Poultry Group

Case 1: Allergen-reduced Chickens

- Ovomucoid (OVM) is very stable against heat and digestive enzymes, making it difficult to remove physiochemically and inactivate allergens.

- This leads to persistent allergenicity, limited food choices, risk of accidental exposure, impact on quality of life of people who are allergic.
- To address this issue, TALEN genome-editing technology was used to knock out the gene responsible for ovomucoid, thereby producing eggs that are safer for individuals with egg allergies.

Transcription activator-like effector nuclease-mediated deletion safely eliminates the major egg allergen ovomucoid in chickens

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Scientists from Hiroshima University produced OVM knocked out chickens using genome editing tools. Colored chickens are knockout chickens.

Case 2: Single-Sex Chickens- a null segregant

- The widespread and ethically contentious practice of culling male chicks in the egg-producing poultry industry.
- led to animal welfare concerns, ethical and societal backlash, regulatory pressure and it is economically inefficient hence the need for alternative technologies.
- This technology uses marker gene (e.g., fluorescent) is inserted on the Z chromosome of breeding hens, enabling male-destined (ZZ) eggs to be identified and removed before incubation, while female (ZW) chicks do not inherit the marker and hatch as non-GM *null segregants*.

Group 3: Poultry
Summary of Discussions

PART 1: Understanding the Biotechnology Application
Reduced Allergen Eggs

1. What is the specific human health problem this technology is designed to solve? Why is knocking out the ovomucoid gene considered an effective way to address it, compared to food processing methods?
Response: The goal of this technology is to help remove egg allergen Ovomucoid (OVM) from the chicken egg. This helps people who are allergic to OVM, a stable protein in the heat and digest to be able to eat egg and egg-based food. OVM knock out was done because it wasnt responsive to treatment like heat and digestion.

2. This case used TALENs instead of CRISPR/Cas9. While the tool is different, the outcome (a gene knockout) is similar. From a regulator's perspective, does the specific tool used to make an edit matter more, or does the final product and the nature of the change?
Response: No, they are all classified as new technology which isn't known to be natural.

Single-Sex Chickens (Null Segregant Model)

1. What is the major animal welfare issue in the egg-laying industry that this technology is designed to address?
Response: Mass culling of male chicks: In the egg industry, male chicks are seen as waste because they can't lay eggs. 50% of day-old male chicks are culled and this is a major welfare issue.

2. Explain the key distinction in this system: The parent birds are transgenic (GMOs), but the final commercial product (the egg-laying hen) is a null segregant and is not transgenic. Why is this distinction so critical for a regulatory discussion?

Response: The parent birds are transgenic (GMOs) while the final commercial product (the egg-laying hen) is a null segregant (not transgenic). A null segregant is an offspring that does not inherit the transgene, even though one parent carried it. They are conventional chicken in that they do not contain engineered DNA.

3. What happens to the male-destined eggs that are identified and removed? What are the potential uses or disposal issues for these eggs, which do contain the genetic modification?
Response: They are identified early and removed before becoming chick, they can be used for feed chain and other biological purposes.

PART 2: Potential Pathways to Harm

Human Health
1. For the allergen-reduced egg, the developer conducted extensive safety tests to ensure no new mutant proteins were created. Are these tests sufficient for a regulatory submission?
Response: For food safety the egg needs to be tested for more details to prove its safety.

What other long-term food safety questions might you have about removing a major protein from a common food?
Response: Does removal of OVM affect health of the consumer, does is affect nutrient intake and environment in the long run?

2. The null segregant hens are not genetically modified. Is there any conceivable food safety risk from the eggs they lay? What about the male eggs that are genetically modified, what safety assessments would be needed before they could enter the human food or animal feed supply?
Response: In the null segregant hens there is no transgenic DNA, regulators don't have any food safety issue, the male egg will need to be checked for composition, molecular alterations, unintended compositional shifts, functional differences due to the marker in it.

Animal Welfare

1. Does the absence of the ovomucoid protein have any negative health effects on the hen that lays the egg or on the development of the embryo within the egg?
Response: The expert reported that there was no effect on the egg or embryo health recorded but others commented that there may be impact on the egg's protection against bacterial since OVM helps protect the egg from bacterial infection.
2. For the single-sex system, what are the specific welfare considerations for the parent transgenic flock? Does the presence of the fluorescent marker gene have any effect on their health? What level of containment and management would be required?
Response: The parent stock will be monitored to ensure their performance aren't affected with the insertion of fluorescent marker. They will be kept in a confined environment to ensure they are contained to reduce the exposure of the community to the world

Environmental Impacts

1. What are the environmental risks if a reduced allergen chicken were to escape and breed with wild or domestic chickens, spreading the null-ovomucoid trait?

Response: The population will be affected by the new set of chickens that lack the OVM which may affect the rate of survival of the chickens.

2. What are the environmental risks if the transgenic parent birds from the single-sex system were to escape and breed with other chickens? How critical is strict biocontainment for this parent flock to ensure the integrity of the system?

Response: We agreed that uncontrolled transgenic parent birds escape will lead to breeding with other chickens; the transgene can spread uncontrollably and may disrupt the entire sex-selection system. We also discussed that strict containment measures including physical, operational, and genetic are critical to maintain system integrity, animal welfare, regulatory compliance, and environmental biosafety.

PART 3: Regulatory Approaches and Trade Implications

Regulatory Triggers

1. This case study presents a complex regulatory question. How would your system regulate the null segregant hen? Is it a GMO because its parent was a GMO? Or is it not a GMO because it did not inherit the modified gene? What is the basis for your conclusion in your country's laws?

Response: We all agreed that they are not GMOs, however the participant from USA claimed they may be regulated as Intentional Genomic Alteration.

Data Requirements

1. What data and testing protocol would you require from a developer to verify that a chicken is truly a "null segregant" and contains no trace of the genetic modification from its parent? How often would this need to be tested to ensure the integrity of the commercial flock?

Response: there is a need for molecular, phenotypic and breeding analyses to prove that null segregant has no trace of genetic modification.

Comparative Models and National Adaptation

1. Australia and New Zealand have explicitly determined that null segregants are not GMOs and are therefore not subject to GMO regulations.
2. The EU, with its strict process-based approach, would likely consider them GMOs because they are the direct product of a GM breeding process.
3. The US FDA regulates intentional genomic alterations (IGAs) in animals, so only the lines of animals containing the IGA would be subject to FDA review.

Which approach aligns best with your country's legal and scientific traditions? What are the practical implications of each choice for your national poultry industry?

Response: members of the group who were from different countries agreed that the animals will be classified as non-GMO but Vietnam and Thailand reported they don’t have a framework on it presently so they can’t ascertain if they will consider it non-GMOs.

Trade and Labelling

1. Imagine your country decides null segregant eggs are not from GM animals and do not require labelling. A major trading partner decides they are from a GM process and must be labelled as such. How would this impact on international trade in eggs and egg products? How could you certify that your eggs are from "null segregant" hens and not from the GM parent flock? Is this a role for government or for the poultry industry?

Response: Loss of income due to lack of transnational traction, an example was made of a crop that was approved in USA but not approved in another country which is the main market for the producers, US farmers couldn't export to the said country, and this led to a legal battle between farmers and the seed company. In this case, the government and industry had to work together to ease trade.

2. What are the regulatory and ethical issues surrounding the use of the male (GM) eggs for other purposes, such as animal feed? Would they need to be approved and labelled as a GM feed product before they could be sold?

Response: Some participants believed that there will be no need for labelling of male's usage in feed production while others differ on the issue stating the all GMO need to be specified.