Registration of Non-phase-in Substance (New Substance)

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Mei Lingxiao
Hangzhou RUIO Technology Co., Ltd
Hangzhou, China

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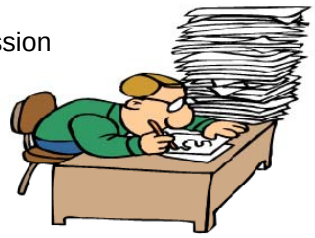

New Substance Registration

- **Definition of non-phase-in substance**

  All substances that are not fulfilling any of the criteria for phase-in substances in Article 3 (20) are considered as non-phase-in substances, also named as new substance.

- **New substances include:**

✓ The substance listed in the European LIst of Notified Chemical Substances（ELINCS）

✓ The substance placed on the EU market after June 1st, 2007

✓ Other substances not fulfilling any criteria for phase-in substances in Article 3(20)

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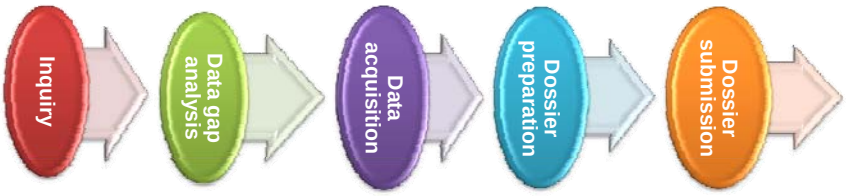
New Substance Registration

- **Registration workflow**



New Substance Registration-Inquiry

- The necessary steps for registration of new substances! *Article 26*
- To obtain the important information

a) Is the substance notified/registered?
b) Who is notifier or previous registrant?
c) How about the existing data ?
d) ……

New Substance Registration-Inquiry

① **Prepare the basic information**

- The identity of the registrant
- The identity of the substance, e.g. CAS No., spectrogram, etc.
- Information requirements

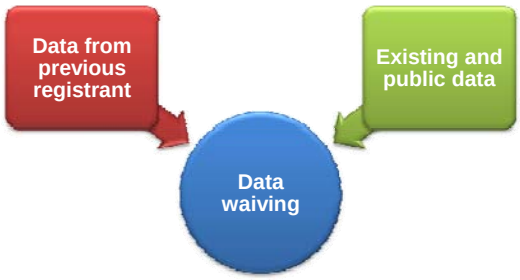
New Substance Registration-Inquiry

② Prepare the inquiry dossier
③ Submit the inquiry dossier
④ Develop registration strategy based on the feedback of ECHA

New Substance Registration-Data Gap Analysis

- Available data based on ECHA feedbacks
- Existing data and public data
- Data Waiving:

✓ Annex 7-10, column 2
✓ Annex 11

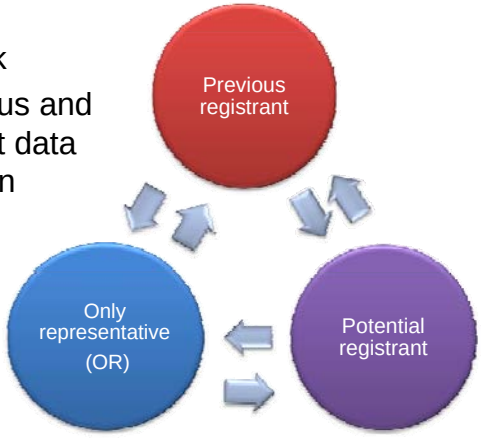


Data waiving

IUCLID 5	Section Name	REACH Annex	REACH Number	Status	Data Source	Data Access	Data Cost(GLP Lab.) EUROs	10-100tpa	100-1000tpa	Remark
4	Physical and chemical									
4.1	Appearance/physical state/colour	7	7.1	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.2	Melting/freezing point	7	7.2	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.3	Boiling point	7	7.3	industrial data available	Creanova Spezialchemie GMBH	data sharing or testing	719			
4.4	Density	7	7.4	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.5	Particle size distribution(Granulometry)	7	7.14	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.6	Vapour pressure	7	7.5	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.7	Partition coefficient	7	7.8	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.8	Water solubility	7	7.7	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.10	Surface tension	7	7.6	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.11	Flash-point	7	7.9	gap		testing	809			
4.12	Auto flammability	7	7.12	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.13	Flammability	7	7.10	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.14	Explosiveness	7	7.11	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.15	Oxidising properties	7	7.13	industrial data available	Rohm& Haas (UK) LTD	free	0			
4.17	Stability in organic solvents and identity of relevant degradation products	9	7.15	gap		testing	3,496			
4.21	Dissociation constant	9	7.16	data waiving	expert judgement	waiving	3,216			
4.22	Viscosity	9	7.17	data waiving	column 2	waiving	0			
5	Environmental fate and									

New Substance Registration-Data Acquisition

- Based on ECHA feedback
- Communicate with previous and potential registrants about data sharing and cost allocation



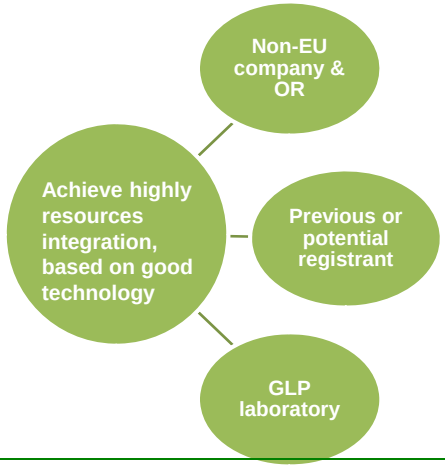
New Substance Registration-Data Acquisition

We need to do more ……

Comparing with the data sharing mechanism of phase-in substance in SIEF

- More involvement
- More technical requirements

New Substance Registration-Data Sharing



Assess the existing data and analyze the data gap

Negotiate data sharing and cost sharing

Test in cooperative GLP Lab.

New Substance Registration-Dossier Preparation

- Technical dossier

- Chemical Safety Report(CSR)

New Substance Registration-Technical Dossier

I. General information -Article 10

- The identity of manufacturer/importer
- The identity of the substance
- The identified uses of the substance
- The classification and labelling of the substance
- Guidance on safe use of the substance
- ……

New Substance Registration-Technical Dossier

II. Information requirements for the different tonnage - Article 12

Include physical-chemical properties, toxicology and eco-toxicology information, pls. see Annex VII-X.

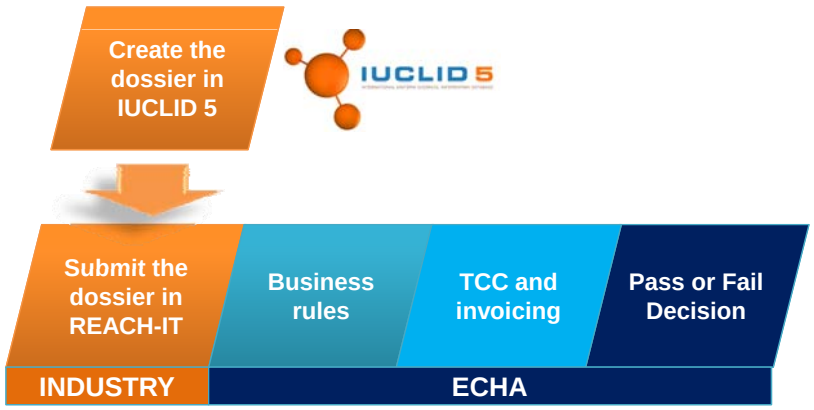
Tonnage (t/a)	Information Requirements (according to REACH regulation)
1~10	Annex VII
10~100	Annex VII + VIII
100~1000	Annex VII + VIII + IX*
> 1000	Annex VII + VIII + IX* + X*
When data is absent, submit testing proposal to ECHA before testing initiated.	

New Substance Registration-Chemical Safety Report

CSR includes:

- Human health hazard assessment of physicochemical properties
- Human health hazard assessment
- Environmental hazard assessment
- PBT and vPvB assessment
- Exposure assessment
- Risk characterization

New Substance Registration-Dossier Submission



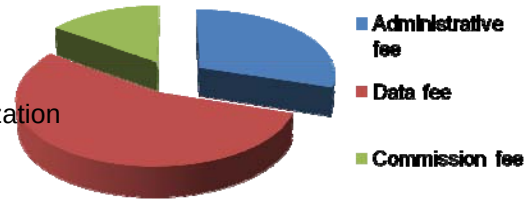
New Substance Registration- Registration Fee

Registration fee is composed of:

1) **Administrative fee,** charged by ECHA (refer to the 340/2008/EC)

2) **Data Fee,** including data sharing cost, testing cost etc.

3) **Commission fee,** pay to the Only Representative or other third party organization



New Substance Registration- Registration Fee

1.Registration Fee:

1) Administrative charge

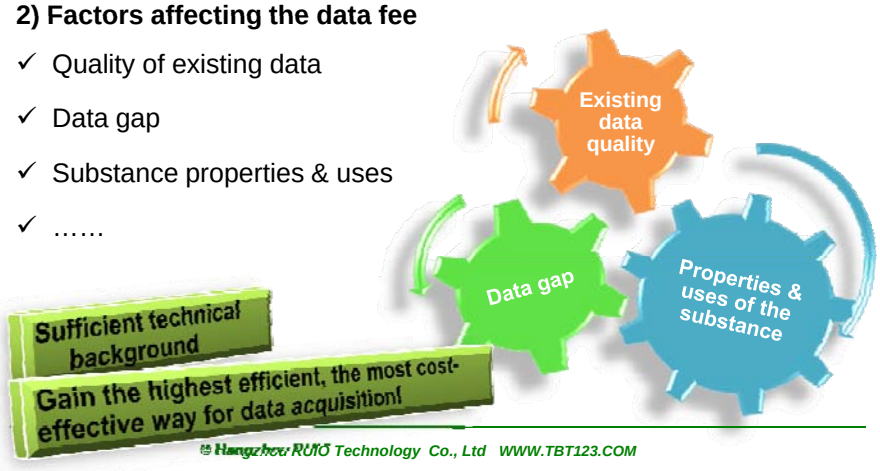
	Individual submission	Joint submission
1~10 t/a	€ 1,600	€ 1,200
10~100t/a	€ 4,300	€ 3,225
100~1000t/a	€ 11,500	€ 8,625
> 1000t/a	€ 31,000	€ 23,250

**Reduced fees for SMEs*

New Substance Registration- Registration Fee

2) Factors affecting the data fee

- ✓ Quality of existing data
- ✓ Data gap
- ✓ Substance properties & uses
- ✓ ……



New Substance Registration- Registration Fee

3) commission fee

Commission fee always depends upon tonnage band, use and data gap etc.

New Substance Registration- Registration Schedule

1. **Inquiry:** At least 3 weeks
2. **Data sharing:** case by case
3. **Registration dossier preparation:** 2 weeks to several months
4. **Submission & Dossier check:** Around one month

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New Substance Registration- Intermediate

- **Definition Article 3 (15)**
  Intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis"):
- ✓ non-isolated intermediate
- ✓ on-site isolated intermediate
- ✓ **transported isolated intermediate**

New Substance Registration- Intermediate

- **Intermediate Registration Article 17, 18, 19**
  Meet the strictly controlled conditions criteria
- **Reduced registration information**
- **Reduced administrative fee payable to ECHA**

New Substance Registration- Intermediate

Strictly controlled conditions

- (a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;
- (b) procedural and control technologies shall be used that minimise emission and any resulting exposure;
- (c) only properly trained and authorised personnel handle the substance;
- (d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;
- (e) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;
- (f) substance-handling procedures are well documented and strictly supervised by the site operator.

New Substance Registration- Intermediate

Check if strictly controlled conditions met or not

- **Questionnaire from Supplier to Downstream User**- Intermediate Used under Strictly Controlled Conditions

  Suppliers deliver the questionnaire to downstream users

- **Self-Declaration**

  Non-EU manufacturer provide OR with self-declaration to ensure that intermediate is manufactured and used under strictly controlled conditions.

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New Substance Registration- Intermediate

- **A registration for a transported isolated intermediate shall include:**

I. Registrant identity, substance identity , C&L, brief general description of uses and RMM.

II. Reduced data requirements according to the tonnage bands

- 1~1000 t/a： any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;
- > 1000 t/a：Annex VII

New Substance Registration- Intermediate

- **The intermediate which is failed to meet the strictly controlled conditions**

  - Intermediates can not enjoy the preferential rules to simplify the required registration information
  - Intermediates need to be registered in accordance with the standard information requirements for registration, i.e. Annex VII~X

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- **New substance workflow**
  - Inquiry
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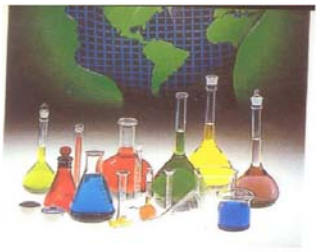
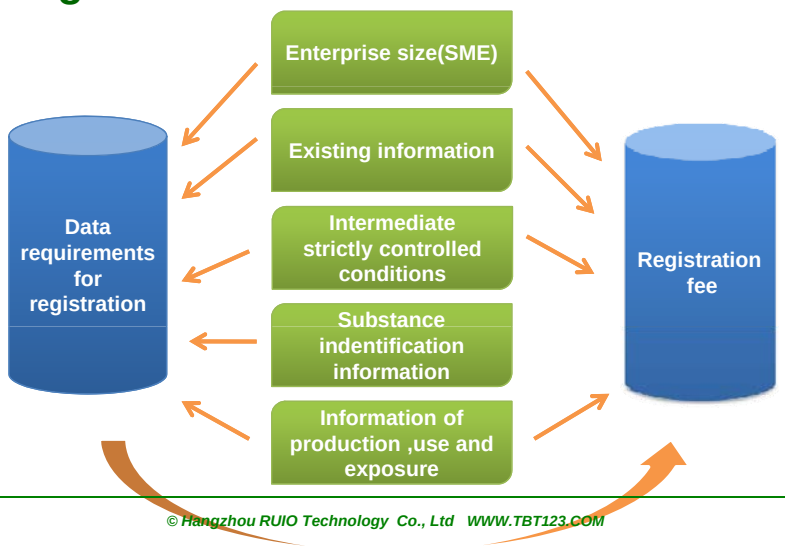
  - Data filling
  - Registration dossier compilation & submission
  - Registration fees and timelines
- **Registration of intermediates**
  - Strictly controlled conditions
- **Conclusions**



New Substance Registration- Conclusion

- **Provide self- declaration for company size**
- **Provide the substance identification information as specified Annex VI**
- **Collect the existing information on physicochemical, toxicology or ecotoxicology etc.**
- **Prepare a brief general description of the production ,use and exposure**
- **Provide self- declaration of strictly controlled conditions for intermediate**

New Substance Registration- Conclusion



THANK YOU!