Protection goals and conceptual models: How science can support risk managers on what to protect?

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TSW on Soil Risk Assessment
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INTRODUCTION TO TOPIC I

Problem Definition and Conceptual Model for Soil Risk Assessment

- **Protections goals and ecological relevance**
  - Setting Specific Protection Goals through ecosystem services
  - EFSA approaches and future developments
- **Soil risk characterisation and environmental impact assessment.**
  - Screening/lower tier: applicability of EPM
  - Higher tiers: SSD; ecological modelling
  - Current approaches (R/B/P): similarities, divergences, harmonisation
  - Update/integration of the conceptual model

GENERAL PROTECTION GOALS IN THE REGULATION

REACH & PPPR: The purpose of this Regulation is to ensure a high level of protection of … the environment

BPR: … improve the functioning … whilst ensuring a high level of protection of … the environment.

- REACH Regulation
  - Place on the market or use … do not adversely affect … the environment
  - Risk to the environment …adequately controlled if the exposure levels do not exceed the PNEC

- Pesticides/ Biocides
  Unacceptable effects on the environment:
  - Fate and distribution in the environment, contamination of water/air/soil (also following long-range environmental transport.
  - Impact on non-target organisms
  - Impact on biodiversity and the ecosystem.

UNACCEPTABLE EFFECTS ON THE ENVIRONMENT

REACH: PEC>PNEC

BIOCIDES: basic tool for decision-making is the PEC/PNEC ratio

- Non-target organisms: **PEC/PNEC ratio greater than 1**
- Soil: the **foreseeable concentration** of the active substance or any other substance of concern, or of relevant metabolites or breakdown or reaction products **in soil, has an unacceptable impact on non-target species**, **unless** it is scientifically demonstrated that under relevant field conditions there is **no unacceptable effect.**

PESTIDES: Uniform Principles define the lower tiers, unacceptable if

- Earthworms: **toxicity/exposure ratio** less than 5 (chronic); **unless** under field conditions earthworm **populations are not at risk**.

- Non-target soil micro-organisms: **nitrogen mineralisation processes affected** by more than 25 % after 100 days; **unless** under field conditions there is **no unacceptable impact on microbial activity**, …, taking account of the ability of micro-organisms to multiply.

CURRENT REGULATORY APPROACH

- General protection goals in the regulation, with limited information on acceptability

Generic protection

- REACH: Threshold option is clearly indicated → risk characterisation based on PNEC

Focus on Non-target organisms

- Pesticides:. Lower tiers defined, unless clauses allows higher tier with no specific indication on level of protection
- Biocides: risk characterisation based on PNEC, but also unless clause for soil

CURRENT REGULATORY APPROACH

By compartment

- REACH: Threshold PNEC soil

Non-target organisms

- Pesticides
- Biocides

Actual levels of protection mostly defined by the scenarios and approaches described in the guidance documents
(PEC estimations, AFs, RMMs, etc.)

ERA scientific challenges for regulated products

- High complexity in defining what is an "environmental harm"
  - Define environmental values to be protected
  - Acceptable level of change, location and timelines
- Variability and diversity are intrinsic elements
  - Natural vs. anthropogenic changes (spatial and temporal)
  - Expected consequences of human changes: indirect and secondary consequences, resilience, redundancy
- Particularly difficult for modified agro-ecosystems

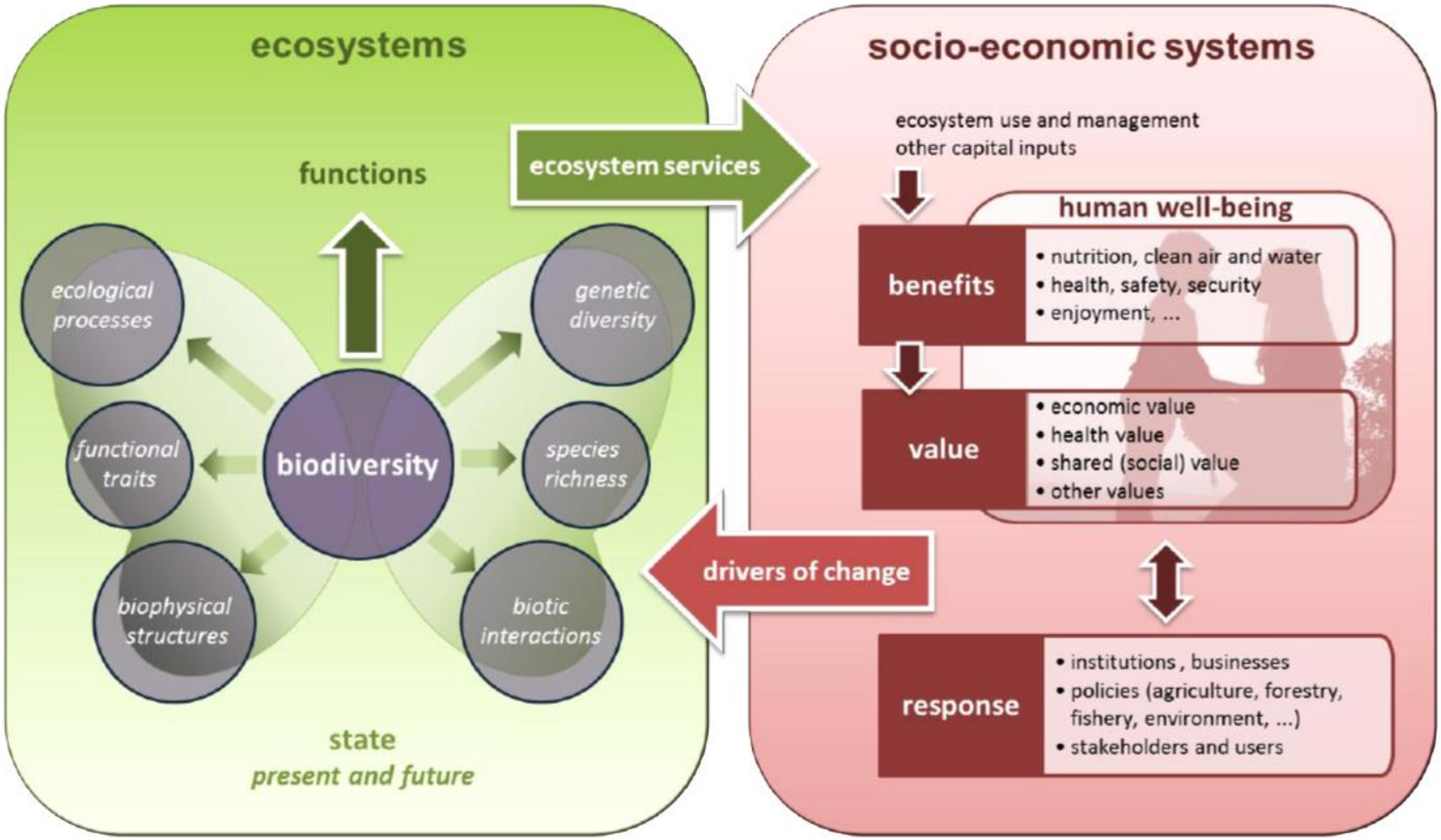


General *vs.* Specific protection goals

- General protection goals: overall goals to be achieved as required by the EU legislation to protect human health and the environment from unacceptable impacts of pesticides

- Specific protection goals: defined by:
  - the **entities** that need to be protected,
  - the **attributes** and/or **functions** of those entities,
  - the **magnitude**, **temporal and spatial scales** of effects on these attributes and/or functions **that can be tolerated** without impacting the general protection goal
  - the required **degree of certainty** with which the protection goal defined should be achieved.

ECOSYSTEM SERVICES: MAES CONCEPTUAL FRAMEWORK



Development of Specific protection goals

1. Ecosystem services as overarching concept
2. Identify relevant services likely to be impacted by pesticides
3. Identify **key drivers** (taxonomic or functional groups) that provide the service
4. Specify **dimensions** of protection goals for each service-driver combination
   - Define protection goal based on **tolerable effect range** and in **measurable** way
5. Identify **vulnerable representatives** for each key driver
6. Develop **risk assessment scheme**

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4.
5.
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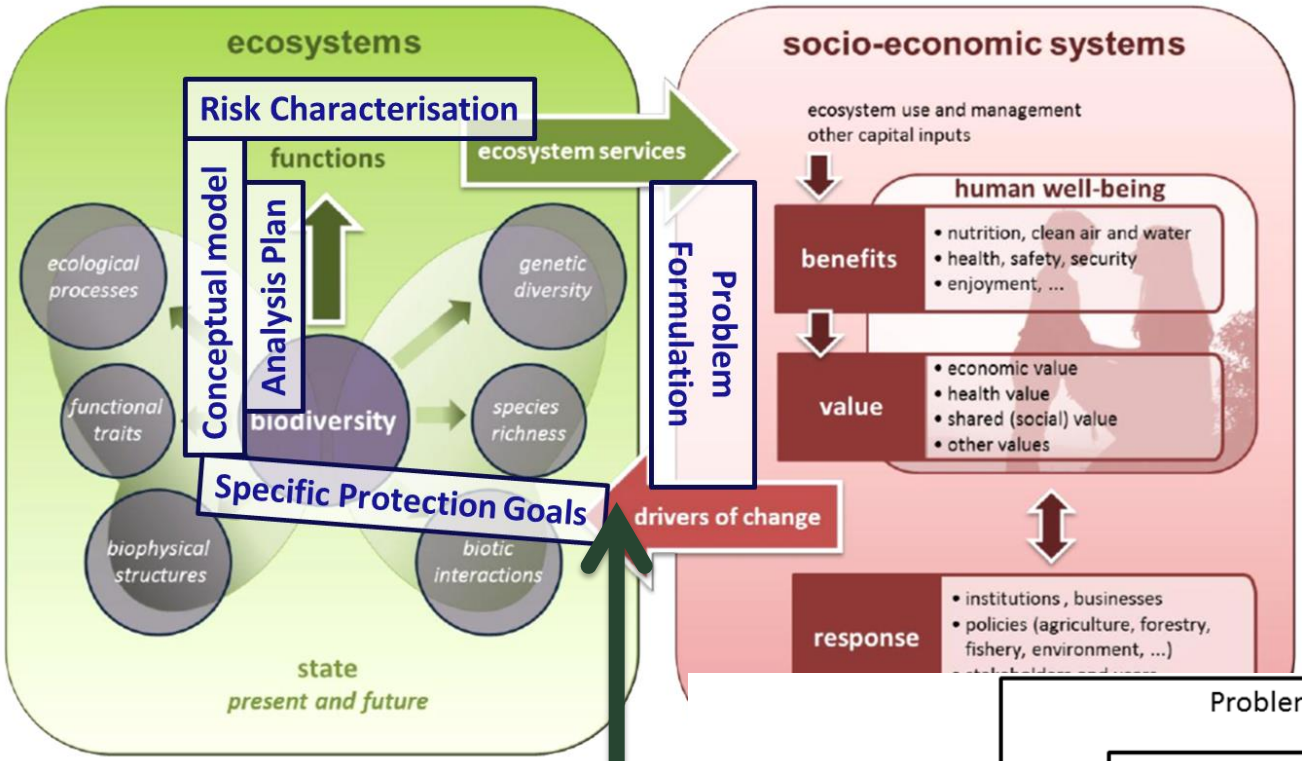
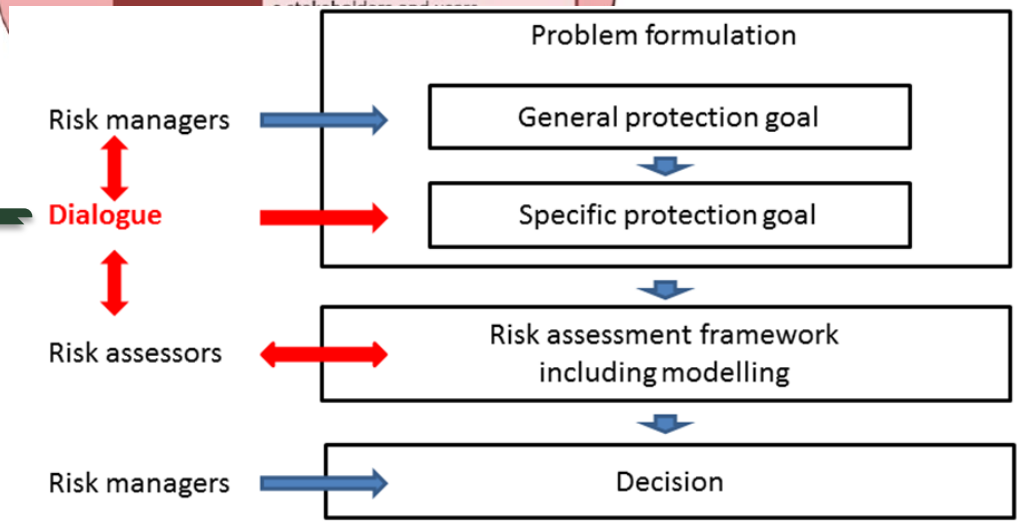
How to link the Ecosystem Services approach in the Risk Assessment Scheme?

INTEGRATION INTO THE RISK ASSESSMENT





IDENTIFICATION OF RELEVANT SERVICES

- The provision of the service is relevant for the exposed area
- The service provided units may be affected by the assessed agent
- E.g. for the assessment of pesticides in the agricultural landscapes:

Ecosystem Service category	In crop areas	Off crop areas
Provisioning	Food Fibre & fuel	Food Genetic resources Fresh water
Regulating	Pollination Pest & disease regulation	Pollination Pest & disease regulation Water regulation Erosion regulation Water purification
Cultural	Education & inspiration Recreation & ecotourism Cultural heritage	Education & Inspiration Recreation & ecotourism Cultural heritage Aesthetic value
Supporting	Primary production Photosynthesis	Primary production Photosynthesis Habitat provision Soil formation and retention Nutrient cycling Water cycling

Development of Specific protection goals

1. [illegible]
2. [illegible] impacted by pesticides
3. Identify **key drivers** (taxonomic or functional groups) that provide the service
4. Specify **dimensions** of protection goals for each service-driver combination
   - Define protection goal based on **tolerable effect range** and in **measurable** way
5. Identify **vulnerable representatives** for [illegible]
6. Develop **risk assessment scheme**

From theory…

… to implementation

PROPOSED METHODOLOGY

Services → Taxa
Taxa → Services

→ Key drivers → Dimensions → Vulnerable Species/Functions

FIVE DIMENSIONS + Degree of uncertainty

Ecological entity:

individual – (meta)population – functional group – ecosystem

Attribute:

behaviour – survival/growth – abundance/biomass – process – biodiversity

Magnitude:

negligible effects – small effects – medium effects- large effects

Temporal scale:

days – weeks – months – seasons - over one year

Spatial scale:

in crop – edge of field – nearby off-crop – watershed/landscape

Development of Specific protection goals

1. Ecosystem services as overarching concept
2. Identify relevant services likely to be
3.
4. Specify **dimensions** of protection goals for each service-driver combination
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From the problem formulation to the SPGs conceptual model

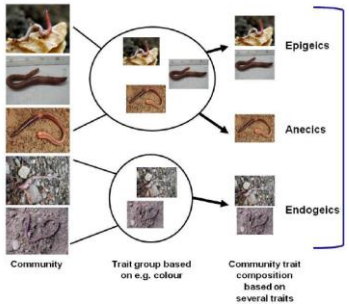
PROPOSED METHODOLOGY

Services → Taxa
Taxa → Services

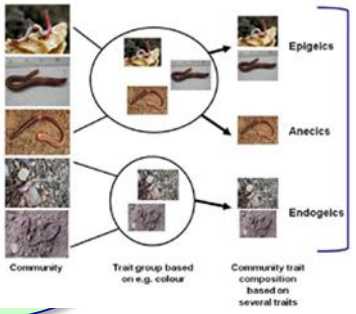
→ Key drivers → Dimensions → Vulnerable Species/Functions

key driver	ecosystem service	legal requirement	specific protection goal	ecological entity	attribute	scale		
						magnitude of impact	spatial scale of impact	temporal scale of impact
Microbes	- nutrient cycling - water purification/ soil remediation/ waste treatment - soil formation and retention	no unacceptable effects	no unacceptable effects on functions of microbial communities	functional groups	functions	negligible effects to medium effects	field to landscape	weeks in fields to days in off crop areas
non-arthropod invertebrates (terrestrial), including earthworms	- food - genetic resources - education an inspiration	no decrease of biodiversity	no decrease of biodiversity in the landscape, temporary impact on local populations	metapopulation	species diversity, species abundance (survival and reproduction)	locally small effects but negligible effects in protected areas and landscape	field to landscape	weeks in field and edge of field and no to days in protected areas and landscape

SPATIAL SCALE DEPEND ON THE SERVICE



EFSA proposed approach: focus on reference tiers



Ecological realism

Proposed approach SPG

4 Field studies and landscape level models

3 Population and community experiments and models

2 Toxicity tests with additional species and/or refined exposure and Toxicodynamics-Toxicokinetics models

1 Core toxicity data

Current approach

Simple (few data)

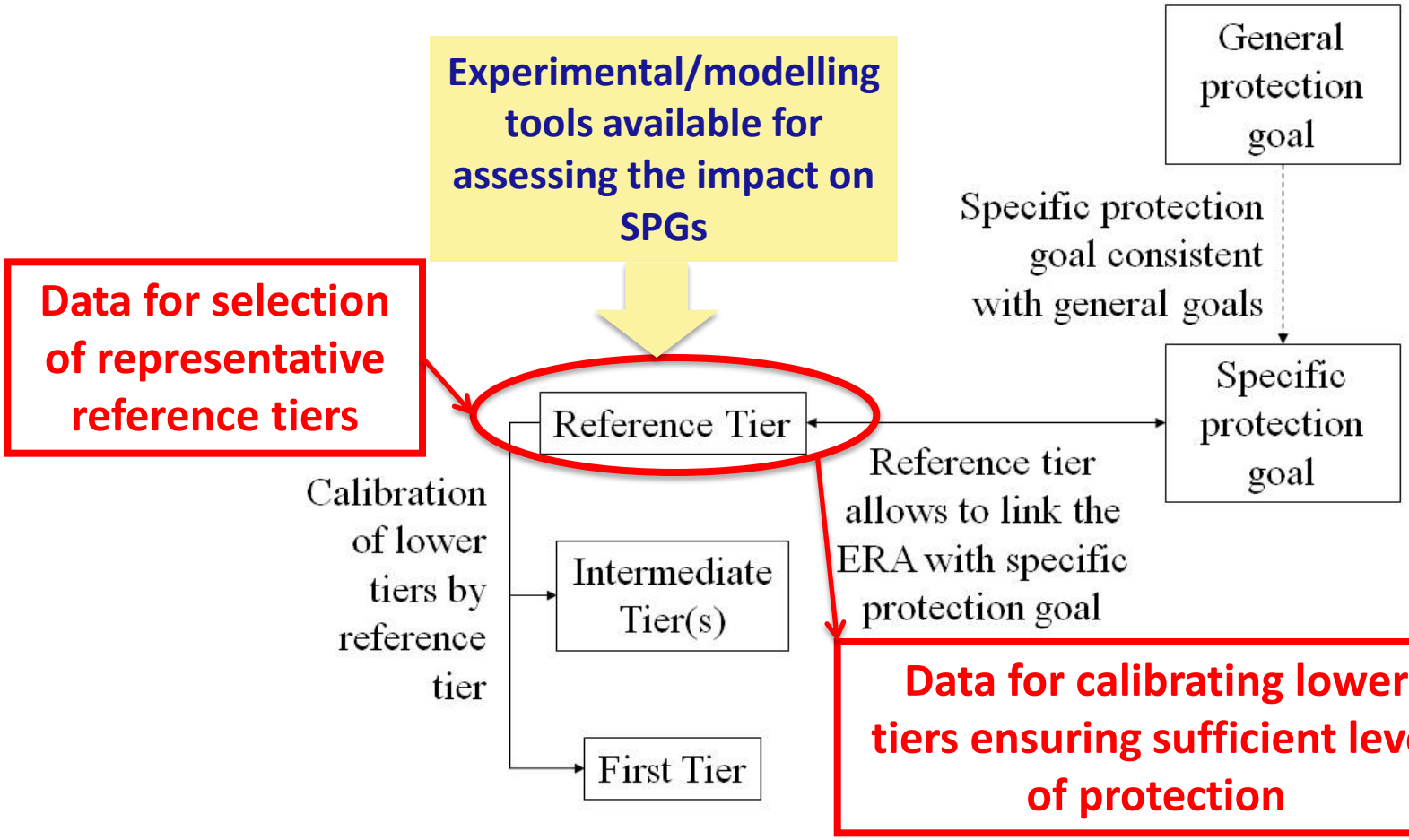
Complex (many data)

Higher tier

Intermediate Tiers

Lower Tier

EFSA proposed approach: focus on reference tiers



IN CONCLUSION, FOR PESTICIDES

- Ecosystem Services are used for setting Specific Protection Goals
- The aim is to ensure the protection of relevant services, including biodiversity, for the level of protection decided by risk managers
- The attributes and links are adapted to the ecological role of each non-target group as services providers
- Realistic reference tiers are used for calibration of lower tiers, offering options (e.g. recovery)
- The next step is moving to landscape assessments

First set: Protection Goals

- Relevance of setting Specific PGs under REACH and BPR for soil organisms
- Relevance of the ecosystem services approach
- Where would harmonisation of the approaches bring added value in the soil risk assessment?

- Proposed issues for further discussion
  - Similarities and differences
  - Elements to be considered
  - Foreseen adaptation needs and regulatory boundaries
  - Calibration from reference tiers

Second set: Analysis plan

- **Equilibrium Partitioning Method**
  - Scientific basis/uncertainty
  - When/how/to-whom?
- **Species Sensitivity Distributions**
  - Species/taxa/functions selection & integration in a PNECsoil
- **Ecological modelling**
  - Prediction of population/functional effects
  - Addressing spatial and temporal variability in exposure and response

Second set (cont.): Conceptual model

- **Current approaches for linking exposure and effects (REACH/BPR/PPP):**
  - Similarities, divergences
  - Harmonisation
- **Updating/integration the conceptual model**

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