Standardization of Marine Environmental Risk Assessment Method for Active Substances in Anti-fouling Systems

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Outline of this presentation

- To introduce updated ISO standard draft prepared in JSTRA[*] since 2006
- Overview of this standard draft
  - background & aims
  - scope of application
  - structure & procedural steps
  - assessment method and result
  - schedule

* Japan Ship Technology Research Association

Background
– Need for global control of active substance in AFS

- Anti-fouling system (AFS) using active substance is common for ships

    - such as anti-fouling paint ...

- Active substances are essentially harmful to aquatic organisms by their nature

- Global control system is needed for sustainable use of active substances while protecting environment and human health

Background
– AFS Convention

- AFS Convention[*] prohibits OTs[†] use in ships' anti-fouling system

- Convention can handle other anti-fouling system

- Annex 2 & 3 show list of information needed to determine whether anti-fouling system is harmful

- Annexes do not include method of risk assessment for evaluating the harmfulness of anti-fouling system

* International Convention on the Control of Harmful Anti-fouling Systems on Ships

† Organotin compounds

Background
– Country-specific control

- **Some countries control risk of OTs-free anti-fouling system and active substances**
  - EU: Biocidal Product Directive (BPD)
  - US: Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)
- **Many of developing countries have no regulation targeting OTs-free AFS and active substance**

Why ISO standard ?

- Global need for international test- and assessment method for scientific environmental risk assessment for active substances or anti-fouling system substituting organotin (OTs)
- ISO is the most appropriate forum for developing such system
  - ❑ transparency in its making process
  - ❑ normative guidelines for regulation & assessment in countries without such system

Series of this ISO standard

- ISO standard draft Part 1 for marine environmental risk assessment method for <u>active substance</u>

- The following parts will also be prepared:
    - Part 2: Marine environmental risk for <u>AFS</u>
    - Part 3: Human health risk for application and removal of AFS

Aims of this ISO standard

- The system being proposed in this draft aims to provide;

  - a useful method to be used for supporting the evaluation of the harmfulness of the anti-fouling system in the Convention

  - a pragmatic approach to introduce systems in the countries with either no system, or a less-well developed system and to allow such countries to further contribute to protection of the aquatic environment

ISO standard draft
– Scope of application

- This draft can be used for the following:
  - Regulation of anti-fouling paints by government organizations
  - Self-regulation or approval system carried out by industries or industrial organizations
  - Evaluation conducted for product development by industries
- This draft only provides methods of risk assessment, and not directly a regulatory scheme/system

– Coverage & definitions

- **Assessment can cover the following:**
  - Marine environment
    - marine includes estuarine and brackish water area
    - Also Applicable to fresh water area
  - Active substance(s)
    - chemical substances for prevention of attachment of sessile organisms, in anti-fouling systems
    - impurities and by-products contained in product > 1%
    - degradates in environment >10% of the parent
- **Definitions**
  - ships: same as AFS Convention
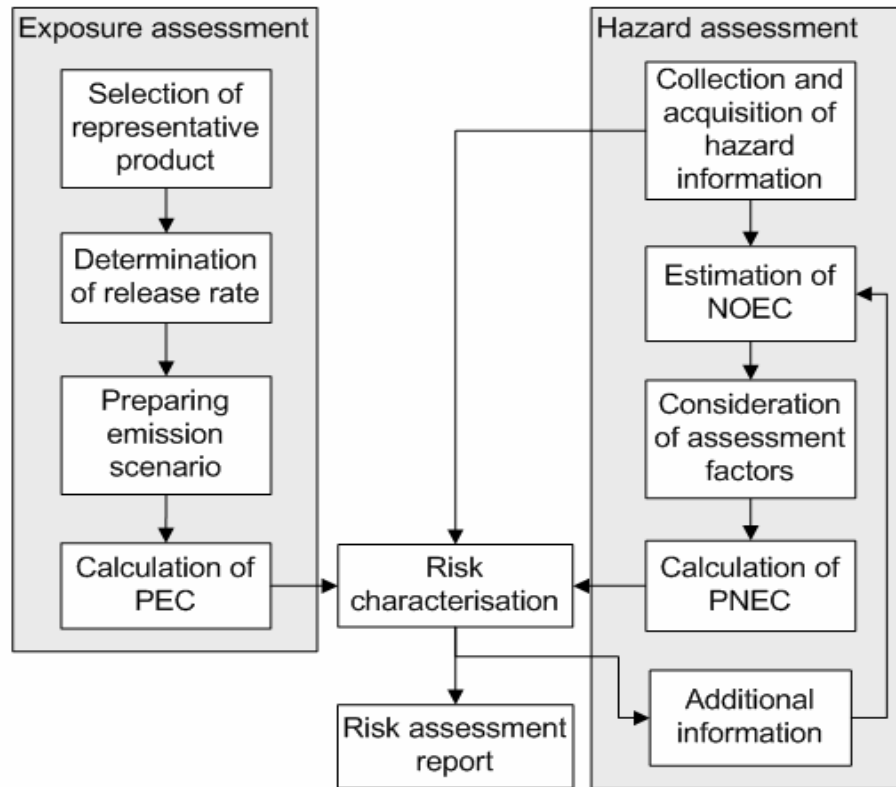
ISO standard draft
– Exclusion of application

- This draft is not applicable for the following life stage of ships:
    - application process of system on ships
    - overhaul, reconditioning
    - disposal, collecting and recycling process of ships, etc.
- This draft is not applicable for the following AFS:
    - applied to ship's surface for acting on harmful aquatic organisms and pathogens in ships' ballast water and sediments, based on BWM Convention*
    - applied to fishing gears, buoys and floats used for the purpose of fishing, fishery stock enhancement and aquaculture
    - applied small patches to ships for the purpose of test, research or development of product

* International Convention for The Control and Management of Ships' Ballast Water and Sediments, 2004

ISO standard draft
– Structure & procedural steps

ISO standard draft – Assessment method:
Exposure assessment

- **Representative product**
  - containing higher ratio of active substance
  - demonstrates effective anti-fouling activity
  - its anti-fouling efficacy is attributed to active substance
  - showing the maximum release rate in plural products
- **Release rate**
  - three existing methods are described in Annex
  - laboratory, calculation and field methods

ISO standard draft – Assessment method: Exposure assessment

- **Emission scenario**
  - existing emission scenarios for anti-fouling products are provided in the OECD ESD
  - considering type of marine environment
    - Open sea, Sea lane, Harbor, Marina
  - determining a representative area
    - major emission area
    - amount of navigation
    - contamination level estimated from monitoring result and transition of existing active substances
- **emission models & parameters**
  - examples of existing emission models are shown in Annex
  - parameters should be set to give a <u>realistic</u> worst case scenario

Hazard assessment & assessment result

- **PBT assessment in risk characterization**
  - Persistency in environment (P)
  - Bioaccumulation (B)
  - PEC/PNEC ratio of parent/degradates (T)
- **Tier system**
  - Tier 1 has severe criteria for P & B
  - if match criteria of Tier 1, "low risk"
  - Tier 2 has mild criteria for P & B, but requires to show;
    - Low adsorption
    - Well-decreased biocidal activity
    - PEC/PNEC for higher trophic organisms (predator, mammal etc.)
    - Risk characterization of degradate >10%

Hazard assessment & assessment result

- ## Level system
  - 2 Levels in Tier 2
  - Level 1 has criteria for P, B, T and adsorption (Kp)
  - Level 2 has requirement for
    - showing decreased biocidal activity
    - PEC/PNEC for higher trophic organisms (predator, mammal etc.)
    - Risk characterization of degradate (>10%)
  - if match criteria of Level 1 of Tier 2, "tentatively classified as relatively low risk"
  - if match criteria of Level 2 of Tier 2, "relatively low risk".
  - if not match criteria of Level 2 of Tier 2, "risk of high concern"

Assessment for metabolites

- ## Metabolite >10 % of parent
  - ❑ acute and long-term toxicity test results
  - ❑ PEC/PNEC $\geq$ 1 : "Risk of high concern" for parent active substance
  - ❑ PEC/PNEC < 1 : continue to assess for parent active substance

ISO standard draft
Schedule

- This ISO standard draft will be submitted to ISO soon

- Please participate after the discussion starts in the Working Group in ISO/TC8/SC2

ISO standard draft

Thank you for your attention.