Norwegian information requirements for authorisation of IBCAs [1]

Because the information and/or data needed tend to be very case specific to individual IBCAs, it is suggested that the applicant discusses requirements with the regulatory authority. This is particularly important for weed IBCAs and nematodes.

Product information	
	State all ingredients in the product Product label (in Norwegian) has to be submitted
Registration in other countries	
	In which other countries in Europe and North America is the organism registered?
1. Information required for characterisation and identification	
1.1	Accurate identification, including name of identifier or, where necessary, sufficient characterisation of the agent to allow its unambiguous recognition: · order, family, genus, species (including scientific authority) and, where appropriate, subspecies, strain, type (synonyms should be included); · letter from recognised (by receiving country) scientific authority stating the identity of the organism; · general diagnostic description of all life stages of the agent, including details on any taxonomic difficulties with the group (e.g. species complexes, cryptic species, poorly studied group); and · known molecular information (e.g. unique microsatellite markers) used for diagnosis, especially of species complexes or cryptic species.
1.2	(a) Information on origin of organism (species or lower taxonomic level): · if field collected, see 1.2 (b) below; and · if from laboratory culture, information on the number of individuals in the founder population, and the number of generations in the culture.
	(b) Where the culture was originally collected: · latitude, longitude of field location; · description of original habitat and host(s) from which collection was made; and · description of time of year when collection was made.
	(c) Immediate source of organism (where it was produced): · name of organisation providing organism; and · country, city where production facility is located.

[1] Based on the OECD information requirements (Guidance for Information Requirements for Regulation of Invertebrates as Biological Control Agents (IBCAs), 2003)

1.3	Available information on distribution, dispersal, biology, host range/specificity, host preference, natural enemies, physical requirements for establishment and distribution, requirements for survival and reproduction: · known geographical and ecological areas where agent naturally occurs; · known regions where agent has been introduced intentionally or accidentally; · potential for dispersal (e.g. good/poor flier, presence of alternate hosts in the wild, known migratory behaviour); · detailed description of biology, including description of all life stages, reproductive potential, · details on natural enemies known to attack the agent; · details on hosts, habitats and climatic conditions favourable for establishment and dispersal of the agent; · biological (including extreme) conditions in which there is potential for agent survival and reproduction; · list of known hosts other than the target; · list of non-target organisms that have been tested; · details on the methodology used to determine host range, including experimental design, experimental conditions of tests, rearing methods for non-target species, life stage(s) tested, statistical tests used, etc.; and · statement of potential host range, including limitations of testing methods.
1.4	Natural enemies of candidate agent or contaminants of candidate agent or rearing hosts/prey, and procedures required for their elimination from lab colonies if necessary: · details on the biology of predators, parasitoids (hyperparasitoids), pathogens or commensal species in the native habitat that might be carried on the candidate agent or rearing hosts/prey to the region of introduction; and · procedures used to ensure purity of the agent before shipment to the recipient (e.g. washing surface of cocoons/mummies with fungicide, removal of individuals with mites).
1.5	Available information on specific characteristics of strain (e.g. resistance to pesticides, mutants): · description of special characteristics (e.g. pesticide resistance, cold hardiness, aggressive searching capacity of the source culture).
2. Information for assessment of safety and effects on human health	
2.1	Provide available information on relevant hazards to human and animal health that may be posed by the use of IBCAs during and following introduction (for example, allergy, skin irritation, disease vectors).
2.2	Summary of information for assessment of safety and effects on human health.

3. 3. Information for assessment of environmental risks	
3.1	Identify any potential hazards posed to the environment by IBCAs, including:
	(a) available information on the role of the agent in original ecosystem, the type of natural enemy (parasitoid, predator, pathogen), type of organisms it attacks, effect of attack on target and non-targets, intraguild effects, higher up trophic level effects, and effects on ecosystem;
	(b) available information on existing natural enemies of the target organism in the area of release; and
	(c) available information on non-target effects from previous use of IBCAs in biological control.
3.2	Host range testing
	(a) Available information and/or data on possible direct effects: · on non-target host/prey related to target host (phylogenetically or ecologically related); · on non-related non-target hosts, such as threatened and endangered species; · concerning competition or displacement of organisms; · concerning potential for interbreeding with indigenous natural enemy strains or biotypes; and · on plants (target crop and non-target plants).
	(b) Available information and/or data on potential of establishment and dispersal of biological control agent.
	(c) Available information on and/or data on possible indirect effects.
	(d) Available information (from rearing facility or from the field) on the ability of the IBCA to carry viruses or micro-organisms that can negatively affect non-target organisms.
3.3	Available information, and/or data on potential host/ prey range in areas of release and potential distribution of the IBCA.
3.4	Available information on environmental benefits (e.g. beneficial effects of release of IBCAs compared to current or alternative control methods).
3.5	Summary of information for assessment of environmental risks.
4. Information for assessment of efficacy	
4.1	Information relevant for determining the efficacy of an IBCA should be provided.
4.2	Information on methods for the evaluation of quality and purity (quality control) of IBCAs.
4.3	Information on benefits of use of IBCAs.
4.4	Summary of information for assessment of efficacy.

Footnote: Recommend that companies which produce IBCAs report any adverse effects from IBCAs on non-targets to regulatory authorities.