental Protection Agency, the U. Department of Agriculture, and the Food and Drug Administration. An anti-browning mushroom developed by plant pathologist Yinong Yang using CRISPR-Cas9 gene-editing technology will have a longer shelf life and resist blemishes from handling and mechanical harvesting. Several laws allow the EPA to do this, but the two relevant for biotech regulation relate to pesticides and toxic materials. Under the coordinated framework, the EPA can regulate any biotech organisms that produce these chemicals in some way. When it comes to biotech, the relevant laws that give USDA power relate to plant health. When the coordinated framework first published, the state-of-the-art genetic engineeringâ€"recombinant DNAâ€"used microbes to deliver new genes. In crops, for example, scientists used agrobacterium, a bacterium that can infect plants. But the microbes are technically plant pathogens, which gives the USDA the authority to regulate any crop made this way. As for the FDA, part of its job is to keep our food safe. Advertisement Policymakers knew the coordinated framework was rickety even before the mushroom came along. One was to commission a report from the National Academies of Science exploring new biotech that may come out over next five to 10 years more on this in a minute. For the other two, the agencies had to update their role in current biotech regulation and spell out a long-term strategy for future products. The update took more than a year and included a series of closed and public meetings. A draft published last September , and the final version came out in early January. It was a lot of work for an underwhelming document. Rather than update the coordinated framework, the document lists a series of hypothetical biotech products and explains how each agency might regulate them. But none of the hypothetical exercises explored how products made with new technologies, like the CRISPR mushroom, may fit the current rules. A better approach may have been to blow the whole thing up and start over: Write a new law that could adapt to future technologies. Ideally, the law would also be more elastic when it comes to risk. But there are other ways biotech laws could change. Remember, the OSTP also tasked the agencies with a long-term strategy for future biotech products. In January, just days before Obama left office, the FDA published draft guidance on regulating genetically altered animals, which will include CRISPR and other new technologies, as well as guidance on gene-edited foods and mosquitoes. Around the same time, the USDA proposed new rules on biotech plants. In addition to potential plant pests that it already monitors, USDA wants to use a law that lets it regulate noxious weedsâ€"plants that pose a threat to the environment, the economy, or society, such as invasive species. The new rules would also allow the USDA to revise previous decisionsâ€"for example, if there is evidence that an approved product is causing unexpected ecological damage. It lays out several possible recommendations for regulating biotech in the future. For example, one suggestionâ€"which has the support of many policy folks, including Jaffe â€"is to create a single point of entry for biotech regulation. This could do away with needless regulatory overlap. It would also be easier for companies to navigate. Some on Team Trump reportedly want to do away with the OSTP â€"a tricky proposal

for biotech, since the office organizes and guides the relevant policies and agencies. A search of his tweets , a direct line into his stream of consciousness, shows no mention of genetically modified organisms. It could be that the agencies will just plug along under the radar and get some real work done. Or the Trump administration could wipe the regulations out completely, like it has with rules on clean water or protecting hibernating bears. Those last two choicesâ€”doing nothing or wiping out regulations altogetherâ€”would be huge mistakes. Either could allow for a flood of unregulated, and potentially risky, products. This article is part of the synthetic biology installment of Futurography , a series in which Future Tense introduces readers to the technologies that will define tomorrow.

Chapter 7 : Will Biotechnology Regulations Squelch Food and Farming Innovation?

Rhode Island: Regulations allow the Rhode Island Environmental Standards Board to oversee commercial biotechnology activities and assure that federal guidelines for work involving recombinant DNA are met.

Chapter 8 : Regulations â€“ Biosafety | Department of Biotechnology

Provides links to relevant laws, regulations, environmental permits and petitions, and related information. From the USDA's Animal and Plant Health Inspection Service. Information Systems for Biotechnology.

Chapter 9 : U.S. biotechnology regulations are woefully out of date.

EPA's Regulation of Biotechnology for Use in Pest Management Biotechnology is the science of modifying the genetic composition of plants, animals, and microorganisms. Historically, biotechnology has relied on conventional plant and animal breeding practices to modify genetic composition.