

The Action through the Supply Chain of Japanese Companies for REACH (EU's New Chemical Regulation)

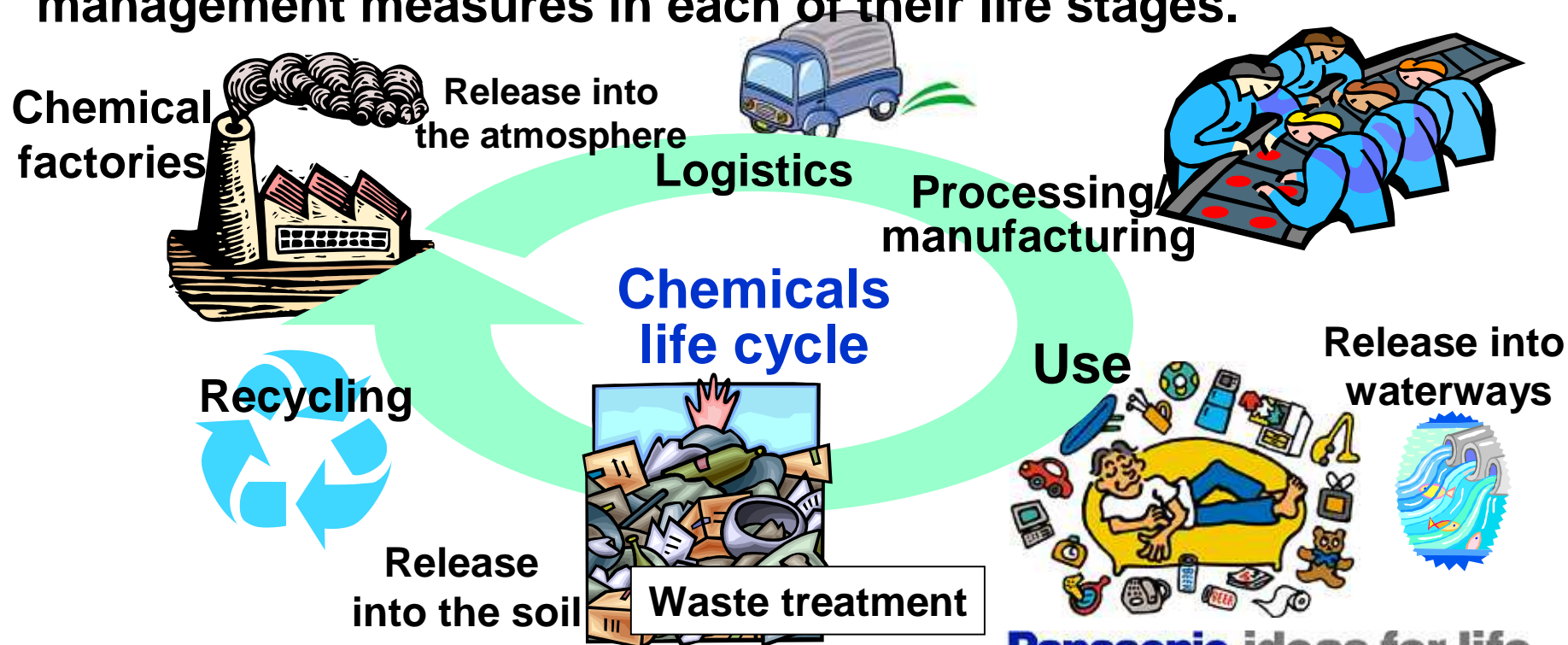
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Outline

- 1. Background of REACH, the New Chemical Substance Regulation**
- 2. Outline of REACH Regulation**
- 3. REACH Compliance by non-EU Companies**
- 4. Compliance by Japanese Companies**
- 5. Expectations for Indian Manufactures**

Chemical Management

- Chemical substances are being used in various aspects of life and in a wide range of products, and they are indispensable for our lives.
- They can become harmful substances for public health and the environment.
- We must prevent problems by implementing adequate management measures in each of their life stages.



Movement of Chemical Management

June 1992 United Nations Conference on Environment and Development (UNCED)

Agenda 21 Chapter 19 :Environmentally sound management of toxic chemicals, including prevention of illegal international traffic in toxic and dangerous products

Rio Declaration on Environment and Development: Principle 15
"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

Ref) <http://www.un.org/esa/sustdev/documents/agenda21/english/agenda21toc.htm>

The World Summit on Sustainable Development (2002)

Main Items of Plan of Implementation about Chemical Management

Renew the commitment, as advanced in Agenda 21, to sound management of chemicals throughout their life cycle and of hazardous wastes for sustainable development as well as for the protection of human health and the environment

Aim to achieve, **by 2020, that chemicals are used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment**, using transparent science-based risk assessment procedures and science-based risk management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration

Rotterdam Convention (Hazardous Chemicals Trade): in force by 2003

Stockholm Convention (POPs): in force by 2004

Implement GHS(classification and labelling): fully operational by 2008

Reduction of the risks posed by heavy metals

etc.

Ref) <http://daccessdds.un.org/doc/UNDOC/GEN/N02/636/93/PDF/N0263693.pdf?OpenElement>

Our Response for RoHS Directive

RoHS Directive is an example of legislation restricting certain hazardous substances in a group of industrial products

Objective

Address problems in waste management caused by the presence of hazardous substances

Push E&E producers to design environmentally friendly products

Restricted chemicals: mercury, cadmium, lead, hexavalent chromium and certain BFR

Requires a substitution of the hazardous materials when technical alternatives are available

Responses by industries

- Corporations conducted surveys on substances contained in their products in accordance with the Joint Industry Guidelines (JIG). These surveys only covered downstream processes and survey formats were not standardized.
- Since small and medium-sized companies and industrializing countries were unable to take quick actions, downstream checks required measurements using analysis equipment.

In future, hazardous substances in products are to be addressed under the new REACH legislation

Background for REACH Regulation

Current chemicals management system is inefficient

- Difficult to identify risks + difficult to address risks
- Lack of information about most chemicals on the market
- Burden of proof lies on public authorities
- No efficient instrument is in place to deal with problematic substances
- Lack of incentives for innovation
- Lack of confidence in chemicals and the chemicals industry.

Outline of REACH Regulation

Regulation on the **R**egistration, **E**valuation and the **A**uthorisation of **C**hemicals

Target


Manufacture, import, placing on market and use of substances (on their own, in preparations or in articles)

Goals

Improving health and safety of workers and the general public.

Environmental protection – avoiding chemical contamination of air, water, soil and damage to biodiversity.

Maintaining a competitive/innovative chemicals industry.

- 
- Hazard data and safe use information is required for a registration.
 - Not only manufacturers and importers but also their customers have the information they need to use chemicals safely.
 - Some substances in articles should be registered or notified.

Framework of REACH

Registration

- Enterprises that manufacture or import **1 tonne or more per year of a particular chemical substance** would be required to register the chemical
- Chemicals in articles become the subject of registration if certain **criteria** (potential release, hazard criteria, etc.) are met.

Authorization

In principle, the marketing of Substances of Very High Concern will be banned. Each use will be authorized upon request.

- CMR (carcinogenic, mutagenic, toxic to reproduction)
- PBT (Persistent, bio-accumulative, toxic)
- vPvB (very persistent and very bio-accumulative)
- Endocrine disruption substances, etc.

Evaluation

- Authorities **verify the adequateness of the registered information, evaluate test proposals** and ask for the submission of information as necessary.
- The European Chemicals Agency prioritizes evaluations based on risks, and then member states formulate evaluation plans.

Restriction

- **Restricts the manufacturing, marketing, and use** in the case where there are unacceptable risks for human life or the environment.
- The introduction of new regulations will be examined based on proposals from the European Commission or member states.

Phase-in Substances and Pre-Registration

Phase-in substances (Article 3 Paragraph 20)

- 1) substances listed in the EINECS**
- 2) substances that have been manufactured in the Community, but not placed on the Community market, in the last 15 years**
- 3) the so-called "no longer polymers" of Directive 67/548**

Pre-registration

each potential registrant of a phase-in substance in quantities of 1 tonne or more per year shall submit all the following information to the Agency:

- 1) the name of the substance (EINECS and CAS number etal)**
- 2) Registrant's name, address and etal**
- 3) the envisaged deadline for the registration and the tonnage band**

By pre-registration the benefit from the transitional regime will be provided

Authorisation and Restriction

Authorisation

- for Substances of Very High Concern ("SVHC", essentially CMR category 1 and 2, PBT, vPvB substances)
- Identification of SVHC (compare Art 58 of REACH Regulation)
- "Sunset date" after which manufacturing and use is only allowed when covered by an authorisation
- Uses or use categories can be exempted from authorisation if the risk is adequately controlled (i.e. if no emissions are expected)

Note: although the number of SVHC is relatively high, authorisation will be a long term process as a strict priority setting will be needed

Restriction

- only minor changes compared to existing system (Directive 76/769/EEC)
- In addition to "marketing & use", now also manufacturing covered

Substances in Articles (Article 7)

- > 1 tonne/year per Manufacturer / Importer
- Not registered for that use



- **Intended to be released**
(regardless of hazard)



- **Substance of Very High Concern**
(CMRs, PBT, vPvB, etc.)
- Placed on candidate list for Auth.
- Conc. of > 0.1% weight by weight



General obligation to **register**

- Timeline in accordance with (phase-in) deadlines



Obligation to **notify** the Agency

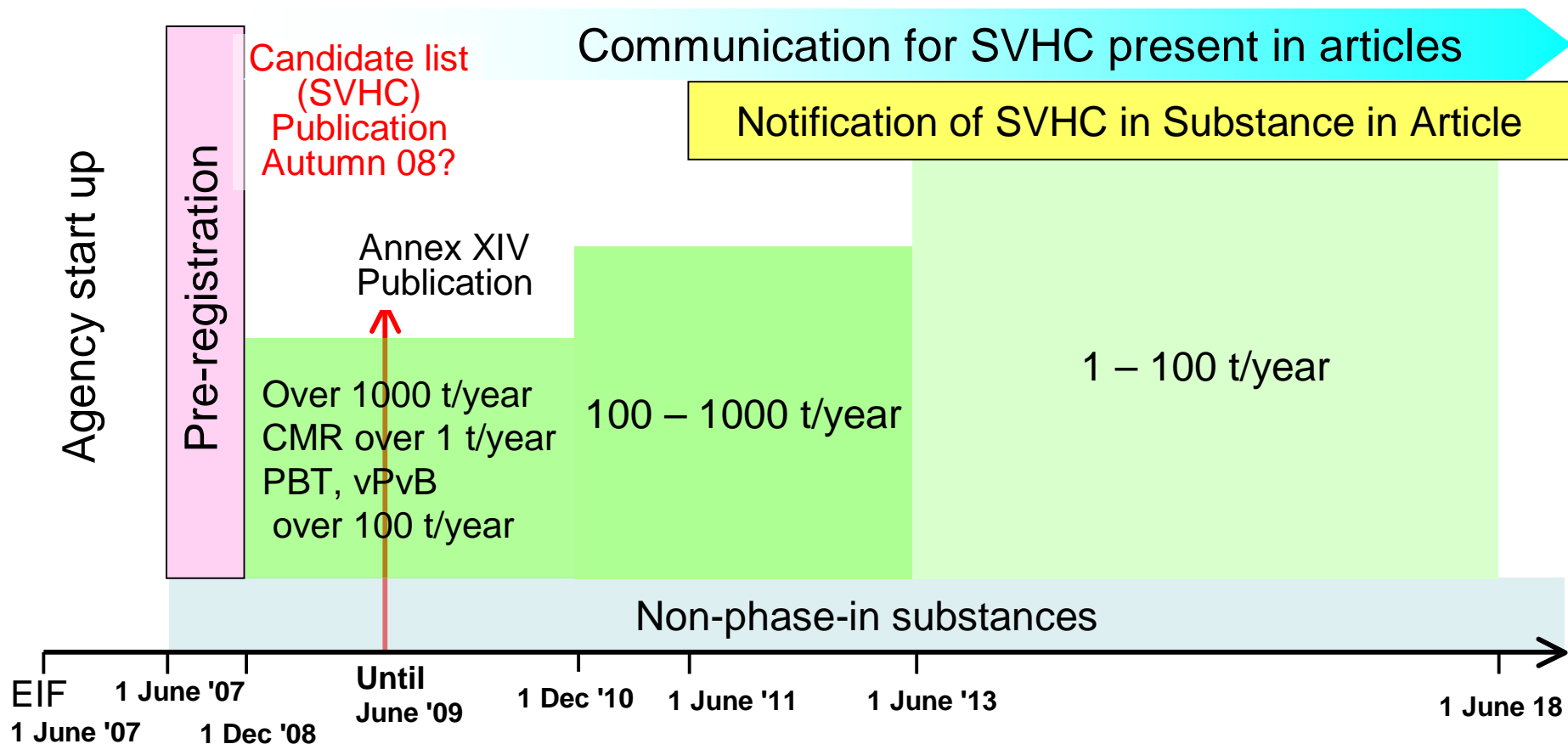
- except where there is no exposure
- At the earliest 1 June 2011, and 6months after SVHC placed on candidate list



Agency may require registration

Timeline of Registration / Notification

Substances intended to be released from articles must be pre-registered
Notification of SVHCs in article is required from 1st June 2011



Duty: Procurement and Manufacture in EU

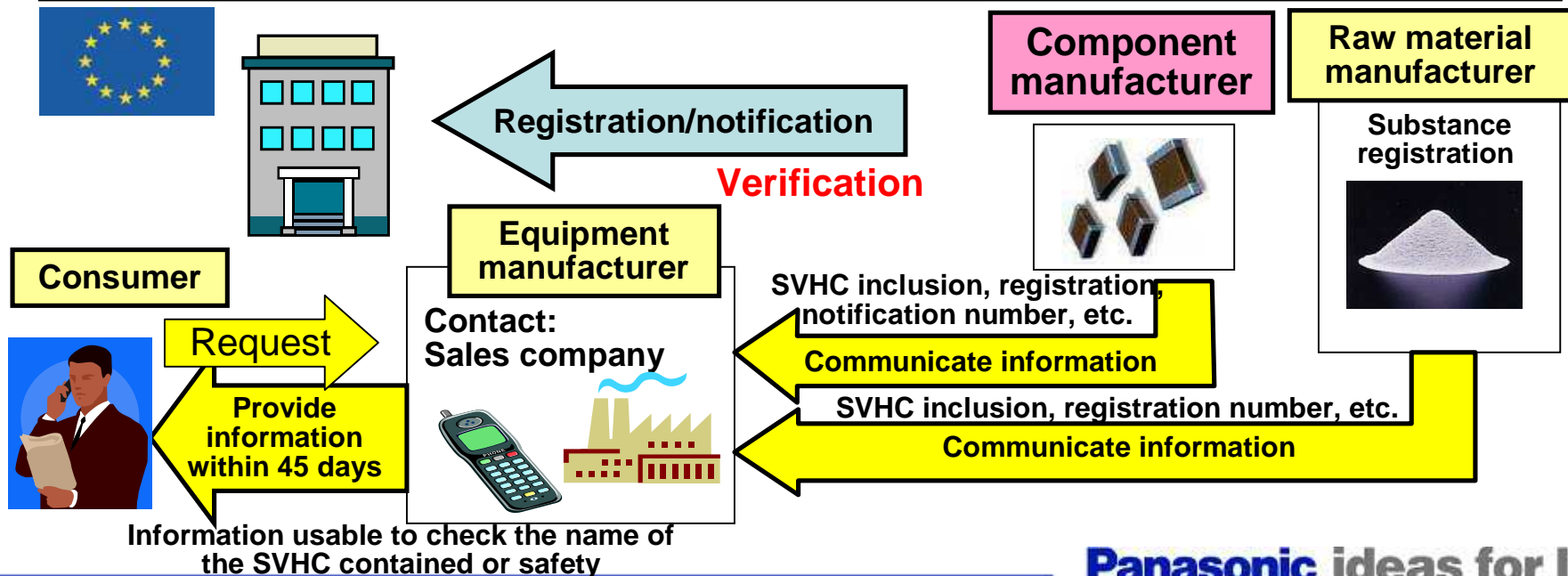
Registration/notification

- 1) Cases of purchasing materials (preparations and articles) manufactured in EU member states and manufacturing equipment in EU member states

Registration (notification): Producers of materials (preparations and articles) perform the registration.

Actions: Purchase preparations and articles whose REACH compliance has been guaranteed.

Verify the information required for assessing whether or not the equipment is subject to registration/notification.



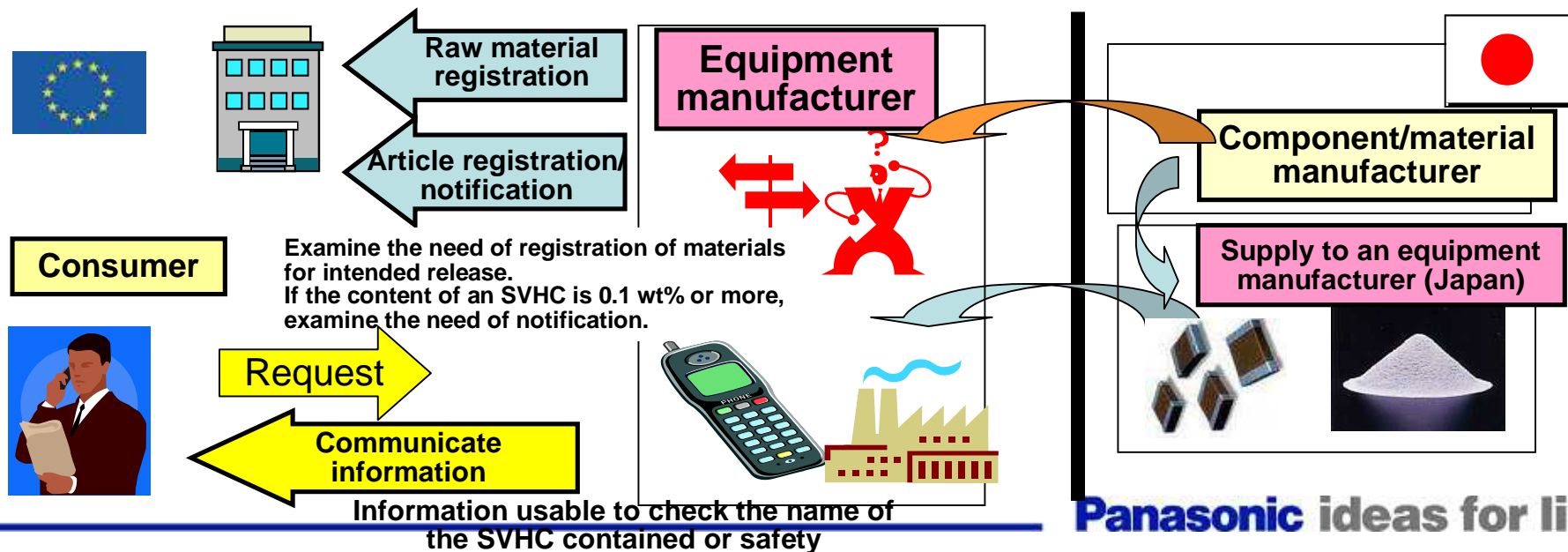
Duty: Procu. Outside of EU and Manuf. in EU

Registration/notification

2) Cases of purchasing preparations and articles from non-EU states and manufacturing equipment in EU member states (purchasers = producers)

Registration (notification):

Equipment producers in EU member states perform registration for both purchased and manufactured goods. If the substance and use have already been registered, producers are not required to perform registration (notification).



Duty: Manuf. Outside of EU and Export for EU (Parts)

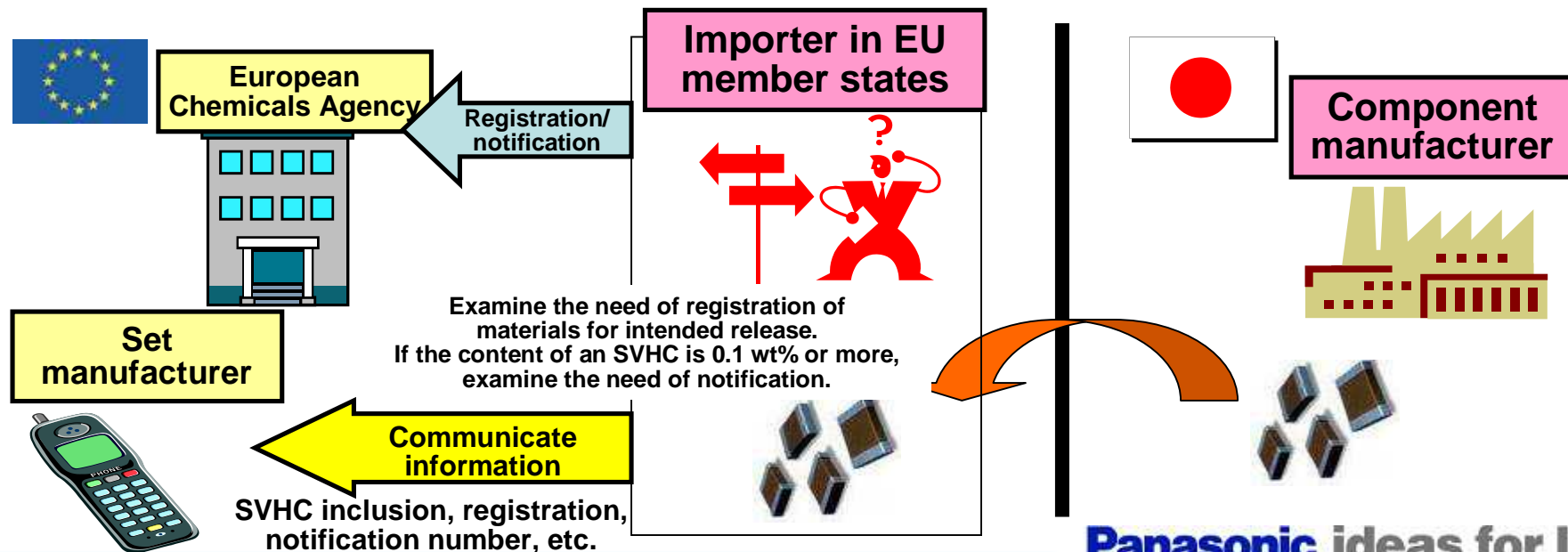
Registration/notification

3) Cases of exporting electronic components from non-EU states to EU member states

Registration (notification):

Electronic component importers in EU member states perform registration. If the substance and use have already been registered, importers are not required to perform registration (notification).

Actions: Check whether or not electronic components are subject to registration/notification and **perform registration if required.**



Duty: Manuf. Outside of EU and Export for EU (End Products)

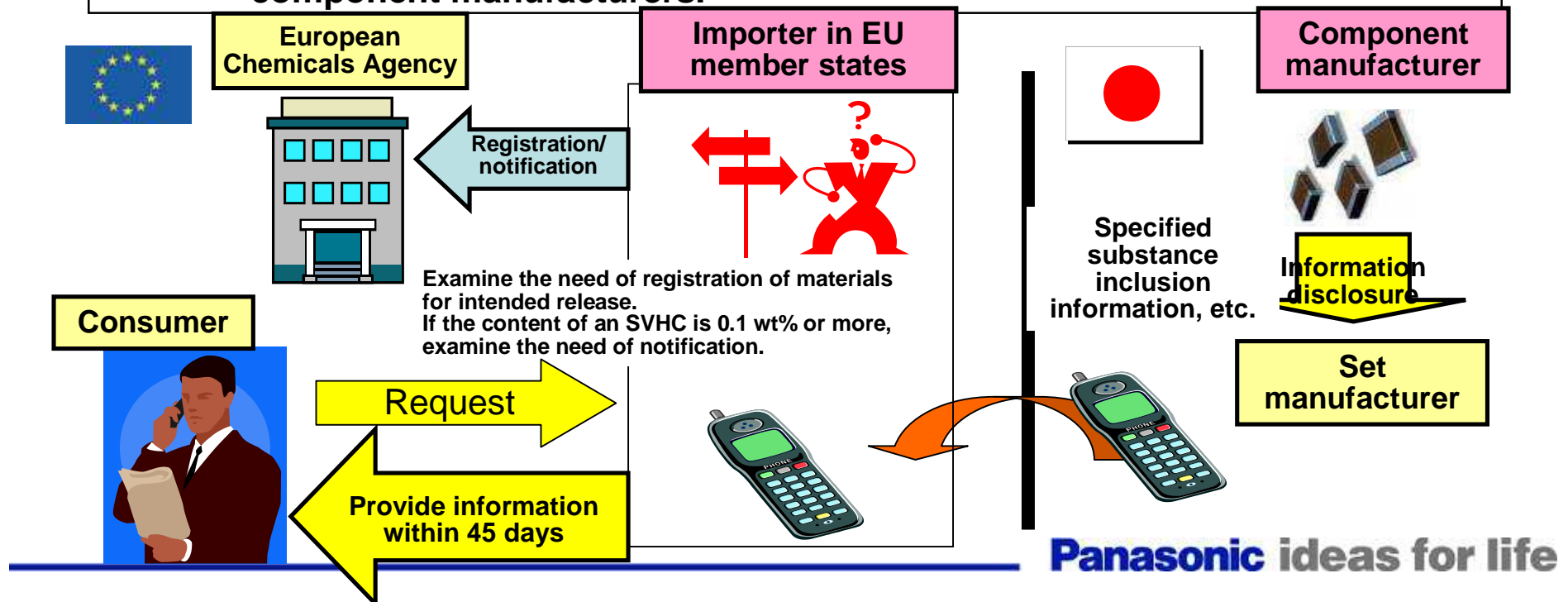
Registration/notification

4) Cases of installing electronic components into electronic equipment in non-EU states and exporting the electronic equipment to EU member states

Registration (notification):

Electronic component importers in EU member states perform registration. If the substance and use have already been registered, importers are not required to perform registration (notification).

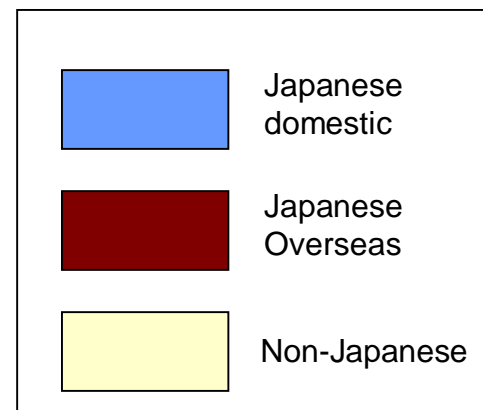
Actions: Acquire the information required for registration/notification from component manufacturers.



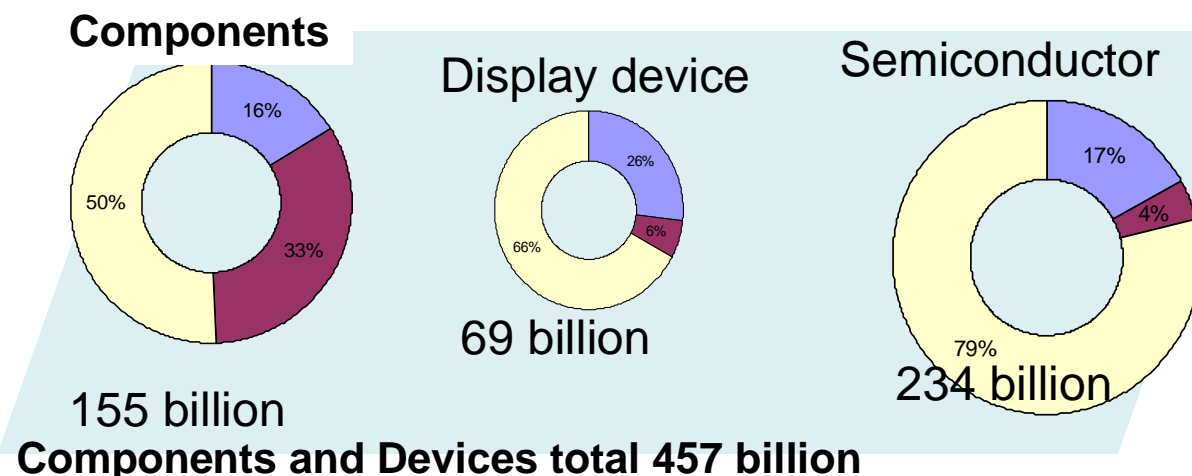
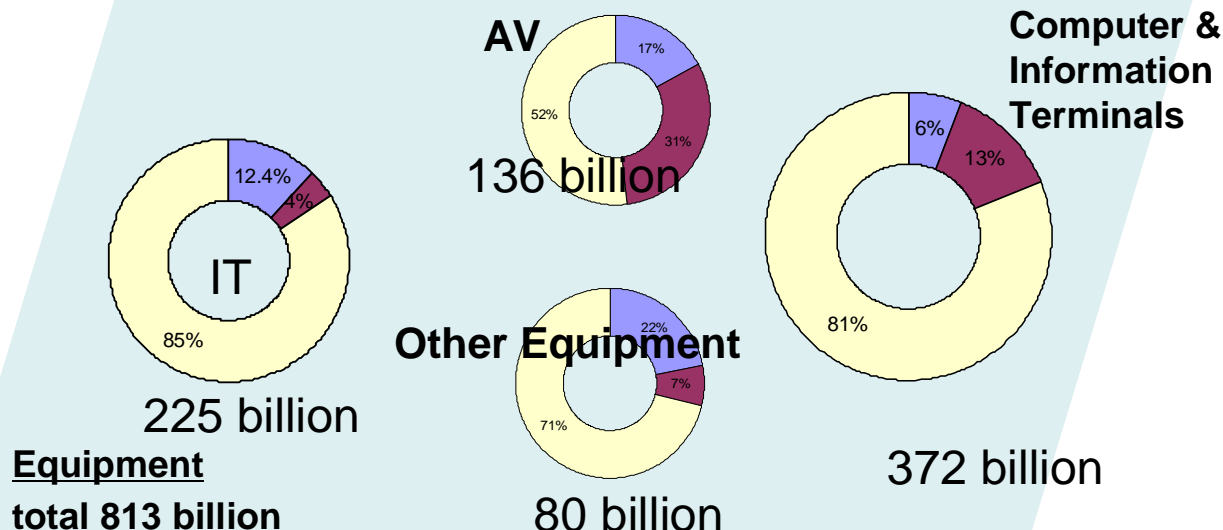
Japanese E&E Industry's Share in Production in the World (2005)

(Source: Japan Electronics and Information Technology Industry Association)

All electronics hardware (1.3 trillions US dollars)



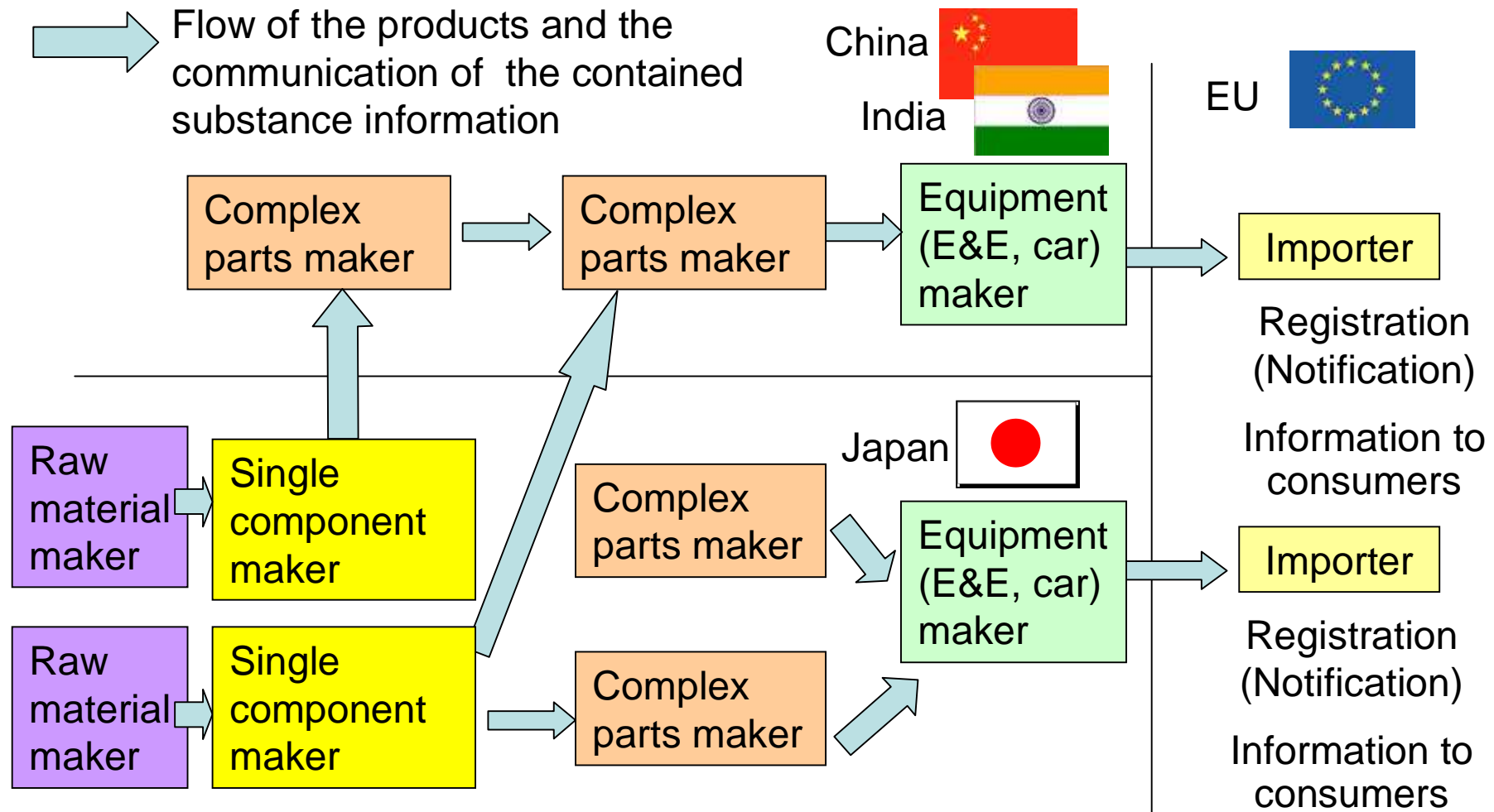
In the electrical and electronic industry, Japanese manufacturers are playing a major role, in particular in the electronic components sector. We must ensure compliance with EU regulations, namely RoHS and REACH. This is also necessary for meeting customers' demands.



Components and Devices total 457 billion

Panasonic ideas for life

The Supply Chain Affected by REACH Expands the Outside of EU



An interruption in the communication flow at some enterprise in some country outside the EU would cause much damage of complying with REACH regulations

Procurement Policy of Panasonic

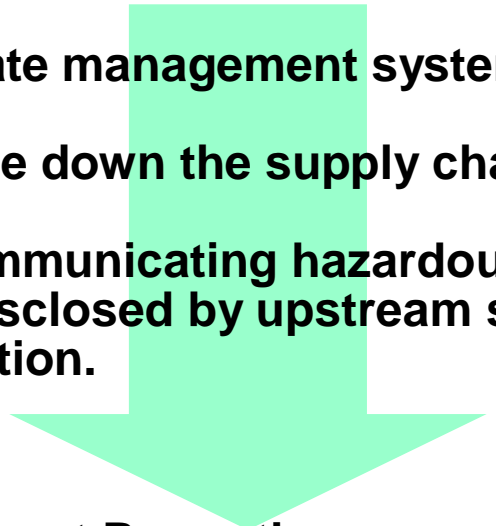
- 1. Working together with Suppliers**
- 2. Implementation Information Gathering and Purchasing during the Development**
- 3. Ensuring Product Quality and Safety**
- 4. Implementation Cost Reduction**
- 5. Achieving Optimum Procurement by Shortening**
- 6. Living in Harmony with the Global Environment through Green Procurement**
- 7. Improving Global Procurement**
- 8. Enhancing Compliance**
- 9. Better Utilizing Information and Enforcing Information Security**
- 10. Respecting Human Rights and the Health and Safety of Labor**

The Approach of Japanese E&E companies

RoHS caused confusion as given in the examples below.

- Individual customers required us to provide different kinds of information.
- The chemical substance information provided by mid-stream processors was inaccurate.

We must prevent similar situations from occurring with regard to REACH, which covers a wider range of chemical substances.

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- Disseminate an appropriate management system for chemical substances contained in products.
 - A scheme to communicate down the supply chain is essential for REACH activities out of EU.
 - Establish a system of communicating hazardous chemical substance information voluntarily disclosed by upstream suppliers/manufacturers who possess the information.

The Japan Article Management Promotion-consortium (JAMP) has been established.

In addition to chemical manufacturers, a number of electrical and electronic manufacturers also joined this consortium.



JAMP'S MSDSplus to Bridge the Gap between National or Regional Chemicals Regulations

Each country's safety data
sheet system

European declarable
substances - SDS

U.S.A's declarable
substances - OSHA

JAPANEse
declarable
substances - MSDS

Each declarable substance list for
MSDS (SDS) is inconsistent with
each other

For declaration of certain substances
in articles for non-EU countries

Tool: MSDSplus

Non-EU countries need to take an
action for certain European
chemicals regulations

1. The certain substances under
REACH (SVHC)
2. Restricted substances under **RoHS**
3. Restricted substances under
Article requirements in **76/769/EEC**

MSDS (SDS) as a tool for each national legislation

**MSDSplus as a tool for article declaration AND FOR declaration of
substances in order to fill in an AIS (Article Information Sheet)**

Solution!

JAMP's AIS to Declare the Information of the Chemicals in the Article



Policy

- **To enable up-stream companies, who cannot know an identified use in the down-stream, to communicate down the supply chain only with the AIS format**
- A common tool for communication of information to meet the REACH requirements (now developing)
- The manufacturers will voluntarily declare with it.
- Declaration of the declarable substance lists:
 - CMR I and II substances in Annex I of EU/67/548/EEC (to be shifted to the SVHC list after the announcement of it)
 - GADSL, JIG substance list, etc.
- Constituent information: the materials corresponding to every part of the article the contained substances to be declared
- The material Classification enables to calculate the recycling rate under ELV Directive as well

Hazardous Substances Management Rule in India

The Manufacture, Storage and Import of Hazardous Chemical Rules 1989, (Amended in 2000)

Scope of Hazardous Chemicals:

- Toxic Chemicals (have **acute toxicity**)
- Flammable Chemicals
- Listed 684 substances are included

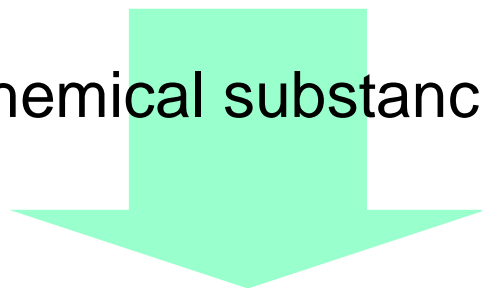
Article 17. Collection, Development and Dissemination of Information.

(3) The occupier while obtaining or developing a **safety data sheet** as specified in Schedule 9 in respect of a hazardous chemical handled by him shall ensure that the information is recorded accurately and reflects the scientific evidence used in making the hazard determination. In case, any significant information regarding hazard of a chemical is available, it shall be added to **the material safety data sheet** as specified in Schedule 9 as soon as practicable.

(Reference) <http://envfor.nic.in/legis/hsm/hsm2.html>
<http://envfor.nic.in/legis/hsm/msihcar.html>

Expectations for Indian Manufactures

- As is the case with Japan, chemical substance information that meets REACH requirements is not available in India.
- There is a large gap between the content of available information and REACH requirements in that the available information does not include chronic and environmental toxicity information.
- We must manage chemical substances in consideration of the entire life cycle.



Must enhance chemical substance management in the wake of ensuring the REACH compliance of industrial products.

Let's work together to increase competitiveness of Asian manufacturing sites as the factory of the world.

Further Information

REACH

European Chemicals Bureau (ECB)

<http://ecb.jrc.it/reach/>

European Chemicals Agency (ECHA)

http://ec.europa.eu/echa/reach_en.html

(Help desk is placed in it)

European commission / Industry Sectors

http://ec.europa.eu/enterprise/reach/index_en.htm

European commission / Environment

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

JAMP (The Japan Article Management Promotion-consortium)

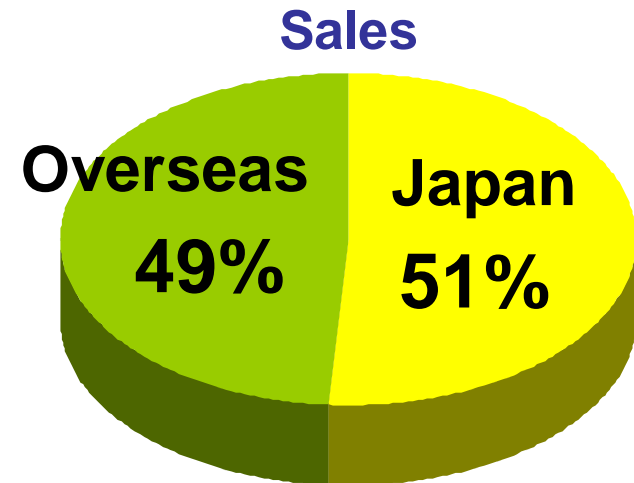
<http://www.jamp-info.com/english/>



Company Profile

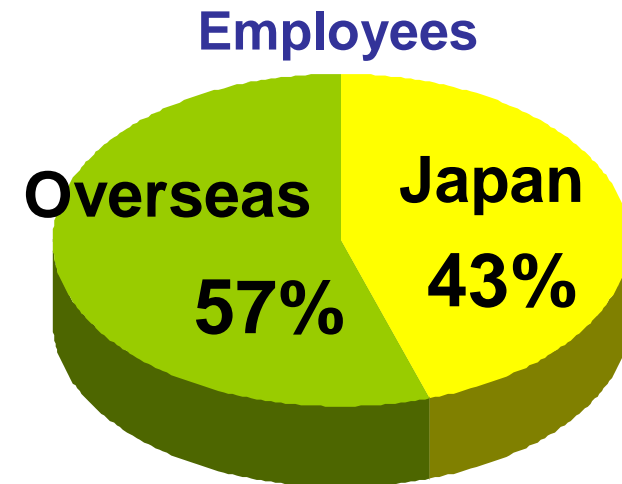
Global (fiscal year ended 2007 Mar.)

■ Foundation	1918	
■ Sales	9,108	bill. J. yen
■ Profit	439	bill. J. yen
■ Employees	328,000	approx.

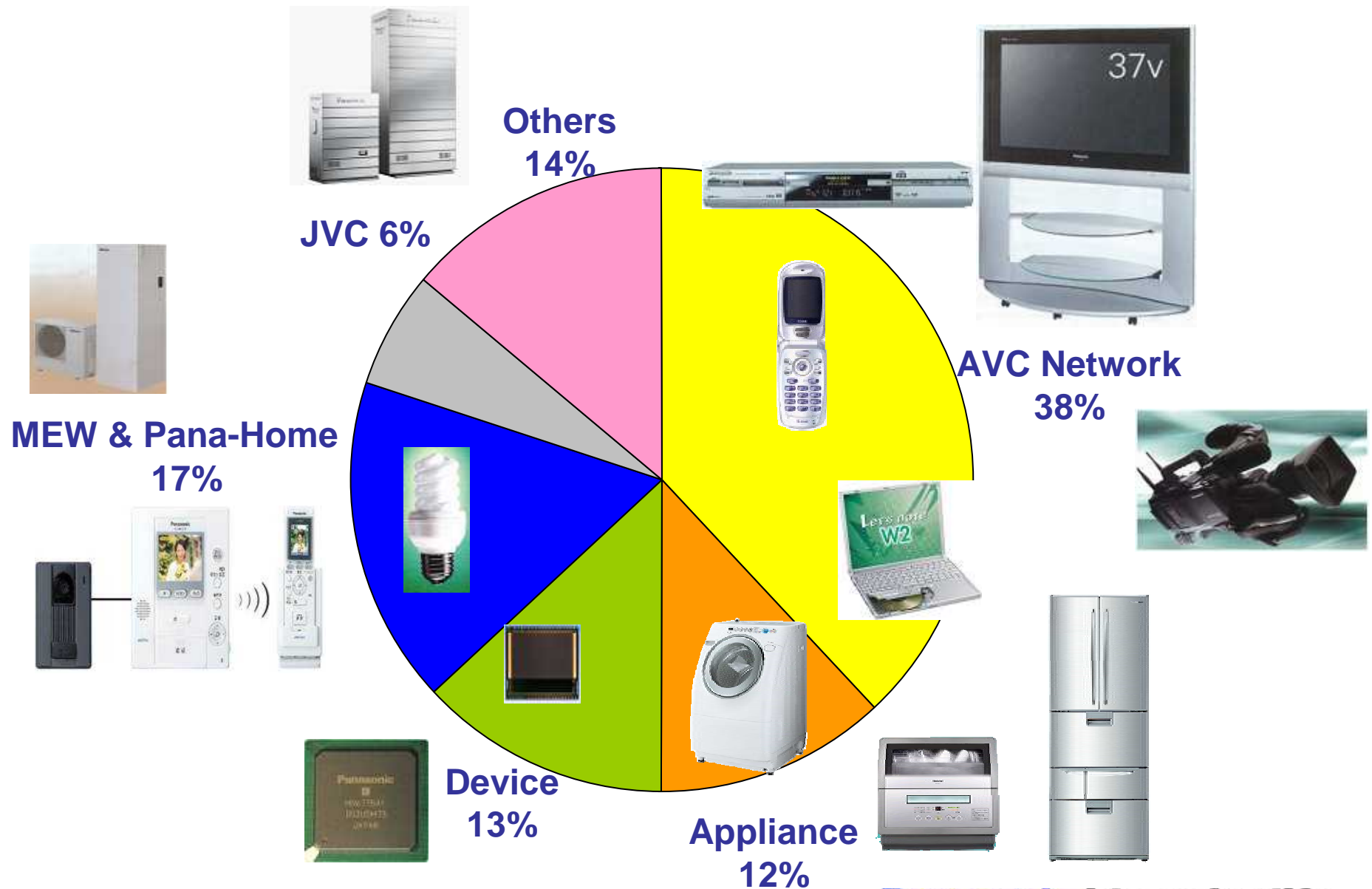


Europe (fiscal year ended 2006 Mar.)

■ Operation	Since 1962
■ Sales	9.5 bill.US dollars
■ Employees	8,000 approx.



Sales by Products Category



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