



INTREXON[®]

Regulation of Insect Biotechnologies An Industry Perspective

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Overview

- Intrexon Overview
- Regulation of Self Limiting Insects
- Learnings—Challenges and Opportunities



Who is Intrexon/ Oxitec? Our Self Limiting Insect Portfolio



We combat disease carrying insects and improve crop yields



through the reduction of the insect populations





with a genetic approach that is safe, sustainable, economic and applicable to many insect species worldwide

Oxitec's Portfolio

Agriculture

Target	Crop
 <p><i>Medfly</i></p>	Citrus/pome/ stone fruit
 <p><i>Olivefly</i></p>	Olive
 <p><i>Diamond-back Moth</i></p>	Brassica
 <p><i>Pink Bollworm</i></p>	Cotton
 <p><i>Drosophila Suzukii</i></p>	Soft Fruit

Public Health

Target	Vector of
 <p><i>Aedes aegypti</i></p>	Dengue, Zika, Yellow Fever & Chikungunya
 <p><i>Aedes albopictus</i></p>	Dengue, Zika, & Chikungunya

Self-Limiting Technology Overview

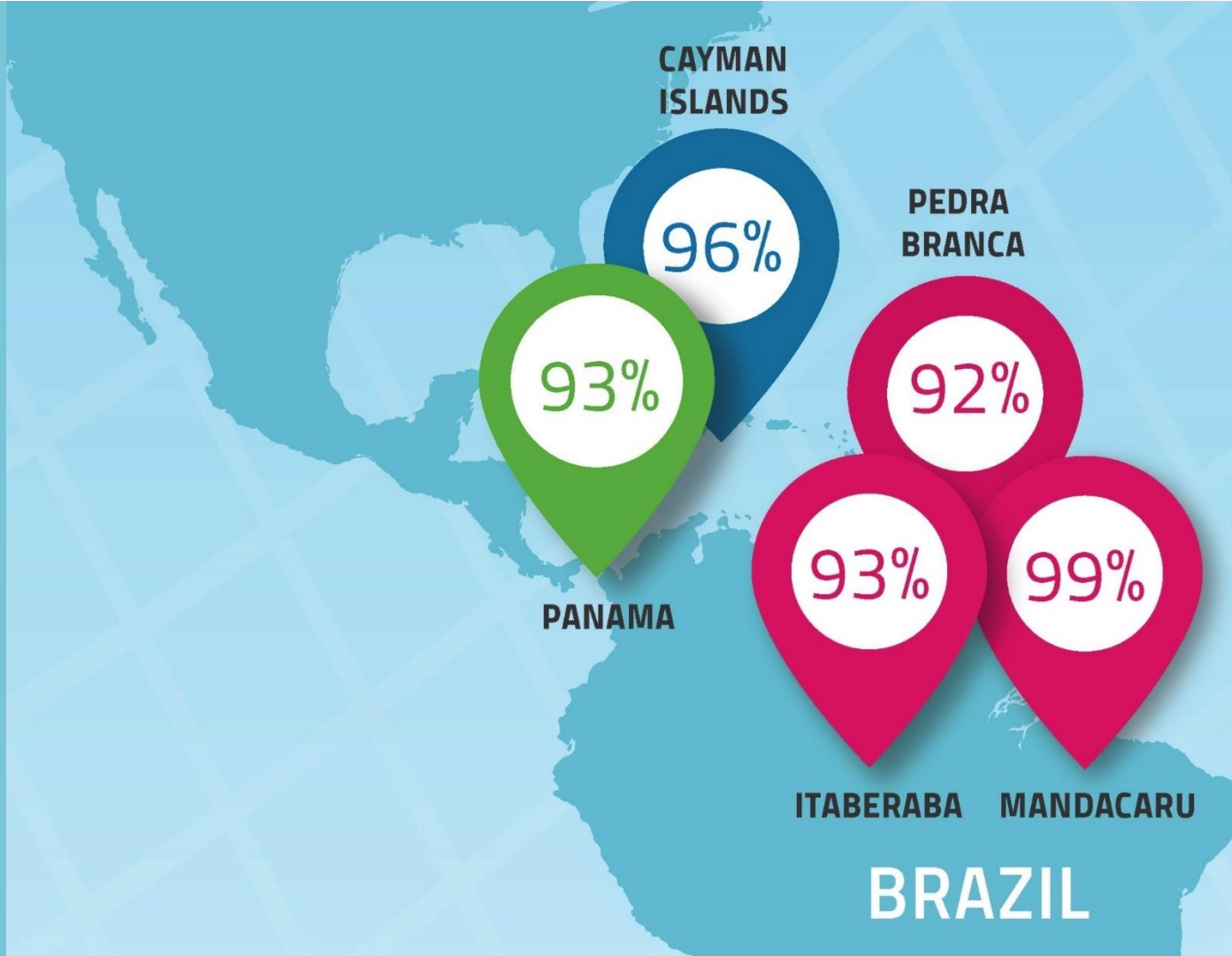


Oxitec male mosquitoes are produced for release and mate with pest females



Offspring die before they can reproduce and transmit disease

Global Suppression of Target Insect Populations



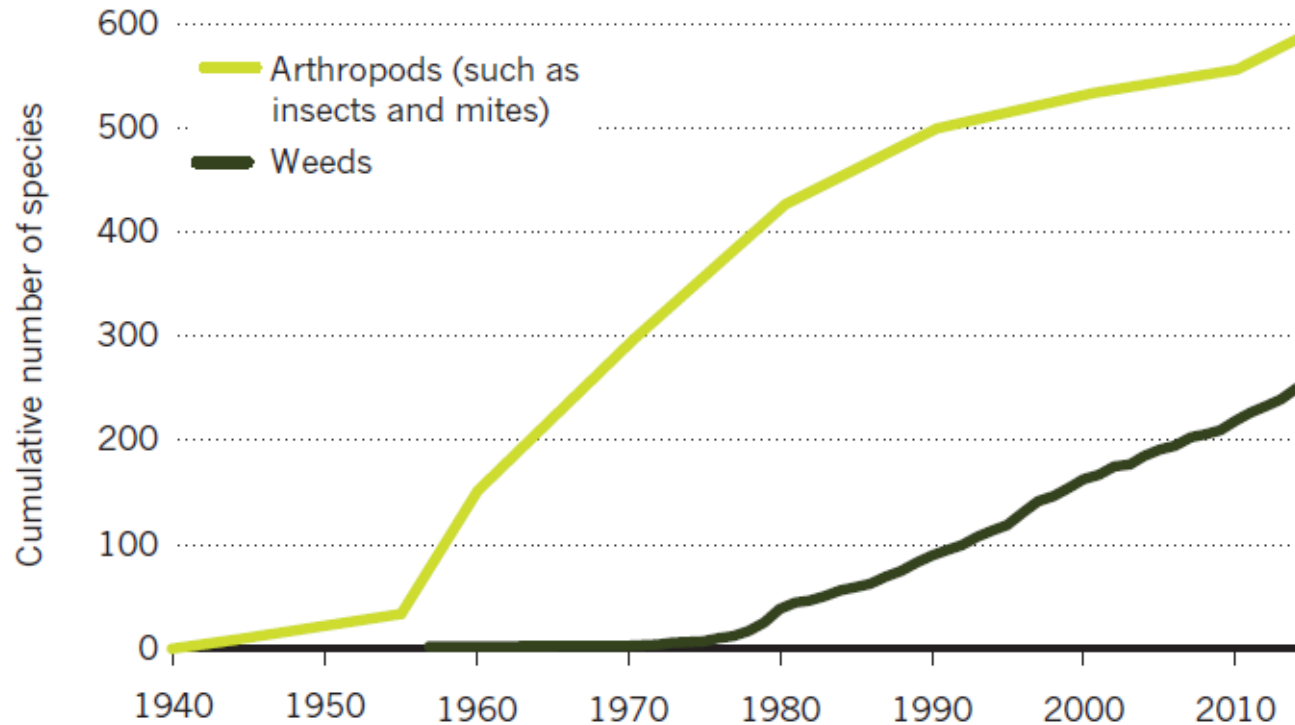
Agricultural Pest Insects



Managing Resistance

THE RISE OF RESISTANCE






The number of pests (including insect and plant species) resistant to at least one form of synthetic pesticide has been steadily on the rise for decades, as has the cost of developing such chemicals.



(When Pesticides Run Out, Borel, 2017)

Current Self-Limiting Insect (SLI) Pipeline

Pipeline of self-limiting insects covers a multitude of end markets with multiple assets poised for continued development

Products	Crop	Discovery Initial Screening	Phase 1 Proof of Concept	Phase 2 Early Development	Phase 3 Advanced Development	Phase 4 Pre-Launch
 Medfly	Hard Fruit	▶				
 Diamondback Moth	Brassica	▶				
 Spotted Wing Drosophila	Soft Fruit	▶				
 Olive Fly	Olives	▶				
 Pink Bollworm	Cotton	▶				
Confidential Target		▶				

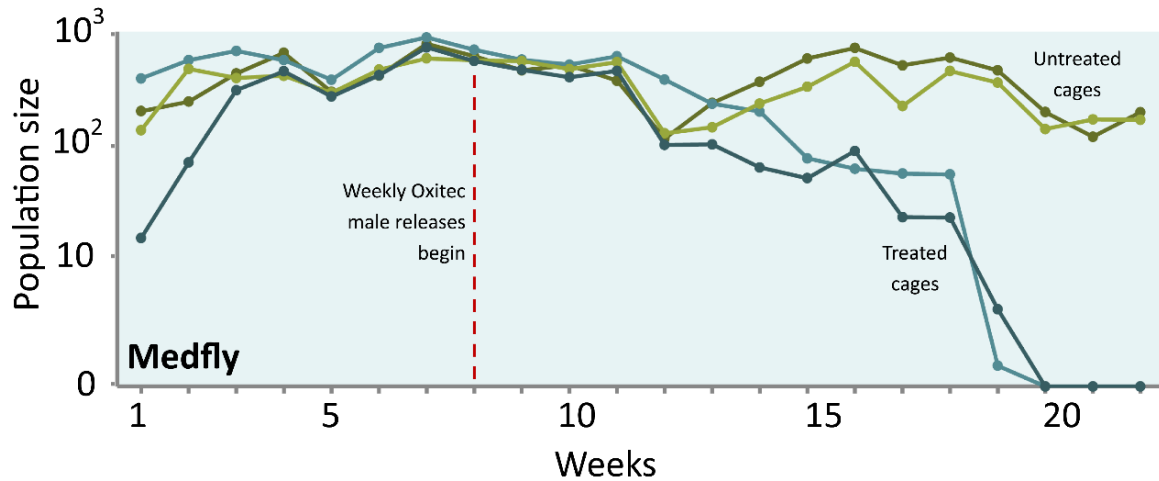
Mediterranean Fruit Fly in Brazil

- Medfly, No. 1 Quarantine pest globally
- Affects exports to USA, Japan, China and Russia
- Large host range (>250 fruits and vegetables)
- Non-native to Brazil
- Most damaging fruit pest, affecting 4 million acres of fruit production



SLI Medfly Reduces Target Pest Population

Contained suppression trials in glasshouses and netted orchards have shown that releasing SLI male flies reduces the target population



Agadir,
Morocco; with
SAOAS



Crete, Greece;
with University
of Crete

The Diamondback Moth Problem



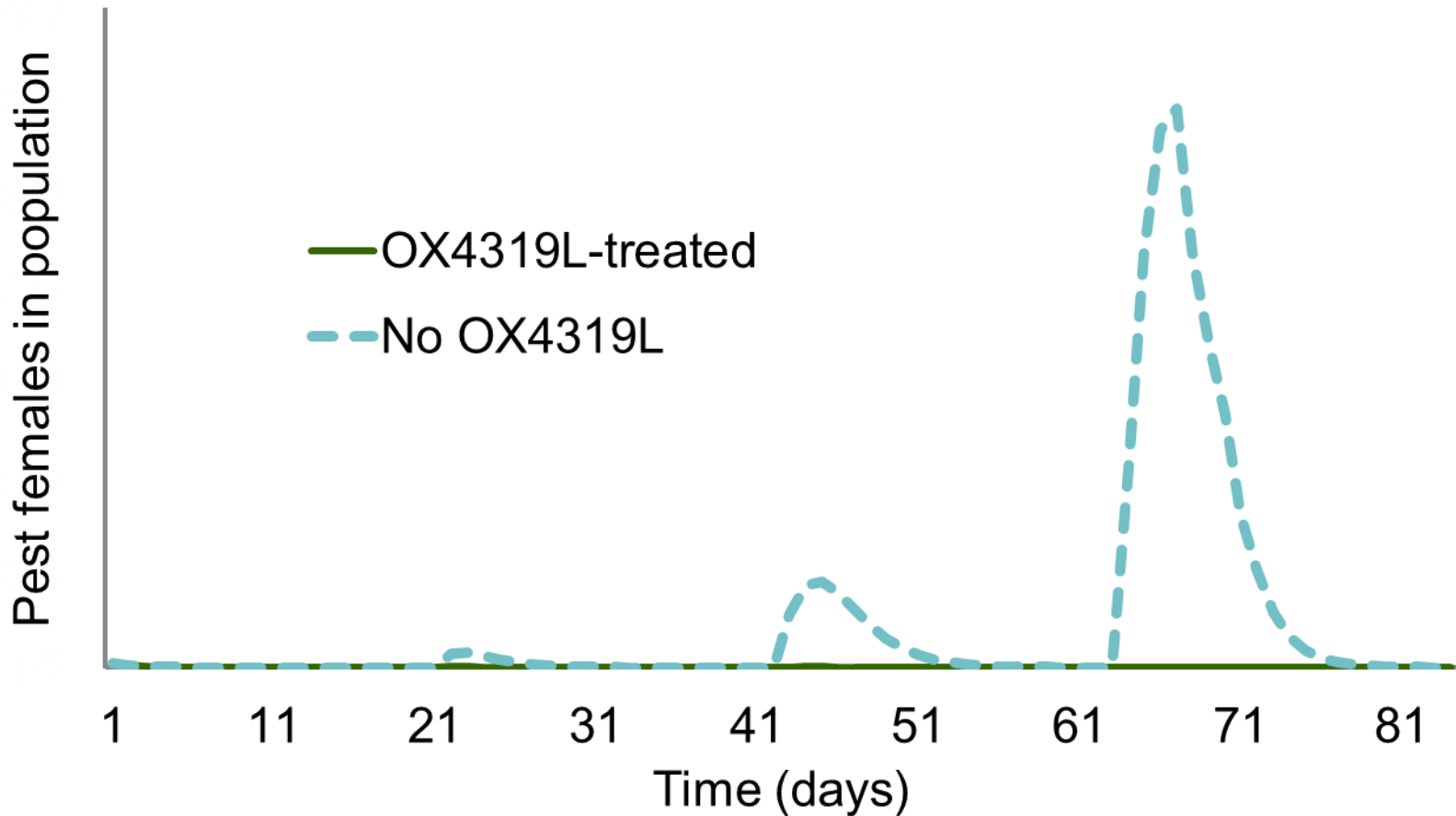
- Major pest of cruciferous vegetables
- Rapidly develops resistance to insecticides
- Costs farmers US\$4-5 billion every year



Plutella xylostella

Oxitec OX4319L DBM Males Suppress DBM

Based on field cage results, population modelling indicates that Oxitec males prevent DBM population growth

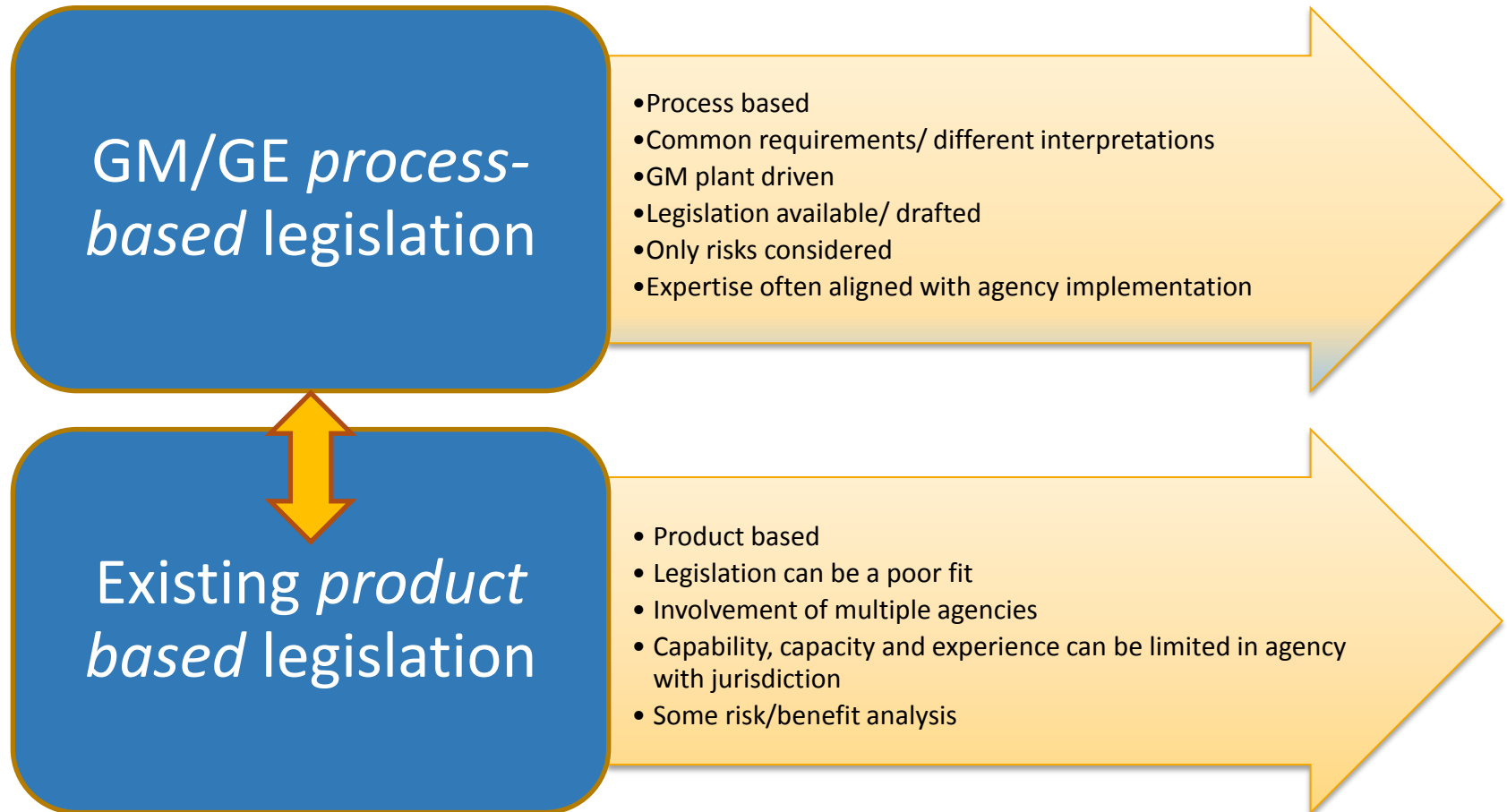


How Should SLI Technologies Be Regulated? It Depends...

	Mosquito	Ag Pest	Plant Biotech
<u>Technology</u>			
GMO	★	★	★
Biopesticide	★	★	★
Biocontrol Agent	★	★	
Disease Vector/ Human Health	★		
Plant Health		★	★
Animal Drug	★		
<u>Risk Assessment</u>			
Human Risk	★	★	★
Environmental Risk	★	★	★
NTO Risk	★	★	★
Biosecurity/ Gene Flow	★	★	★
GMO Risk	★	★	★

General Regulatory Approach

- Mixture of product and genetically modified/genetically engineered (GM/GE) legislation applicable, depending on country

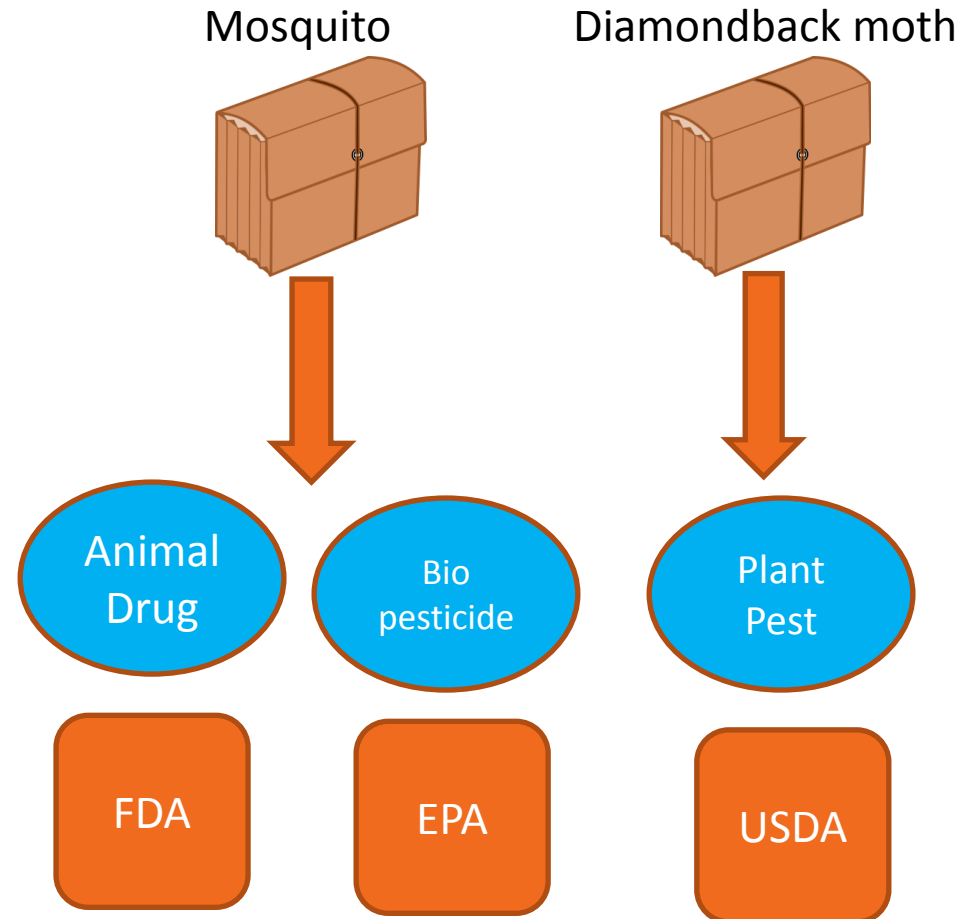


Defining Regulatory Oversight - USA

- Factors:

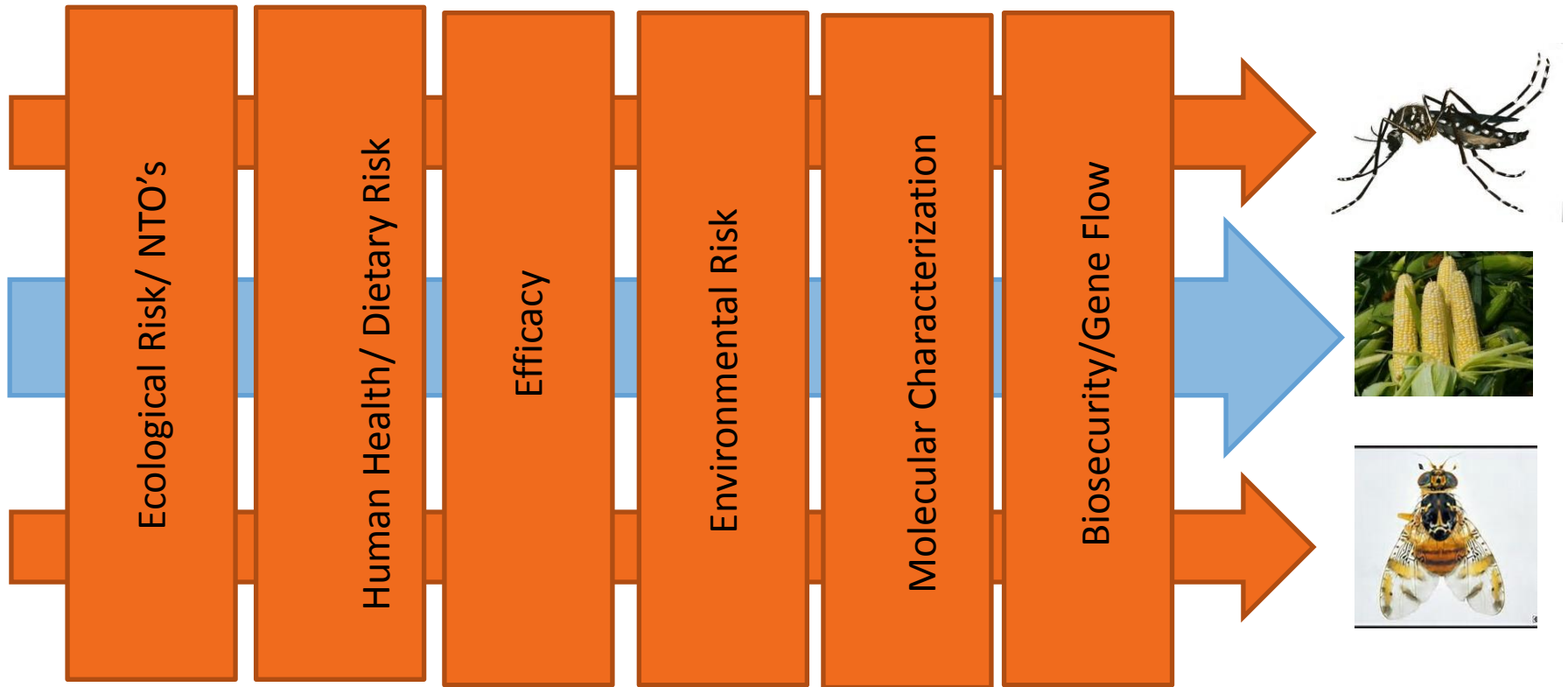
- Legal framework
- Technology/Process
- Product claims
 - Vector control
 - Human Health
 - Pesticidal
- Expertise and capability
- History

- What makes sense and is legally doable?



Risk Assessment Paradigm

Familiar but Different



Regulatory jurisdiction and oversight may differ, but problem formulation and core scientific risk assessments related to human health and environmental safety are very similar.

>14 Years of Studies-Biosafety Profile

- Genetically and phenotypically stable;
>120 generations since 2002
- No toxic or allergenic components used - bioinformatics
- No harm to predators
 - Two oral exposure studies available
- Lifespan 2-4 days in environment
 - Males do not bite or transmit disease
 - No genetic components in saliva
- Fully susceptible to insecticides
- Species specific mating
- No environmental establishment
- Robust environmental monitoring methods
- Female vector competence not increased



- No unmanageable risks identified by regulators to date

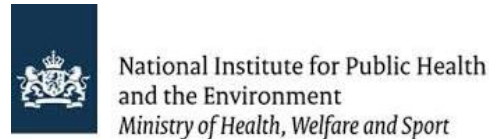
Global Regulatory Progress

Import and contained trials approved



- Austria
- France
- Greece
- Guatemala
- Israel
- Singapore
- Thailand
- Vietnam
- India
- Australia

Current proposals for outdoor release



Multiple ongoing

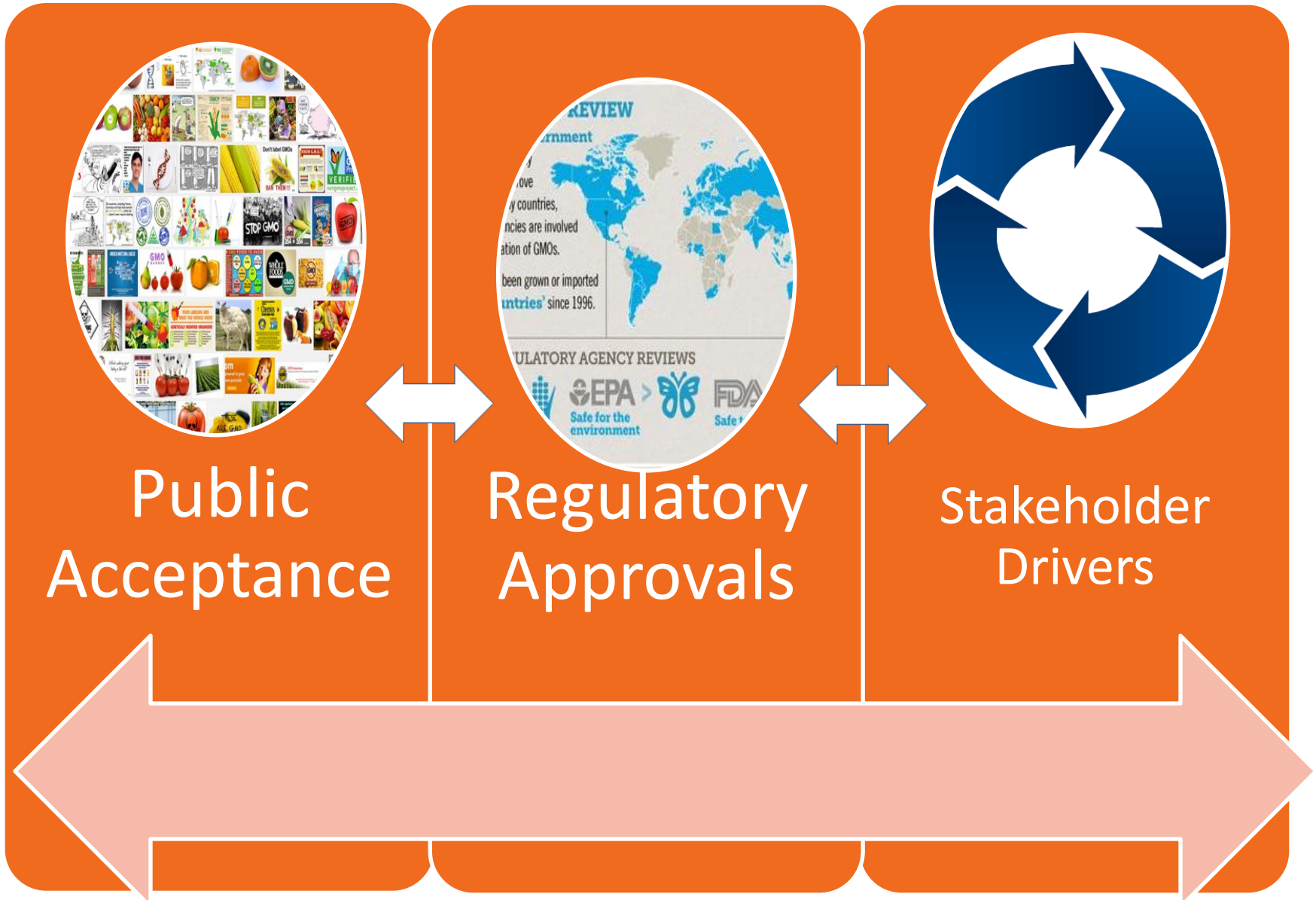
- USDA - DBM
- Dutch - EU standard

Environmental release approved



- Brazil
- Cayman
- Malaysia
- USA
- Panama

Regulatory Drivers



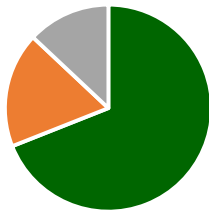
Public Engagement

Fundamental component of release program

- Robust public engagement plan
- Stakeholder mapping
- Adopt culturally appropriate methods
- Train staff
- Train partnering public health/vector control agents
- 6-8 week intensive campaign before release
- Ongoing engagement throughout project
- Channels for 2 way communication – listen and respond

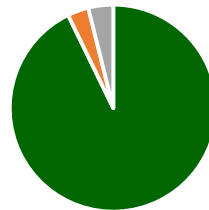


Cayman Islands



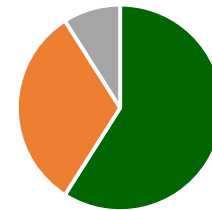
■ Support ■ Neutral ■ Oppose

Piracicaba, Brazil



■ Support ■ Neutral ■ Oppose

Florida, USA



■ Support ■ Neutral ■ Oppose

In Closing...Summary and Learnings

- Positively ‘moving the needle’ on novel animal GE product
- Most countries have shown a keen ability to adapt to a novel technology utilizing existing authorities and guidelines
- Global regulatory templates evolving for transgenic insects
- Common risk assessment principles apply across GM/GE organisms released into the environment, including insects
- Harmonization of regulatory requirements and transportability of data will be necessary to ensure timely regulatory approvals
- Proactive engagement and communication with regulators, the public and value chain stakeholders critical
- Risk-benefit aspects need to be consistently considered in regulatory decision-making and actions

THANK
YOU!

