CONCLUSIONS

• Introduction and use of a biological control agent is potentially subject to a wide range of different types of regulation and recommendations.

• Internationally these include the IPPC, the CBD (provisions on IAS and on ABS), and OECD guidance on biopesticides

• At EU level relevant regulations include those aimed at plant pests, invasive species, marketing of pesticides and protection of habitats

• The first three of these EU regulations have been recently amended, and further amendments to accommodate biological control agents are unlikely in the near future

• Implementation at national level varies considerably, even within EU

• Inappropriate implementation of regulations (the wrong regulation, or the implementation in a way which is not tailored to the specifics of use of biocontrol agents) risks losing the opportunity for significant benefits from increasing use of biological control agents for crop protection and for reducing environmental damage from invasive pests (including plants). For example it endangers the possibility of BCA making a significant contribution to the National Action Plans under the Sustainable Use Directive

• Evidence of real problems from use of properly authorised biological control agents is very limited – generally BCAs have demonstrated their safety over a long period

• Technically there is a strong case for an eco-regional approach to regulation because BCAs may spread across national borders

• EU Member States have not yet introduced tailored regulations for biological control agents at EU level despite opportunities to do so

• EPPO Member Countries have previously decided against establishing a ‘First Release Expert Group’ at EPPO level

• IBMA have recommended against regulating at EU level

• There is scope for ‘soft harmonisation’ at EU or EPPO level through more guidance and establishment of an independent expert review mechanism
RECOMMENDATIONS

• Guidance is needed on which regulations should be applied in which cases (e.g. the scenarios presented at this workshop). EPPO/IOBC and EU (SUD Steering Group) could have a role in this.

• Common definitions would be useful (e.g. indigenous)

• National authorities should be encouraged to establish effective co-ordinating mechanisms to ensure a coherent respond to requests to use and release BCAs (e.g. between authorities responsible for environment, agriculture and health regulation)

• Proposed releases of BCAs should be discussed early on with the national authorities in order to agree host test lists etc. in advance

• More harmonisation should be achieved through recognition and use of existing EPPO guidance, additional guidance where needed, sharing of information on applicable regulations and on specific applications for releases (subject to the need for commercial confidentiality) between regulators in neighbouring countries, and development of a form of “mutual recognition” between countries with similar conditions

• An independent expert review group for applications at European level should be explored again, building on EFSA’s experience at reviewing the evidence on release of a non-native BCA against an invasive acacia in Portugal

• A distinction should be made between agents expected to establish (normally introduced with the intention of classical biological control) and agents not expected to establish (normally introduced on a commercial basis as augmentative control)

• Decisions on import and release of BCAs should be made in the context of a background level of introductions of new organisms to the EPPO region and their spread within the region. Not all of that spread of organisms can be avoided – particularly within the EPPO region across land borders

• Potential use of biological control should be included in contingency planning for arrival of new pests in the EPPO region, so that some of the information needs and regulatory hurdles can be addressed in advance

• Some of this contingency planning should take place at a European level

• Fast track procedures should be considered for emergency situations

• The Euphresco research funders and managers network offers one way in which research on biological control options might be co-ordinated between countries to which a pest is native (or where it is well established) and countries to which that pest is likely to spread

• Analysis of a proposed release should include the environmental, economic and social benefits as well as risks including:
  - benefits from reduced environmental damage by the target pest
  - benefits from reduced use of other control options, including operator exposure and reduced MRL exceedences
  - other benefits e.g. human health benefits from control of allergenic plants and pests

• Benefits and risks should be quantified where possible, even though there may be a large measure of uncertainty e.g. about the efficacy of a classical BCA

• Inclusion of benefits in the analysis requires some evidence of efficacy

• Information should be exchanged between national authorities on the spread and impacts of BCAs which have been released (with or without authorisation)