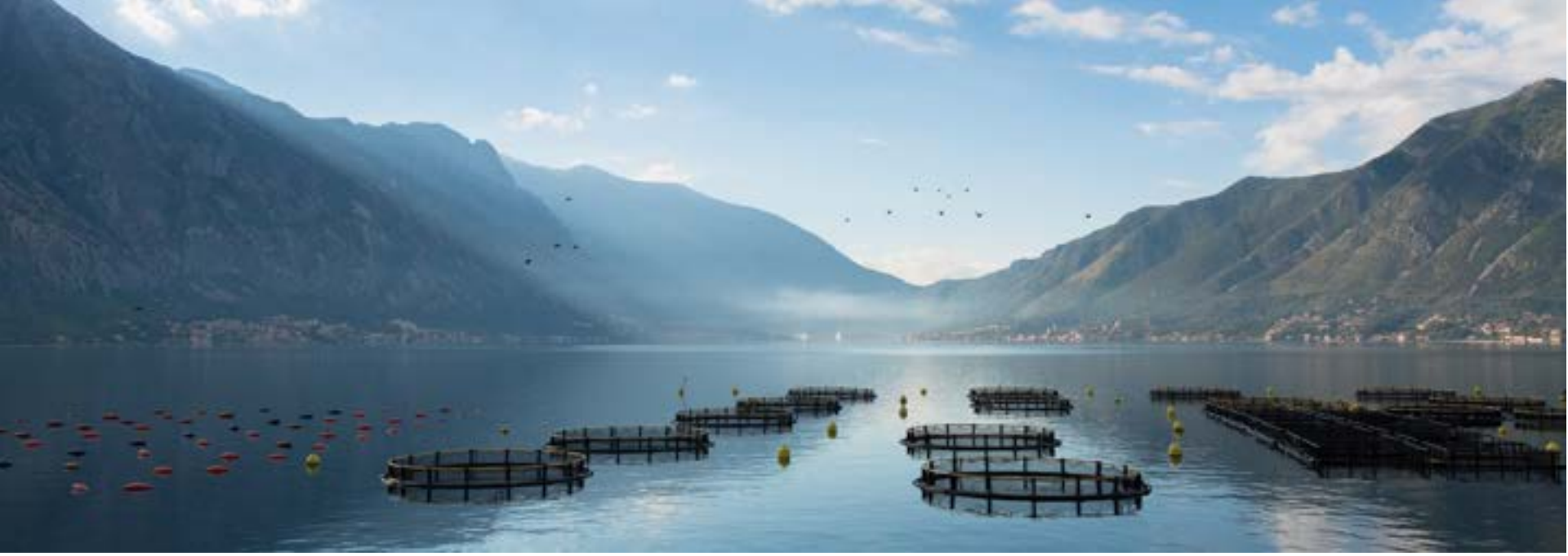


Challenges in exposure modelling of fish veterinary medicines

Fabienne Ericher, Jacqui Carnall

SETAC, Brussels, 9th of May 2017

Cambridge Environmental Assessments

Content

- Current risk assessment framework
  - Guidance
  - Exposure scenarios
  - Models available
- Proposed approach
- Areas for improvement

EU Guidance
Environmental impact assessment

- 2000: VICH GL06 – Phase I
- 2005: VICH GL38 – Phase II
- 2008: EMA guideline (revised 2016)
- 2016: EMA Q&A

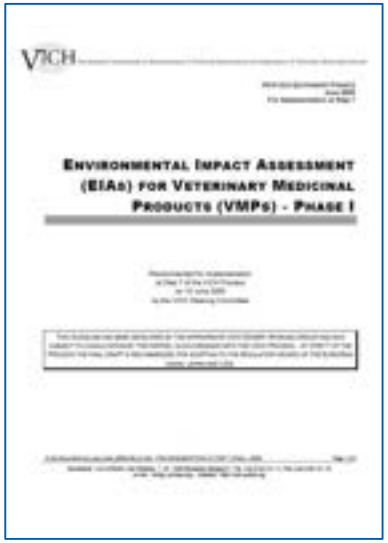
Also…
- EFSA 2007 – Opinion paper on animal feed
- EMA 2012 – Reflection paper on risk-mitigation measures
- EMA 2016 – Guideline on PBT and vPvB substances

→ Clear guidelines for terrestrial use
Recommendations for aquaculture

→ To be released for consultation (Q2 2017):
Reflection paper on environmental risk assessment of veterinary medicinal products used in aquaculture

EU Guidance
General framework

GL06 (Phase I)



Confined facility? no
Effluent can be treated
Discharge controlled

yes

EICaquatic <0.1µg/L no

yes

STOP

GL38 (Phase II)

Tier A

If risk is identified

Tier B

PEC vs. chronic PNEC

- Phase I serves as a screening step
- Phase II based on the comparison of predicted environmental concentrations (PEC) with predicted no-effect concentrations (PNEC)

EU Guidance
General framework (Phase II)

Exposure

Mathematical models

Risk

PEC / PNEC

Must be <1

AF

Hazard

Ecotox endpoints (Testing)

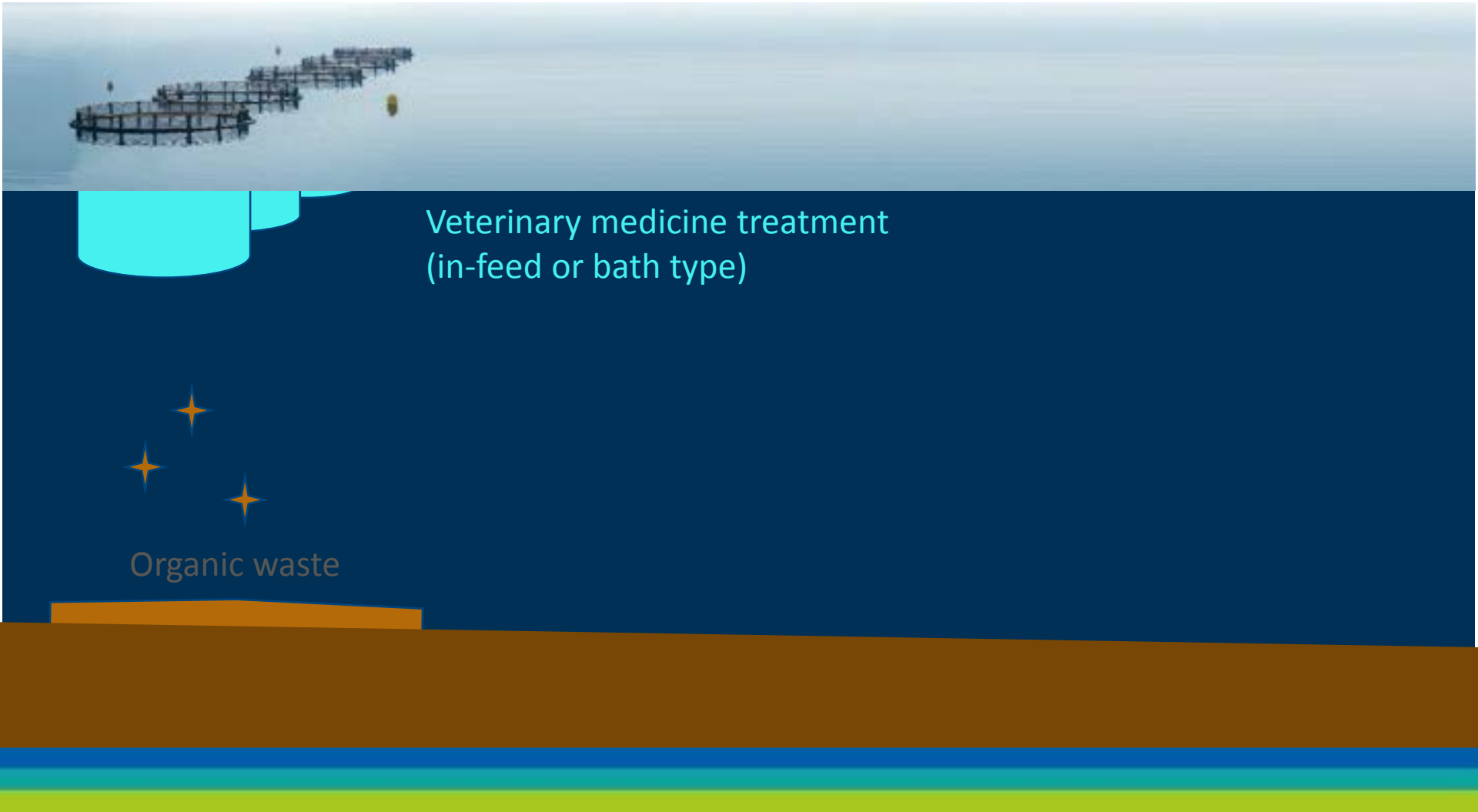
PEC calculation advice in EMA guidelines:
Use of models designed by the Scottish Environmental Protection Agency (SEPA)

How?

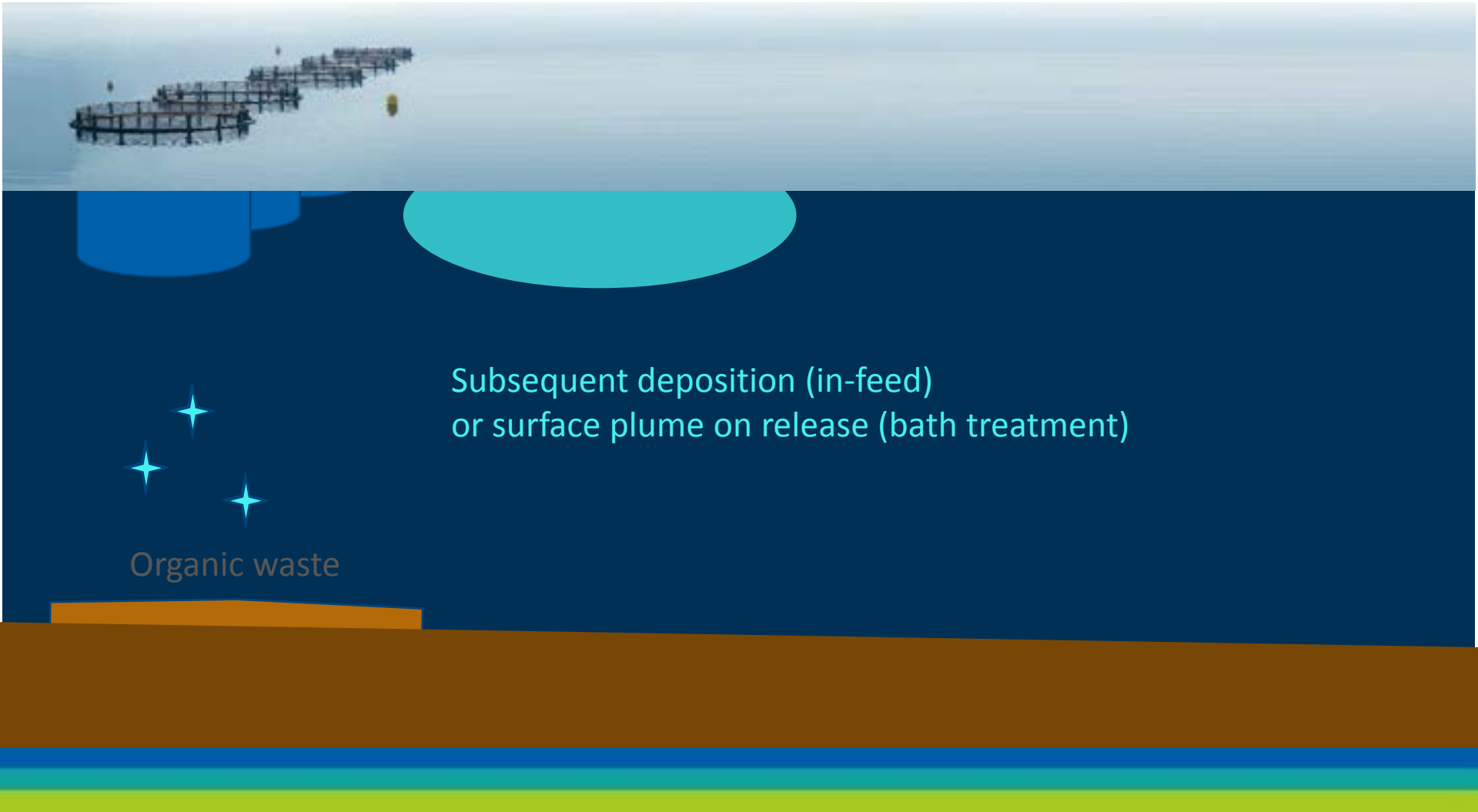
PNEC calculation rules described in GL38:

Tier A	standard acute testing and large assessment factors (AF)
Tier B	refinement options (inc. chronic testing and smaller AF)

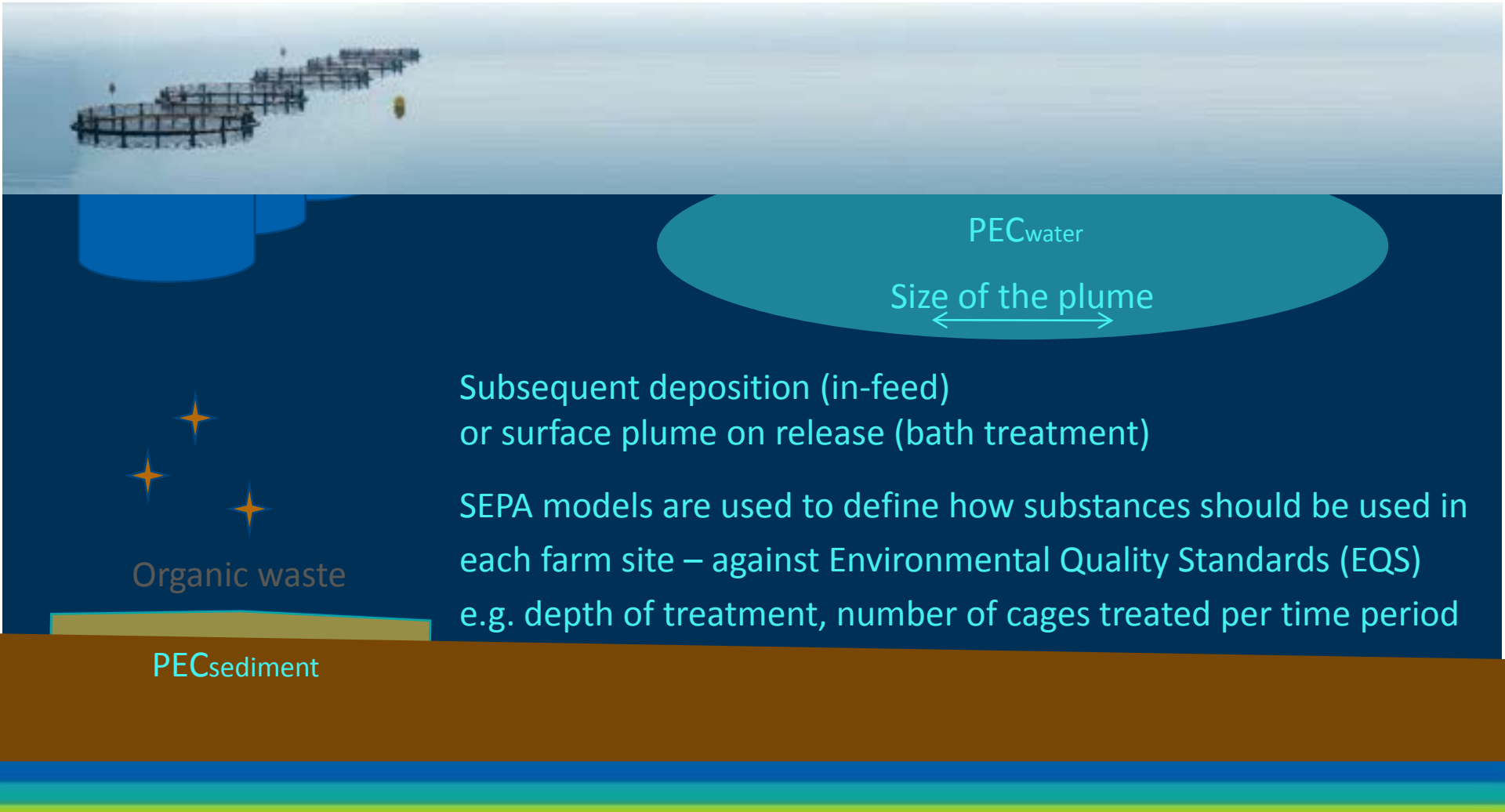
Exposure scenarios
Conceptual model



Exposure scenarios
Conceptual model



Exposure scenarios
Conceptual model



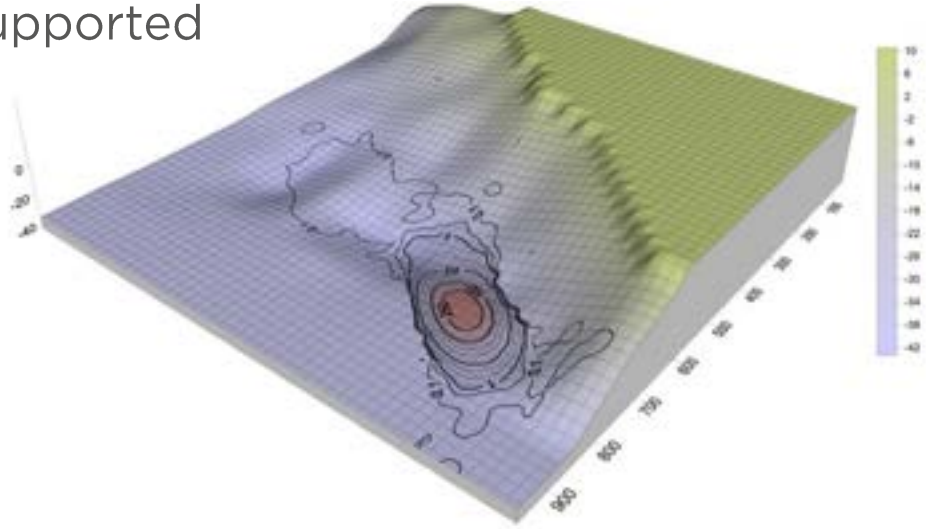
Subsequent deposition (in-feed)
or surface plume on release (bath treatment)

SEPA models are used to define how substances should be used in each farm site – against Environmental Quality Standards (EQS)
e.g. depth of treatment, number of cages treated per time period

Exposure models
Depomod (PEC$_{sediment}$)

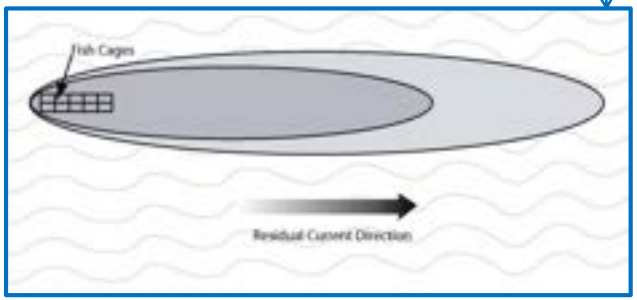
- Typically, AutoDepomod is used by SEPA and farm owners to determine the farm's footprint
- The original model, Depomod, has added functionalities
- Can be used to determine concentration from in feed treatments and substances where fish faeces is a significant pathway
- Degradation in sediment is supported

Mostly relevant to substances of high Koc and in-feed products



Exposure models
Bath treatment (PECwater)

where $s \geq w$	$A = \pi.L.w$
where $s < w$	$A = \pi.L.w-(L.w.ACOS((w-s)/w) - L.(w-s).\sqrt{(1-((w-s)/w)^2)})$

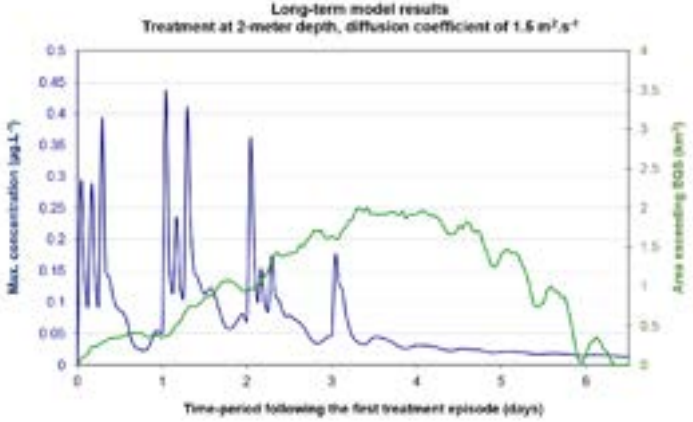


Short-term model

- Simple site parameters
- Maximum PEC value to be compared with a 3hr-EQS or a 6hr-EQS (Environmental Quality Standard)

Long-term (MLA*) dispersion model

- Detailed current data and farm info
- Maximum PEC value to be compared with a MAC (Maximum Allowable Concentration) after 72hr
- Area exceeding a longer-term EQS (72hr-EQS) to be compared with a maximum threshold value



*Marine Laboratory Aberdeen

Exposure models

There are 2 obstacles to the use of the tools:

- The use is site-specific rather than generic
- PEC are meant to be compared with EQS

Proposed approach
From site-specific to generic

No MS or EU approved scenario available

For a generic risk assessment, our dataset combines:

- Conservative farm specifications
  e.g. 90th percentile in size
- A range of country-specific environmental conditions
  inc. tidal amplitude, residual current, depth

Potential for EU registration to be used to indicate combinations of environmental conditions and farm specs where risk is controlled

Can be followed by a site-specific discharge consent licencing scheme

Exposure models

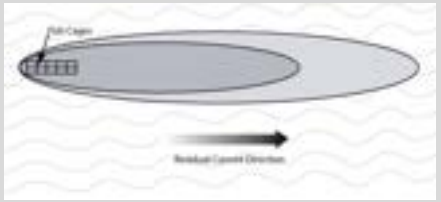
There are 2 obstacles to the use of the tools:

- The use is site-specific rather than generic
- PEC are meant to be compared with EQS

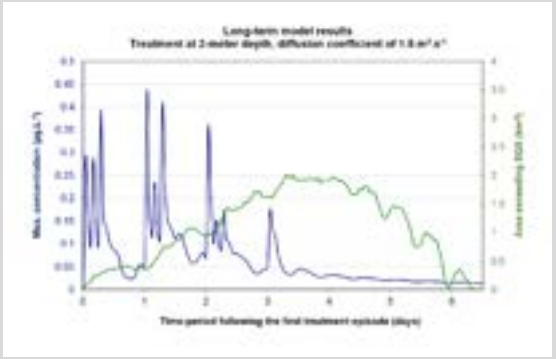
Proposed approach
From EQS to PNEC

PEC

Short-term model



Long-term model



Tier A

Tier B

PNEC

Substituting 3 or 6hr-EQS for Tier A PNEC (acute)

Substituting 72hr-EQS for Tier B PNEC (chronic)

PNEC value required by the model

Challenges
Standards and purpose

PNEC derivation

- *Aim: No observed effect*
- *Assumption: exposure is constant*
- *Each standard represent a Tier*

Example: freshwater invertebrates

Acute daphnia study
OECD 202: 48hr EC50 → AF 1000 → **Tier A** PNEC

Chronic daphnia study
OECD 211: 21 days NOEC → AF 10 → **Tier B** PNEC

EQS derivation

- *Aim: Limited local effects on non-target organisms*
- *Assumption: exposure is intermittent*
- *Each standard represents a snapshot (temporal and geographical)*

Example: azamethiphos (source: SEPA, 1998)

5 hr NOEC → AF 10 → 3-hr EQS = 250 ng/L

To be used with the short-term model

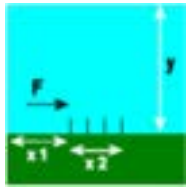
70 hr EC50 → AF 10 → 72-hr EQS = 40 ng/L

To be used with the long-term model

Should standards at the EU level be reviewed for aquaculture, to make sure we are making best use of the models, with appropriate protection goals in mind?

Other EU frameworks

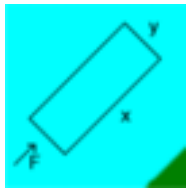
Other regulatory frameworks look at the marine environment but address different patterns of use and different concerns



Biocide

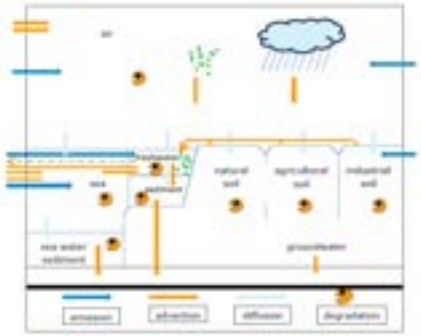
The MAMPEC model is commonly used for marine assessment

- Service-life release i.e. Product type 21: Antifouling substances on fish farm nets, (Norwegian Environment Agency, 2015)
- Background concentrations from several point-source i.e. Product type 11/12: Off-shore oil exploration industry, (NL, 2015)



REACH

The SimpleBox model considers chemical flux to and from the marine compartment at the regional and continental scale,
inc: adsorption, degradation, sedimentation and transfer to the atmospheric compartment



Conclusion

- The proposed approach has been favourably evaluated
- Technical guidelines would be helpful to reduce uncertainty - *2017 reflection paper?*
- Review of the standards and purpose of the approach would be helpful - *2017 reflection paper?*

  e.g. do they meet the protection goals, are standards appropriately set in view of the expected zones of impact and organisms behaviour? better clarity on the requirements for sediment assessment

- Future developments for the proposed approach

  Use of an extended MLA model
  e.g. better understanding of the exposure pattern – *see our poster* -

Meet us on Booth 11

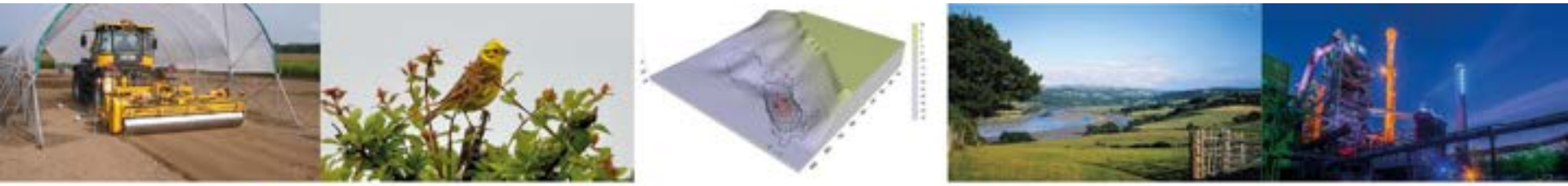
Contact the author: Fabienne.ericher@cea-res.co.uk

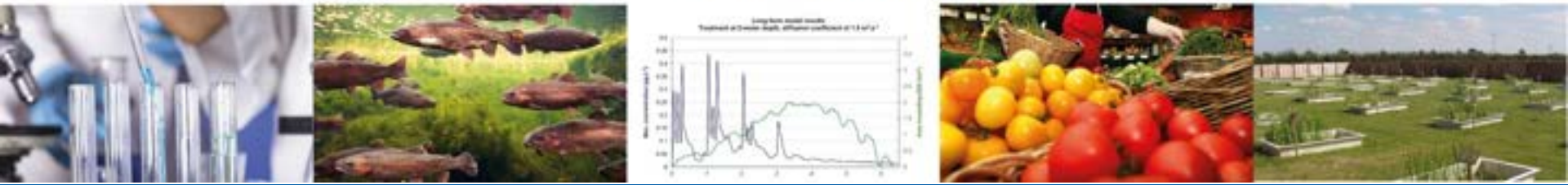
Find more information on our website:

www.cea.adas.co.uk

You can also now follow us on LinkedIn:

https://www.linkedin.com/company/cambridge-environmental-assessments



Cambridge Environmental Assessments

providing novel solutions for an increasingly demanding regulatory world