BioAg World CONGRESS

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Regulatory Streamlining & Harmonization in BioAg- Need Globally Local

Global Overview for Biopesticides Regulatory and its Implications on Food Systems Transformation

Nicolás Cock Duque

President

BioProtection Global

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BioProtection Global

Nicolás Cock Duque

- BioProtection Global, President
- Gowan, External Affairs Manager
- Ecoflora, Co-founder and Ex-CEO
- Food and Landuse Coalition (FOLU), Ambassador
- The Nature Conservancy (TNC), Trustee
- Sistema B Colombia (B-Corps), President

BioProtection Global

UNITED NATIONS FOOD SYSTEMS SUMMIT 2021

THE BIOPROTECTION INDUSTRY

a fundamental one to accelerate food systems transformation

Harmonized and proportionate regulations needed to enable biobased solutions catalyze this change

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BioProtection Global

BioProtection Global (BPG) is an inernational federation of biocontrol and biopesticides industry associations

Comprised primarily of manufacturers of bioprotetion products for professional use in agriculture, public health, forestry, animal health and other non-crop uses

BioProtection Global

BPG's Purpose

BPG exists to help expand and accelerate the adoption of **bioprotection solutions** to protect crops, forests, people, homes, and life on Earth.

BioProtection Global

Our Member Associations

Association of Natural Biocontrol Producers

Asobiocol
Asociación Colombiana de Bioinsumos

bpia

CABIO
Cámara Argentina de Bioinsumos

CropLife BRASIL

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

JBCA
Japan BioControl Association

PMFAI

SABO
South African Bioproducts Organisation

Partnerships:

CABI

The Food and Land Use Coalition

BioProtection Global

Key Figures

9 regional and national member associations (representing: Argentina, Brazil, Colombia, EU, India, Japan, North America, South Africa, and USA)

Representing **56 countries.**

Member associations representing **821 bioprotection / biocontrol entities*** (we estimate that we may cover and represent roughly **60% of the global bioprotection industry**).

The member companies of our member associations deliver > 4,000 bioprotection solutions globally.

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*Some of these may have been counted more than once (since they may be represented by more than one member association)

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HOW TO FEED

8 billion people **without destroying**

THE PLANET A.C.*?

*After COVID-19

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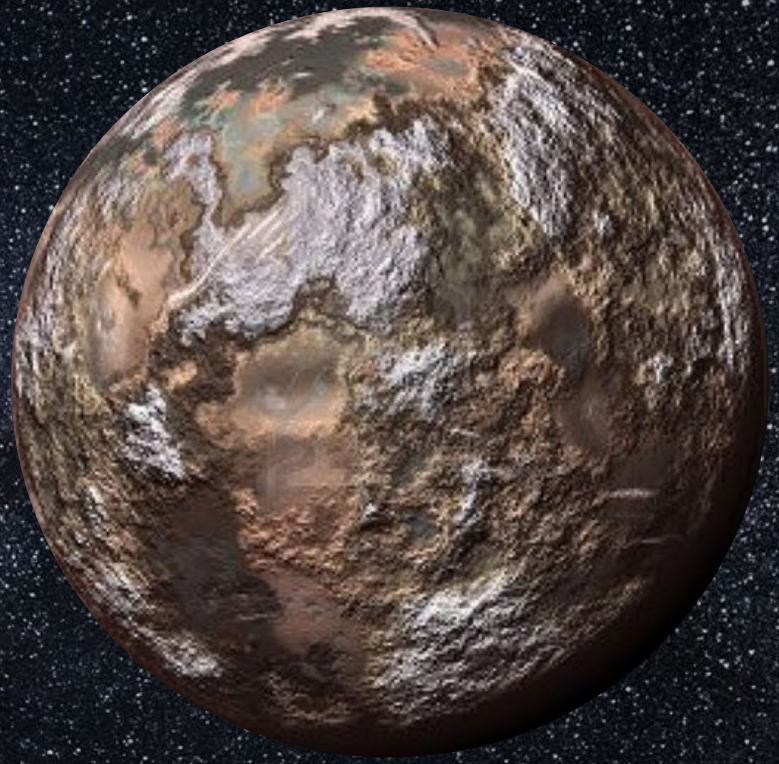
2020

2050



It takes 1.7 Earths to
support humanity's demand on nature

EARTH
OVERSHOOT
DAY

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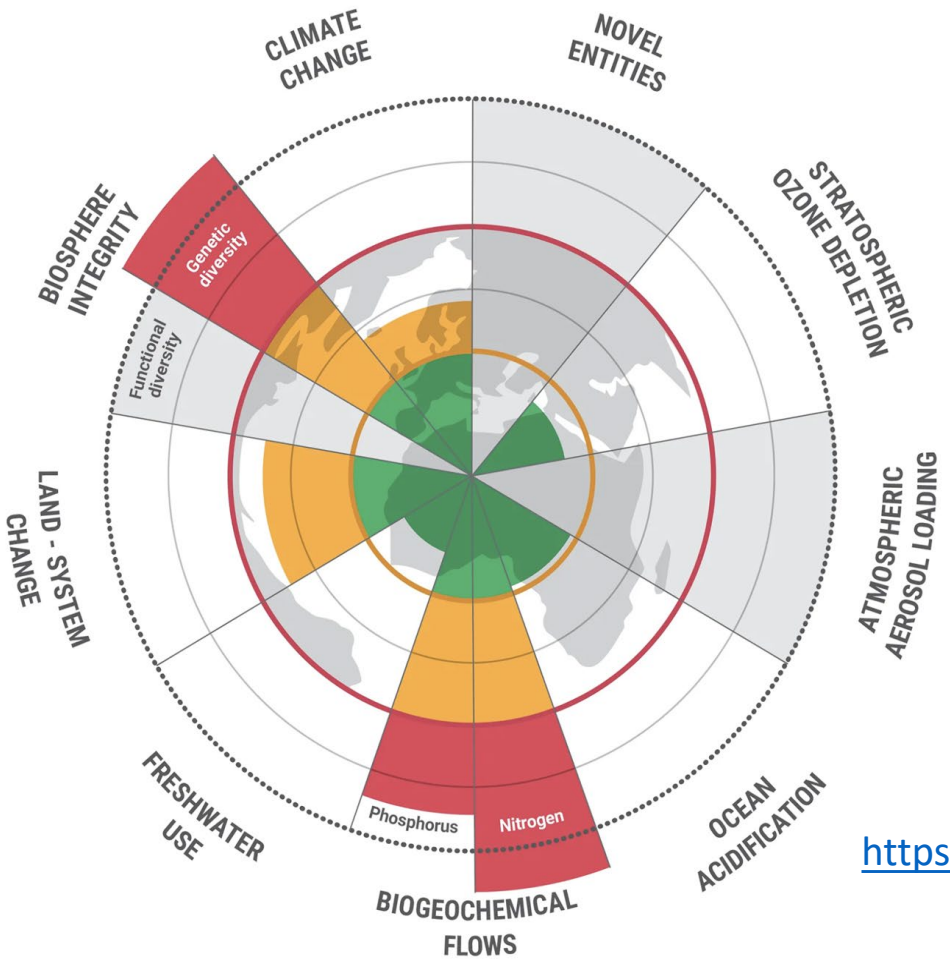
Planetary Boundaries:
Exploring the Safe Operating Space for Humanity



https://www.ecologyandsociety.org/vol14/iss2/art32/

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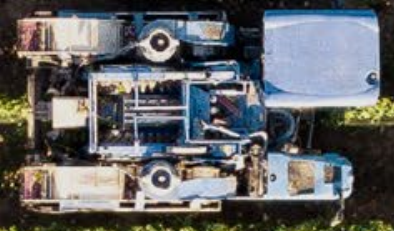
“Agriculture production as a major driver of the Earth system exceeding planetary boundaries”
(Bruce M. Cambell)

https://www.ecologyandsociety.org/vol22/iss4/art8/

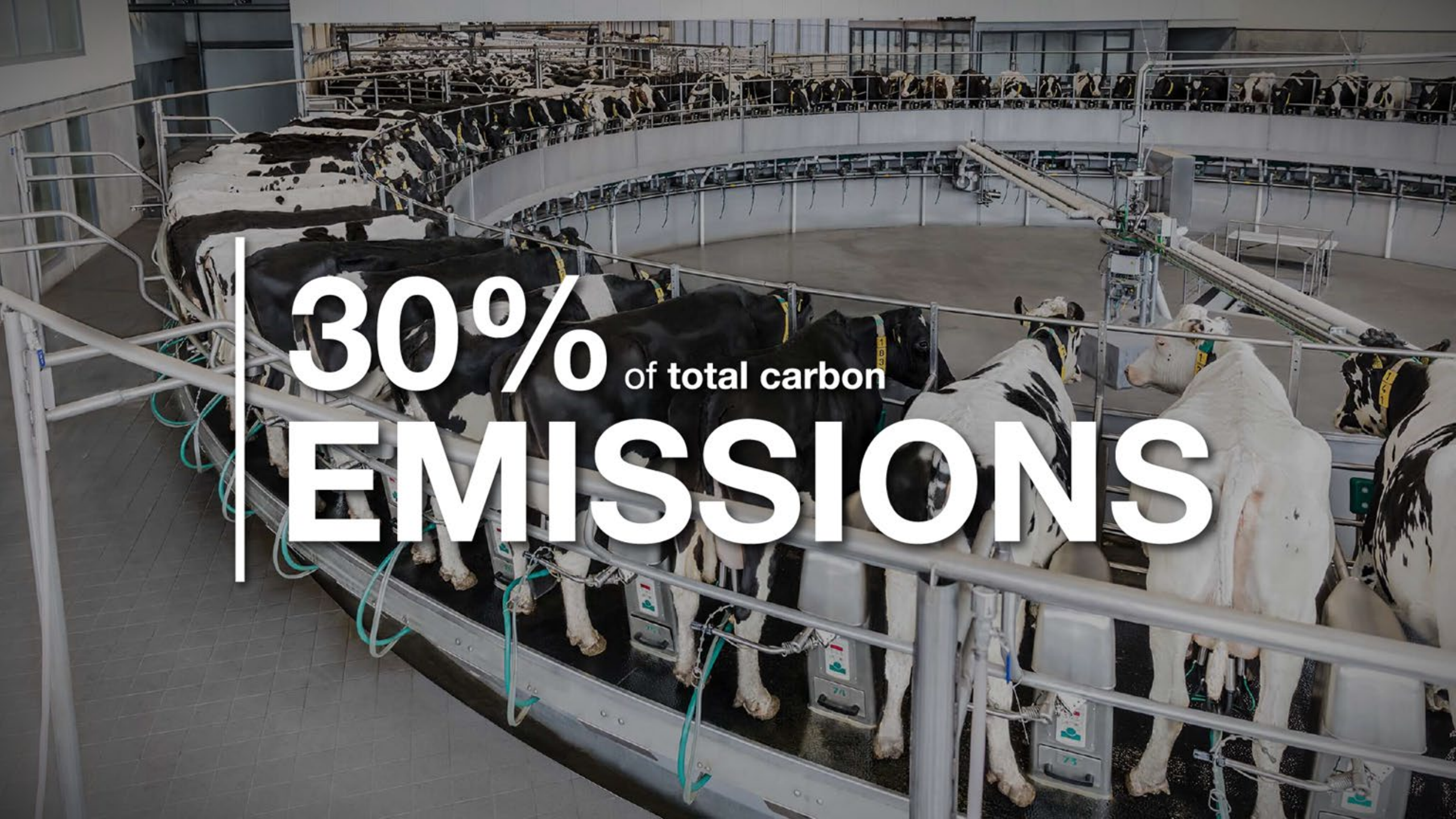
Agricultural system is



IN CRISIS


70% of fresh
WATER USE

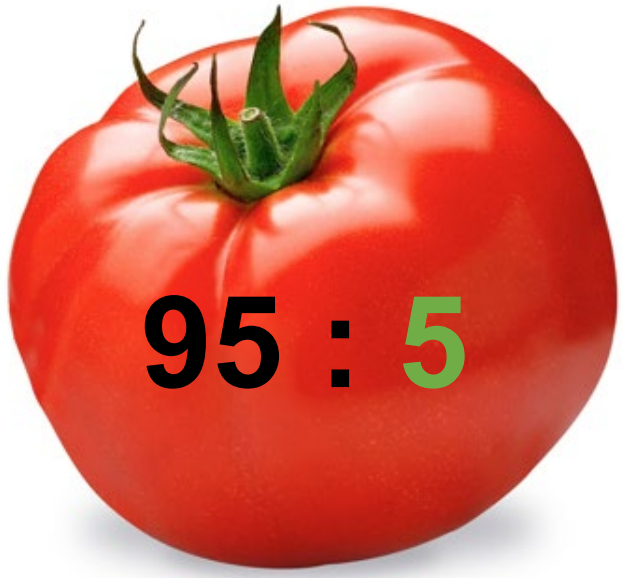

60% loss of
BIODIVERSITY

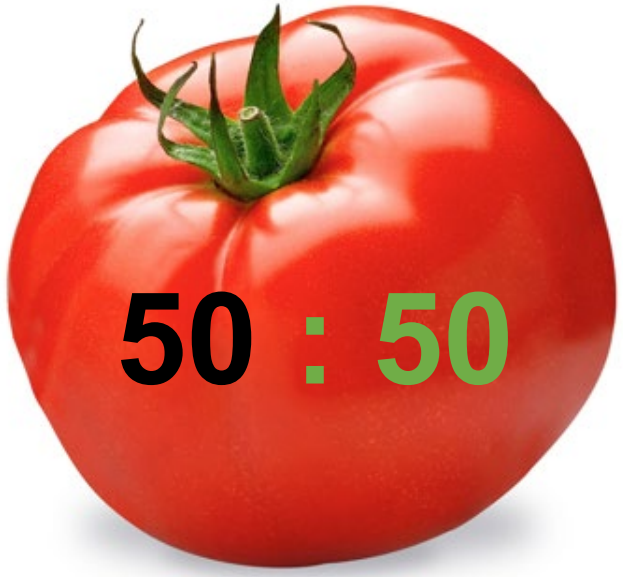

30% of total carbon
EMISSIONS

Chemical pesticides : Bioprotection (global market share)

B.C. (Before COVID-19) | **A.C.** (After COVID-19)

2020 — 2030





SUSTAINABLE DEVELOPMENT GOALS

BioProtection Global

BioProtection, Food Systems, and SDGs 2030

SUSTAINABLE DEVELOPMENT GOALS

FOOD SYSTEMS SUMMIT 2021 DIALOGUES

1. Ensuring **access to safe and nutritious food**
2. Shifting to **sustainable consumption patterns**
3. Boosting **nature-positive production**
4. Advancing **equitable livelihoods**, and
5. **Building resilience**

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BioProtection industry´s contribution to the UN 2030 SDGs

BPG´s Strategic Objectives

Strategic Objective 1:

To expand and accelerate the **adoption** of bioprotection solutions through **partnerships** (SDG 17) that contribute to the **achievement of the UN 2030 SDGs** including those related to food, health, wellbeing, water, climate, and life on Earth

BPG´s Strategic Objectives

Strategic Objective 2:

To enhance public policies, global harmonization and proportionate regulatory frameworks that are favorable for bioprotection solutions

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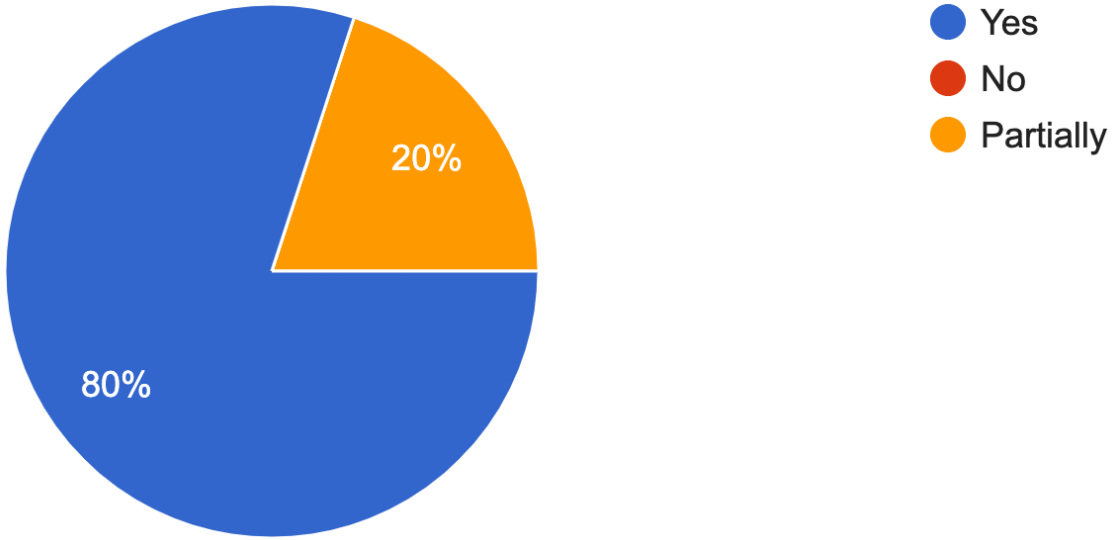
Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs*

Are there specific regulations for Bioprotection / Biocontrol / Biobased products in your country (or region)?

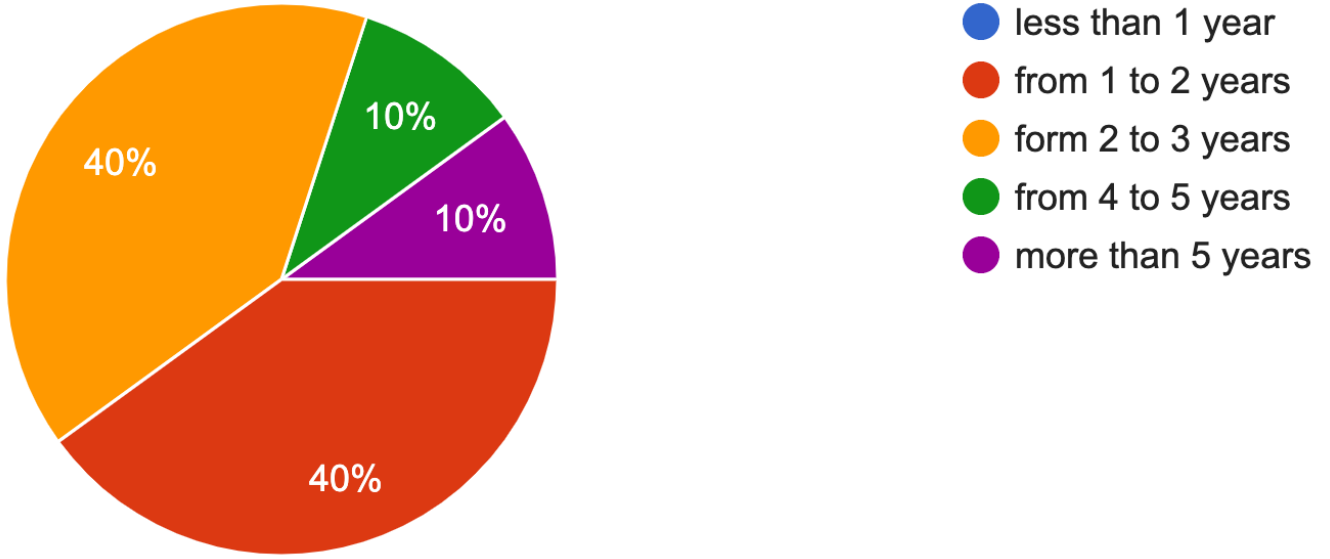


* During March 2021

BioProtection Global

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs*

What is the average time it takes in your country (or region) for a bioprotection / biocontrol / biobased product since its is filed for registration until its approval?

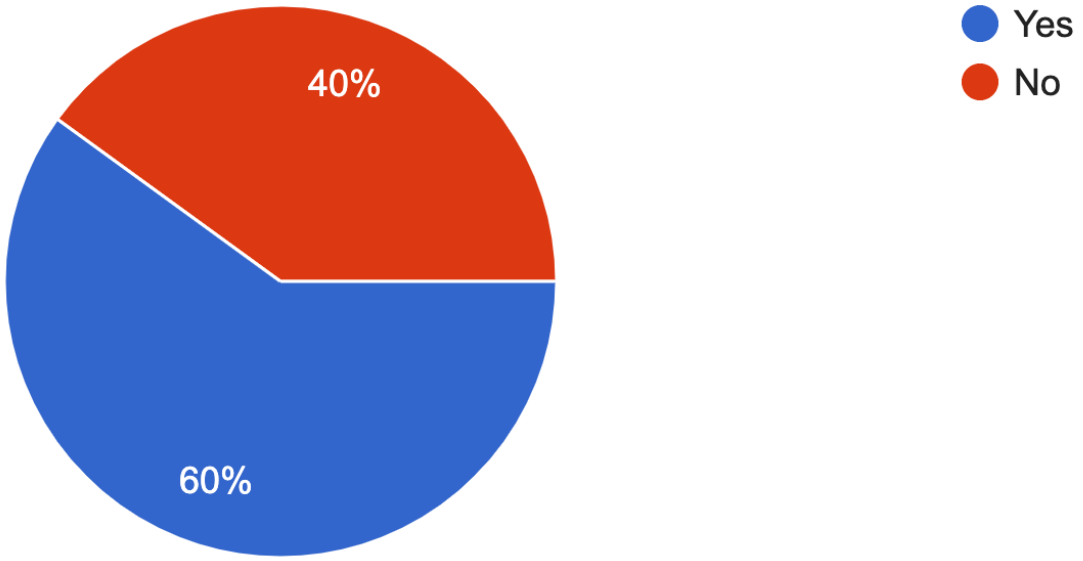


* During March 2021

BioProtection Global

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs*

Are regulations and requisites related to the registration of bioprotection / biobased products in your country or region harmonized with best international regulatory frameworks?

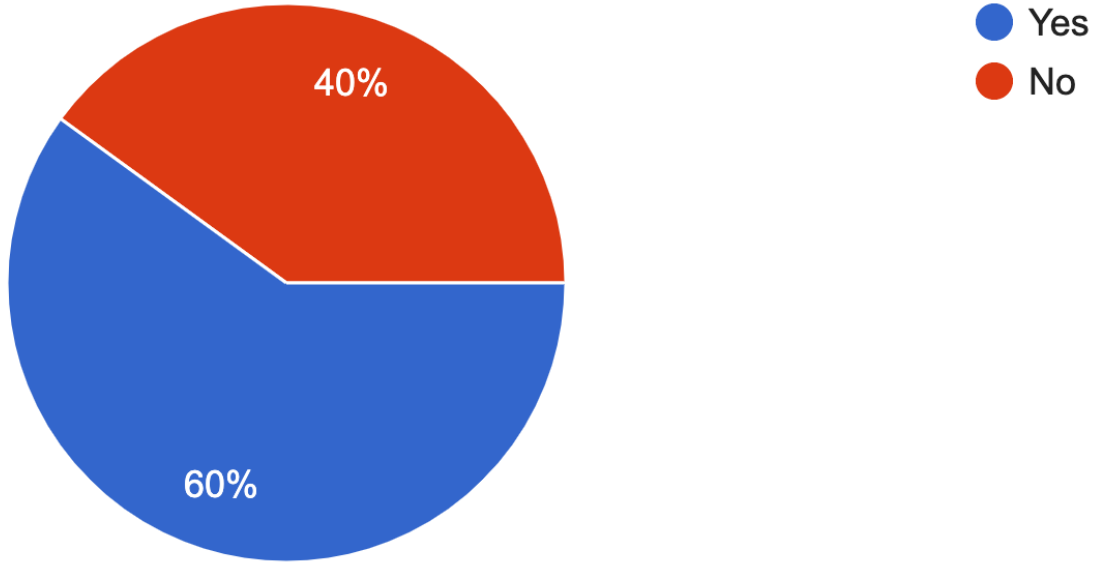


* During March 2021

BioProtection Global

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs*

Are regulations and requisites related to the registration of bioprotection / biobased products in your country or region proportionate to these products nature and safety profile?



* During March 2021

Major regulatory challenges for biobased inputs

ANBP / USA	• **Getting new biological control agents permitted** by the Federal government, requires the submission of a comprehensive package of scientific data to prove the species has no non-target effects and is not invasive. It **can easily take 4-5 years, sometimes more for approval (or to hear "not")**. • **Shipping** of live natural enemies, means **packages are scrutinized at borders** (state and country) **often resulting in death of the contents, a costly result.**
ASOBIOCOL / Colombia	• **Lack of articulation** between the different **regulatory authorities** involved (agriculture, health, environment) • **Slow** evolvement **of regulations vs. speed of innovation**

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs (during March 2021)

Major regulatory challenges for biobased inputs (2)

BPIA / USA & Canada	• **The main roadblock is time**. While there are established review timelines, they are **frequently extended** due to questions or issues raised by the regulators during the review process. **Rarely** are those questions or issues **of significant scientific or risk import**. • **A quicker review time is much desired by industry**.
CABIO / Argentina	• **Lack of national regulations specific for biobased inputs** • **Lack of regulations for novel or unique types of bioinputs** • **Lack of harmonization of regional legislation**

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs (during March 2021)

Major regulatory challenges for biobased inputs (3)

CropLife Brazil / Brazil	• **No regulations for biostimulants** • **Introduction of Exotic Organisms to Brazil**
IBMA / EU	• **Bioprotection is regulated within the chemical PPP legislation.** • **Competent authorities do not have enough trained biologists** especially microbiologists to evaluate microbials as PPPs, **slow registration and poorly adapted regulations mean high costs of market entry limits Bioprotection product availability**
JBCA / Japan	• **Natural substances such as neem, tea tree oil can not be registered**

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs (during March 2021)

Major regulatory challenges for biobased inputs (4)

PMFAI / India	• **Eco-Toxicity Data waivers are not granted** • **For certain safe products Mammalian, Avian and Fish Toxicity Data waivers are not granted** • **Efficacy Data broad-basing is not allowed**
SABO / South Africa	• The **limited capacity at the Registration body** (The Registrar, Act 36 of 1947). There are few technical advisors to support the amount of bioproducts submitted • **Costs of toxicological tests required** in order to comply with local legislation for registering biocontrol products, with **no local service providers being able to assist**

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs (during March 2021)

Key regulatory achievements / advances for biobased inputs

ANBP / USA	• In the past three years, the **USDA-APHIS (and Canadian services) did publish lists of species that no longer need permits to ship**. Just having access to this list was a **big help**
ASOBIOCOL / Colombia	• **Alliances with strategic productive sectors / ag industry associations** in the country that need bioproducts, **partnering to ask for proportionate and harmonized regulations** more in line with the nature of biobased products • Important (public and private) R&D centers have defined bioproducts as one of their strategic lines of work for the next few years
CABIO / Argentina	• No new advances in this topic

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs (during March 2021)

Key regulatory achievements / advances for biobased inputs (2)

BPIA / USA & Canada	• In the **United States**, there is a **specific regulatory division devoted to biopesticides**, which as **reduced data requirements,** reduced **fees,** and reduced **timelines in comparison to conventional pesticides** • **In Canada, there is not a specific division, but there are reduced data requirements and reduced fees for biopesticides**
CropLife Brazil / Brazil	• **Public Consultation** that provides for the **modernization of regulations for the registration of microorganisms and plant extracts** applied to pest control • **Publication of the Bio-inputs Decree that encourages adoption, education and innovation for biobased products**

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs (during March 2021)

Key regulatory achievements / advances for biobased inputs (3)

IBMA / EU	• **Farm to Fork strategy promotes alternatives to pesticides** • **Microbial part of regulation to be revised** to take better account of biology of microbials • **Biodiversity and eco-schemes** supported within **EU green deal**
JBCA / Japan	• **Biostimulants possibly regulated in fertilizer arena**

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs (during March 2021)

Key regulatory achievements / advances for biobased inputs (4)

SABO / South Africa	• **Updated biofertilizer guidelines** to assist companies to register products that fall in this category was established recently • **Reevaluation of the current law** to update it to current standards
PMFAI / India	• **Access Benefit Sharing of Data is allowed if the source of the Product is same** • **Fast Tracking of granting Registration of Bio-Pesticides** is usually implemented

Regulatory Survey Answered by 10 regional / national Associations working with Biobased Inputs (during March 2021)

Bioprotection – New Regulation Principles

Precautionary
Precautionary at farm level – safety to farmers, the environment and the public

Proportionality
Inherently low risk of bioprotectants merits a reduced evaluation and minimal re-evaluation process

Safe Use
Where safe use demonstrated on one crop and no MRL they could be used on all crops

Right to know
A bioprotection specific regulation can give consumers more information on the origin of their food and boost their confidence

Adapted from IBMA

BioProtection Global

Conclusions / Need of "Globally Local" Regulations

- BioProtection solutions / **BioBased Products** can serve as key catalysers towards **nature positive production** (true IPM, sustainable, and regenerative agriculture)

- **Harmonized and proportionate regulations are instrumental to enable biobased products adoption and to materialize their contribution to the needed food systems change**

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Conclusions / Need of "Globally Local Regulations"

- A paradigm shift is needed to accelerate the transformation of agrifood systems:
  - Aknowledge an interdepeendent global community living in a planet with ecological bundaries
  - With unique local particularities (trade, biodiversity / ABS, bioinnovations, cultures, diets, etc.)
  - Food and agriculture as nature based solutions to counteract climate change and sustainably feed and heal people and planet Earth

Draft / Proposed

BioProtection & BioBased inputs industry´s 2030 Food Systems Vision

Global, national, and local food systems thrive as nature positive prosperity motors of human well being and planetary health. Biobased technologies and nature based solutions become a fundamental bridge to achieve these goals. Sustainable and regenerative agriculture become the main means to counteract climate change and to restore planet Earth´s ecosystems functions and biocapability. For this to happen "globally-local", harmonized, and proportoinate regulatory frameworks (for biobased solutions) are an urged moral imperative.

ecoflora
Integrated BioSolutions from Gowan

BioProtection Global

The Food and Land Use Coalition

SUSTAINABLE DEVELOPMENT GOALS

www.gowanco.com
www.bioprotectionglobal.org
www.foodandlanusecoalition.org

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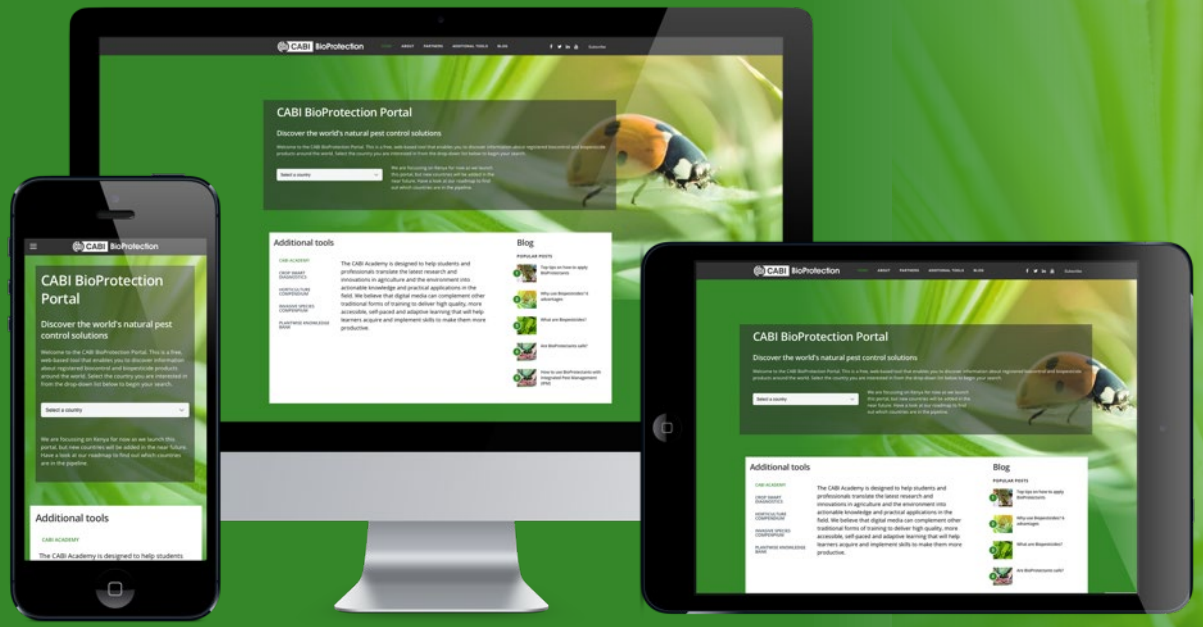
Annexes

CABI BioProtection Portal:

an innovative free-access decision support tool



www.bioprotectionportal.com

The Food and Land Use Coalition

A brighter future for people and the planet

Vital solutions for food and land use systems delivering for all

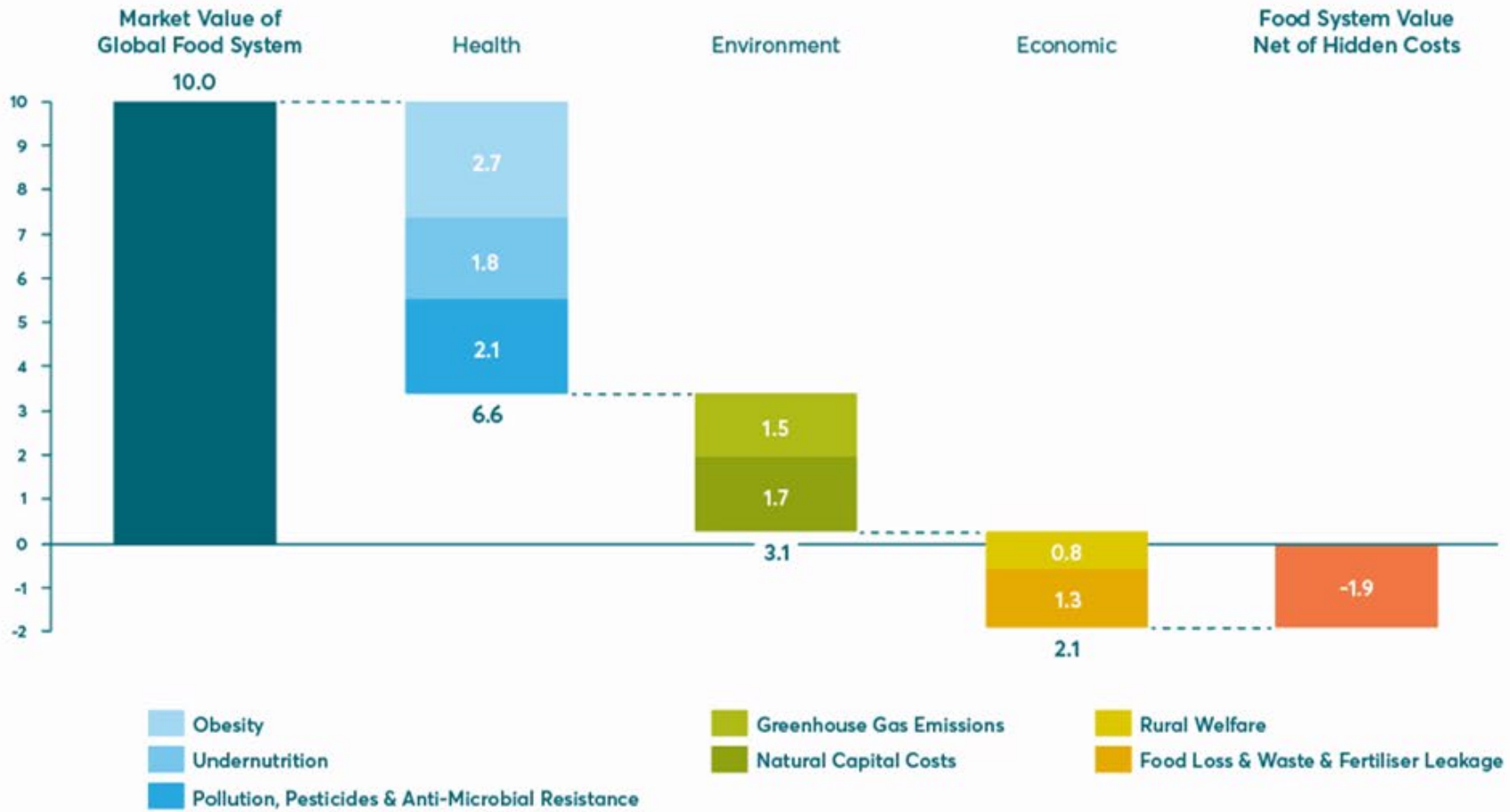
The Food and Land Use Coalition

Hidden costs of food and land use systems

Trillions USD, 2018 prices

The "hidden costs" of global food and land use systems sum to **$12 trillion**, compared to a market value of the global food system of $10 trillion.

And if we continue along current trends, these hidden costs could rise to more than **$13 trillion** a year by 2030.



Source: Food and Land Use Coalition, 2019

The Food and Land Use Coalition

A better future is possible...

Better environment.

Food and land use systems are net carbon-neutral, contributing up to one-third of the mitigation needed to stay within 1.5°C; biodiversity loss halted; ocean fish stocks restored; 80% reduction in food and land use system air pollution.

Better health.

Eliminate under-nutrition and halve the disease burden associated with consuming too many calories and unhealthy food.

Inclusive development.

Boost income growth for the bottom 20% of the rural population, increase yields of low-productivity smallholders, create over 120 million extra decent rural jobs and contribute to a more secure future for indigenous and local communities across the world.

Food security.

Increase food security significantly by helping to stabilise or even lower real food prices, to supply enough food of the right quality and quantity and to improve access for the poorest and most vulnerable.

Source: Food and Land Use Coalition, 2019

The Food and Land Use Coalition

Ten critical transitions

Investment Requirements

$300-$350 billion required each year for the transformation of food and land use systems to 2030

Business Opportunity

$4.5 trillion annual opportunity for businesses associated with the ten critical transitions by 2030

Economic Prize

$5.7 trillion economic prize by 2030 and $10.5 by 2050 based on avoided hidden costs

Source: Food and Land Use Coalition, 2019

The Food and Land Use Coalition

Key recommendations (1)

Cross-cutting

- **Governments:** put a price on carbon & repurpose agricultural subsidies
- **Business:** organise pre-competitively to support positive government reform agendas
- **Finance:** establish a TCFD for nature
- **Civil society:** drive information campaigns for food and land use reform and campaigns against serial offenders

1. Promoting healthy diets

Government: Establish and promote planetary and human health dietary standards through repurposed agricultural subsidies, targeted public food procurement, taxes and regulations on unhealthy food.

Business: Redesign product portfolios based on the human and planetary health diet.

2. Scaling productive & regenerative agriculture

Government: Scale up payments for ecosystem services (soil carbon/health and agrobiodiversity) plus improve extension services (training and access to technology, seeds, etc.).

Finance & Business: Deploy innovative finance to reach currently underfinanced parts of supply chains.

3. Protecting & restoring nature

Government: Put in place & enforce a moratorium on the conversion of natural ecosystems, & give legal rights & recognition to the territories of indigenous peoples.

Government: Scale REDD+ to $50 billion per year by 2030 if results delivered and establish a Global Alliance Against Environmental Crime.

Source: Food and Land Use Coalition, 2019

The Food and Land Use Coalition

Key recommendations (2)

4. Securing a healthy & productive ocean

Government: Protect breeding grounds, end both illegal fishing and overfishing, and provide title/ access rights to artisanal fishers.

Government & Finance: Develop new approaches and business models for insurance against catastrophic events affecting fisheries and for compensating poor fishermen for the cost of fish stock recovery.

5. Diversifying protein supply

Government: Increase R&D spending in alternative proteins (especially those with large benefits for lower-income consumers), ensuring resulting IP remains in the public domain.

Finance & Business: Prepare for disruption of the food industry by strengthening risk analysis and reallocating capital in line with the results if need be.

6. Reducing food loss & waste

Government & Civil Society: Leverage behavioural science to design grassroots campaigns to make wasting food as unacceptable as littering has become in many countries.

Finance: Finance income-sensitive, climate-smart storage technologies.

Source: Food and Land Use Coalition, 2019

The Food and Land Use Coalition

Key recommendations (3)

7. Building local loops and linkages

Government: City governments to foster local circular food economy through targeted public procurement and zoning.

Finance: Invest in emerging technologies and innovations which will close the food system loop.

8. Harnessing the digital revolution

Government: Open access to public sector data (e.g. national land registries, fisheries, etc.) and regulate and incentivise the private sector to provide open source data where appropriate.

Civil society: Create, maintain and communicate results from real-time platforms for transparency.

9. Strengthening rural livelihoods

Government: Safety nets for individuals and stranded communities to ensure a just transition.

All: Scale up rural roads and digital investments to drive productivity, end rural isolation, and, in particular, initiate a global campaign for renewable electricity access for all.

10. Gender equality & the demographic transition

Government: improve access to finance and agricultural extension services for female agricultural workers.

All: Invest in maternal and child health and nutrition as well as education for women and girls.

Source: Food and Land Use Coalition, 2019