ABIM®
Annual Biocontrol Industry Meeting®

15th Annual Biocontrol Industry Meeting
19-21 October 2020, The virtual conference and exhibition in conjunction with Congress Center Basel

www.abim.ch

Jointly organized since 2006 by

International Biocontrol Manufacturers Association (IBMA) and

Research Institute of Organic Agriculture (FiBL)

Since 2020, ABIM is hosted by ABIM AG, a jointly owned venture of the International Biocontrol Manufacturers Association IBMA and the Research Institute of Organic Agriculture FIBL.

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

FiBL

ABIM AG

ABIM AG Board of Directors: Martin Andermatt (president), Karine Grosbeau, Pia Pedross, Marc Schärer, Lucius Tamm

ABIM AG Executive Board Members: Lucius Tamm MD, Jennifer Lewis, David Cary, Anne Merz

IBMA
INTERNATIONAL BIOCONTROL MANUFACTURERS ASSOCIATION

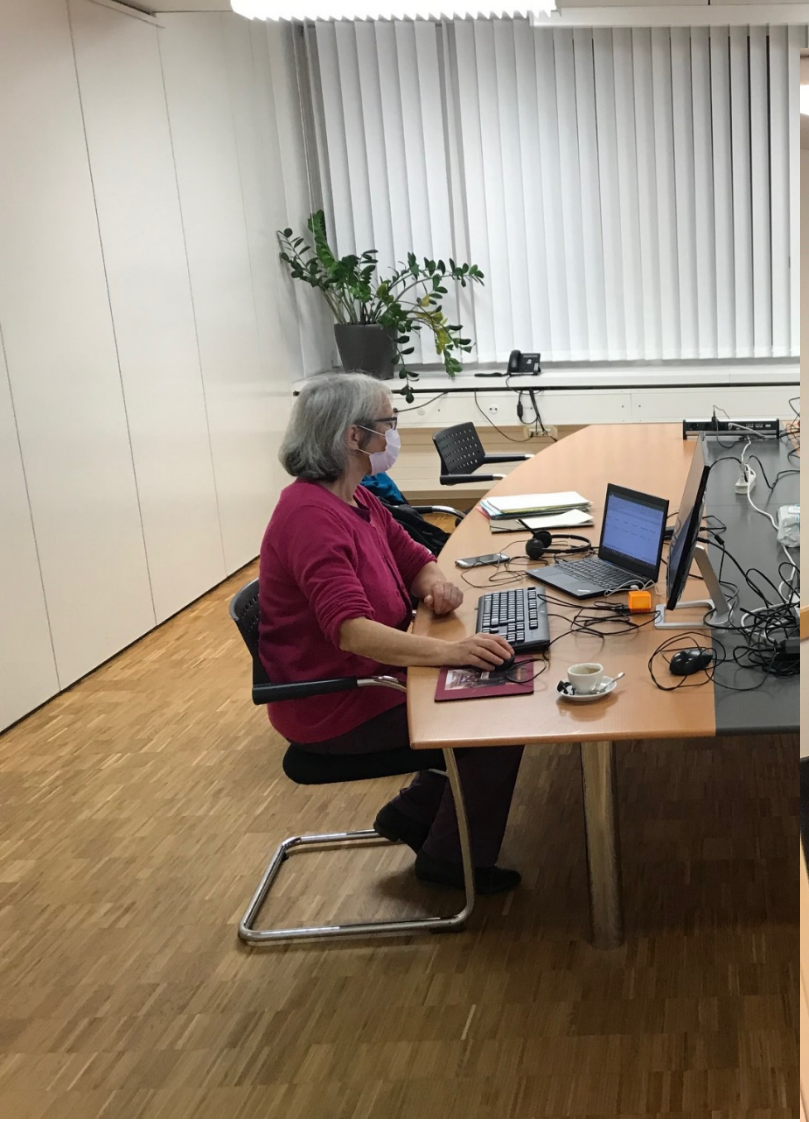
FiBL

Highlights of today‘s programme

- Welcome address State Councillor Christoph Brutschin, Head of Departement of Economic, Social and Environmental Affairs, Basel.
- Setting the scene by Jennifer Lewis and Lucius Tamm
- Bernard Blum Award Presentation
- A 30 minute **Guided Walk** through the exhibition leaving from the **Sponsors ABIM Info desk at 12:00**
- **Celebration** of 15th ABIM, 25 years of IBMA and 47 years of FiBL **at the IBMA Pavilion 3/booth 10 at 12:30** including an address by Michael Hamell, former Head of Unit DG Environment, EU Commission.

Highlights of ABIM 2020 programme

- There are 47 exhibitors with interactive virtual booths.
- There are over 500 delegates participating in our 1st ever virtual ABIM exhibition and conference.
- There are 4 workshops on topical issues for biocontrol.
- There is our largest ever programme with talks of interest to all sectors of the biocontrol community.
- Wednesday key note by Dr Sally Uren OBE: CEO of Forum for the Future Transformation and the role of biocontrol

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ABIM 2020
19–21 October 2020
In conjunction
with Messe Basel
www.abim.ch

The Premier Global Meeting Place for the Biocontrol Industry

The importance of the biocontrol industry to solve major agricultural challenges

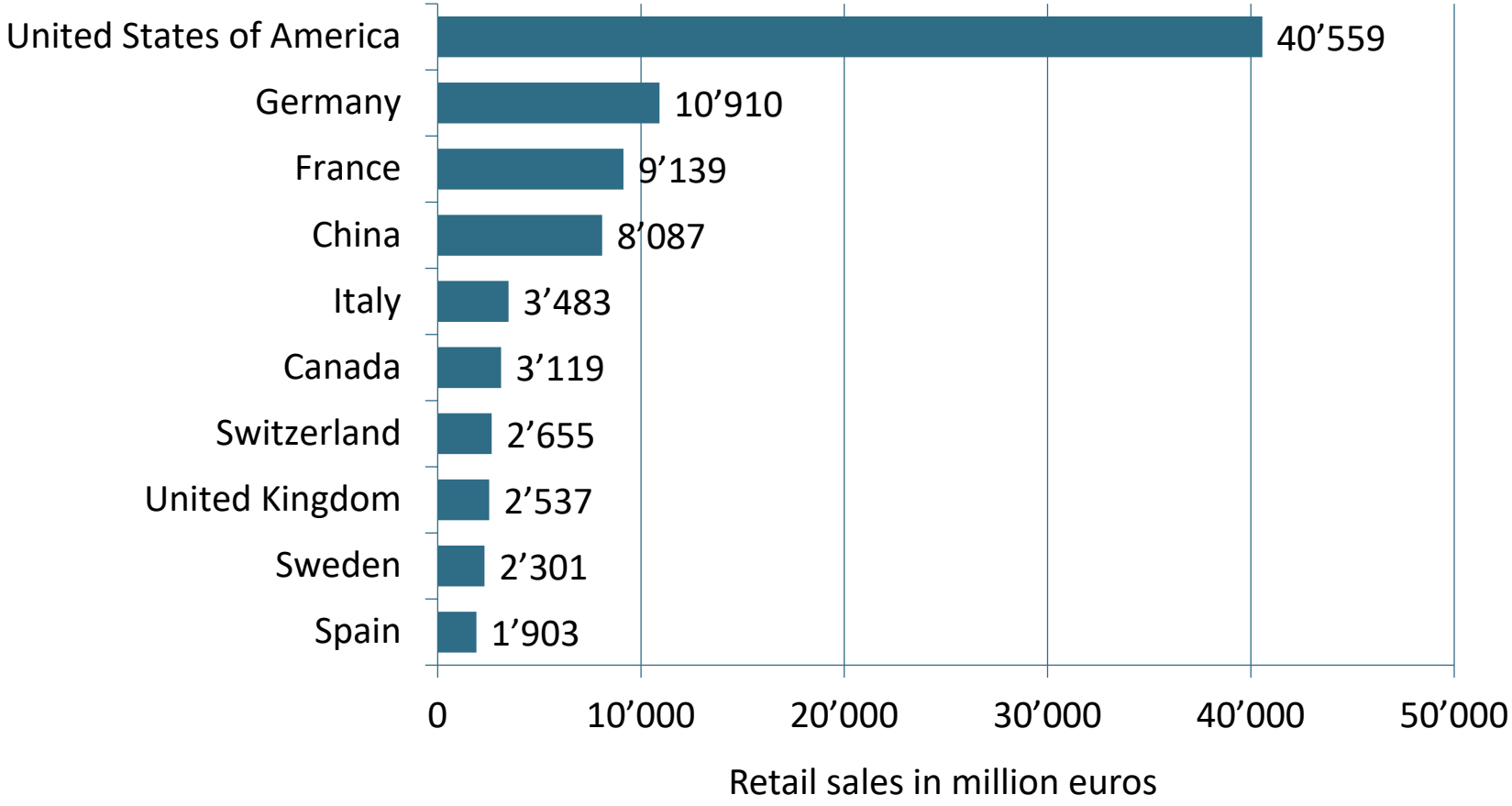
Lucius Tamm (lucius.tamm@fibl.org)

ABIM 2020

19 October 2020

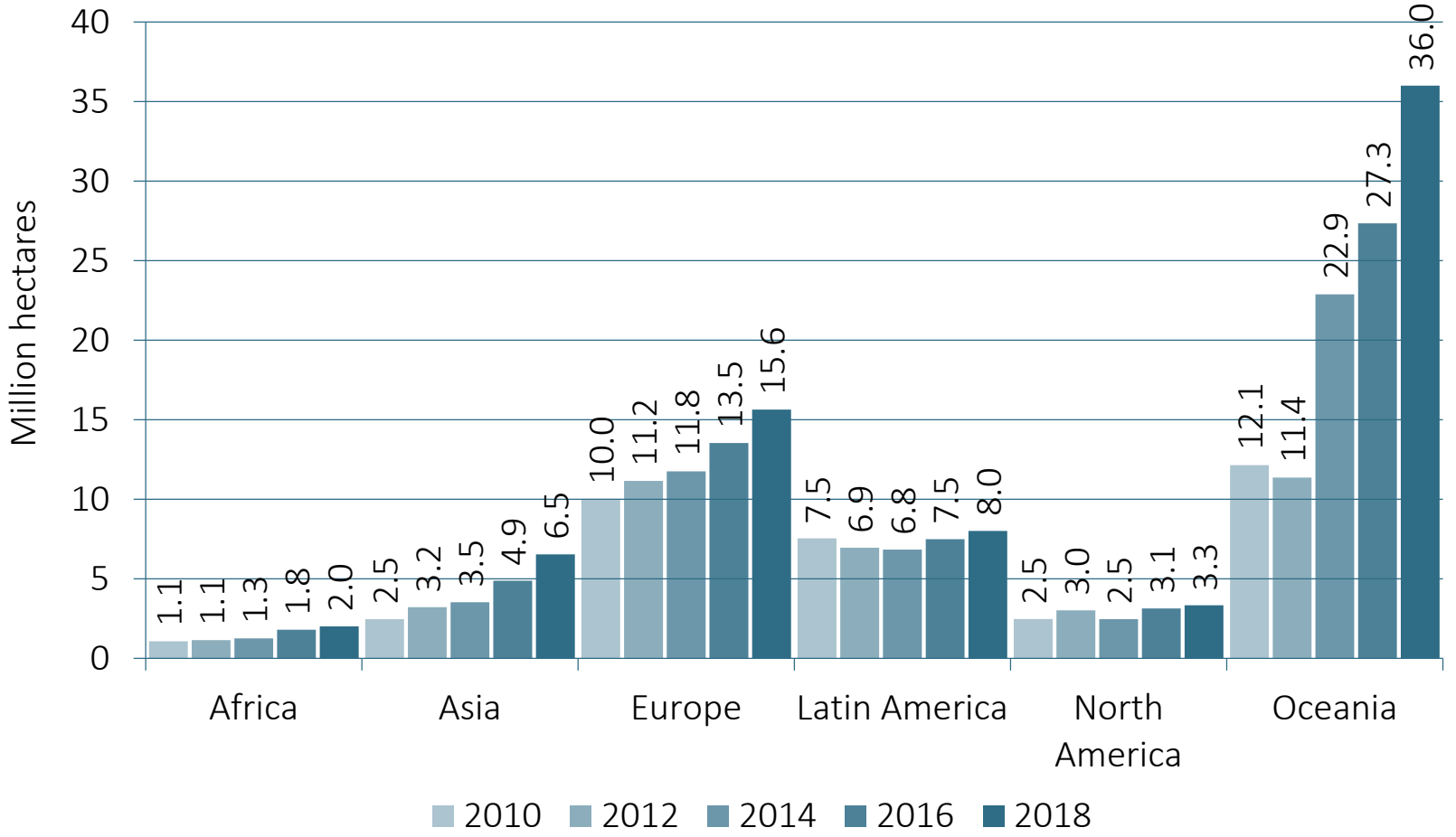
The ten countries with the largest markets for organic food 2018

Source: FiBL-AMI survey 2020



Growth of the organic agricultural land by continent 2010-2018

Source: FiBL-IFOAM survey 2012-2020



Policy development in Europe

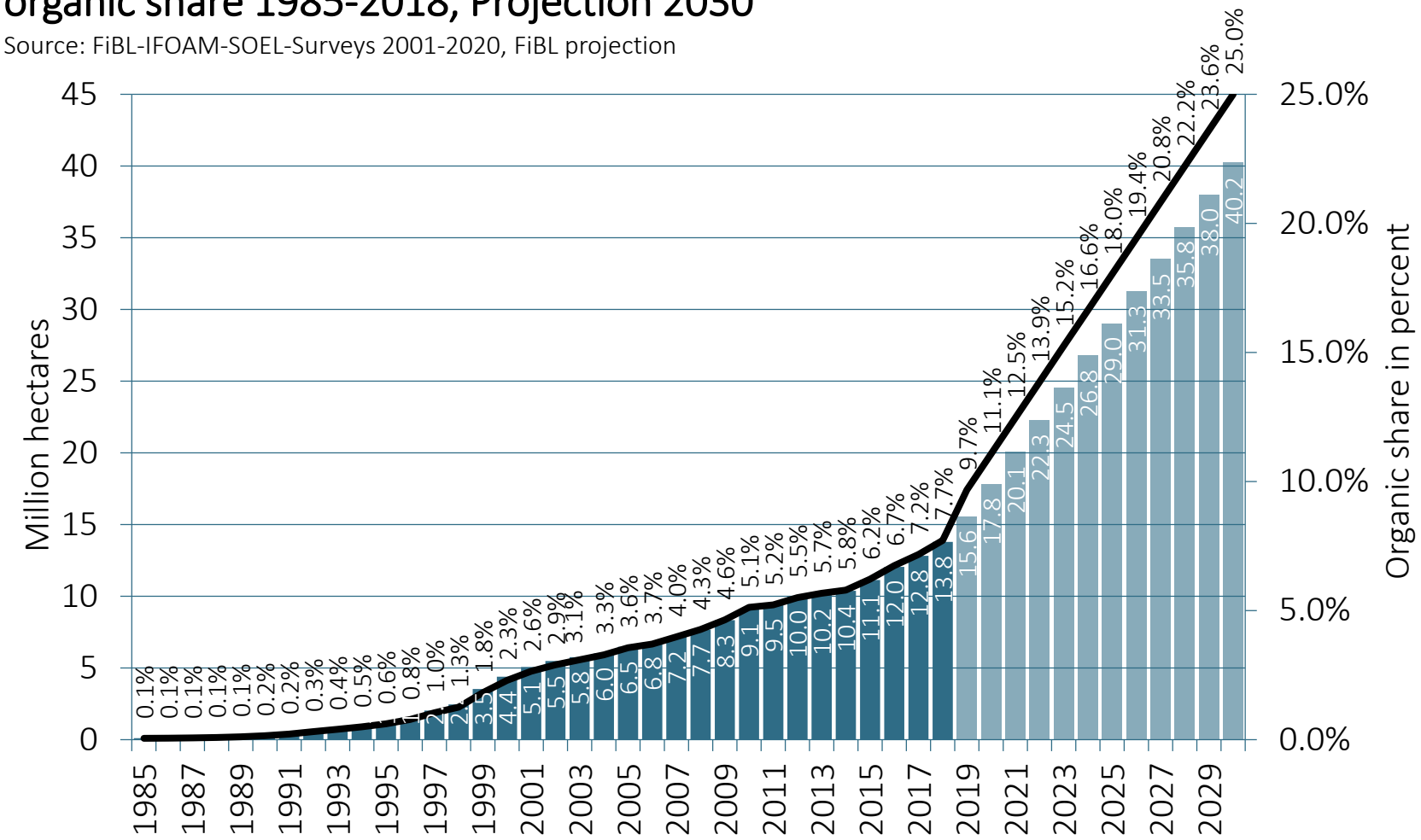
- The European Union Farm to fork strategy:
- The use of pesticides in agriculture contributes to pollution of soil, water and air. The Commission will take action to reduce the use of chemical and more hazardous pesticides by 50%
- Organic farming is an environmentally-friendly practice that needs to be further developed.
  The Commission will help the EU's organic farming sector to grow, with the goal of 25 % of total farmland being used for organic farming by 2030.

- Swiss referendums on pesticide bans ('Trinkwasserinitiative' & 'Sans Pesticides de synthèse'):
- Organic farming and agroecology farming are seen as important instruments in the transition towards a sustainable agriculture

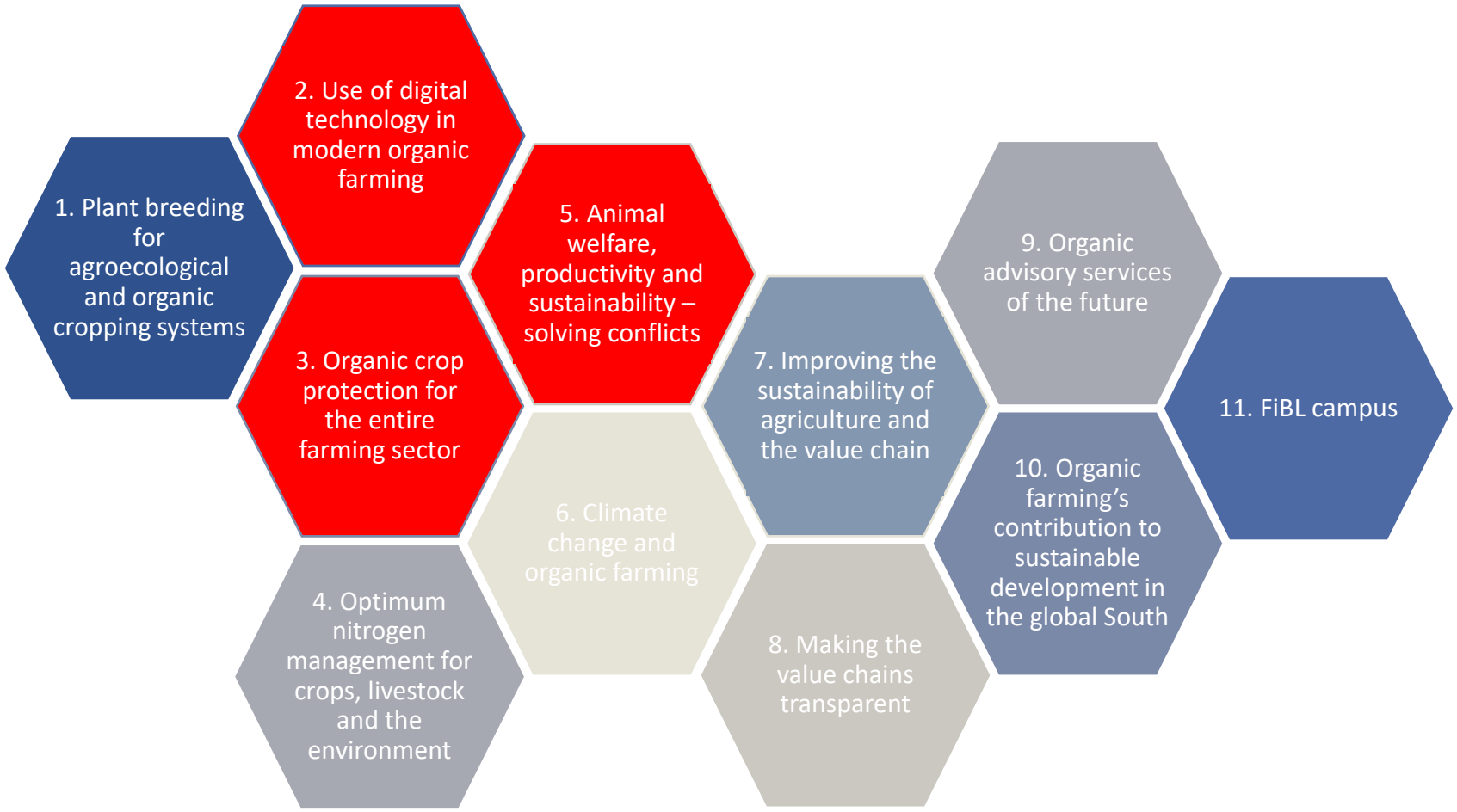
- Programs at national or regional level
- e.g. Action Plan: ‚BIO AUS BADEN-WÜRTTEMBERG" (aim = 30-40% of farmland used for OF)

European Union: Growth of the organic agricultural land and organic share 1985-2018, Projection 2030

Source: FiBL-IFOAM-SOEL-Surveys 2001-2020, FiBL projection



The 11 Core Missions of FiBL 2018 – 2025



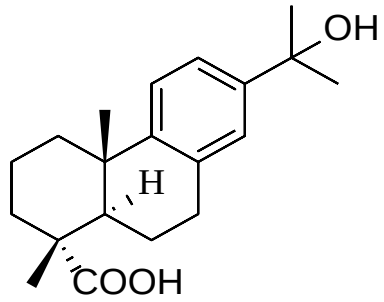
Plant breeding, e.g. Organic Cotton

Precision Farming (e.g. pesticide-free weed control)

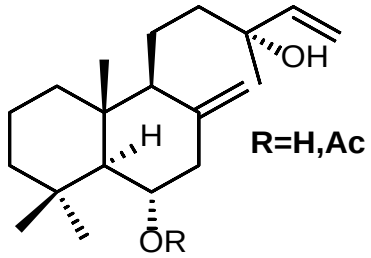
Pest control through biodiversity

Saving orange juice production: Citrus Greening Disease control in Mexico

Crop protecion: development of biopesticides



Larixol



Larixyl acetate

Thuerig B, James EE, Schärer H-J, Langat MK, Mulholland DA, Treutwein J, Kleeberg I, Ludwig M, Jayarajah P, Giovannini O, Markellou E and Tamm L (2018). Pest Managment Science. DOI 10.1002/ps.4733

How can Biocontrol solve major agricultural challenges in the near future?

- Rapid development of MANY tailored and specific novel solutions
- Rapid introduction into farming practice in sufficient quantity

- Rapid and adopted PPP approval systems

Interesting recent developments

- Comparative risk assessment that takes into account the extent of usage of specific active substances.

- Fast track approval processes

Coronavirus treatment + Add to myFT

EU fast-tracks process for Pfizer and BioNTech's Covid-19 vaccine

German group says any accelerated regulatory approval would not dilute safety standards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Regulatory expectations and flexibility (human medicines)
Regulatory expectations and flexibility (veterinary medicines)
The European Medicines Agency (EMA) is providing guidance for medicine developers and pharmaceutical companies to help speed up medicine and vaccine development and approval for COVID-19, and on how they should address the regulatory challenges arising from the COVID-19 pandemic.
Early support for medicine and vaccine developers
EMA encourages developers of potential vaccines or treatments for COVID-19 to contact EMA as soon as possible to discuss their strategy for evidence-generation.
They should email their proposals to 2019-ncov@ema.europa.eu.
Depending on the maturity of development, EMA will set up initial discussions on suitable mechanisms to fast-track development and approval, with priority given to the most relevant proposals.
Establishing contact early in the development process is important for ensuring that developers can submit well-prepared applications and make use of the accelerated procedures EMA has put in place for COVID-19 treatments and vaccines.
Accelerated procedures for COVID-19 treatments and vaccines
Guidance is available for developers of potential COVID-19 treatments and vaccines on the rapid review procedures EMA has put in place to speed up development and approval:
EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines
These rapid procedures can accelerate every step of the regulatory pathway while ensuring that robust evidence on efficacy, safety and quality is generated to support scientific and regulatory decisions.
They are available for initial marketing authorisation applications and extension applications for authorised medicines that are being repurposed for the treatment of COVID-19.
Overview of rapid procedures

Overview of rapid procedures

PROCEDURE	FEATURES
Rapid scientific advice	• Free of charge (in accordance with the decision of EMA's Executive Director) • No pre-specified submission deadlines • Review is reduced to a maximum of 20 days (from 40-70 days) • Flexibility on type and extent of briefing dossier, agreed on a case-by-case basis
Rapid agreement of paediatric investigation plans (PIPs) and rapid compliance check	• No pre-specified submission deadlines • Review of a PIP is reduced to a minimum of 20 days (from 120 days). Exact timeline depends on complexity of PIP and the preparedness by the sponsor to respond to questions • EMA decision following a review is reduced to 2 days (from 10 days) • Possibility for developer to provide a focused scientific documentation, agreed on a case-by-case basis • Compliance check can be reduced to 4 days if necessary
	• EMA's scientific committees (Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Risk Assessment Committee (PRAC)), with the support of th… e available on a rolling basis, while

Allgemein (Fonds FiBL Projekte und Controlling) _ Microsoft Teams

Rolling review

- EMA's scientific committees (Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Risk Assessment Committee (PRAC)), with the support of the COVID-ETF, review data as they become available on a rolling basis, while development is still ongoing
- Several rolling review cycles can be carried out during the evaluation of one product as data continue to emerge, with each cycle lasting a minimum of two weeks depending on the amount of data to be assessed
- Each submission occurs in eCTD format. In addition to the newly available data, this would normally include also an application form, Module 2 overview(s) and responses to all outstanding questions from previous review cycles
- Once the data package is complete, the developer submits a formal marketing authorisation application which is then processed under a shortened timetable

Accelerated assessment

- Can be considered for medicines and vaccines not undergoing a rolling review
- Requires a complete application to be available at the time of submission (unlike a rolling review)
- Review is reduced to 150 days (from 210 days) or less after validation of a complete application

Instruments to accelerate the approval process of vaccines

- Rapid scientific advice
- Rolling review
- Accelerated assessment
- Extension of indication and extension of marketing authorisation

NEWS · 25 SEPTEMBER 2020

COVID-vaccine results are on the way — and scientists' concerns are growing

Researchers warn that vaccines could stumble on safety trials, be fast-tracked because of politics or fail to meet the public's expectations.

Smriti Mallapaty & Heidi Ledford

PDF version

RELATED ARTICLES

Conclusions/outlook

- To meet the ambitious societal goals in agriculture, all processes involved in biocontrol development (R&D, approval) must be accelerated
- COVID-19 demonstrates the feasibility of adoption of fast track procedures
- Substantial resources are needed to facilitate acceleration of registration without compromises to safety

- It is a complex message to convey but COVID-19 may serve as a door opener!

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