The EU ABS Regulation and how it will work for business

presentation by Daphne Yong-d'Hervé

JBA seminar, Tokyo 19 February 2015
Current Status of Implementation of
the Nagoya Protocol in EU

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ICC mission

ICC, the world business organization, promotes cross-border trade and investment and the multilateral trading system.

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ICC members

ICC's global network comprises over **6 million** companies, chambers of commerce and business associations in 130 countries:

- **Companies**
  Of all sizes and from all sectors
- **Chambers of commerce**
  Regional, national and local
- **Business associations**
  National and sectoral

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ICC activities

ICC has three main activities:

Rules-setting

Arbitration

Policy

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Biological Diversity

ICC involvement in ABS

ICC Task Force on ABS

- **Focal point for businesses**
  - Coordination and consensus-building between sectors
  - Information exchange, networking and awareness-raising
  - Business contact point for CBD secretariat and governments
- **Cross-sectoral and global businesses views** to governments

- **Represented business during negotiations on Nagoya Protocol**
- **Coordinating role during implementation phase**
  - Exchange on national implementation
  - Input on EC Regulation: coordination of different sectors
  - Awareness raising and dialogue (ICC ABS Conference)

COP10/MOP5 AICHI-NAGOYA JAPAN 2010

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EU ABS Regulation

- **Background**
- **Structure and contents**
- **Industry perspective**
- **Process and timeframe**

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Background

EU : first Nagoya Protocol party to implement user compliance measures

Why the rush?

- EU wanted to be part of first Meeting of the Parties to influence international discussions
- Needed to have legislation in place to ratify

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Birth of EU ABS Regulation

EU ABS Regulation

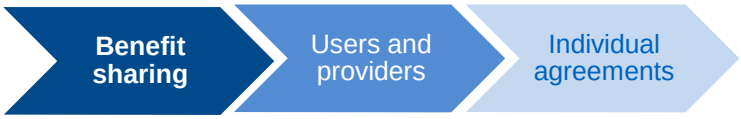
- adopted 16 April 2014;
- entered into force 12 October 2014

Longstanding dialogue between European Commission (DG Environment) and member states with stakeholders

- During NP negotiations (ICC coordination)
- During elaboration of Regulation
- On-going consultation to understand practices of different sectors

Key priority: Regulation that supports innovation and employment within Nagoya framework

Nagoya implementation: Roles and responsibilities in EU



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Legislative structure

EU ABS Regulation (not Directive)
direct application in EU member states

Implementing Act

Guidance

Member states measures

- Designate competent authority
- Recognize registered collections
- Compliance checks
- Penalties

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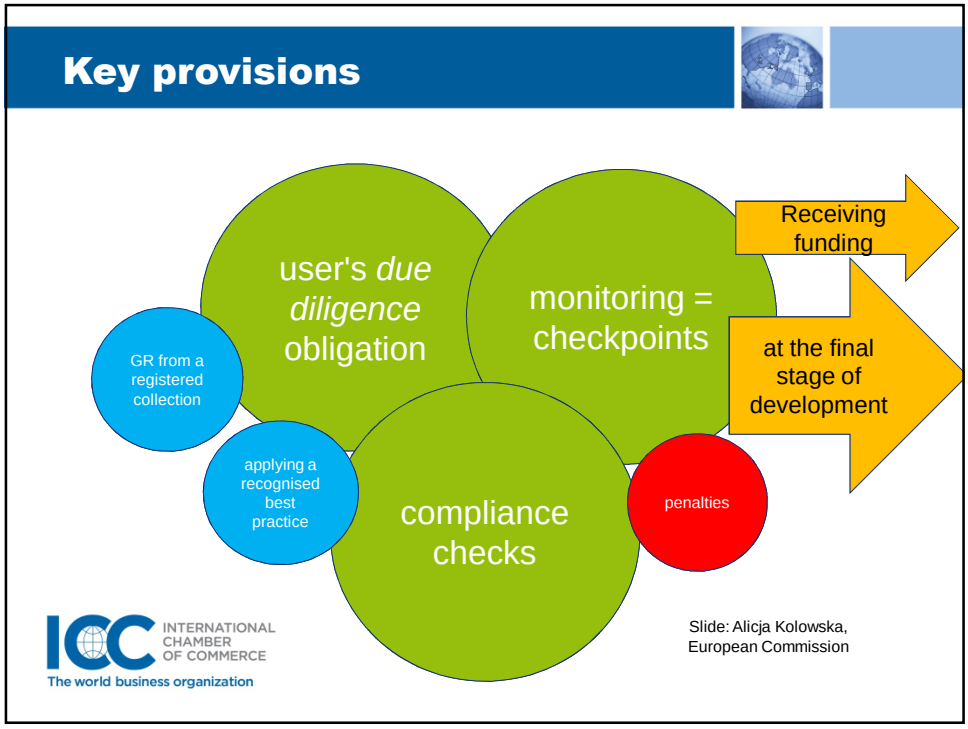
Key provisions
user's *due diligence* obligation
monitoring = checkpoints
Receiving funding
at the final stage of development
GR from a registered collection
applying a recognised best practice
compliance checks
penalties
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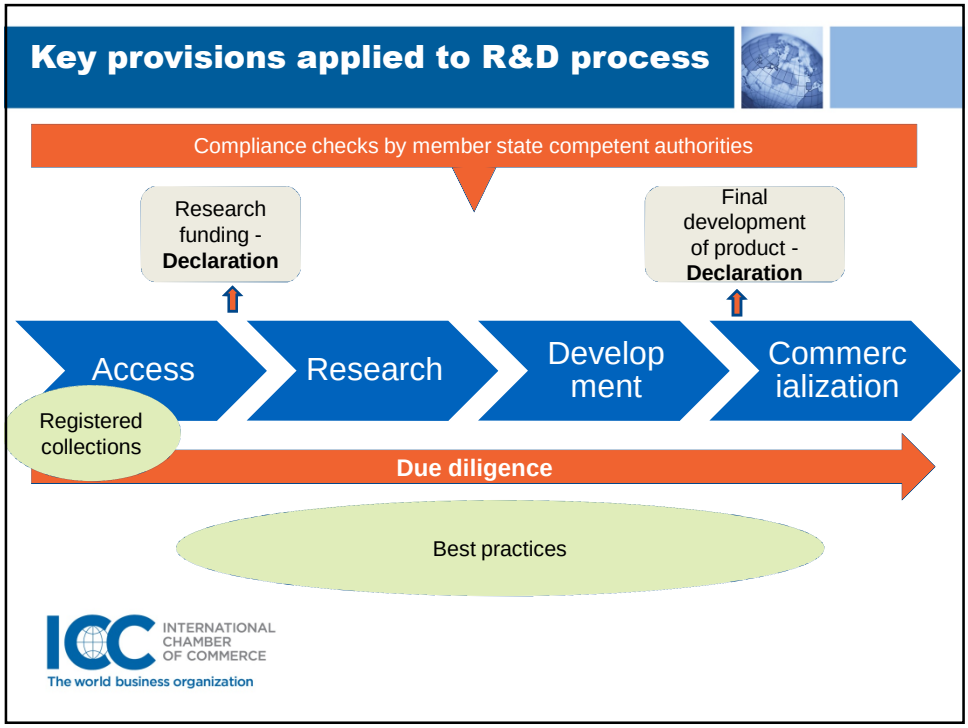
Slide: Alicja Kolowska, European Commission


Key provisions applied to R&D process
Compliance checks by member state competent authorities
Research funding - **Declaration**
Final development of product - **Declaration**
Access
Research
Develop ment
Commerc ialization
Registered collections
Due diligence
Best practices
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Scope – what is covered?

GRs : ABS governed by specialized international instruments) (e.g. FAO International Treaty).

OUT

GRs outside national jurisdictions (e.g. high seas; Antartica)

IN

Genetic resources + associated traditional knowledge (aTK)

- Under sovereign rights of States
- Accessed after the entry into force of the Nagoya Protocol (NP) for the EU.
- Acquired in Nagoya Protocol party
- Utilized for R&D on genetic and/or biochemical composition of genetic resources, including through biotechnology

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Key provisions applied to R&D process

Compliance checks by member state competent authorities

Research funding - **Declaration**

Final development of product - **Declaration**

Access → Research → Development → Commercialization

Registered collections

Due diligence

Best practices

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Core concept - Due diligence

Core concept of EU Regulation

Due diligence

Stated aims

- Focus on processes not individual transactions
- Based on existing business practices
- Low transaction costs, flexibility, business friendly

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Due diligence requirements (1)

Users must **seek, keep** and **transfer to subsequent users:**

Internationally-recognised certificate of compliance (IRCC)
(access permit →ABS Clearing House)
+
Content of the mutually agreed terms relevant for subsequent users

Or, if no IRCC

Information / relevant documents

- **Date** and **place** of access
- **Description** of GR or aTK utilised;
- **Source** where GR or aTK directly obtained + subsequent users
- **ABS rights and obligations** (e.g. permitted use and commercialisation);
- **Access permits**, where applicable;
- Any mutually agreed terms (including benefit-sharing arrangements)

Due diligence requirements (2)

Insufficient information

Uncertainties about legality of access and utilisation

Users must:

- obtain access permit + establish mutually agreed terms

OR

- discontinue utilisation

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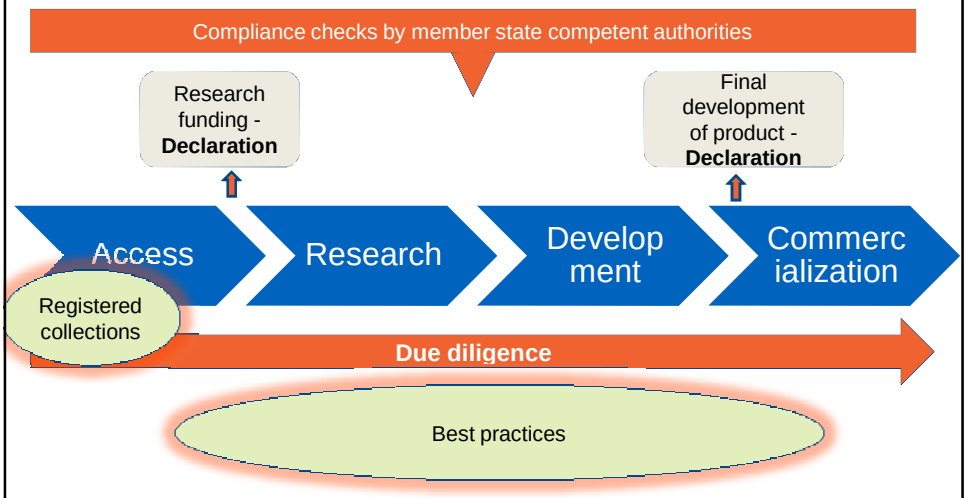
Key provisions applied to R&D process



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Tools to faciliate compliance

Registered collections

Tools to facilitate compliance

Recognized best practices

Obtaining GR from registered collection
=
Compliance with due diligence

Modalities for application in Implementing Act

User implementation of recognized best practice
=
Reduced risk of non-compliance

Compliance checks less likely

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Recognized best practices

What

Combination of procedures, tools and mechanisms

Enabling user compliance with due diligence obligations

Who can apply

Association of users
or
other interested parties

Who develop and oversee best practices

Recognition given by European Commission

European Commission

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Registered collections (1)

Conditions to be in register of collections

Standardised procedures	• GR exchange with other collections, • GR supplied to users for utilisation
Documentation	• showing access GR + related information was in accordance with applicable requirements • mutually agreed terms (where relevant)
Records	• all GR samples and related information supplied to users • unique identifiers (where possible) for GR samples
Tracking/monitoring tools	• exchanging GR samples and related information with other collections

Registered collections (2)

Recognition granted by → **Member States**

Register established and maintained by → **European Commission**

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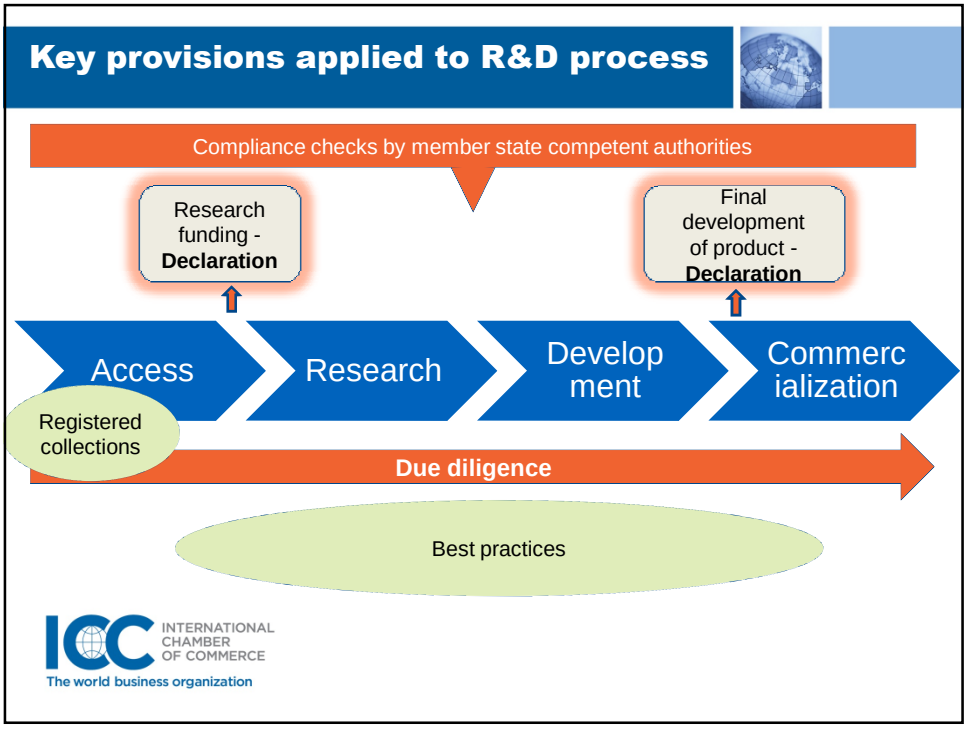
Key provisions applied to R&D process



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Check points

Two checkpoints

Research funding application

Final stage of product development

Due diligence declaration

European Commission

National competent authorities

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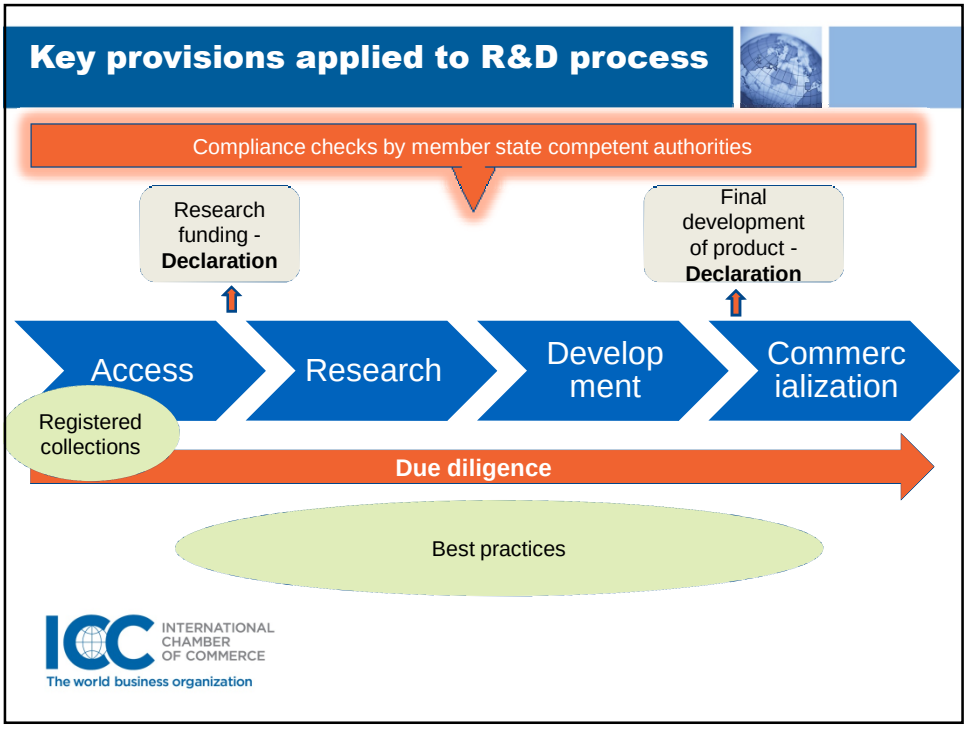
Key provisions applied to R&D process



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Compliance checks

Compliance checks

- By national competent authorities
  - in accordance with periodically reviewed plan (risk-based approach)
  - on the basis of substantiated complaints
- Effective, proportionate, dissuasive

Non-compliance

- Remedial action or measures
- Penalties - effective, proportionate and dissuasive
  - defined by member states

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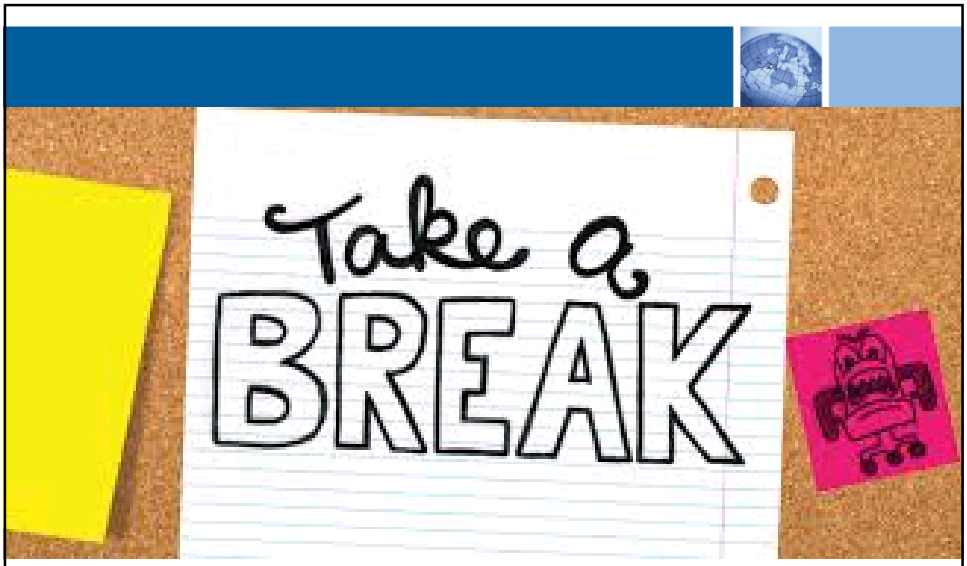

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What does business think?

Key business concern

System **not** the flexible, low cost, business friendly solution originally intended

Heavy adminstrative burden and legal uncertainty

Specific issues

- Scope
- Due diligence
- Monitoring of best practices
- Declarations

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Scope - temporal

Temporal

EU compliance measures should only apply to GRs accessed after the entry into force of the Nagoya Protocol (NP) for the EU

BUT

How about GRs accessed before NP application in EU but considered by provider country to be subject to PIC and benefit sharing (e.g. countries which consider utilization not access as trigger for PIC and benefit sharing.)

- Probably not covered ?

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Scope - geographical

Geographical

- Products manufactured or sold in EU resulting from R&D activities taking place outside the EU
  In Discussion Paper but not in draft Implementing Act. Probably will not be covered.

- Which laws applicable in complex access chains, Original provider country, or also intermediary countries?
  ?

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Scope - material

Material

- Pure information - probably not included
- Research tools - to be addressed in Guidance ; probably not included)
- What is definition of R&D? Manufacturing included?
- Research on GRs sourced as commodities ?

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Due diligence

- Very burdensome, requires detailed information
- How to get required information when GRs come through complex cross border supply chains or as commodities
- Unclear to which activities and GRs due diligence required. ?
- Problems of transferring confidential information
- When does due diligence end?
- Concerns about penalties (including criminal)

Check point declarations

- Research funding – includes private funding - draft Impl. Act
  Definition: *grant to carry out research, not internal budgetary resources*
- Which competent authority if utilization in several m-states?
  Industry request: centralize declaration in one authority
- « Placing on market » includes pre-commercial trials? - draft Impl. Act excludes pre-commercial clinical, field or pest resistance trials
- Application only to GRs within scope of Regulation
  Industry request for confirmation – not in draft Implementing Act
- Minimum link between product and GR necessary to require declaration
- Confidentiality of information in declarations ?

Best practices

- Degree of oversight necessary by associations of best practices
  Still unclear
- Who can develop recognized best practices
  Draft Impl Act: cumulative requirement - legitimate interest + access, collect , transfer or commercialize GRs or aTK
- Factors determing recognition of best practices
  Industry requests more guidance
- Possibility of different best practices in same sector?

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Registered collections

- Not key concern for industry but interest for industry
  - Sourcing from registered collections = due diligence
  - Some companies have own collections
- Some collections think current requirements too burdensome to make registration worthwhile
- For the moment, registered collections outside EU not envisaged

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Specific sector concerns

Pharma
- Inclusion of pathogens not covered by other international instruments eg seasonal flu; Ebola
- Industry proposal: : pathogens obtained from global health authorities to be deemed compliant

Plant breeding
- Inclusion of commercially available varieties
- Industry proposal: exclusion. Court case to annul Regulation
- Draft Imp Act : use of sMTAs considered exercise of due diligence (no further info necessary)
- Incompatibility with breeders exemption free exchange system
- Research funding declaration: Difficult to know which GRs will be in final product

Biocontrol
- Cannot use registered collections so very burdensome

Cosmetics
- Supply chain confidentiality (identity of suppliers and sources in information transfer)
- Differentiation betweeen biotrade and 'utilization'

Process status

EU level:

- Work on implementing act– will define modalities for:
  - Art. 5 – collections
  - Art. 8 – best practices
  - Art. 7 - checkpoints
  - Discussion paper circulated for comment and stakeholder hearing
  - Current review by member states
  - Expected entry into force – 3Q 2015

- Preparation of (sectoral) guidance documents
  - Other points not addressed by Implementing Act e.g. scope

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Process status (2)

Member State level:

- Designation of competent authorities
- Lay down rules on penalties
- Organize monitoring of compliance checks
- Modalities for recognition of registered collections

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Process with stakeholders

EU and member states

- Consultation with users (industry, research, collections)
- Stakeholder meetings
- Participation in conferences (e.g.ICC)
- Comments by stakeholders

Business and other stakeholders

- Input to EC and member states on implementing act and guidance
- Development of best practices
- Awareness raising

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Time frame

Implementing Act	▪ Final draft – June 2015 ▪ Adoption – October 2015
Guidance	▪ Mid-2015
Entry into force of EU Regulation **articles 4** (due diligence) , **7** (check point declarations) and **9** (compliance checks)	▪ 12 October 2015

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