The Korean REACH
Overview & Regulatory Implementation

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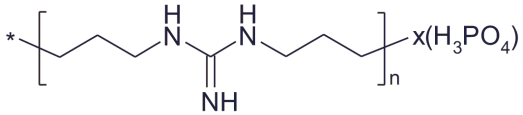
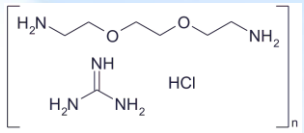
Humidifier Sterilizer Incidents in Korea (2006 ~ 2011)



Polyhexamethyleneguanidine phosphate (n/x=1~2)
(PHMG phosphate)
CAS RN 89697-78-9



Oligo(2-(2-ethoxy)ethoxyethyl guanidinium chloride (PGH)
CAS RN 374572-91-5

- ✓ 1994, 1st Humidifier Sterilizer introduced to market
- ✓ 2006 ~ 2010, Numerable damaged lung cases reported, but cause not identified
- ✓ Apr 2011, Epidemiological Investigation initiated
- ✓ Aug 2011, Investigation concluded: humidifier sterilizer responsible
- ✓ Sep 2011, Animal test initiated
- ✓ Nov 2011, Relevant products driven out of market
- ✓ Apr 2014, Study of 361 cases completed: 75 deaths, 93 damages
- ✓ Apr 2015, Study of addition 169 cases: 17 deaths, 32 damages
- ✓ ☞ Total of 217 victims (92 deaths, and 125 damages)

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Korean Act on Registration and Evaluation of Chemicals

* 12 Implementing guidelines finalized(Dec 2014)

Major Arguments during Legislation

Arguments	Settled
① Registration exemption for R&D	Exempted same as at present, but w/ additional safety devices (submission of management plan , etc.)
② Registration of non-phase-in substance in small amount	Even small amount of substance should be registered, & Simplified materials for submission & Shortened registration period

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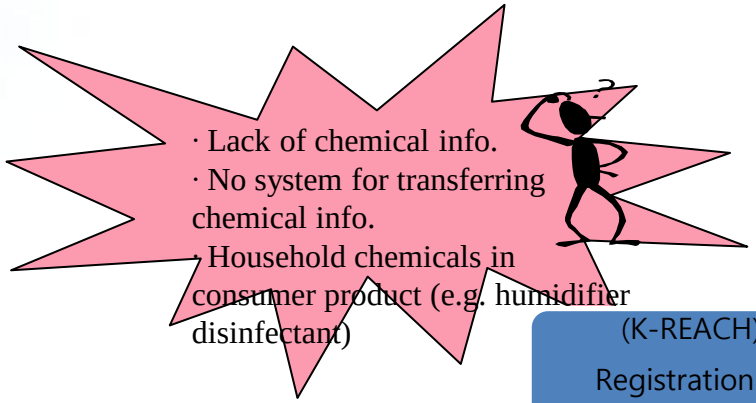
Toxic Chemicals Act

(enacted in 1992)



·Leak of hydrofluoric acid in Gumi,

Continuous occurrences of chemical accident

(K-REACH)
Registration & Evaluation of Chemical Substances

Chemicals Control Act

Promulgation of K-REACH enactment on May 22, 2013

Promulgation of revised CCA on Jun. 4, 2013

Enforced on Jan. 1, 2015

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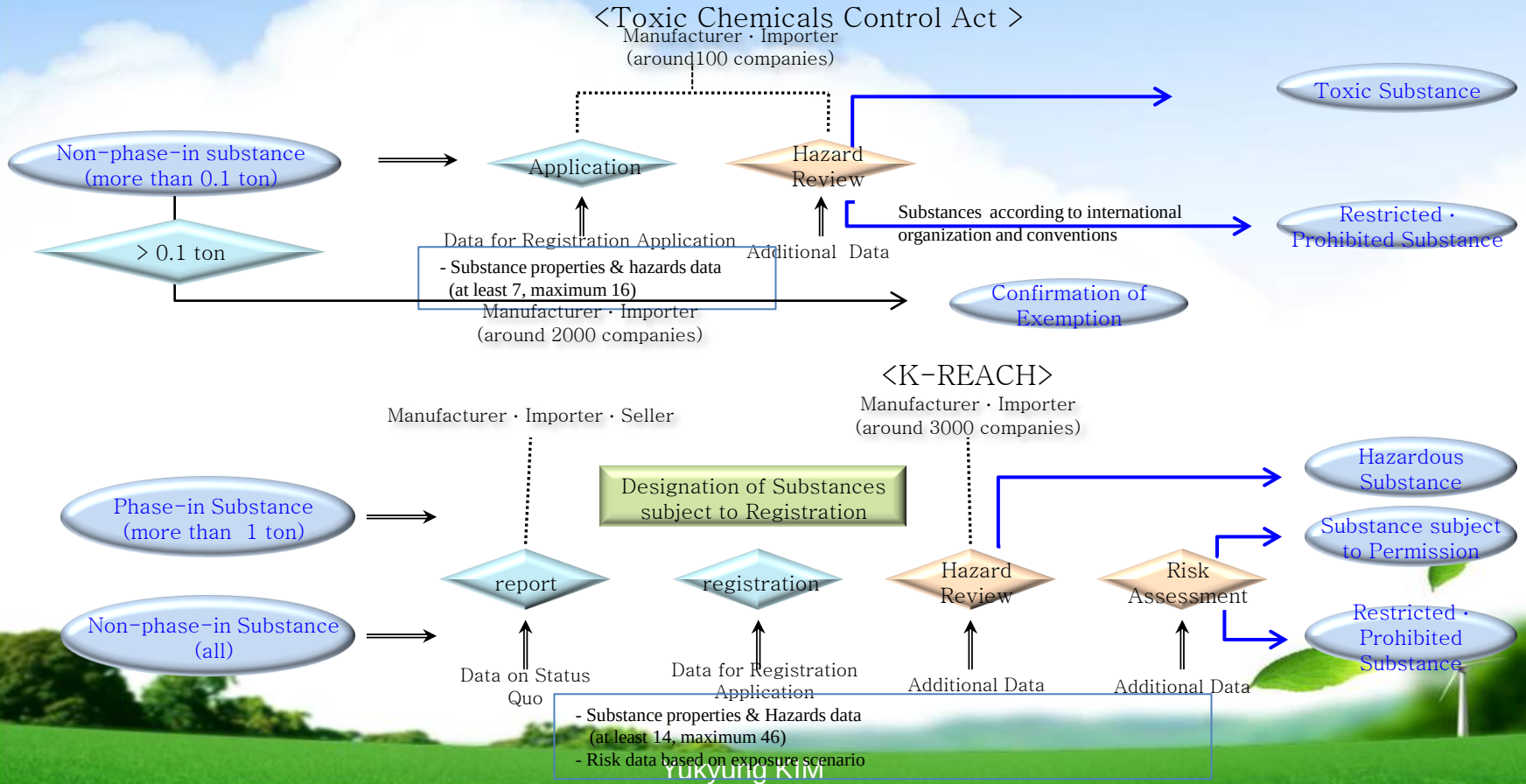

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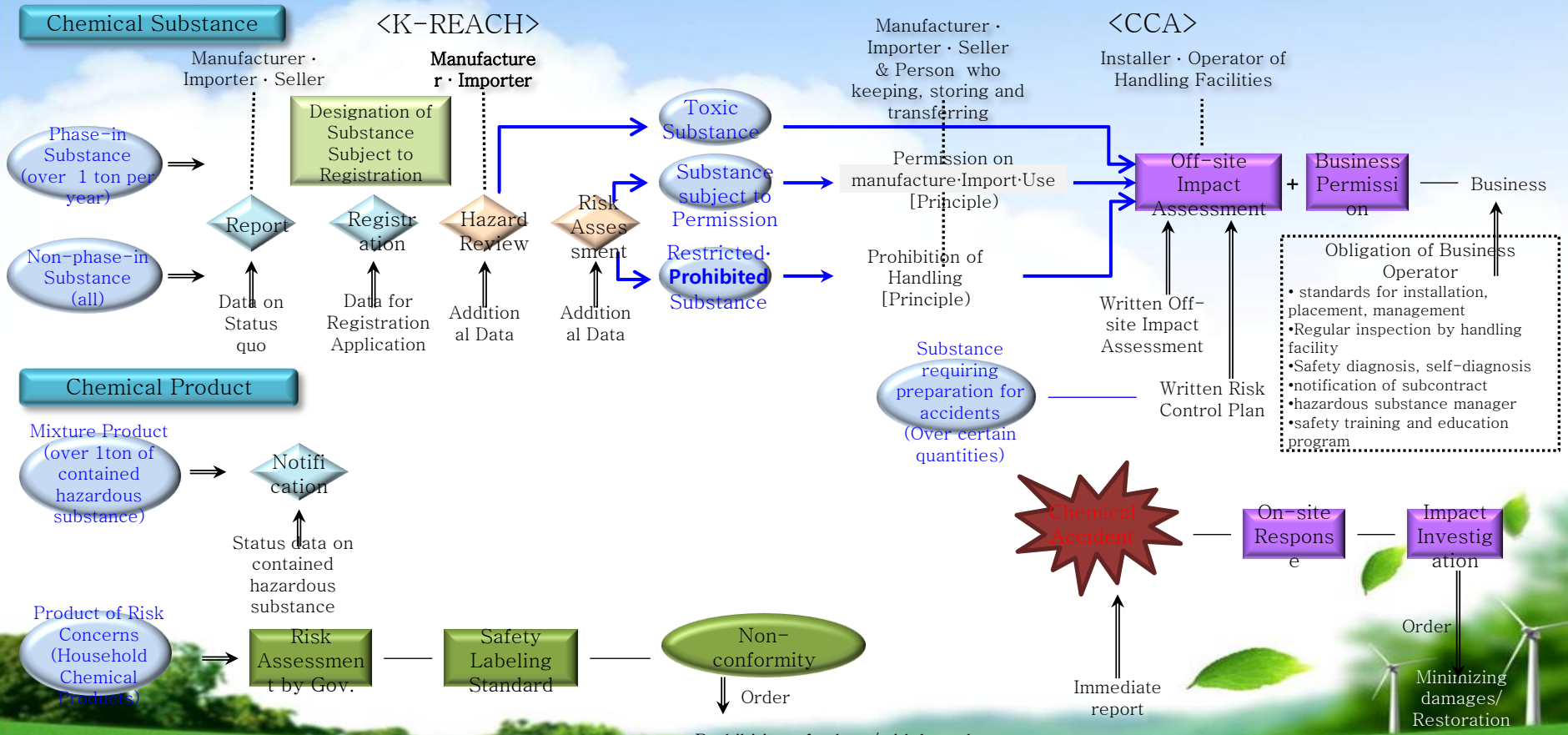

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Chapters

- ✓ Chapter 1 : General provision (Article 1~ 7)
- ✓ Chapter 2 : Registration of Chemicals (Article 8 ~ 17)
- ✓ Chapter 3 : Hazard evaluation & Risk assessment (Article 18 ~ 24)
- ✓ Chapter 4 : Designation of authorization chemicals and etc. (Article 25~28)
- ✓ Chapter 5 : Communicaion on chemicals information (Article 29 ~ 31)
- ✓ Chapter 6 : Management of risk concerned product (Article 32 ~ 37)
- ✓ Chapter 7 : Supplementary provisions (Article 38 ~ 48)
- ✓ Chapter 8 : Penalties (Article 49 ~ 54)
- ✓ Addendum (Article 1 ~ Article 7)

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Exempted from the Act:

- ✓ Radioactive substances
- ✓ Medicinal products and quasi-drugs
- ✓ Narcotics
- ✓ Cosmetics
- ✓ Agrochemicals and active ingredient
- ✓ Fertilizer
- ✓ Food and food additives, packaging
- ✓ Feed
- ✓ Explosives such as gunpowder
- ✓ Military supplies
- ✓ Health functional food
- ✓ Medical appliance

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Definitions (1)

Phase-in Chemicals

- Chemicals domestically distributed for commercial purpose prior to February 2, 1991 and publicly announced as such by the MoE (37,021 substances)
- Chemical substances that has undergone the Hazard examination process after February 2, 1991 under TCCA and publicly announced as such by the MoE (6,163 substances)
- Most of the chemical substances that has undergone the Hazard examination process between Jan 1, 2012 and Dec 31, 2014, but not yet announced as such by MoE(1,277 substances) → to be confirmed and announced after consultation with the companies

Non-phase-in Chemicals

- All chemical substances excluding phase-in chemicals

Phase-in Chemicals subject to Registration

- Chemicals designated out of phase-in chemicals based on exposure potential such as circulation volume, hazards of chemicals, etc., published by MoE

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Definitions (2)

Hazard

- properties of chemical substances, including toxicity, which are detrimental to human health or the environment

  → (1) **Hazard Examination**: initiated by the registration of companies

  (2) **Hazard Evaluation**: initiated by the government (without the registration)

Risk

- degree of damage to human health or the environment when exposed to hazardous chemical substances

  → **Risk Assessment**: If production/import volume ≥ 100ton/year (to be strengthened as 10ton/year by 2020)

  or needed by the result of the hazard examination/evaluation

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Definitions (3)

Intermediates

- Chemical substances that are produced in the process of making some other chemical substances and entirely consumed within that process.

→ (1) **Non-isolated Intermediates**: Not intentionally removed or isolated from the production facility
☞ exempted from registration

(2) **Isolated Intermediates**: Other than isolated intermediates
☞ exempted from registration if leak or exposure is technically blocked

Polymers

- Molecules characterized by the sequence of one or more types of monomer units

→ Polymers of low risk concern are exempted from registration

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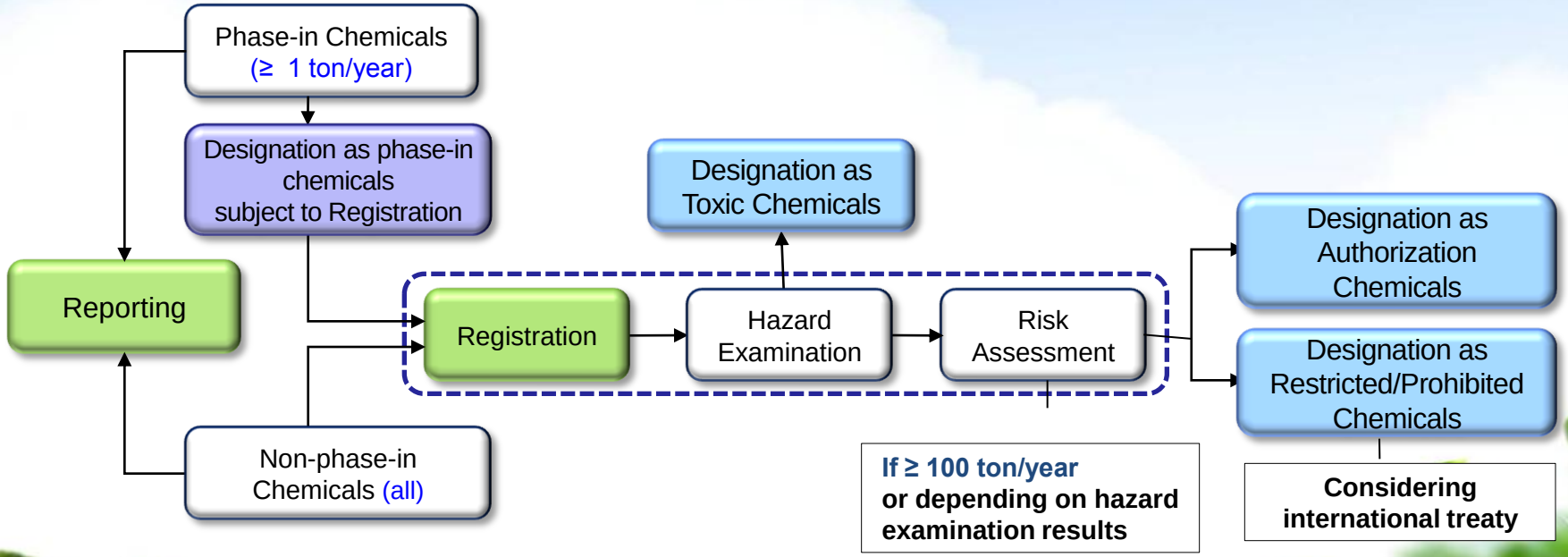
Overview of Registration Process



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Reporting (Article 8)

- **Purpose :**

- **What to Report** : Non-phase-in substance & at least 1 ton per year of Phase-in substance
- **How to report : Manufacture, import and sale from Jan 1 to Dec 31,** by Jun 30 every year
- **Who Reports?**
  Those who manufacture, import and sell chemical substances
  (VS. Registration is for those who manufacture and import chemical substance)

  ⇒ Only those selling chemical substance to person who uses it as raw material in workplace
  (except those selling a product to person who consumes it in workplace & person who sells a product directly to consumer)

Exempted from reporting

① Chemicals in imported machineries

② Chemicals in imported machinery devices for test-run

③ Chemicals contained in solid form product that is not released during use

④ Manufactured/imported substances for the purpose of research and studies

⑤ Others chemicals listed in Presidential Decree etc.

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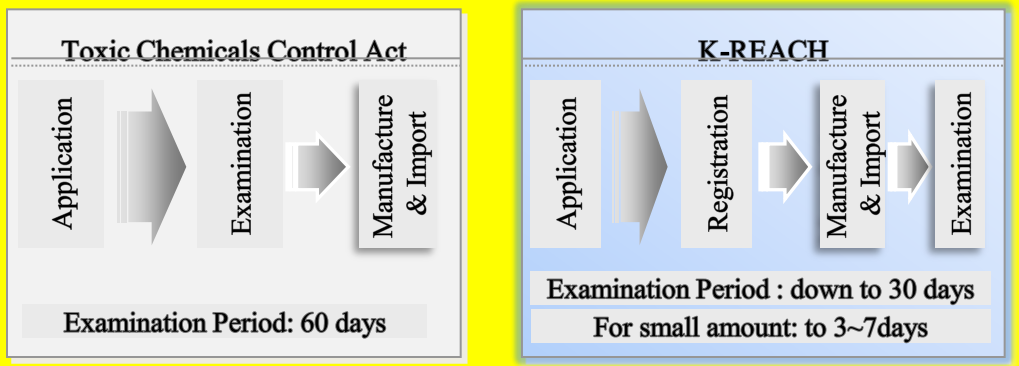
Registration (Article 10)

- **Purpose** : To get the health and safety information of chemicals
- **What to Report** : "ALL" non-phase-in substance **& at least 1 ton per year of phase-in substance subject to registration**
- **Who reports HOW? : Prior to manufacture or import.**

◈ **Separation of registration and examination procedures (same as EU)**

- Registration: procedure for checking whether all dossiers are rightly prepared
- Examination: procedure for reviewing contents of all dossiers



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Phase-in Substances subject to Registration (Article 9)

- Designated every 3 years : **Consider amount of use & data on hazards and risks**
- 3 years of grace period
- **Prior notice and public comments**

1st (2015) **2nd(2018)** **3rd (2021)**

※ Prior notice of 1st list given in Dec 2014, and scheduled to be finalized in June 2015

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Registration Dossier (Article 10 & 14)

	Info. For Regis.	Standard for Regis.	Note
1	Identity of Manufacturer/ Importer	○ Non-phase-in substance ○ Phase-in substance subject to registration (more than 1 ton per year)	- Name, location, representative
2	Identity of Substance		- name, identity data (e.g. molecular formula, structural formula)
3	Use		- classification system of uses, confirmed use, impermissible use
4	Classification & Labeling		- items of global classification and labeling standard (i.e. GHS)
5	Physicochemical Properties		- differentiated according to tonnage (maximum 46) - submitted as full test data or summery
6	Hazards		
7	Guidance on Safe Use		- PPE, responses when explosion, fire or release is occurred, etc.
8	Hazards	○ More than 100 tons per year (getting stricter)	1) hazard evaluation 2) exposure evaluation (exposure scenario / exposure forecast) 3) prepared in priority of safety confirmation
9	Exposure info., Estimated quantities		