Comments of Jaydee Hanson, Policy Director, International Center for Technology Assessment to interagency hearing on the "Coordinated Framework"
October 30, 2015

Not a Coordinated Framework:

The Coordinated Framework is a weak policy guidance document that gives an illusion of regulation while failing to coordinate agency actions and failing to stimulate needed regulations specific to new GE organisms. Let me give a few examples of where the coordinated framework is failing in the areas of GE insects and animals.

GE Insects

Both the USDA and the FDA have been regulating genetically modified insects. The FDA regulates genetically engineered insects through their new animal drug authority. Thus, they make the huge leap that the genetically engineered construct introduced into the insect is actually a "drug" for the insect. The first GE insect drug that we know that FDA is reviewing is a mosquito that is engineered to breed with and sterilize other wild mosquitoes. (I saw that because by using its drug authority, the FDA is obligated to keep secret the existence of the GE insect "drug" until its approval. We only know about this mosquito because its engineer, the UK company Oxitec revealed the application.) Note that the insect is going to be released into the environment to breed with other mosquitoes and sterilize them. In this respect, it is more like a pesticide than a "drug" and should be reviewed by EPA, not FDA.

Ironically, it seems that the FDA is only reviewing this mosquito because the wild type can carry Dengue fever, a human disease. Two other GE insects (a cotton boll worm and a moth whose worms feed on cabbage) from the same company have been reviewed by the USDA because they are considered to be plant pests. The USDA/APHIS was asked by its inspector general in 2011 to develop new regulations for GE insects and animals and APHIS agreed with the recommendation, but has not developed any new regulations. Instead, APHIS has approved field trials of genetically engineered diamond back moths (a cabbage pest) with little public input and basically in secret. Last year, APHIS took comments on whether it should approve an Oxitec GE moth trial at Cornell University labs, but then approved the trial without commenting on the comments it received. No approval was posted on its website and we only learned of the approval when the agency admitted to one of our colleague groups that the trial had been approved.

In short, the "coordinated framework" for GE insects is an ad-hoc framework. The same basic GE techniques are used in all of the company's products, but staffs in two different agencies are reviewing them. Who would review a honey bee genetically engineered to produce more honey? It is not a plant pest and it is not a carrier of a human disease. What about a mosquito engineered to fight bird malaria? Would Fish and Wildlife review it because it is been targeted

for wild birds? Staff resources in all agencies are limited, it would be best if we had one agency that could develop the expertise to review genetically engineered insects, not parceling the review out in an ad-hoc manner and depending more on the expertise of the company than on government staff.

GE animals:

At least four GE animals have been reviewed by the FDA. For two of the animals, a GE pig and a GE cow we know that they were sent to the FDA for review only because the developers publically disclosed their submissions. By using the new animal drug regulations of the Center for Veterinary Medicine to review GE animals, FDA is required to keep the review secret until the very end of the process. The first animal that was approved by FDA was a goat engineered to express a human anti coagulation protein in its milk. In effect, the goat was a drug production laboratory, a little bit like making human insulin in an E. coli. The goat is making a drug, but not one for the goat.

The second GE animal that the FDA has reviewed is an Atlantic salmon engineered with growth hormone genes from another unrelated salmon and DNA from an artic eel pout. The company, AquaBounty, claims that this fish grows faster than other Atlantic salmon. Still, calling this human food a new animal "drug" stretches credulity. This salmon should be reviewed a new human food, not as a "drug" for the salmon. Other countries have developed novel food regulations that can review all GE food products. We suggested that the FDA should at least use its new food additive authority to review the DNA construct as new human food additive. That would have a better step than using the animal drug fiction to review a human food. What is really needed are new regulations that cover the both the effects of GE animals as human food and the effects that GE animals will have on the environment.

Again, the USDA inspector general has asked APHIS to develop regulations for GE animals, but that has not happened. But having two agencies have primary reviews of GE animals does not make any more sense for animals than it does for insects. We need one agency with regulations designed for genetically engineered animals reviewing all of the food animals.

Transparency.

Among the many flaws of the way the coordinated framework reviews GE animals and insects is the lack of transparency in the review process. The FDA use of its new animal drug authority guarantees too much secrecy. To its credit, in the cases of the GE goat and the GE salmon, the FDA held public meetings at the end of its review process. When I pointed out to the CVM staff that their GE animal guidance called for a hearing before approval and wanted to know when that hearing would be for the GE mosquito, they seemed surprised, but two weeks later they changed the language of the guidance so that it no longer requires such a hearing.

But just having a hearing won't solve the problem if the agency accepts claims by developers of GE animals and insects that the health and environmental safety effects of the product can be hidden and claimed as confidential business information.