International Center for Technology Assessment

660 Pennsylvania Ave., S.E., Suite 302, Washington, DC 20003
phone (202) 547-9359 fax (202) 547-9429

COMMENTS OF JAYDEE HANSON
POLICY DIRECTOR
NOVEMBER 1, 2016
ON
COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY AND DEVELOPING A LONG-TERM STRATEGY FOR THE REGULATION OF THE PRODUCTS OF BIOTECHNOLOGY

Thank you for the opportunity to review this draft of the proposed revision to the coordinated framework. We are focusing on just a few main points. We have separately commented to the EPA on their rewrite of their guidance on GE microbes and our colleagues at the Center for Food Safety have commented on the revisions to the framework needed for crops and trees.

ALL AGENCIES "COORDINATED" UNDER THE COORDINATED FRAMEWORK NEED TO USE THE SAME DEFINITIONS OF BIOTECH.

The various agency regulations and guidelines need to be modified to make clear that all kinds of genetic engineering should be covered. This approach would recognize that synthetic DNA even if it copies intragenic DNA may not be identical to the original. The White House memorandum on the revisions of the coordinating framework makes clear that it intends agencies to include all genetic engineered products, not just those that are intergeneric. The language is found in the first footnote to the memo.
https://www.whitehouse.gov/sites/default/files/microsites/ostp/modernizing_the_reg_system_for_biotech_products_memo_final.pdf

The White House should make this an explicit requirement for the coordinated framework. All kinds of genetic engineering, whether they use DNA from another organism, or synthesized DNA/RNA, or are reorganizing the DNA of an existing organism using gene editing techniques like CRISPR Cas9, should require explicit decisions by the various agencies.

HUMAN GENOMES SHOULD NOT BE "REWRITTEN"

We are deeply concerned about the prospect of genome editing for human reproduction. We believe that the coordinated framework must call on agencies to refrain from any human germline modification.

We very much appreciated Dr. Holdren's May 2015 note on genome editing that stated, "The Administration believes that altering the human germline for clinical purposes is a line that

should not be crossed at this time." We also welcomed the culminating statement from the December 2015 International Summit on Human Gene Editing that it would be "irresponsible to proceed" with human germline modification in the absence of "broad societal consensus."

The public opposes efforts to genetically modify future generations, but efforts to approve human mitochondrial engineering are being undertaken by this Administration as are efforts to develop human/animal chimeras. We use you to be clear in this document that the US opposes human germline interventions of all kinds.

GENETICALLY ENGINEERED ANIMALS AND INSECTS ARE STILL NOT RATIONALLY REGULATED IN THE DRAFT FRAMEWORK.

Insects—
Genetically engineered (GE) insects are regulated as "plant pests" by the US Department of Agriculture and as "new animal drugs" by the Food and Drug Administration. Currently, all the GE products are pesticidal products using the same genetic sequences that are intended to cause sterility in the offspring of the insects. Even new kinds of techniques that researchers have envisioned using gene drives are still essentially pesticidal techniques. The EPA currently regulates another pesticidal technique in insects, namely the infection of mosquitoes by the Wolbaccia bacteria. It would make most sense to write new regulations that would have the EPA review ALL techniques intended to work as pesticidal products in the bodies of insects whether they are genetic constructs or bacterial infections.

Animals—
The Food and Drug Administration has used its "new animal drug" regulations to review and approve animals engineered to produce human drugs in their milk or eggs and one animal, the GE Salmon to produce food. While it makes some sense to have GE animals designed to produce human drugs via genetic constructs within their bodies. It only makes sense because the FDA has turned that "drug" approval into a two-step process: 1. First approve the "safety" of the genetic insertion for the animal and then; 2. Review the resultant human drug through the appropriate human drug approval process.

The approval of the GE salmon failed to have this two-step process. The FDA approved the GE Salmon for human food without rigorously testing the products of the GE salmon as a "new food additive". The FDA has food additive approval processes that could have provided a parallel for human food approvals like the agency reviews of GE drugs for humans. Instead, the FDA had the company do the most cursive of food safety reviews and never tested the safety of the GE salmon in human subjects like human drugs from GE animals are tested.

The cobbled together two-step process may work for human drugs produced in GE animals, but there is no parallel process for food animals. New regulations for food animals need to be drafted. Moreover, other new animals that are proposed include engineered rodents and engineered mosquitoes that are intended to be released into the wild. The FDA does not have on is staff persons trained to adequately review animals that are intended to be released into the wild, or like the salmon, which may escape into the wild. The Coordinated Framework needs to

add the Fish and Wildlife Service as an agency with explicit assignment to develop regulations for animals to be released in wild environments. This needs to be coordinated with the EPA if EPA is given the responsibility for all pesticidal insects.

The US Department of Agriculture has responsibilities for the safety of research animals, including GE animals, but it has avoided issuing regulations related to GE animals. Its Inspector General recommended that the agency develop such regulations in 2011, but despite having agreed to develop such regulations, APHIS/USDA has not yet issued them. The White House needs to direct APHIS to finish those regulations.

Thank You for considering these comments.