



Uniqueness and Harmonization Efforts of Biostimulants Internationally

Moderator : Roger Tripathi

Wednesday March 7th, 2018

2:30 to 4:00 PM

tsg



Panel: Expectation Management!

bpia



Uniqueness and Harmonization Efforts of Biostimulants, Internationally!



Speakers and Panelists:

- **Roger Tripathi GBAL and GreenCorp**
- **Benoît Planques, Itaipollina;**
- **Hong Chen, TSG Consulting;**
- **Jesús Yáñez, GreenCorp;**
- **Ry Wagner, GBAL**



Panel Agenda



- Roger T : global regulatory alignment or lack of it? and introduction to the panel
- Benoît Planques: challenges, opportunities, timelines for Europe Regulation, mainly from biostimulant point of view



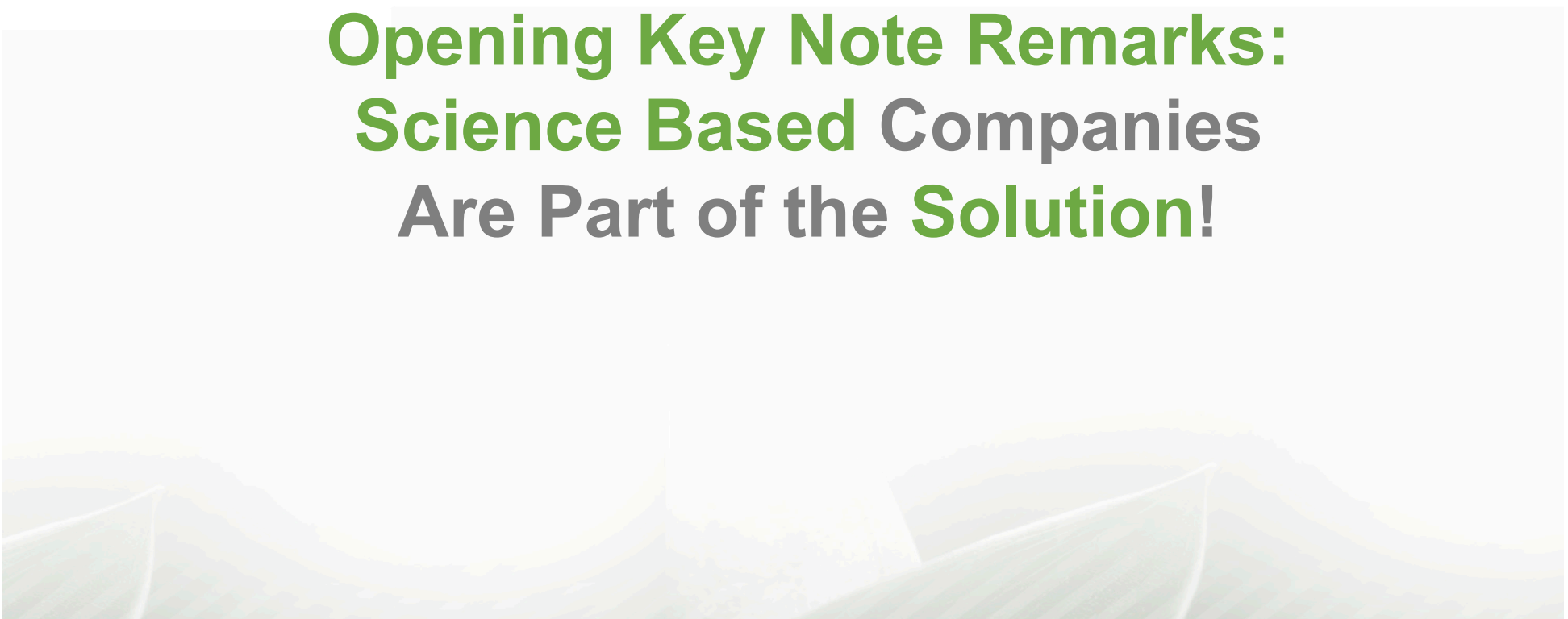
- Hong Chen: challenges, opportunities, timelines for Asia Regulation, mainly from biostimulant point of view



- Jesus Yanez: challenges, opportunities, timelines for LATAM (Mexico) Regulation, mainly from biostimulant point of view



- Ry Wagner: challenges, opportunities, timelines for NA Regulation, mainly from biostimulant point of view
- Roger and All – open Q&A and panel discussion
- Panel Round Table and Questions

A background image showing a field of solar panels in the foreground, with rolling hills and a bright sky in the distance.

**Opening Key Note Remarks:
Science Based Companies
Are Part of the **Solution!****

Biological Products: A Continuum



Biopesticides

Weed, disease,
insect control
Pesticides/plant
regulators



Biostimulants

Increased nutrient
availability/yield/abiotic
stress tolerance



BioFertilizers

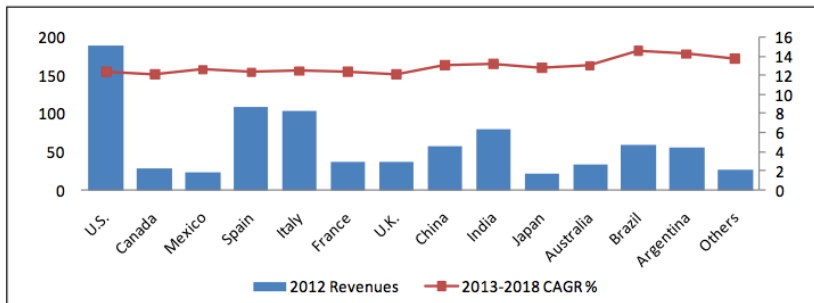
Macro and micro
nutrients
Fertilizers

Product claims and marketing intent are critical

Global Biostimulants Market Overview

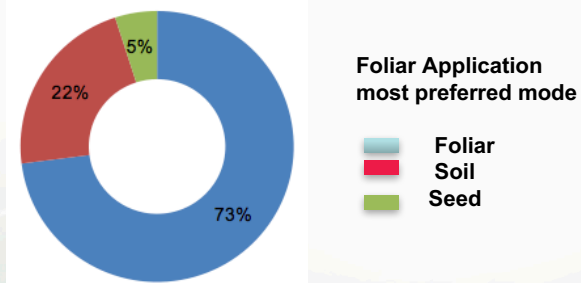


Key Markets for Biostimulants



U.S. largest single country / Brazil fastest growing market

Biostimulants Market Revenue, by Applications



Foliar Application most preferred mode

- Foliar
- Soil
- Seed

Source: FAOSTAT, USDA, Biostimulants Coalition, EBIC, Agline, Expert Interviews, MarketsandMarkets Analysis

Key Findings

- Acid-based dominated global biostimulants market with around 53.4%
- Seaweed extract-based biostimulants controlled around 37%
- Microbials and extract-based biostimulants are expected to be fastest growing market segment
- B-vitamins, Chitin, and Chitosan are few other important active ingredients for global biostimulants industry
- Europe is the most dominating market for both acid- and extract-based biostimulants market

Biostimulants Regulation & Regulatory Approval Process



- Globally there is no current standard for “Biostimulants” in the regulatory registration process
- Unlike biopesticides, there are no significant differences in registration timelines across geographical regions – generally 1 to 2 years
- European Biostimulants Industry Council (EBIC) and the Biostimulants Coalition in the USA are working with industry and regulators on purpose standards
- Quote from EBIC web site “Farmers, investors, regulators, consumers, scientists and other industries are still learning about biostimulants and their role in sustainable agricultural”
- EBIC has recommended placing Biostimulants under an expanded category of “fertilising materials” in the EU – this would be a step toward full harmonization

New Regulatory Initiatives Are Bringing Credibility to Biostimulants



- **The European Biostimulant Industry Council (EBIC) was founded in 2011 to promote plant biostimulants in Europe. EBIC is Currently working to modify the fertilizer legislation to create new harmonized standards for biostimulants under the modernized fertilizer regulations, that will differentiate them from snake oils.**
- **The United States Biostimulant Coalition (USBC) and Biological Products Industry Alliance (BPIA) are working collectively to address regulatory issues surrounding biostimulants, that will differentiate us from snake oils. These two groups are currently working with the US EPA to find a solution for the proper regulation of these innovative products.**

New Regulatory Initiatives Are Bringing Credibility to Biostimulants/Biologicals

- **The CABIO (Camara Argentina de BioInsumos) is representing BioStimulants and BioControl products in Argentina.**
- **ABC Bio and ABISOLO are two groups who are representing Biostimulants and Biocontrol products in Brazil but with lots of gray areas.**
- **A new group is formed in India under ICFA, which will represent BioStimulant interest with Government of India.**
- **Similar groups need to be formed in Africa (SABO should take lead) and China (new initiative required).**
- **Global regulatory agencies recognize the need for allowing market access and differentiation to Biostimulants while imposing some level of control to prevent fraudulent and harmful or ineffective products, we need to coordinate with out wasting any time.**

New Regulatory Initiatives Are Bringing Credibility to Biostimulants/Biologicals



- **BioProtectionGlobal (BPG) is the new name that has been adopted by the Federation of the world's leading Biocontrol and Biopesticide Associations, established in fall 2014.**
- **The new name was approved and Board members were elected at the Annual Biocontrol Industry Meeting (ABIM) 2015 in Basel, Switzerland.**
- **The objective of BPG is to achieve international harmonization for regulation of biological pest control solutions and to be the central contact for governmental and non-governmental stakeholders worldwide related to biocontrol and Biopesticides.**

New Regulatory Initiatives Are Bringing Credibility to Biostimulants/Biologicals



- **BPG's founding members are,**
 - **Associscao Brasileira das Empresas de Controle Biologica (ABCBio),**
 - **Association of Natural Biocontrol Producers (ANBP),**
 - **Bioproducts Industry Alliance (BPIA),**
 - **International Biocontrol Manufacturers (IBMA),**
 - **South African Bioproducts Organisation (SABO),**



Challenges, opportunities, timelines for **Europe Regulation**, mainly from biostimulant point of view

Benoît PLANQUES
ITALPOLLINA - Global Regulatory
Manager

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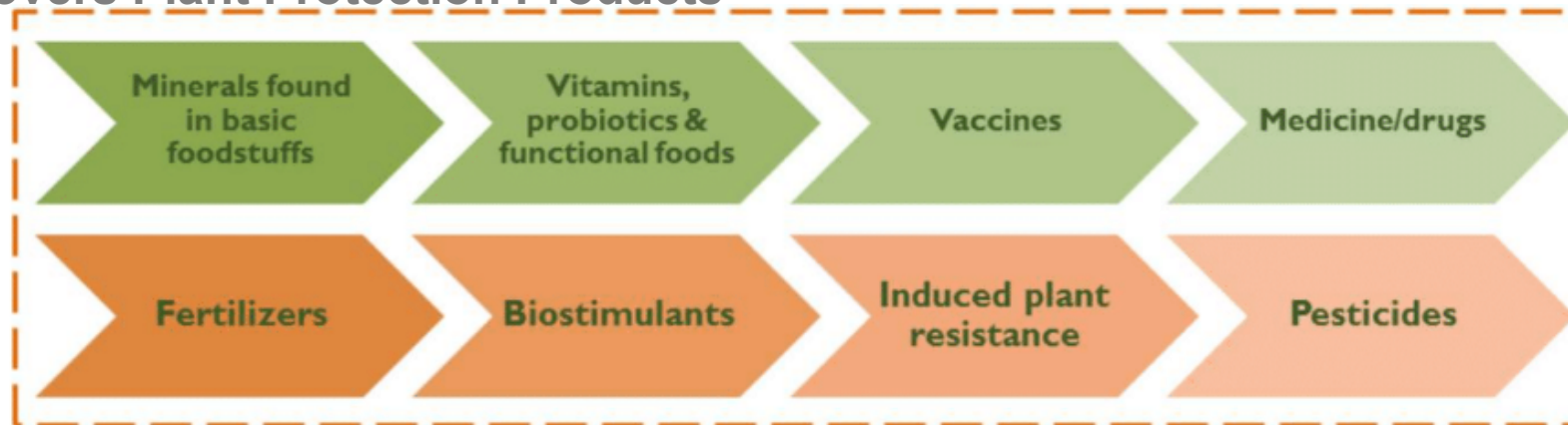


We need to rethink the outdated regulatory framework to keep up with science and innovation



- The EC 2003/2003 fertiliser regulation successfully created an EU internal market for mineral fertilisers and liming materials
- The EC 1107/2009 regulation covers Plant Protection Products

...But some products are out of the harmonized market: organic fertilizers, soil improvers, inhibitors or plant biostimulants



Progress made so far...

Consultation with Member States, industry, and stakeholders

2011-15

Roadmap for the regulatory revision published

Oct 2015

Draft fertilizing products regulation published

March 2016

July 2017

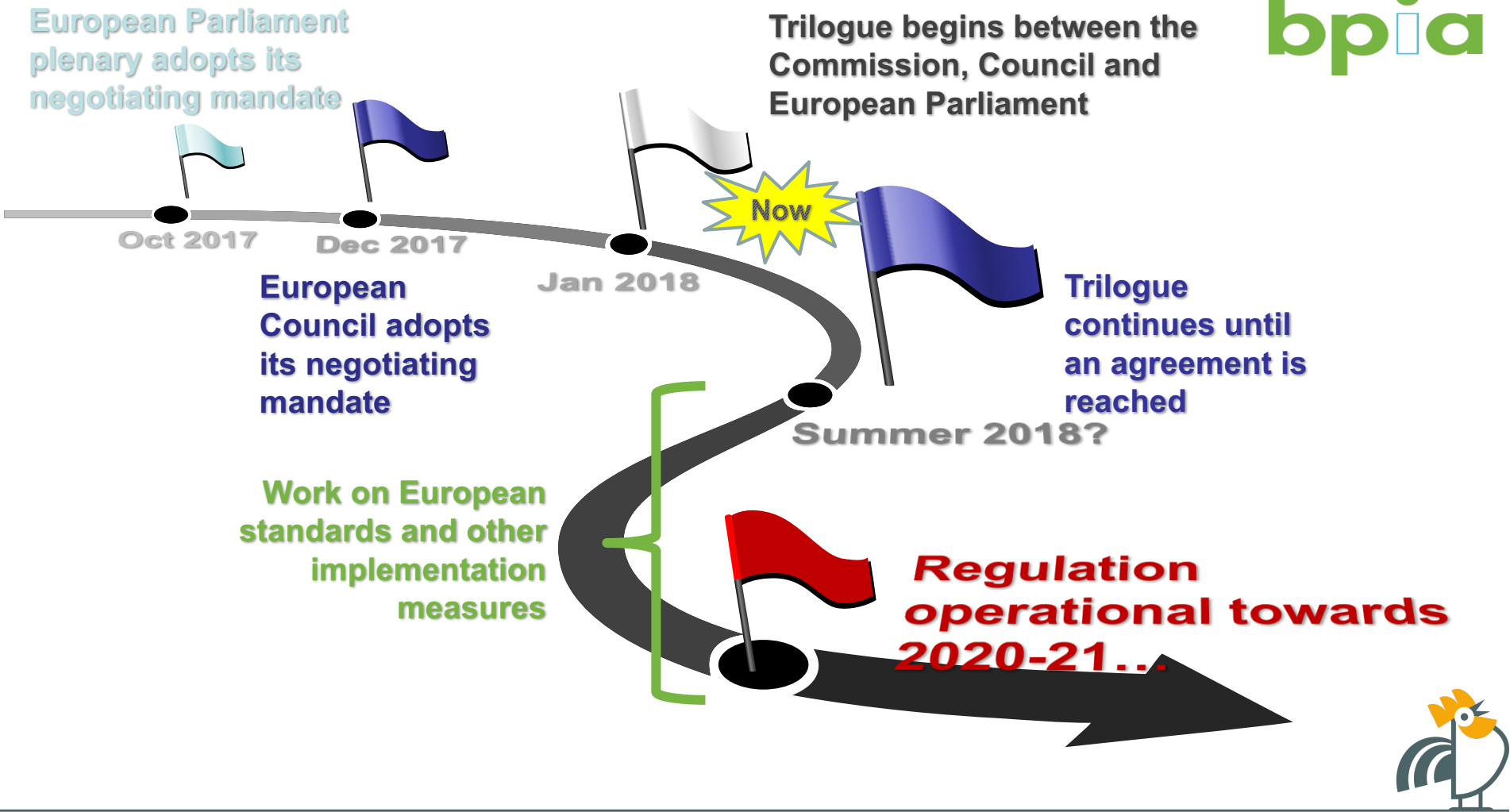
Single Market Committee votes on European Parliament report

2010

Evaluation of existing EU fertilizer regulation

bpia





Definition of plant biostimulants in the European Parliament position



‘plant biostimulant’ means a product containing any substance or micro-organism stimulating plant nutrition processes independently of its nutrient content, or any combination of such substances and/or micro-organisms, with the sole aim of improving one or more of the following characteristics of the plant or the plant rhizosphere:

- nutrient use efficiency
- **degradation of organic compounds in the soil**
- tolerance to abiotic stress
- crop quality traits
- **availability of confined nutrients in soil, rhizosphere or phyllosphere**
- **humification**



Issues within the regulation yet to be resolved...

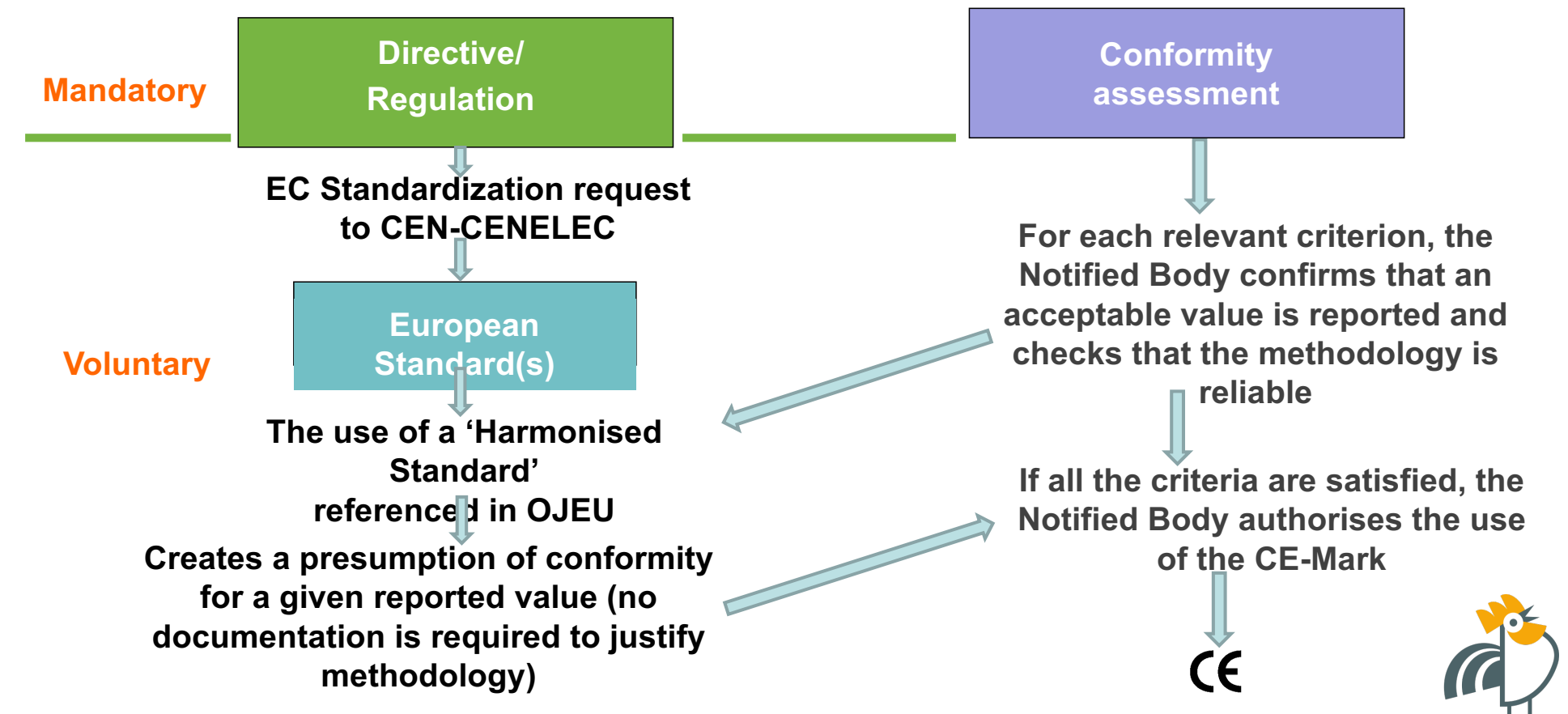
bbia



- Need a **clear boundary with plant protection** without impeding innovation
- The European Commission needs **the delegated power to adapt the regulation's requirements** to reflect updated science and technological progress
- **Development of Harmonised standard** which means a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation,



Relationship between EU legislation & EN standards



The value of a European standard

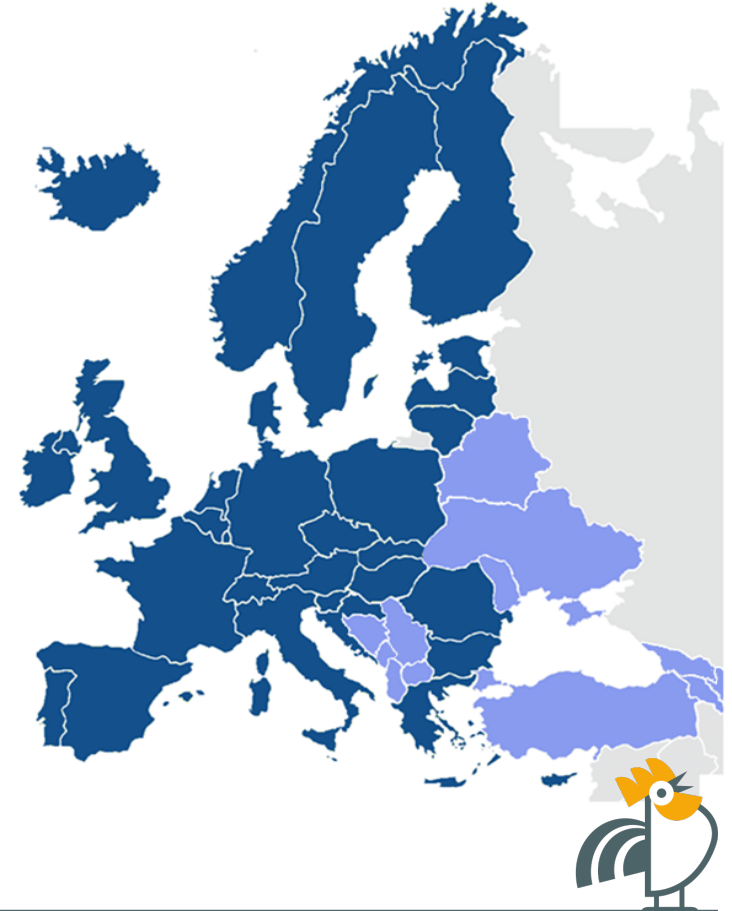


→ **1 European standard**

... Replaces **34 different national standards** in Europe

... Creates access to a **market of approx. 600 million people**

... May be used as a reference in another jurisdiction that doesn't have a relevant standard



Main actors in European standardization & the example of **CEN/TC 455**



Technical Committee – CEN/TC 455 on Plant biostimulants

- **Chair – Benoît Planques** chairman of EBIC's internal Standardization Task Force (Italpollina)
- **Secretary (NSB/NC) – Stéphanie Tiprez**, Afnor (French national standardization body)
- **5 Working Groups: Sampling** (Spain), **Claims** (France), **Pathogenic and non-pathogenic microorganisms** (Netherlands), **Other safety parameters** (Czech Republic), **Labelling and denominations** (UK)
- **Liaison** with CEN/TC 223 (**soil improvers and growing media**) and CEN/TC 260 (**fertilizers and liming materials**) to ensure coherence and ISO/TC 134

National delegations – Each of the 34 CEN members

- **National position** – EBIC has encouraged members to become designated as national experts in as many countries as possible
- **Voting Right**

European Partners (CEN CENELEC Guide 25)

- **Observers** – EBIC secretariat has obtained liaison status; European Commission
- **No voting right**



European Conclusions



- **Standardization** can help the industry **achieve similar requirements** across different regulatory regimes
- Standards are **responsive to improved knowledge**
- Standards are **reviewed regularly** and, if needed, **updated to reflect changes in scientific or technical knowledge, regulation, etc.**
- The use of standards can **help industry and SMEs to access global markets.**
- **International standards (ISO)** facilitate trade help remove technical barriers to trade, increase market access and international trade, and enhance cooperation at the international level.
- **ISO/TC 134 “fertilizers and soil conditioners”** could help us !





Challenges, Opportunities, Timelines for China Registration of Biostimulants



Hong Chen, Ph.D.
Director, Asia-Pacific Affairs, TSG Consulting
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- **Biostimulants are not treated “equally” among Asian countries, for example:**
- **China: a relatively new concept and categorized based on the claims**
- **Japan and Korea: PGR**
- **S.E. Asia: Categorized based on the claims**
- **Key factors:**
- **Ingredients**
- **Mode of action**
- **Uses and use methods**



- **A relatively new concept, mostly considered as fertilizer products**
- **Some products with dual functions of pesticide and fertilizer can be registered for both – with different names/trade names**
- **Products are registered based on the existing pesticide or fertilizer category, not “biostimulants”**



Pesticides or Fertilizers?

- Based on the claims:
- A pesticide: if claims to have pest control functions or as a PGR
- A fertilizer: if claims to provide nutrients to plants
- Both a pesticide and a fertilizer: if claims to have both pest control functions and provide nutrients to plants
- Registering as a pesticide: apply with ICAMA (The Institute for the Control of Agrochemicals, Ministry of Agriculture)
- Registering as a fertilizer: apply with the Fertilizer Center, Ministry of Agriculture
- If apply for both pesticide and fertilizer registrations: use different product names/trade names
- Time, cost of registration and sales prices are much higher for a pesticide than a fertilizer



- Currently no “Biostimulants” categories, and can be registered based on the claims such as:

- Bio-insecticides
- Bio-fungicides
- Bio-herbicides
- Plant Growth Regulators (PGRs)
- Induced-plant-resistance agents



- The new data requirements for “biopesticides” vs conventional pesticides:
- Reduced field study time, and residue, toxicology, environmental requirements
- Environmental risk assessment not required
- Time: > 2-3 years
- Fees: varies based on actual product, for example:
 - In-China test fees: 30-80K USD (depending on products & uses)
 - Local agent fee: 6-30K USD (based on workload/test fees)



- Currently no “Biostimulants” categories, and can be registered based on the existing fertilizer categories:

- **Example categories:**

- Organic fertilizer

- Microbial fertilizer

- Trace element or medium element fertilizers

- **Crop Grouping for fruits and vegetables**





Fertilizers – MOA Fertilizer Center **bpia**

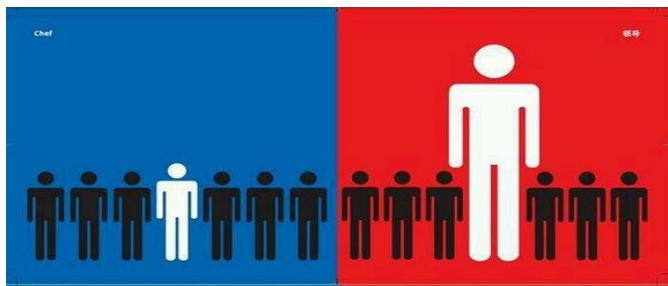
- **Time: 1 - 2 years**
- **Fees: varies based on actual product, for exaple:**
 - **Field trial: \$3.5 K USD per crop**
 - **Local agent fee: ~\$10K USD**
 - **Test & review fee: ~\$10K USD**



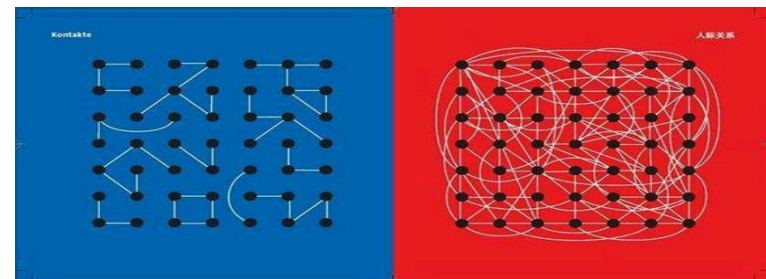
Know the Policy and the “Culture” – Equally Important

- Chinese regulation is ever-changing
- Registration is case-by-case
- Policies are directly affected by politics and politicians
- “Cultural environment” West (blue) vs China (red):

The Government



The Network



- Do your homework – registration feasibility analysis
- In-person meetings between your consultant/agent and regulatory agencies
- “Attitude” – information sharing
- Contract a good local distributor/importer
- Provide required documents/data in a timely manner
- Relationship building





Challenges Opportunities and Timelines in LATAM (Mexico) Regulation

Jesus N. Yañez



SAGARPA SEMARNAT-SEC DE SALUD

México: The Federal Commission for the Protection from Sanitary Risk (COFEPRIS)

It is a decentralized organ of the Department of Health with technical, administrative and operational autonomy.

Mission is to protect the population from sanitary risks, through sanitary regulation, control and promotion under a single command, which provides unity and homogeneity to the policies which are determined.

MAGA-Guatemala

MAG – Costa Rica

40-50 Companies have Biological products officially registered in Mexico

CONCERN: >100 small and medium size companies are informally or illegally Commercializing biostimulants-type products and biopesticides in Mexico, this can also be happening in other LATAM countries.



MICROBIALS

INOCULANTS

ORGANIC
PGR'S

SOIL
AMENDMENTS

SOIL
MOISTURIZER
S

ORGANIC
ACIDS

ORGANIC and
MINERAL
FERTILIZERS



CHALLENGES



- Current Mexican legislation for Biostimulants is covered by the **FERTILIZERS** law in COFEPRIS, but without any reference to biostimulants.
- Biofertilizers containing one single strain or bioconsortium of beneficial fungi, bacteria are registered under the category of **Microbial Inoculants** for seed treatments or direct soil application.
- Products containing humic substances, fulvic acids, proteins, enzymatic extracts, hydrolyzed proteins, Seaweeds extracts and kelp, organic extracts, phytohormones, chitosan, amino acids are being registered under the Category of **Non Synthetic Fertilizers or Non synthetic PGR´s**.
- Mexican representatives for the industry are not still organized, but Amphydiobe (a 12 years old Association for Organic Inputs) is a private group that could enable a fast integration of Biological companies to the formation of an strong and very well representation of the industry.
- The input organic sector, its leaders and legislative figures have been participating in the review, the adequation of norms and technical procedures for the regulatory safety, validation of products, facilitation and reasonable timelines for the registration process of these inputs.

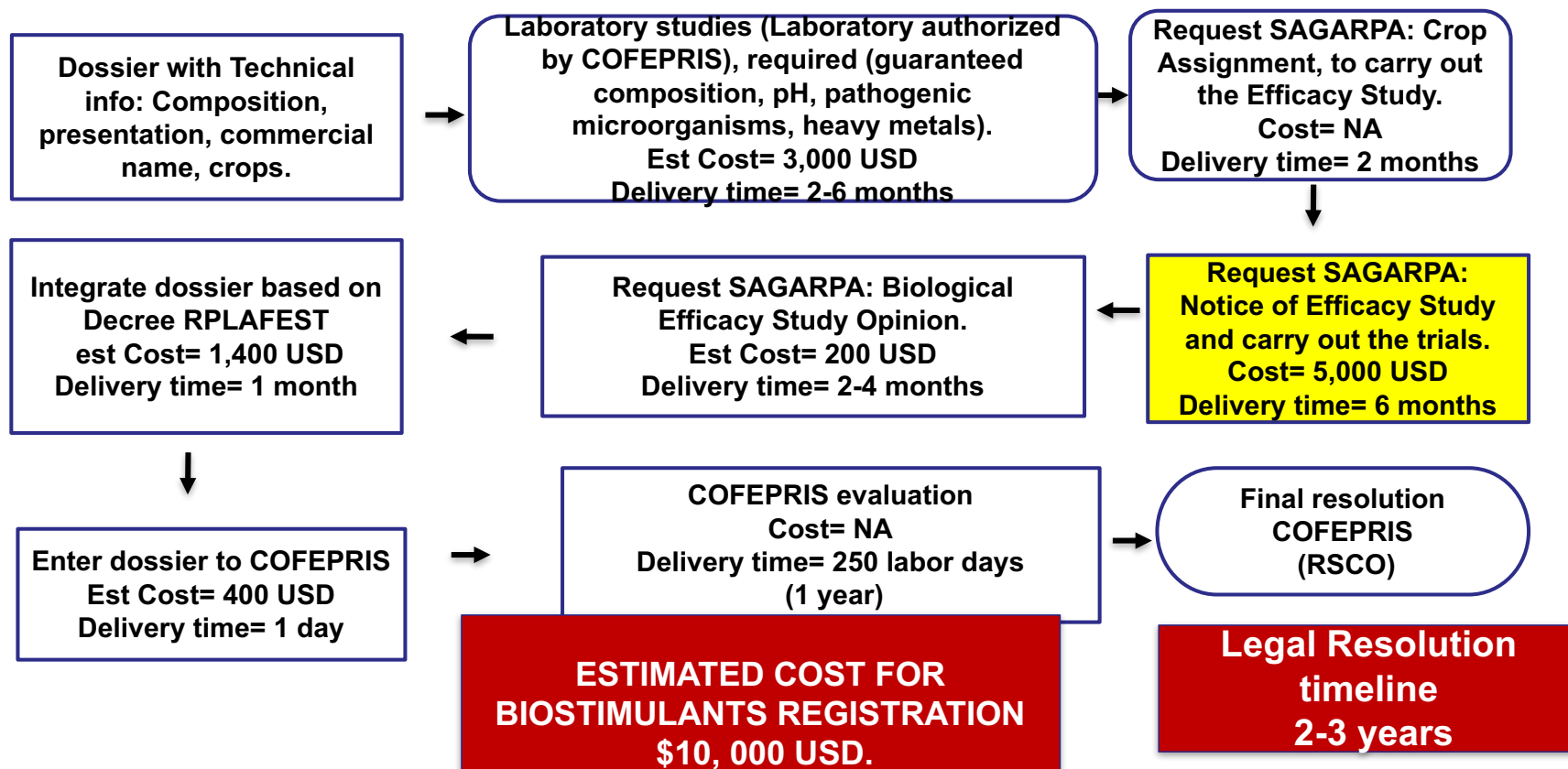


TIMELINES FOR REGISTRATION-MEXICO



DOSSIER REGISTRATION SUMMARY PROCESS

“NON SYNTHETIC FERTILIZERS, INOCULANTS, NON SYNTHETIC PGR’s “

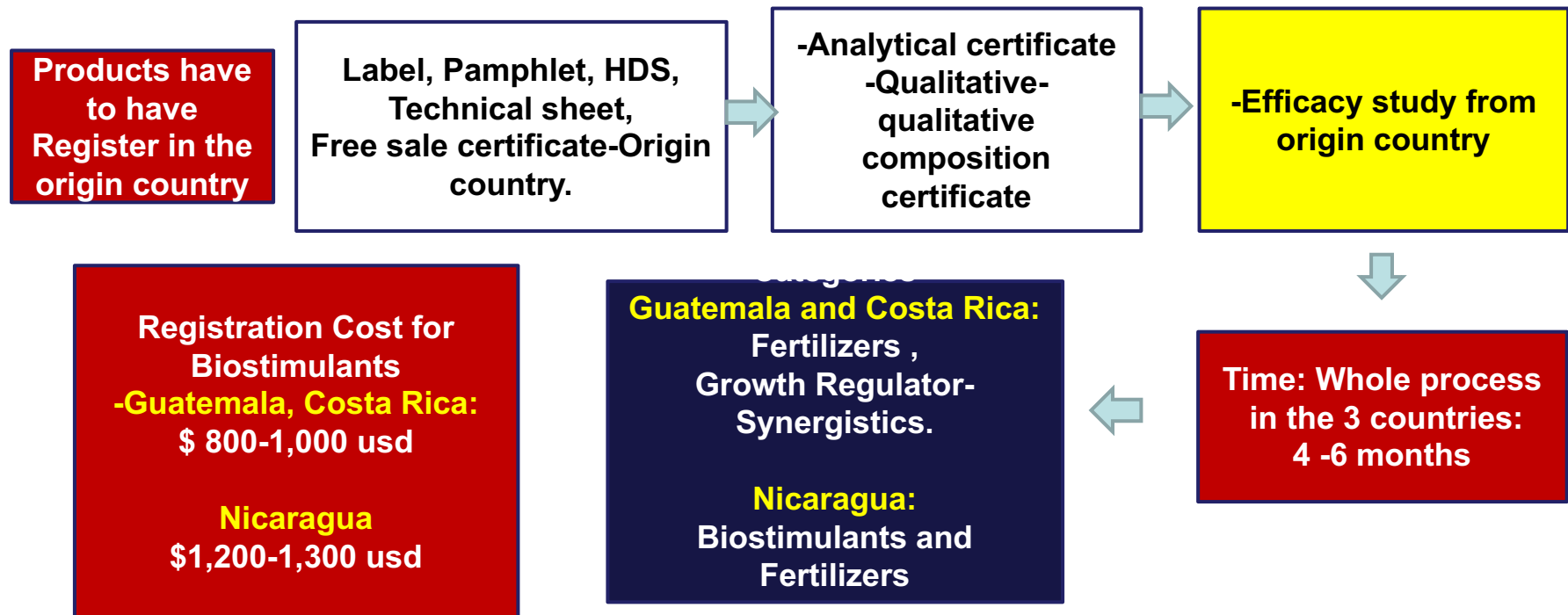




TIMELINES FOR REGISTRATION-LATAM



DOSSIER REGISTRATION SUMMARY PROCESS -BIOSTIMULANTS GUATEMALA, NICARAGUA, COSTA RICA-





LATAM OPPORTUNITIES & CONCLUSIONS



- **Right moment to integrate a strong and well represented organization for Biological Manufacturing Industry in Mexico.**
- **Central America should be considered to participate and have a regional Mexico-CA-LATAM Biological Organization.**
- **The New Organization should look for alliances and support with highly experienced and organizations like BPIA, EBIC, IBMA and others AsoBiocol, ABCBio, Abisoló in LATAM.**
- **Biostimulant and Biopesticides mexican market estimates a CAGR´s 15-20% for both groups of products.**
- **Regional biological companies must be forced for the registration of products otherwise should be penalized or suspended for not being legally selling those products.**
- **The growth in farmers' income due to the growing exports is making the new agricultural technologies and latest biocontrol products affordable.**



Challenges and Opportunities for North America (and Globally)

Questioning the Credibility of Biologicals

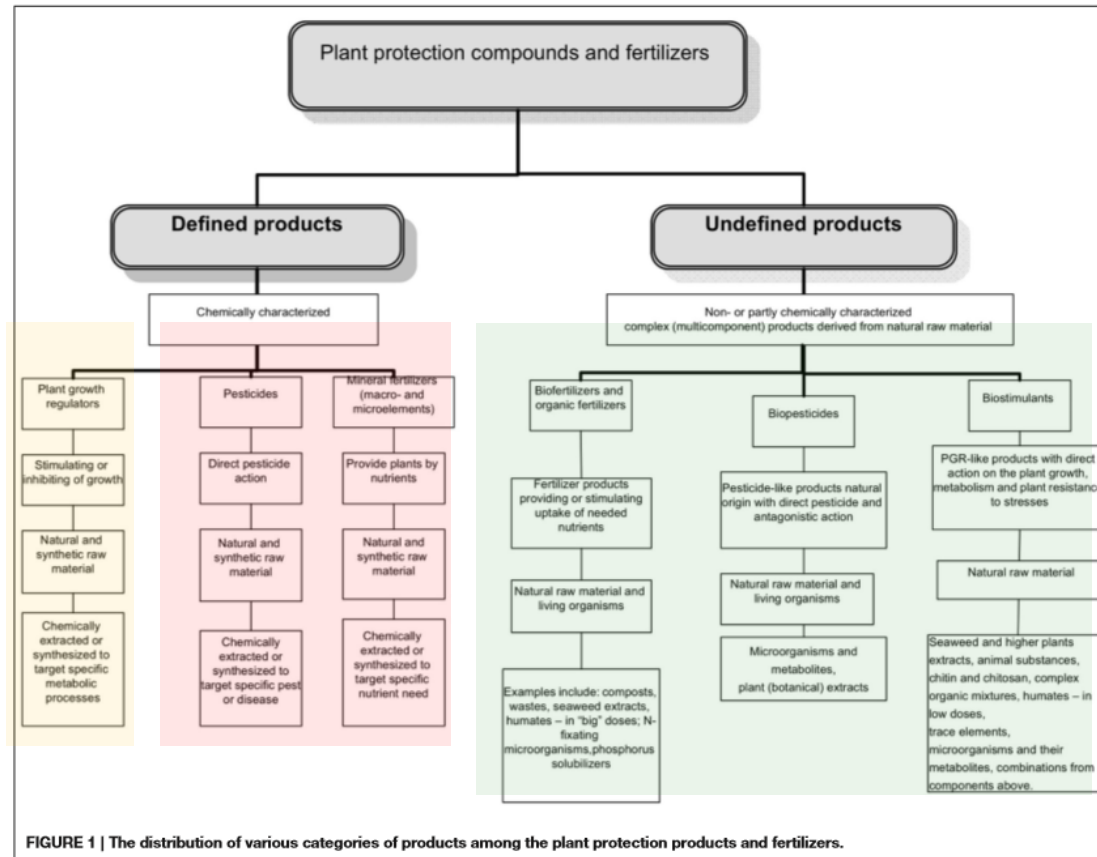


FIGURE 1 | The distribution of various categories of products among the plant protection products and fertilizers.

Biostimulants in Plant Science: A Global Perspective

Oleg I. Yakhin^{1,2*}, Aleksandr A. Lubyantsev¹, Ildus A. Yakhin² and Patrick H. Brown²
¹Institute of Biochemistry and Genetics, Life Science Center, Russian Academy of Sciences, Ufa, Russia; ²FBIQ Company Eco-Phosco, Ufa, Russia; ³Department of Plant Sciences, University of California, Davis, Davis, CA, USA



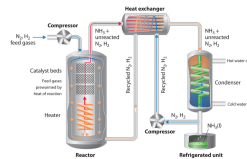
How Did We Get Here? Where Are We Going Next?

20th Century Agriculture The Shift to Chemistry

Development of
“Humus
Farming”
 (“Agricultural
Bacteriology” &
 “Biological
Control”)



Haber-Bosch
Process

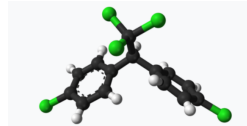


Plant Growth
Regulators
Discovered &
Commercialized

2,4 - D
Commercialized

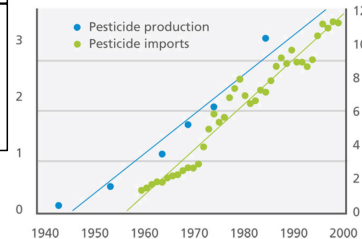
Sporeine (Bt)
Commercial
BioPesticide

DDT 1st Synthetic
Pesticide
Commercialized



Nitrogen
Fertilizer Use
Accelerates

Industrial Scale
Chemistries &
Mode of Action
for Pesticides



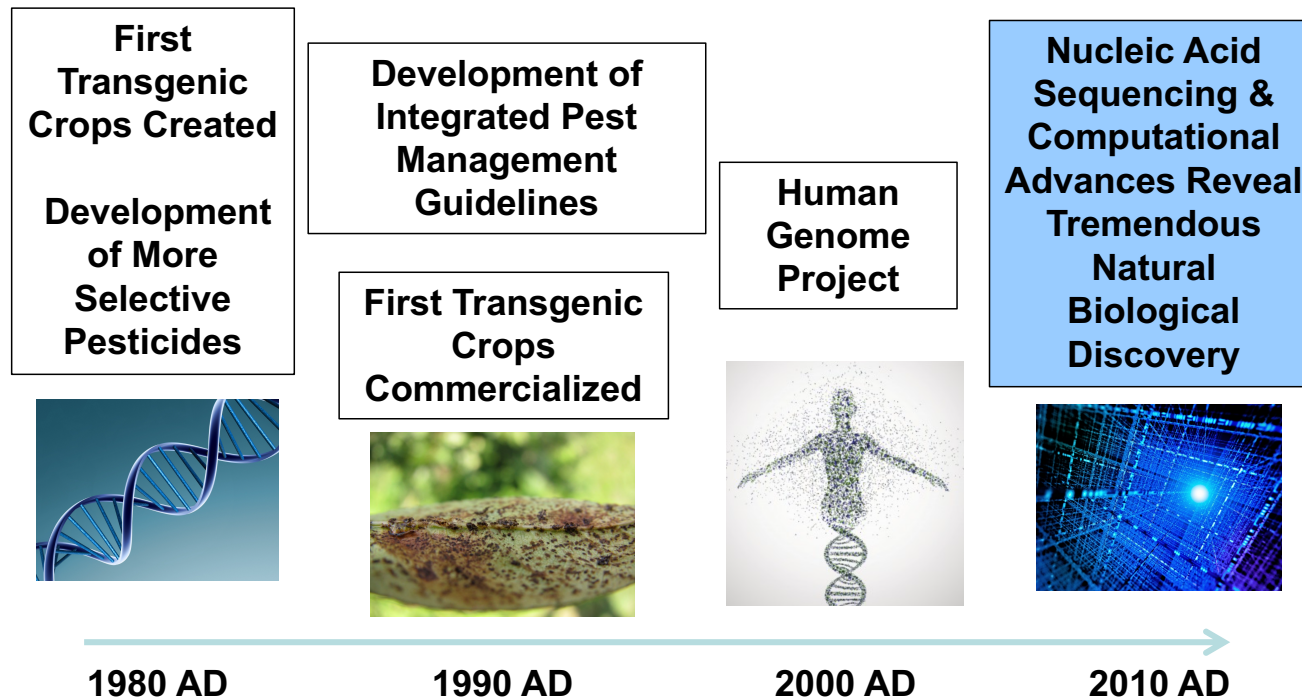
1900 AD

1920 AD

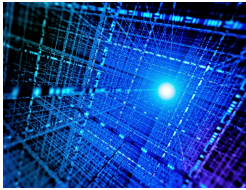
1930-1950 AD

1950-1980 AD

20th Century Agriculture The Shift to Biology

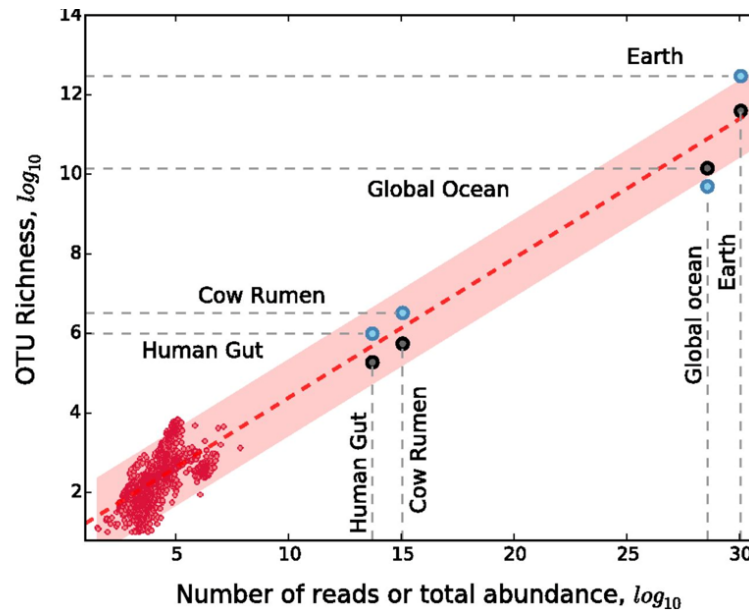


Unlocking Microbial Diversity: **bpia** A Revolution in Biologicals



**99% of all
Microbial
Species
remain
Uncultured**

~ 1 Trillion Microbial Species on Earth



Kenneth J. Locey, and Jay T. Lennon PNAS 2016;113:5970-5975

Biostimulants as an Example: **bpia** Some “Known Unknowns”

Several topical questions need consideration in the future:

1. Can living cultures of microorganisms, which have the ability to stimulate the growth of plants be referred to biostimulants?
2. Are non-essential elements that result in improved plant productivity, biostimulants?
3. How should biostimulants with a complex completely unidentified structure where all the components and modes/mechanisms involved have not been established be registered and regulated in national and international legislation?
4. What standard of proof of efficacy is appropriate that both stimulates development and discourages the sale of materials of no benefit?
5. On what principles, should the final classification of biostimulants be based and what categories should it contain?

Biostimulants in Plant Science: A
Global Perspective

Oleg I. Yakhin^{1,2*}, Aleksandr A. Lubyantsev¹, Ilus A. Yakhin¹ and Patrick H. Brown³

¹Institute of Biochemistry and Genetics, Life Sciences Center, Russian Academy of Sciences, Ufa, Russia, ²FBI Company Eco-Products, Liberty, Russia, ³Department of Plant Sciences, University of California, Davis, CA, USA



frontiers
in Plant Science

January 2017



New Regulatory Initiatives Are Bringing Credibility to Biologicals

- **The United States Biostimulant Coalition (USBC) and Biological Products Industry Alliance (BPIA) are working collectively to address regulatory issues surrounding biostimulants, that will differentiate products of known quality and standards from products that do meet defined criteria. These two groups are currently working with the US EPA to find a solution for the proper regulation of innovative biological products.**



What Would an “Ideal” Regulatory Environment Entail?



- A definition for **biostimulants** recognized by regulatory agencies
- A **clear, consistent and predictable** process for market entry
- Clarity on **acceptable claims** for biostimulants
- A **single label** for all US states
- A clear approach for registration of active ingredients that may have **dual use**
- **Global harmonization** of standards and practices (to the extent possible)
- Supports industry practices that enhance **market credibility**



Panel Conclusions



- Use **solid, credible science** and work on trust equation
- Relay that biostimulants are **not promising miracles**
- Point out that they are most effective in **integrated crop programs**
- Make a **strong bridge** between the laboratory and the field
- **Work closely** with research community, universities, government researchers and respected technical partners
- Focus on **agronomic benefits**
- Deliver **best-use application information** to growers and end-users to maximize their ROI

Regulatory: Expectation Management! **bpia**

