Classification, Labelling and Packaging: Process & Practice

Darren Abrahams

Ruxandra Cana

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Topics for Today

1. Timelines
2. Procedures
3. Opportunities to Challenge
4. Some Conclusions
5. Q & A

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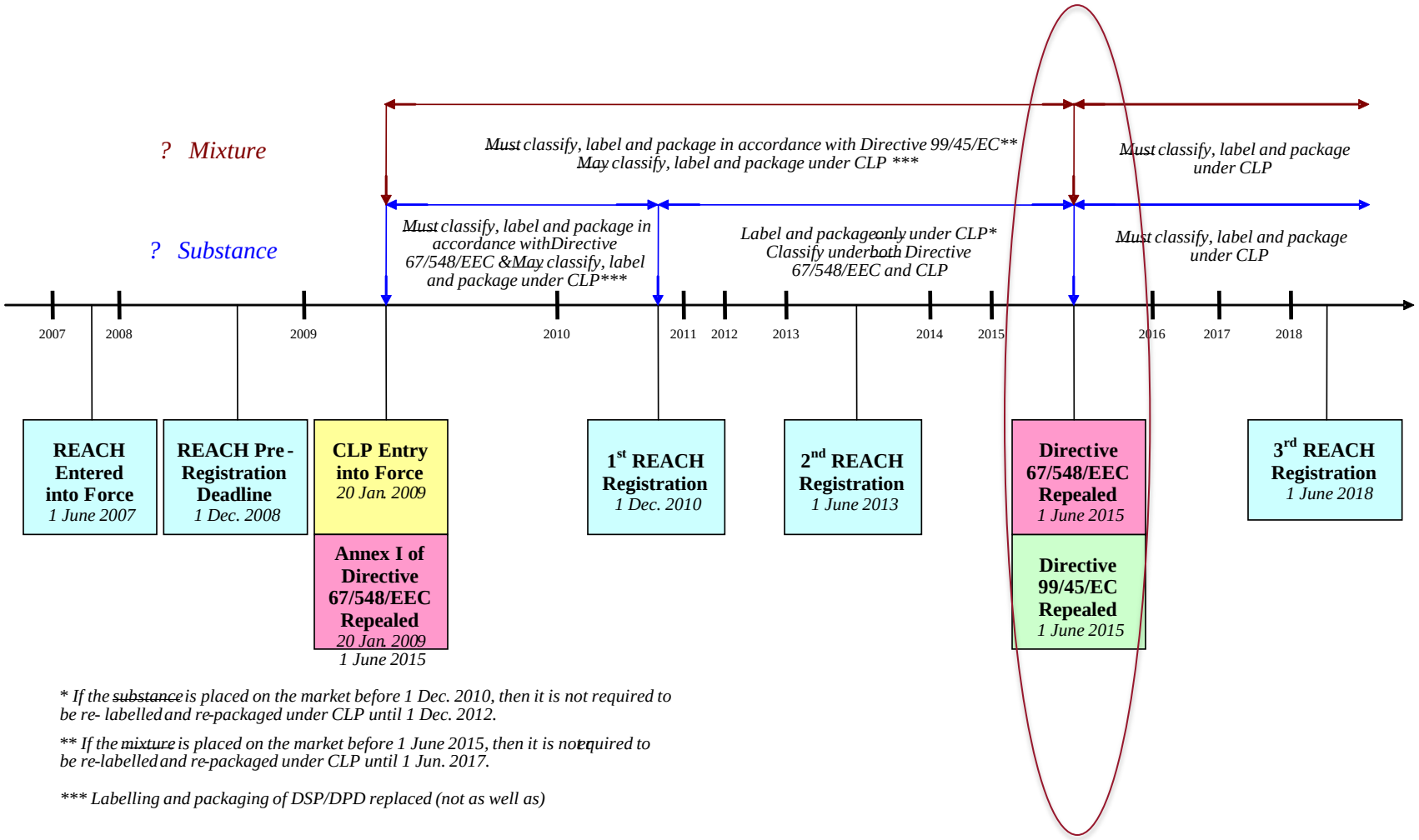
CLP Timelines

CLP Regulation Timelines



** If the ~~substance~~ is placed on the market before 1 Dec. 2010, then it is not required to be re- labelled and re-packaged under CLP until 1 Dec. 2012.*

*** If the ~~mixture~~ is placed on the market before 1 June 2015, then it is not required to be re-labelled and re-packaged under CLP until 1 Jun. 2017.*

**** Labelling and packaging of DSP/DPD replaced (not as well as)*

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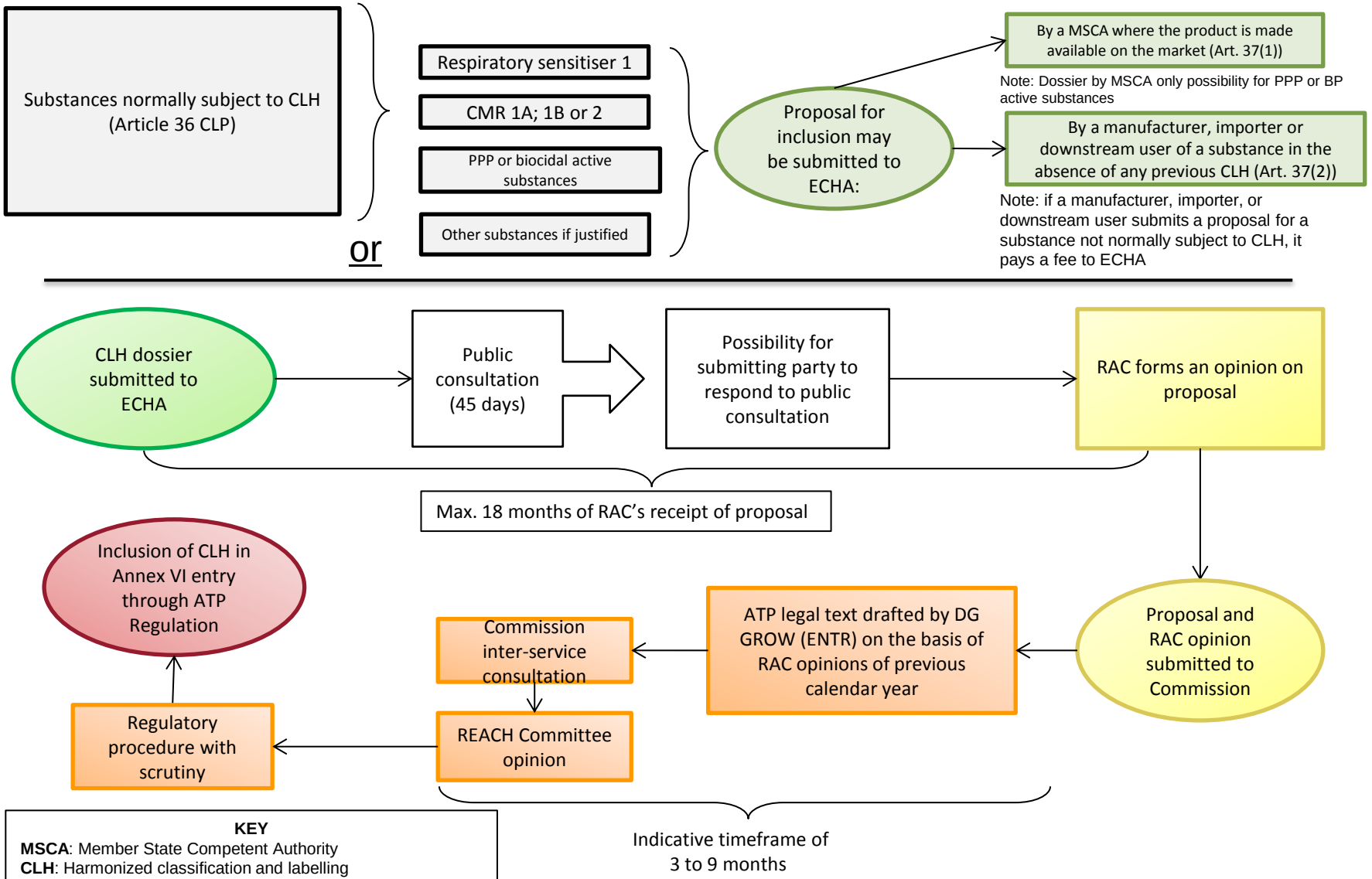
CLP Regulation Timelines

- 1 June 2015 deadline – see Article 61 of the CLP Regulation – what does this mean?
  - For classification, labeling and packaging of mixtures
  - For Safety Data Sheets for mixtures
  - For stocks

CLP Procedures

Procedure for establishing harmonized classification and labelling (CLH)
Article 37 Regulation (EC) No. 1272/2008 (CLP)[1]



KEY
MSCA: Member State Competent Authority
CLH: Harmonized classification and labelling
ECHA: European Chemicals Agency
RAC: Risk Assessment Committee of ECHA
ATP: Adaptation to Technical Progress
EP: European Parliament

[1] See also ECHA "Guidance on the preparation of dossiers for harmonized classification and labelling" (August 2014)
[2] Must be in format specified in second paragraph of Art. 37(2)

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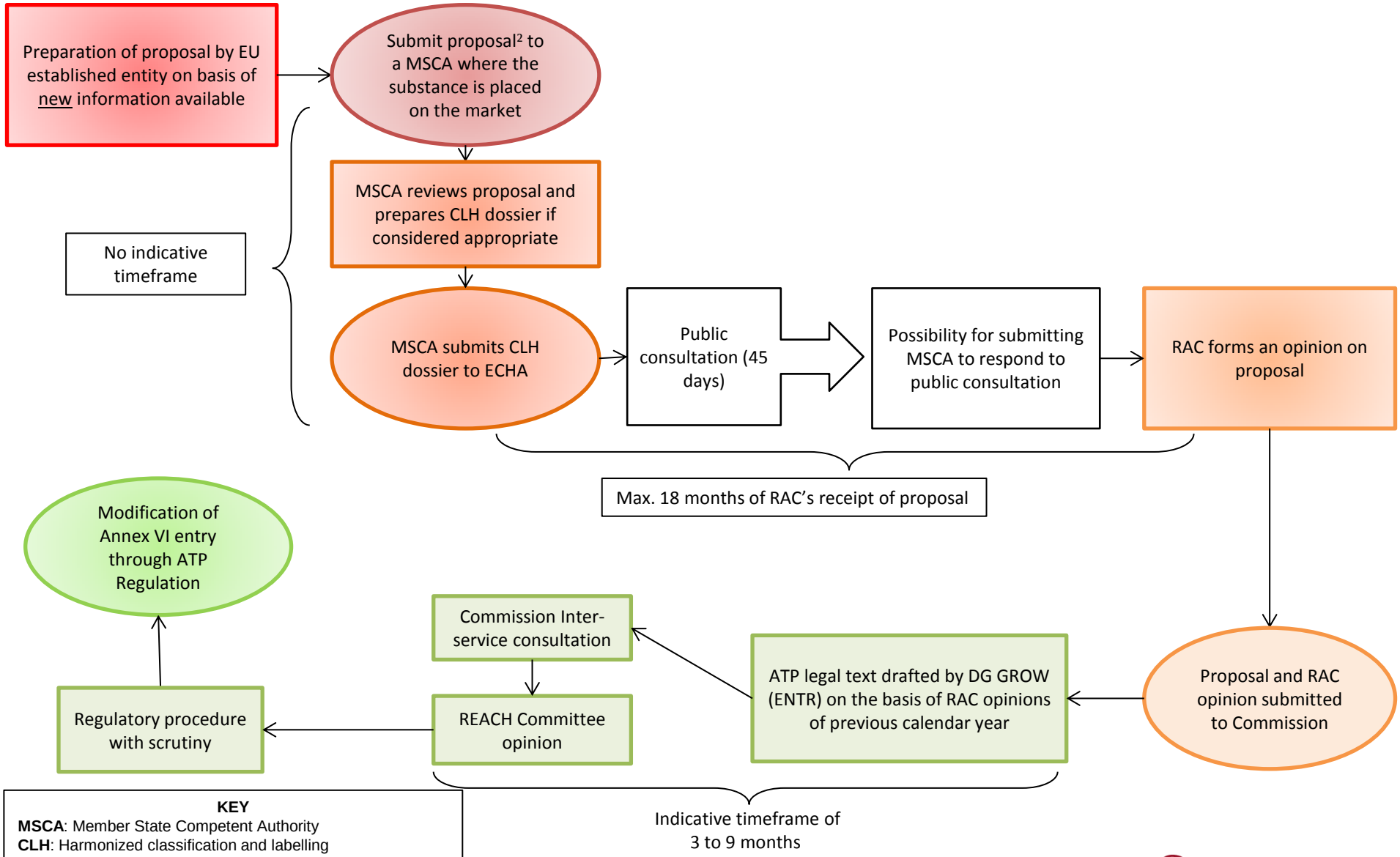
Procedure for revision of harmonized classification and labelling
Article 37(6) Regulation (EC) No. 1272/2008 (CLP)[1]



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Use of Article 37(6) CLP Regulation

- (1-methylethylidene)di-4,1-phenylene tetraphenyl diphosphate; Bisphenol A Diphosphate; Bisphenol A Polyphosphate
  - Proposal for reclassification, September 2011, UK MSCA
  - RAC opinion, 28 November 2012
- Tetrakis(2,6-dimethylphenyl)-m-phenylene biphosphate
  - Proposal for reclassification, March 2012, UK MSCA
  - RAC opinion, 30 November 2012
  - 6th ATP introduced by Commission Regulation (EU) No 605/2014 of 5 June 2014
- 1,2-epoxybutane
  - Proposal for reclassification, January 2013, MSCA Germany
  - RAC opinion, 11 September 2013
- Tinuvin 123
  - Proposal for reclassification, MSCA Germany
  - RAC opinion, 6 June 2014
- Iodomethane
  - Proposal for reclassification, November 2013, UK MSCA
  - RAC opinion, 12 Septembre 2014

Opportunities to Challenge

Classification Procedures

- **The CLP Regulation** (EC) no. 1272/2008 has detailed procedures for adoption of:
  - harmonised classifications (Annex VI inclusion)
  - re-classiffications (Modified Annex VI inclusion)
- **Consider <u>which</u> stages are apt for legal advocacy and which may <u>also</u> be susceptible to legal challenge:**
  - MSCA submits CLH proposal (admin. conduct review by national courts + ECJ)
  - ECHA launching of public consultation
  - RAC opinion (Case T-311/06, *FMC Chemical SPRL v EFSA*)
  - REACH Committee opinion
  - ATP Regulation (Direct annulment action)

  Issues of "legal effects" and "ripeness" to be considered.

Case T-532/08, *Norilsk Nickel* (Nickel Compounds)

- **Direct Annulment Action against 30th ATP, a Commission Directive. Inadmissible (under pre-Lisbon Art. 230) - no "individual concern":**
  - **Dir. 67/548 gave no expressly guaranteed procedural rights** during adoption of the contested classifications to distinguish the Applicants individually i.e. "*all those concerned (manufacturers, importers, national authorities) with methods of classifying…*". Contrast with competition, State aid or dumping, where express rights of defence.
  - **Participation in process** by which EU measure adopted ≠ distinguishing individually unless provision has been made under EU rules for procedural guarantees in his favour (e.g. a procedural right to be heard). Applicants conceded this was not the case.
  - **Under the CLP**, any procedural guarantees provided for (Art 37) would apply only in the event of a national authority or a manufacturer, importer or downstream user submitting a CLH proposal (Applicants had not made such a proposal in this case).
- **Same result in Case T-539/08 against 30th ATP (Borates):**
  - **Possibility of suffering** serious economic disadvantage ≠ individual concern.

Case T-532/08, *Norilsk Nickel* (Nickel Compounds)

- **Same inadmissibility result in Case T-539/08 against 30th ATP (Borates):**
  - **Possibility of suffering** serious economic disadvantage ≠ individual concern.
- **Good news is that the admissibility issues are not the same under a post-Lisbon regime:**
  - Classification is a process which results in a "regulatory act" (not based on Article 289 TFEU procedure) but adopted via *comitology* (resulting in an amending Regulation)
  - So there is only a need to be directly concerned and not individually (much lower threshold).

Case C-14/10, *Nickel Institute* (Nickel Compounds)

- **Preliminary Ruling on validity of against 30th & 31st ATP (both Directives) and 1st ATP to CLP (a Regulation):**
  - **Read across method is permissible in context of assessment of intrinsic properties**
    - even though thought not expressly provided for under Dir. 67/548, it is under REACH and CLP and was used following years if expert scientific discussion
    - application is not manifestly flawed because is within the limits of Commission's discretion when relying upon expert advice
    - "*in this complex technical and legal context, which in essence is in a state of flux, Directive 67/548 gives the Commission, in respect of the substance of the assessment, a broad discretion as to the scope of the measures to be taken to adapt the annexes to that directive to technical progress …*
    - *where the European Union authorities have a broad discretion, in particular as to the assessment of highly complex scientific and technical facts in order to determine the nature and scope of the measures which they adopt, review by the European Union judicature is limited to verifying whether there has been a manifest error of assessment or a misuse of powers, or whether those authorities have manifestly exceeded the limits of their discretion… the…judicature cannot substitute its assessment of scientific and technical facts for that of the institutions…*"

Case C-14/10, *Nickel Institute* (Nickel Compounds)

- **Preliminary Ruling on validity of against 30th & 31st ATP (both Directives) and 1st ATP to CLP (a Regulation):**

  - **Assessment of intrinsic hazards linked to intrinsic properties must not be limited to specific circumstances of use (contrast with a risk assessment)**

  - **Reasons given to support a classification must be sufficient but not exhaustive and varies to degree:**
    - *"…requirements to be satisfied by the statement of reasons depend on the circumstances of each case, in particular the content of the measure, the nature of the reasons given and the interest which the addressees of the measure, or other parties to whom it is of direct and individual concern, may have in obtaining explanations…"*
    - "*…the scope of the obligation to state reasons depends on the nature of the measure in question and that, in the case of measures of general application, the statement of reasons may be confined to indicating the general situation which led to the adoption of the measure and the general objectives which it is intended to achieve… if the contested measure clearly discloses the essential objective pursued by the institution, it would be excessive to require a specific statement of reasons for the various technical choices made …*"

Case T-291/04, *Envirotech* (N-Propyl Bromide)

- **Direct Annulment Action against 29th ATP - Inadmissible (under pre-Lisbon Art. 230) - no "individual concern":**

  - **Same analysis as in *Norilsk Nickel*. Extreme limits of Individual concern underlined:**
    - "*… if it were proved that the applicants were the only operators to have focused their economic activity on the marketing of an nPB-based cleaning solvent, which is particularly affected by the contested classification on the ground that it is 95% composed of that substance, that fact would also not be sufficient to distinguish them individually as long as there are other operators producing and/or marketing similar solvents or other nPB-based products and the number and identity of those operators are not defined, that group may even change after the entry into force of that classification…and that classification affects their products in the same way as it affects the applicants' products*".

  - **However, in the context of a damages claim the Court examined various arguments (all rejected so no illegality to found non-contractual liability).**

General Principles for Classification

- **General Principles of EU law ultimately apply before and after a challengeable decision is adopted**:
  - duty "*to **examine carefully and impartially** all the relevant elements of the individual case*"
  - must verify "***whether the evidence relied on is factually accurate**, reliable and consistent but also whether that evidence **contains all the information** which must be taken into account in order to assess a complex situation and **whether it is capable of substantiating the conclusions drawn from it***"
  - "*[take] **into account of all the relevant factors and circumstan**ces of the situation the act was intended to regulate*"
  - **non-retroactivity** - cannot anticipate a legal regime/thresholds which does not yet apply. If not done - puts final decision in peril.

Good decision-making is a benefit to all stakeholders.

Some Conclusions

- Decisions on classification and labeling, authorization (broadly speaking) have clear effects on business and result in market disruption
- The EU legal system offers legal remedies, mainly as direct challenges before the EU Courts
- So far the EU Courts acted conservatively, reluctant to rule on substance ("manifest error of assessment" standard in "complex technical and scientific matters")
- Good precedents on procedural grounds
- Further cases can be expected
- **Companies have to prepare legal arguments and legal strategy early**
  - Use legal arguments during preliminary stages before adoption
  - Be prepared to use legal arguments in court actions
  - Introduce court actions timely, when justified and when useful

Questions?