



Main challenges for the approval of Bio-solutions in Italy and how Italy is planning to simplify procedures

WEBINAR

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Gerardo Caricato

Vice president IBMA Italia

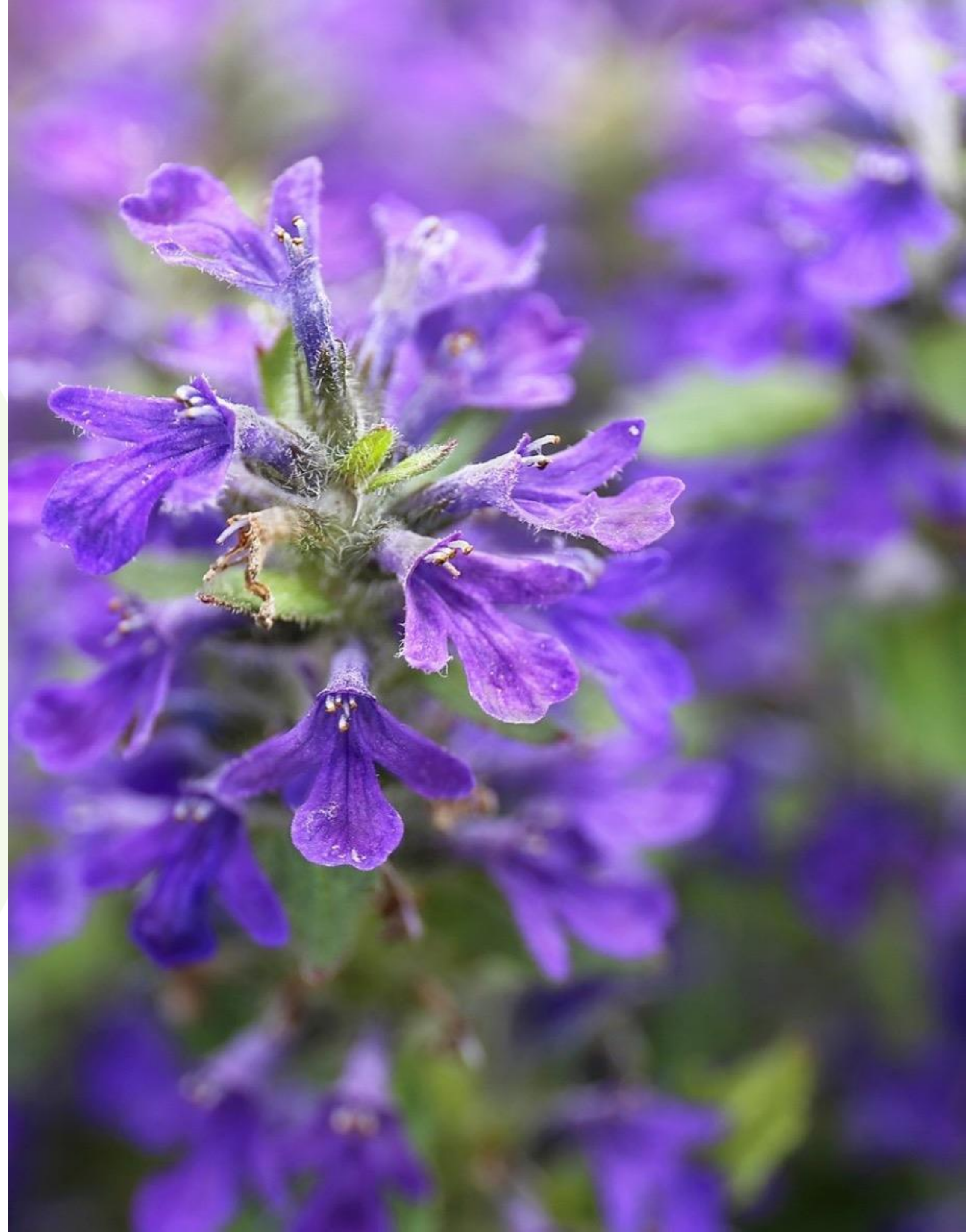
Summary

Biocontrol categories for plants

The different Italian rules

National Actors/Bodies

Conclusions



IBMA: International Biocontrol Manufacturers Association with more than 250 associated companies in Europe

In Italy 30 associated companies (Biocontrol Manufacturers, Test Facilities and Regulatory Consultants)

Biocontrol technologies originate from nature for management of pests, weeds and diseases in agriculture as well as home, garden and forestry. Our Biocontrol solutions achieve the sustainability goals that consumers urgently demand for food safety, human health and protection of the environment.

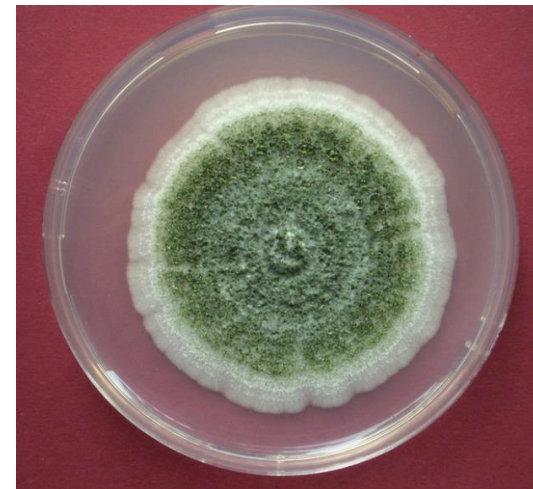
MACROBIALS

INVERTEBRATE BIOCONTROL AGENTS



Invertebrate Biocontrol Agents are natural enemies such as insect, mite and nematode species providing control of pest populations through predation or parasitism.

MICROBIALS



Microbials are based on microorganisms, including but not limited to bacteria, fungi, protozoans, viruses, viroids, mycoplasmas, and may include entire microorganisms, living and dead cells, any associated microbial metabolites, fermentation materials and cell-fragments.

NATURAL SUBSTANCES



Natural Substances consist of one or more components that originate from nature, including but not limited to: plants, algae/microalgae, animals, minerals, bacteria, fungi, peptides, protozoans, viruses, viroids and mycoplasmas. They can either be sourced from nature or are nature identical if synthesized. This definition excludes semiochemicals and microbials.

SEMIOCHEMICALS



Semiochemicals are substances emitted by plants, animals and other organisms used for intra-species and/or inter-species communication and have a target-specific and non-toxic mode of action.

Biocontrol Products: 4 categories under different Rules



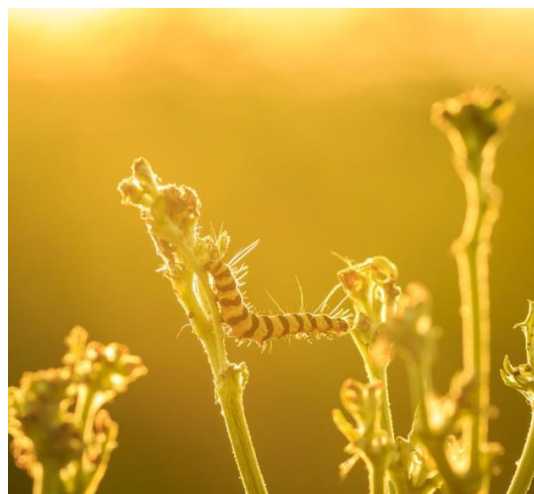
IBMA recently updated the definition of Bioprotection as the global term for all Biocontrol technologies

IBMA Italia is working to introduce a regulatory domestic definition of Biocontrol / Bioprotection and formally applied for it

Currently in the Italian rules we can find definition only for Pesticides/Plant Protection Products (including Basic Substances), Fertilizers and Strenghtners/Corroborants

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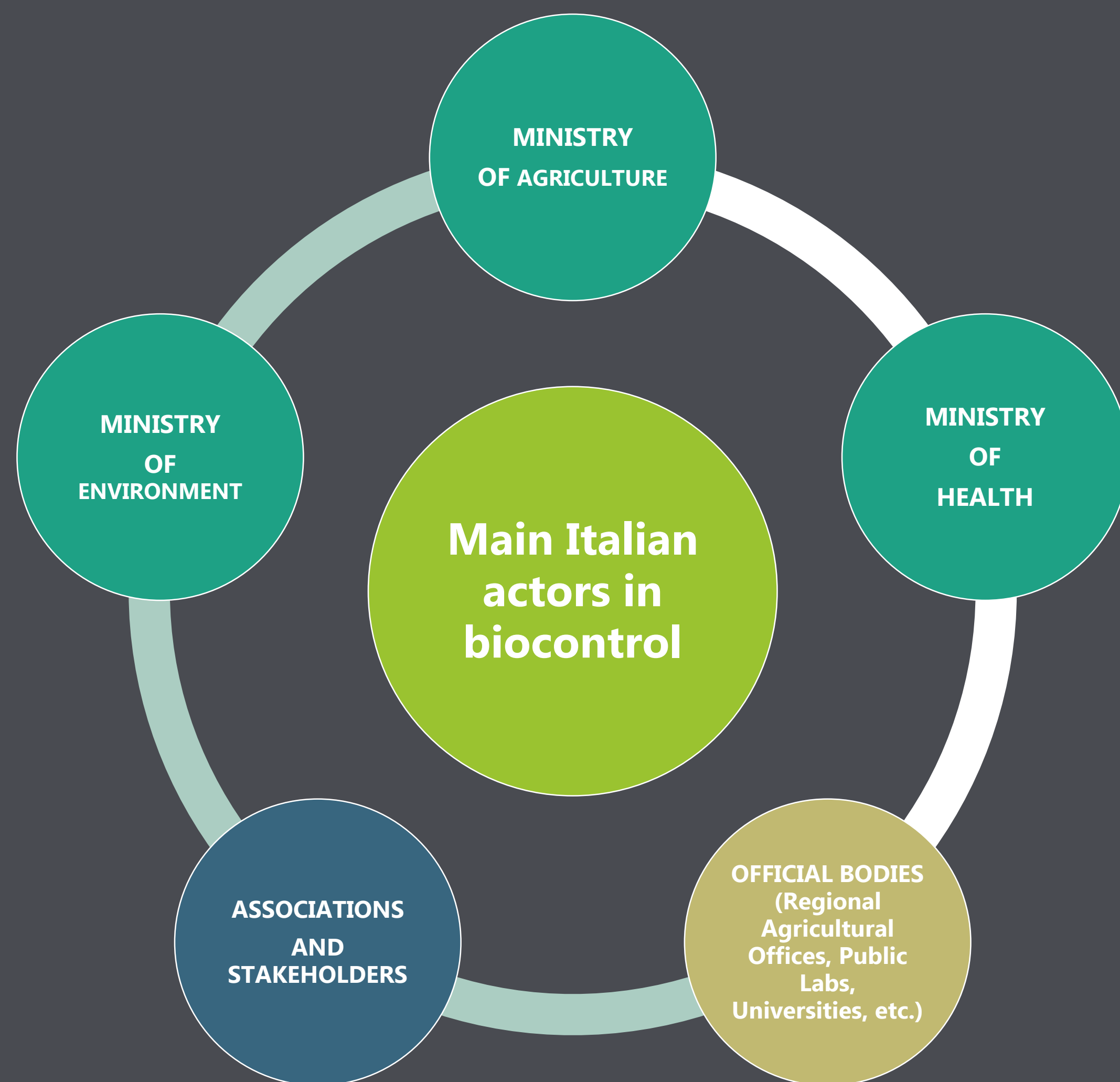
NATURAL SUBSTANCES



SEMIOCHEMICALS



Bicontrol Category	IPPC (International Plant Protection Convention) Guidelines on beneficials	Plant protection products Reg. EU 1107/2009	Fertilizers Reg. EU 1009/2009	National fertilizers Law D. Lgs 75/2010	National Strengtheners / Corroborants Law DM 6793/2018
Macrobials	X				
Microbials		X	X	X	X
Natural substances		X	X	X	X
Semiochemicals		X			X



Criticisms

Lack of an official definition of biocontrol in national rules and cases of dual use products (copper, acetic acid, ecc)

High number of different actors

Different Rules/Regulations on:

- PPPs including Basic Substances
- Fertilizers
- Strengtheners (Corroborants)

Recent events

Training for the development of Biocontrol addressed to technicians and farmers with the partnership of the Union of farmers (CIA) and the Researcher Association (AIPP).

Partnership in the first National Biocontrol Conference (November 2021). The second edition in October 2022.

Meetings and working groups at the Ministry of Agriculture level for a formal and legal definition of Biocontrol/Bioprotection in the framework of Italian rules.

Conclusions



- There is a lack of legal definition for biocontrol in Italy even if we requested for amendment of NAP (National Action Plan) which is expected in few months.
- All stakeholders underlined the need of a new bioprotection specific regulation covering all biocontrol categories.
- Still unclear scenario about the registration process of biocontrol products, due to the coexistence of national regulations that are not repealed by the EU regulations.
- Need of a common framework at the authority level with a dedicated evaluator body for biocontrol products.
- We are confident in a soon positive response by the authorities in simplifying procedures.

Thank you for your attention



Char

Giacomo De Maio

direzione.ibmaitalia@ibma-global.org



Vice Char

Gerardo Caricato

direzione.ibmaitalia@ibma-global.org



Secretariat

Francesca Antonazzo

amministrazione.ibmaitalia@ibma-global.org