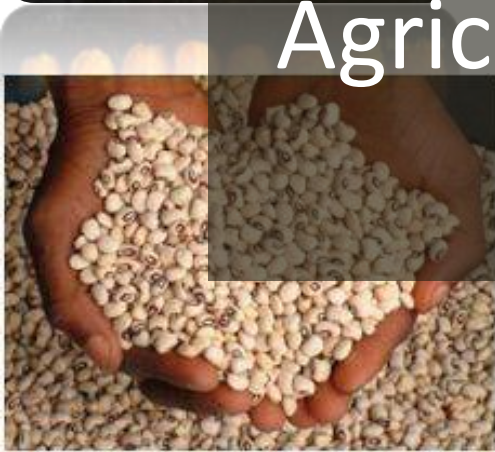




# Feed Safety Assessment on Agricultural-biotech product in Indonesia



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- Some of GM crops function as feed (grain and leave of maize, soybean meal, and sugarcane young leave)
- Indonesia import maize and soybean (also soybean meal)



# Indonesia import (x thousand ton)



Year	Maize	Soybean meal
2014	3381	3902
2015	1754	4203
2016	639	4255
2017	530	4454
2018	800	4850
2019	400	5000

Indonesia imports about 2 - 3 million tons of soybean annually



- There have been some concerns that functional transgenes from GM-derived from feeds or feed materials might be incorporated into livestock products for human consumption (milk, meat and eggs).



- According to EFSA, animals that have eaten genetically modified (GMO) feed show no residual traces in their eggs or meat

<https://www.reuters.com/article/us-eu-gmo-food/no-gmo-from-feed-found-in-meat-or-eggs-eu-agency-idUSL0392209120070803>



# From more than 20 years experience of consumption GM products:

- An article published in the peer-reviewed Journal of Animal Science concludes feeding livestock diets that contain genetically engineered (GE) crops **has no impact on the health or productivity of those animals.** In a thorough review of scientific literature and field data sets, the article documents evidence that the performance and health of food-producing animals fed GE crops are comparable with those of animals fed non-GE crops.



- [Food Chem Toxicol.](#) 2018 Jul;117:3-12. doi: 10.1016/j.fct.2017.08.031. Epub 2017 Aug 31 (Health effects of feeding genetically modified (GM) crops to livestock animals: A review)
- [J Anim Sci.](#) 2014 Oct;92(10):4255-78. doi: 10.2527/jas.2014-8124. Epub 2014 Sep 2 (Prevalence and impacts of genetically engineered feedstuffs on livestock populations)



# Legal Protection

- Government order PP no 21/2005 on risk assessment of GMO
- Minister of Agriculture decree no 36/2016 on risk assessment of GM feed
- Director of IAARD decree no. 466 / Kpts / OT.210 / H / 11/2016 on guideline and procedure of GM feed risk assessment





# Permentan no 36/2006

## Type of Feed Ingredient and Feed derived from GMO

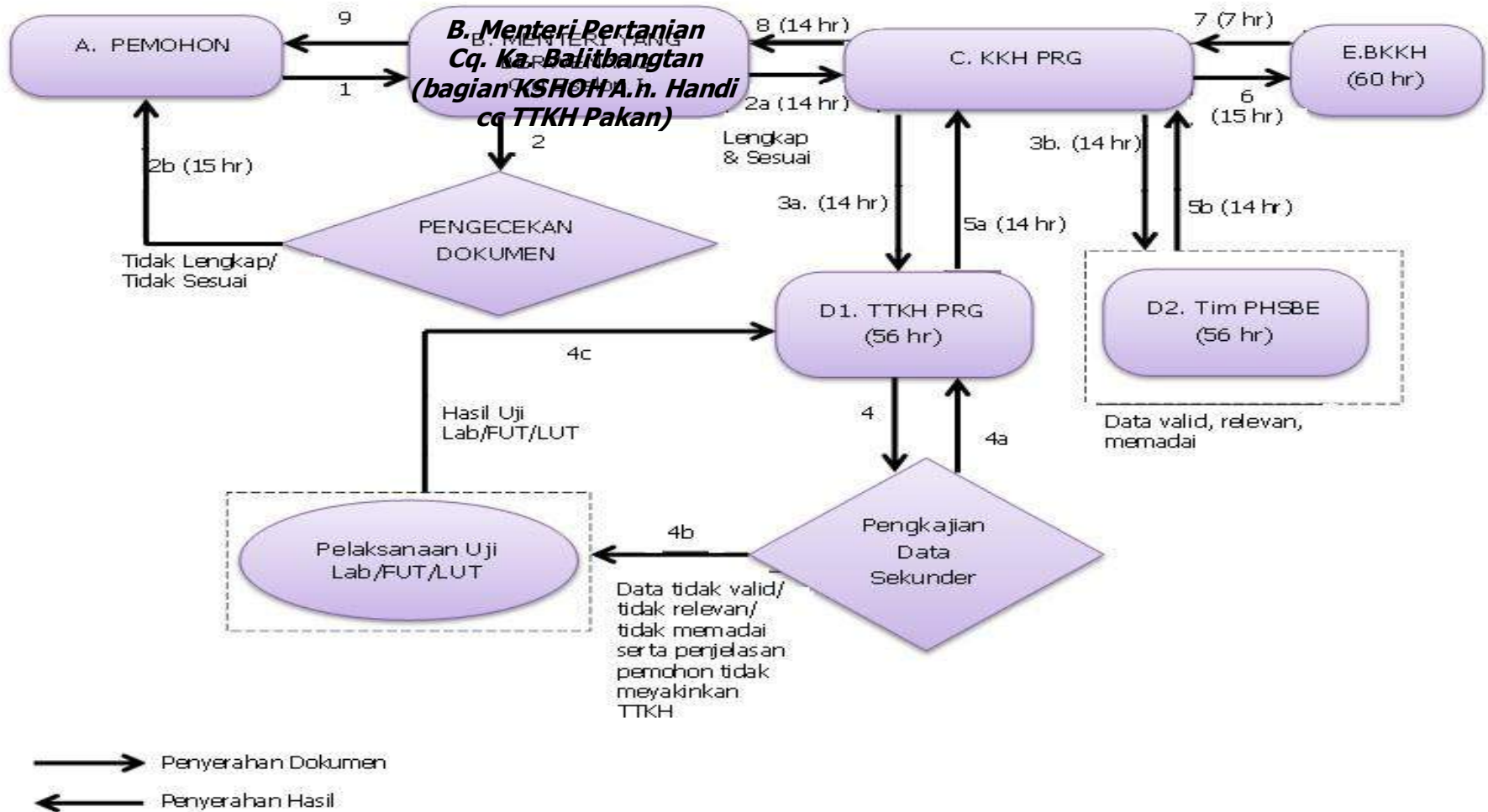
### □ Chapter II. article 4:

**Type of feed material and feed derived from GMO :**

- a. GM plants, ingredients from GM plants and their processed products.**
- b. GM Microbes, ingredient from GM microbe, and their processed products**
- c. GM fish, ingredient from GM fish and their processed product**
- d. GM animal PRG, ingredient from GM animal and their processed product.**



# Flow chart of getting food approval



# FEED SAFETY ASSESSMENT

- *The data elements considered for a feed safety assessment are almost similar to that utilized in a food safety assessment*
- *Codex published guideline assessment of food derived from recombinant-DNA plants (CAC/GL 45-2003) ; adopted globally*



- In the case of imported feed ingredient/feeds derived from GMO, beside having data of genetic information and feed safety, it also has to be completed with a statement stating that those GM feed has been permitted to be freely traded (**certificate of free trade**) in country of origin





- Because in Indonesia, cattle, goat and sheep was fed by forage feed, the regulator also ask comparative study not only using grains/silage but also on forage or leaves.



# Data needed for GM feed safety assessment (article 7)

- Genetic information
  - General description of feed and why there is a need to modify
  - Description of Host (the plant that being modified)
  - Description of Donor (the source of the insert gene)
  - Method of plant transformation
  - The transformant
    - Stability (inheritant)
    - Level of expression and history of safe use



# Data for feed safety

- Substansial equivalent
  - compositional analysis
    - Proximate
    - Amino acid
    - Fatic acid
    - Key Nutrients and key of antinutrients (vitamins, minerals, enzyme inhibitors)
- Toxicity
  - In vitro simulation model using gastric fluid (SGF and SIF)
  - Mamalian model via rodent model
    - Mortality, body weight, histopathology
  - Bioinformatic (*Similarity to known mammalian toxins*)
- Others (feeding trials limited adresing nutritional adequacy)



## – Toxicity

- In vitro simulation model using gastric fluid
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# Toxicology

- Acute Oral Gavage
  - Single High Dose (e.g. 500 - 2,000 mg/kg body weight)
  - Dose reflective of potential human dietary exposure
  - 14 Days



**Group Assignments**

Group Number	Dose Level (mg/kg)	Number of Animals	
		Male	Female
1	0 (Control)	10	10
2	2000	10	10



- In life
  - Cageside: mortality, morbidity, injury, food and water consumption
  - Clinical: Days 1 (approximately 1 hour postdose), 7, and 14.
    - skin, fur, eyes, ears, nose, oral cavity, thorax, abdomen, external genitalia, limbs and feet, respiratory and circulatory effects, autonomic effects such as salivation, and nervous system effects including tremors, convulsions, reactivity to handling, and unusual behavior



- In life
  - Body weight
  - Food consumption
- Post Mortem
  - Body weight
  - External abnormalities
  - Abdominal, thoracic, cranial cavity abnormalities
  - Organ abnormalities
  - Organ weights



# Example feeding study (40 days)

feeding trials limited addressing nutritional adequacy

- Broilers (male and female)
- Comparative : GM and non GM
- Parameters:
  - Survival, body weight, feed conversion, carcass yield



# Approved GM events for feed

- 1 **Ronozyme AX (CT) (2011)**
- 2 **Corn MON 89034 (2013)**
- 3 **Corn NK 603 (2013)**
- 4 **Sugarcane NXI-4T (2018)**
- 5 **Corn BT 11 (2018)**
- 6 **Corn GA21 (2018)**



# Thank you



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