

# THE ARGUMENT FOR SPECIFIC PROTECTION GOALS IN BIOCIDAL PRODUCTS RISK ASSESSMENTS – case studies

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The lack of progress in the development of Specific Protection Goals (SPG) within the Biocidal Products Regulation (BPR) has been having a detrimental impact on product development, investment and registrations.

For product use resulting in i) temporal exceedance, ii) a limited impact area, iii) impact on land use not permitting ecological viability or iv) protection to human health, standard BPR risk assessment approaches (Predicted Environmental Concentrations less than Predicted No-Effect Concentrations) may be less appropriate. **Currently, decision on acceptability may be determined on a case-by-case basis.** This results in a high level of uncertainty as to the acceptability of the dossier, which makes it difficult to invest, and a reluctance to generate relevant data.

An EU position on SPG would assist stakeholders in designing scenarios consistent with a product's purpose, and provide a framework within which understanding of each product's potential impacts and benefits could be improved.

## Case study 1: Vector Control treatments, required to safeguard public health (see urban outdoor scenario<sup>1</sup>)

A definition of pathways to consider and the level of impact that may be tolerated to safeguard human health, would allow an appropriate cost/benefit assessment of life-saving products.

## Case study 2: Aquaculture products, necessary to support food production (see marine plume scenario<sup>2</sup>)

A definition of the benthic level, community species and geographic zones to be protected would help in the design of relevant scenarios and derivation of appropriate endpoints.

## Case study 3: Garden treatments, supporting the socio-ecological benefits of urban outdoor spaces

An EU position on acceptable level of temporal exceedance, tolerable effect on individuals, populations, and on benchmark species to be protected would help in designing a relevant scenario (see conceptual garden scenario<sup>3</sup>). Temporal exceedance in the treated area is expected for some products, for example ant nest or wasp nest treatments (product type 18) or patio treatments (product type 2), to achieve efficacy. This may be better evaluated through the use of field studies or through the development of population models. However, without a clear description of regulatory requirements, it is not possible to invest in defining an appropriate scenario.

An individual-based population model was developed to illustrate gaps in guidance that would need to be filled to exploit the potential of ecological modelling. The model was derived from the ALMaSS bembidion model<sup>4</sup> and coded in C# within the Unity platform.



Figure 1: Screenshot of an instance of the model.

All individuals are at the adult stage on the represented day. Each is represented with a different colour to easily observe behaviour – currently settling in an hibernation habitat.

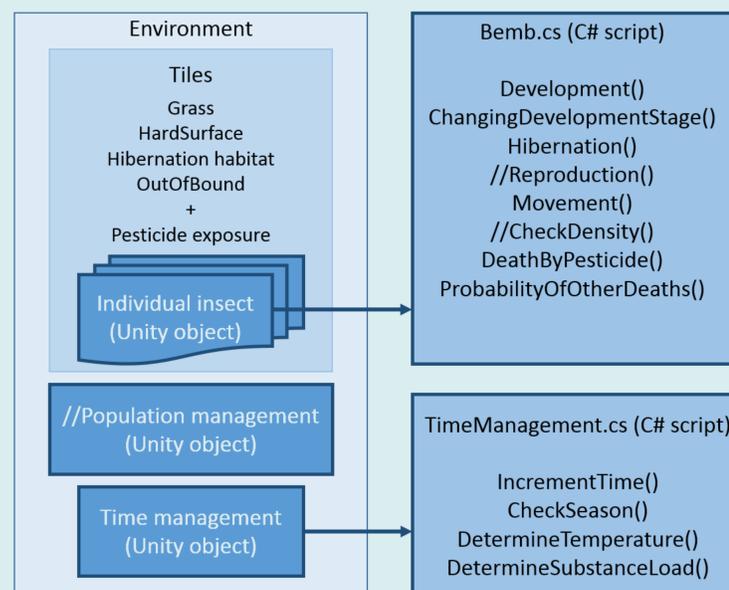


Figure 2: Main Unity objects, C# scripts and methods associated with the environment and individuals' behaviour. Elements in development at the time of writing the poster are indicated by preceding "//". The model is currently simulating a single generation.

SPG may provide definitions for:

- What garden and urban environments should serve as models. **e.g. size and number of plots, structure, variety**
- What organisms should be the protection targets. **e.g. based on substance toxicity, the most sensitive representative species may be selected. Work is required to establish models of behaviour and development, inc. review of/carrying-out ecological studies**
- When does the level of impact become unacceptable. **e.g. level of detectable impact on individuals, or on the population**
- What type of recovery may be considered as acceptable. **e.g. at the level of individuals, internal populations (single garden) or external populations (urban area)**

## REFERENCES AND FURTHER READING

- [1] Fabienne Ericher, 2016. SETAC poster: Outdoor use of biocidal products – considering contaminated rainwater pathways in the urban context and potential for harmonisation - [Link](#)
- [2] Fabienne Ericher and Jacqui Carnall, 2017. SETAC platform: Challenges in exposure modelling of fish veterinary medicines - [Link](#)
- [3] Fabienne Ericher, 2016. SETAC poster: Example of a conceptual garden scenario and potential for ecosystem services and ecological modelling to support the regulatory process - [Link](#)
- [4] Chris J. Topping, 2009. ALMaSS Bembidion ODDox Documentation Dept. Wildlife Ecology, National Environmental Research Institute, Aarhus University, DK-8410, Roende, Denmark 15th February 2009; [https://projects.au.dk/fileadmin/dmu.dk/en/animalsplants/almass/ALMaSS/Carabid\\_B/index.html](https://projects.au.dk/fileadmin/dmu.dk/en/animalsplants/almass/ALMaSS/Carabid_B/index.html)
- [5] ECHA/EFSA Topical Scientific Workshop on Soil Risk Assessment 7-8 October 2015 [https://echa.europa.eu/documents/10162/22816427/soil\\_risk\\_assessment\\_bog\\_summary\\_en.pdf/87727171-6858-4bcb-8429-a6c2d59660a3](https://echa.europa.eu/documents/10162/22816427/soil_risk_assessment_bog_summary_en.pdf/87727171-6858-4bcb-8429-a6c2d59660a3)
- [6] EFSA Scientific Committee, 2016. Guidance to develop specific protection goals options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services. EFSA Journal 2016;14(6):4499, 50 pp. doi:10.2903/j.efsa.2016.4499