

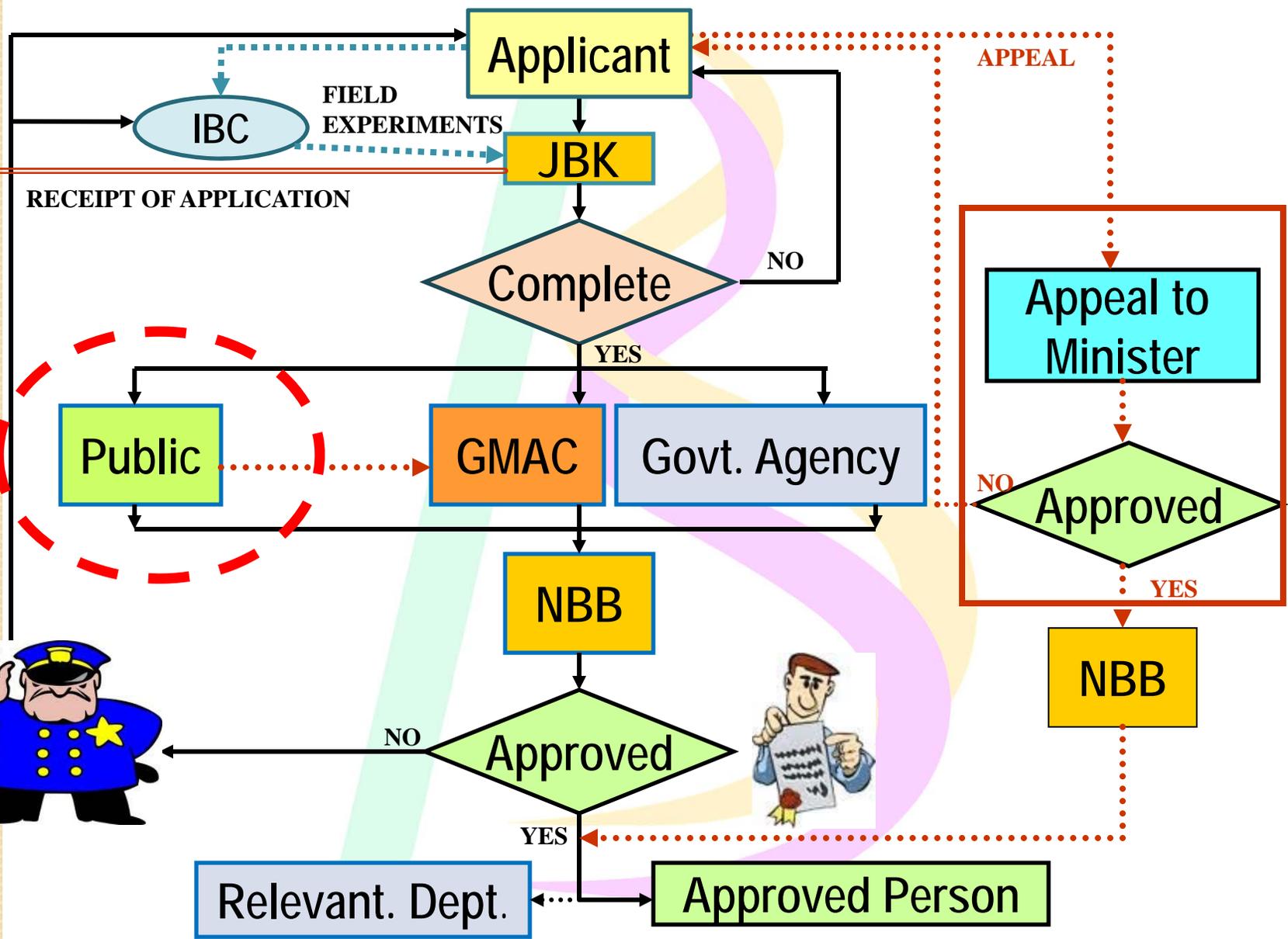


Second International Workshop for Regulation of Animal Biotechnology: Preparing Markets for New Animal Product Opportunities

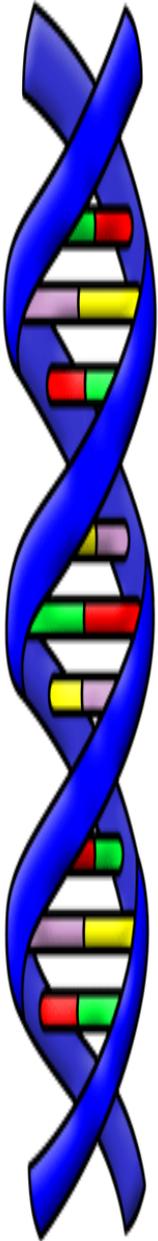
**Session 5: Case Studies -
Malaysia – Regulatory Experiences with GM Mosquito
19 August 2014**

Letchumanan Ramatha

180 days



APPROVAL PROCESS



GM MOSQUITO FIELD TRIAL

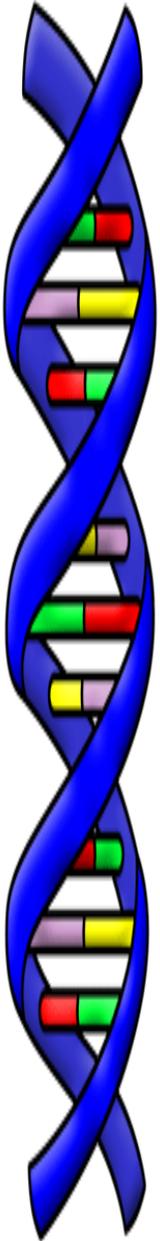
- Limited Mark-Release-Recapture [MRR] Field Trial
- To release 6000 each of male *Aedes aegypti* OX513 A (MyI) and the wild type
- Objective– Compare & evaluate longevity & dispersal distance
- - Add important information to existing data
- Modified Traits – (i) Dominant lethal mutation (ii) Red fluorescent marker gene
- Release in inhabited & uninhabited sites



Aedes aegypti

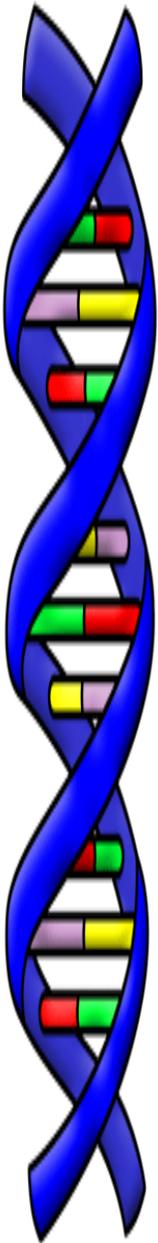


2 suggested release sites



RESULTS

- **Survival:** Life expectancy of 2.0 to 2.3 days were calculated for both strains.
- **Dispersal:** Maximal dispersal distance was 220m and 223 m downhill for GM and non GM males respectively.
- Mean distance travelled (MDT) was 52.4m for GM mozzies and 99.8m for non GM.
- Flight range estimates were significantly lower in GM mozzies compared non GM.

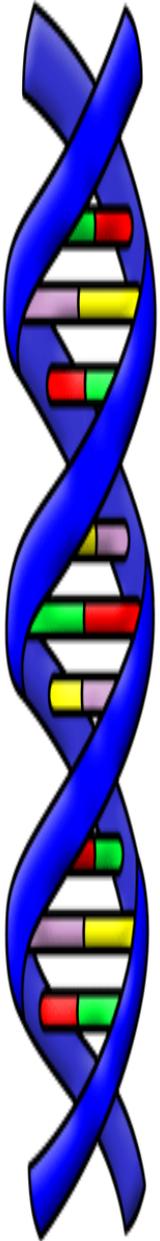


PUBLIC COMMUNICATION PRIOR TO APPROVAL

- Announcement in 2 national newspapers
- Fact Sheet available in website
- 30 days period to receive public input
- Contacted 9 Env. NGOs to get input
- Invitation to TWN and WWF scientists for a discussion
- Immediate response to direct queries, articles in newspapers/media or emails etc.
- Complemented by additional initiatives by applicant

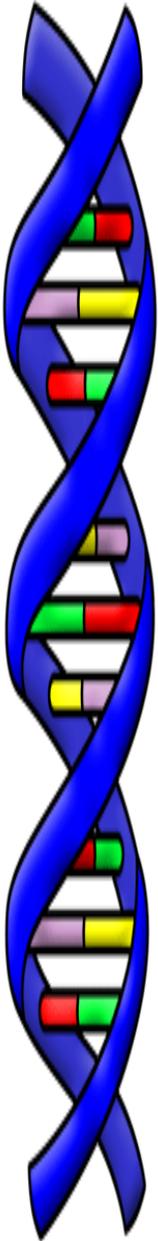
FACT SHEET

- Project purpose
- Info about the GM mosquito
- Release site and the how the release will take place
- Control measures taken
- Emergency Response Plan
- Contact details of NBB for any clarifications / further queries



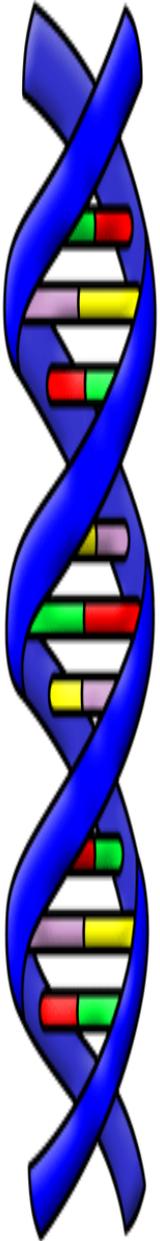
ADDITIONAL INITIATIVES BY APPLICANT FOR COMMUNICATION PRIOR TO APPROVAL

- Fliers were distributed in four major languages - *Bahasa Malaysia*, (the national language), English, Mandarin and Tamil
- Posters were hung up near trial site in four major languages - *Bahasa Malaysia* (the national language), English, Mandarin and Tamil
- Local councils and community leaders briefed on details of field trial and site selection and permission obtained
- A scientific forum was conducted at the National Academy of Sciences and the public were invited to this forum
- Risk communication workshops were conducted for scientists, project managers and health professionals in selected districts
- The applicants together with the local authorities briefed the residents in two public talks in two languages, the National Language (*Bahasa Malaysia*) and the Chinese language (*Mandarin*)



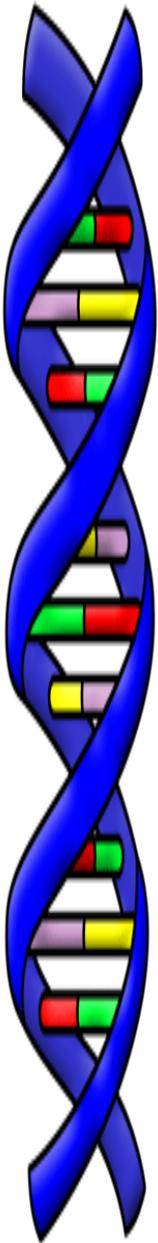
COMMUNICATION AFTER APPROVAL

- After the decision was made to approve the field trial, all issues and concerns raised with approved mitigation strategies and basis of decision were consolidated into a **Decision Fact Sheet** and uploaded in the National Biosafety Department website (www.biosafety.nre.gov.my)
- A press conference to announce the decision and provide information to the public on the approval field trial with opportunity for media to seek clarifications on decision – FAQ session was documented and uploaded
- Risk assessment report and country decision was made available in the international database for biosafety (BCH) to ensure accuracy of facts



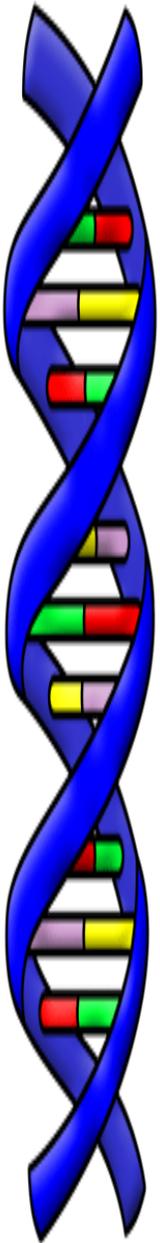
OUTCOME OF PUBLIC CONSULTATION

- Some 32 comments were received from scientist, academia, NGOs, private companies and public (both local and global). Input/Opinion from public may be categorized as information seeking, positive, neutral and negative
- Generally positive comments come from industries/promoters of modern biotechnology and negative comments from NGOs and those against modern biotechnology
- When public is provided with benefits of GM Mosquito and the purpose of the field trial – they are supportive; and when provided with information on some uncertainties – some take a more cautious position.
- Often we can see somewhat repetitious comments – indicating possible influence



LESSONS LEARNED

- Public at large in Malaysia do not know much about GMO issues thus the lack of active participation – *Public awareness about GMO has to be increased for effective participation*
- Invitation for comments in two newspapers published twice i.e once in two weeks may not be sufficient – *Now it is published in 4 main languages, twice per language.*
- Regulators going out of the way to seek views is good. Many have indifferent attitude on GM. We should aim to empower many.

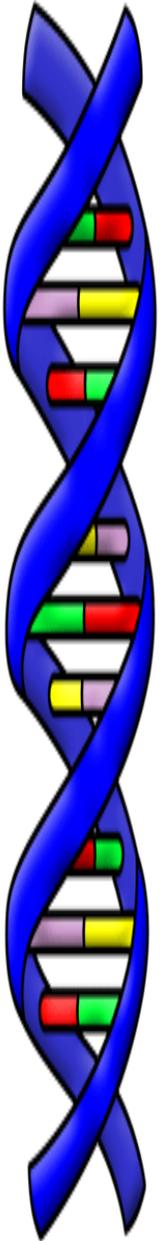


LESSONS LEARNED

- Transparency in providing information is important for accuracy of facts to be disseminated and to minimize speculations
- Extra efforts by applicant to provide information helps the regulatory process and address concerns raised
- Quick response is needed on all all issues submitted.
- The role between MOH and NRE must be clear when dealing with media



AGANSI
BIOKESELAMATAN



THANK YOU