

Identifying ecological and human-health issues associated with the deliberate or accidental release of gene-drive modified organisms

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## Staged release protocol (WHO, 2009)

## Laboratory

- Develop construct
- Characterise and confirm design function
- Generate transgenic line and confirm combined function
- Look for adverse target or non-target effects\*

#### Laboratory population cages

- Test efficacy and stability
- Evaluate fitness
- Evaluate spread of target effects
- Look for adverse target and nontarget effects\*
- Introgress into field ready strains

#### Confined field trials

- Evaluate fitness in contained semi-field conditions
- Evaluate spread of target effects
- Look for adverse target and nontarget effects and other safety requirements

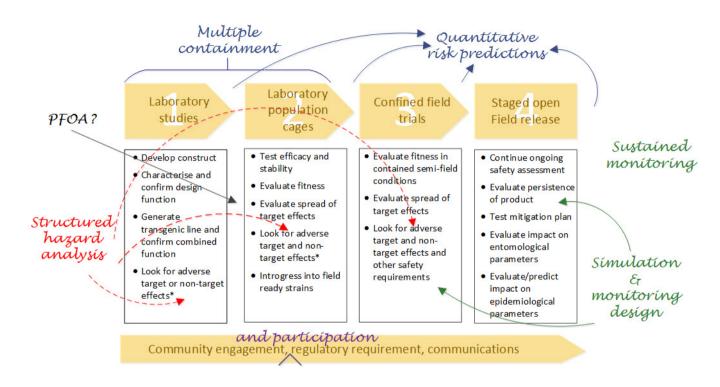
#### Staged open Field release

- Continue ongoing safety assessment
- Evaluate persistence of product
- Test mitigation plan
- Evaluate impact on entomological parameters
- Evaluate/predict impact on epidemiological parameters

Community engagement, regulatory requirement, communications

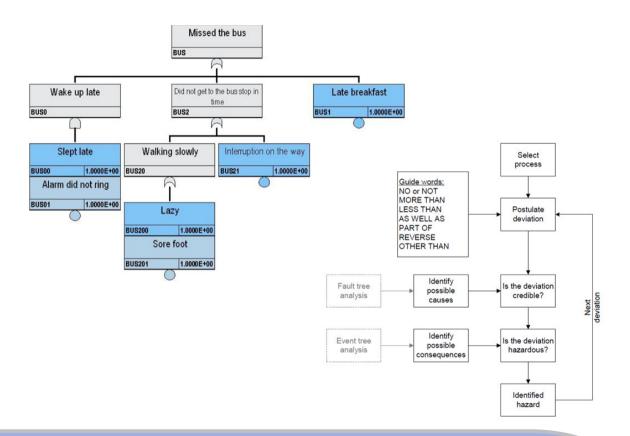


#### Identifying adverse effects within a staged release protocol



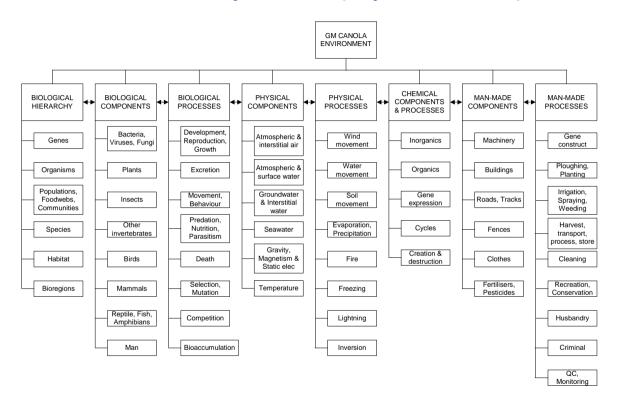


## Structured hazard analysis: FTA and HAZOP



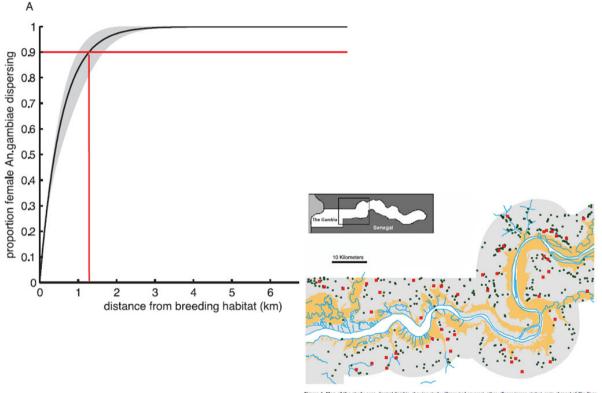


#### Structured hazard analysis: HHM (Hayes et al., 2004)





## Quantitative predictions: data sometimes (Thomas et al., 2013)







## Quantitative predictions: elicitation if no data

#### **Keith** Comments Options FT1-6b (n=3) **Pick distribution** ■ Truncate distribution? Beta **Enter data** 3 Confidence **Bounds** 2 Enter CI Enter Lower Bound Enter Upper Bound **Fitting options** 0 Fit with Use criteria SB SS Median + Tertiles

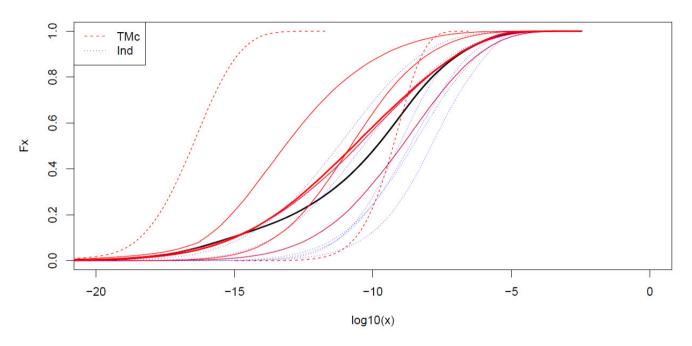
Average weekly dispersal distance (km)



Median + Tertiles + Decilies

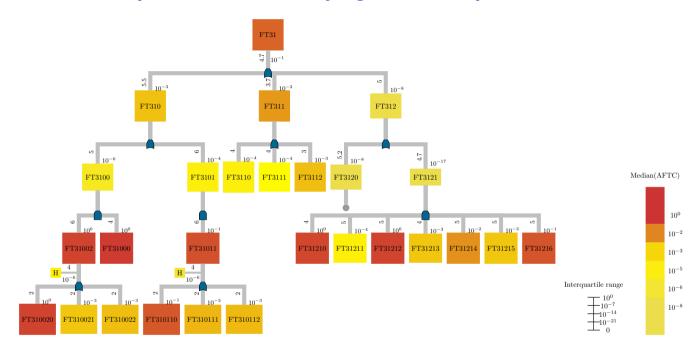
## Quantitative predictions: FTA results based on elicitation





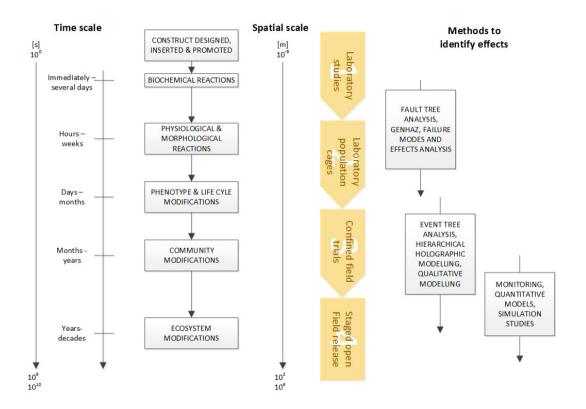


## **Quantitative predictions: identifying critical steps**



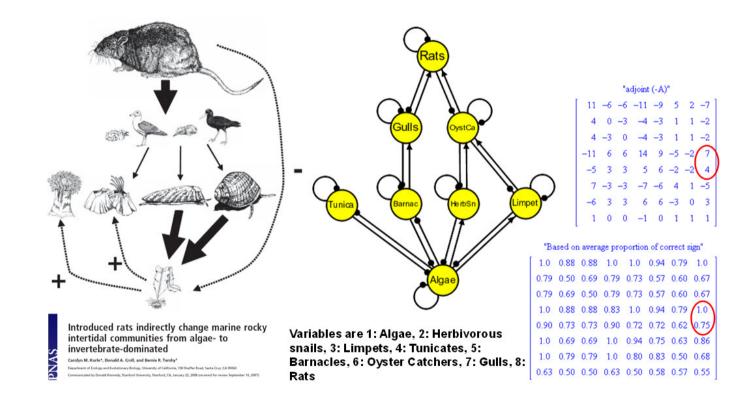


## **Spatio-temporal challenges**



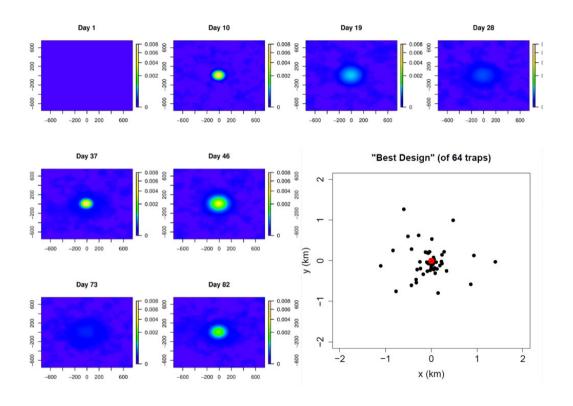


#### Community participation and qualitative systems modelling





## Model assisted/based monitoring design





#### **Sustained monitoring**

#### Sustained environmental monitoring

- some hazards occur at large spatio-temporal scales
- implicit expectation that monitoring will occur at equivalent scale
- well established precedent large scale monitoring of epidemiological outcomes
- relatively poor precedent for large scale monitoring of environmental outcomes

#### Some challenges

- securing and maintaining funding
- establishing causality at landscape scales
- monitoring targets



#### References

- Hayes, K. R., Greg, g. P. C., Gupta, V., Jessop, R., Lonsdale, W. M., Sindel, B., Stanley, J., and Williams, C. K. (2004). Identifying hazards in complex ecological systems. part 3: Hierarchical holographic model for herbicide tolerant oilseed rape. *Environmental Biosa*, 3:109–128.
- Thomas, C. J., Cross, D. E., and Bogh, C. (2013). Landscape movements of *Anopheles gambiae* malaria vector mosquitoes in rural gambia. *PLoS ONE*, 8(7):e68679.
- WHO (2009). Progress and prospects for the use of genetically modified mosquitoes to inhibit disease transmission. Technical report, World Health Organisation, Geneva, Switzerland.



# **Thank You**

#### **CSIRO Health and Bisecurity**

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