



June 2017

Inclusion of PFOA and PFOA-related substances to the Stockholm Convention / Exemption request







Introduction to Daikin Industries

Corporate Data

Company Name	Daikin Industries, Ltd. (Head Office: Osaka , Japan)
Incorporated	1934 (founded in 1924)
Capital	EUR ~670 millions
Sales	EUR ~16 billion (fiscal 2015:consolidated)
Number of Employees	60,805 (March, 2016:consolidated)
Number of Group Companies	213 consolidated subsidiaries (28 in Japan; 185 overseas) (March, 2016)

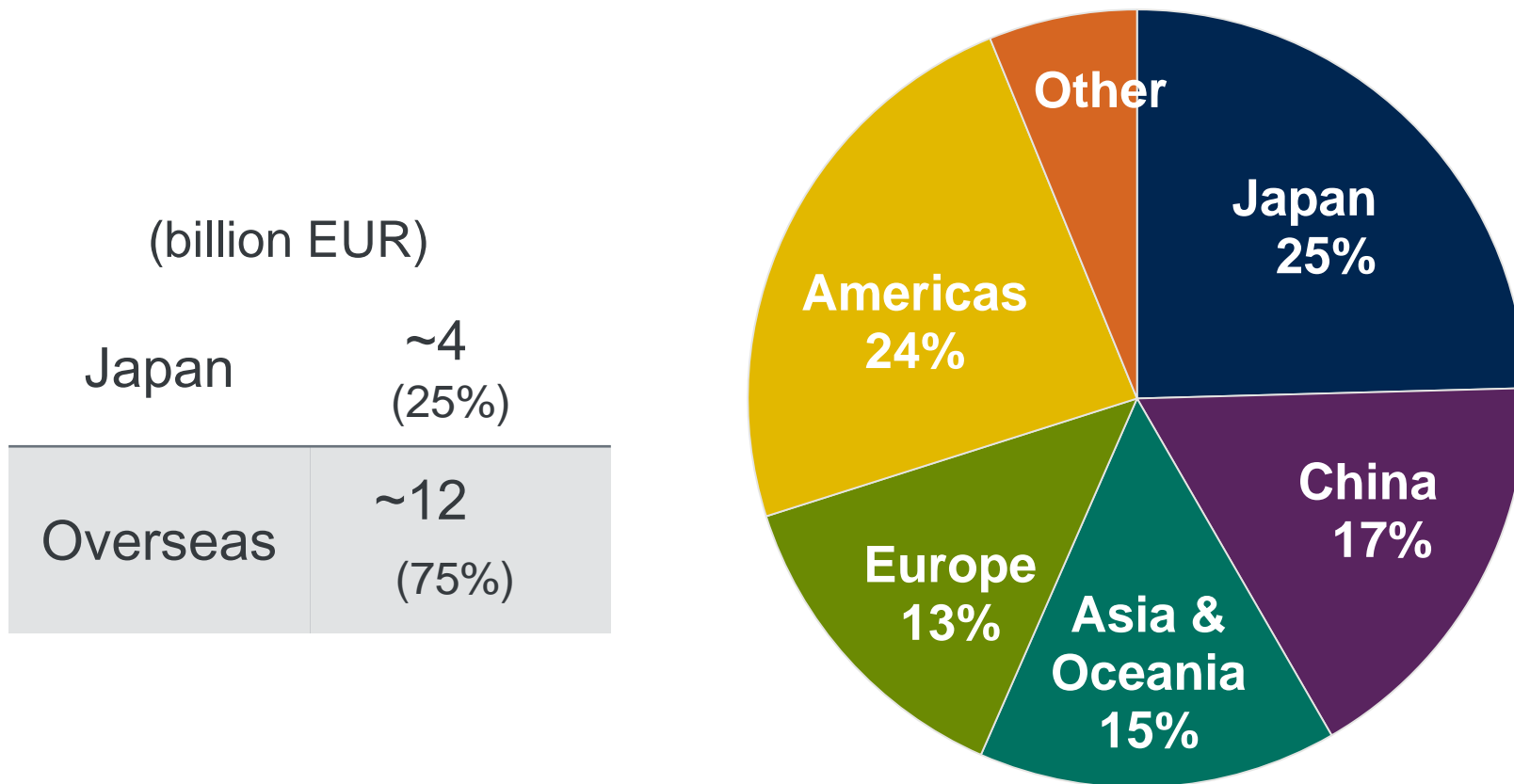
Sales Breakdown by Division

Total EUR ~16.6 billion (fiscal 2015:consolidated)

<p>Air Conditioning and Refrigeration Business</p>	<p>14.8 (89%)</p>	 <p>次世代エアコン うるさら7 NEXT AIR CONDITIONING</p>	
<p>Chemicals Business</p>	<p>1.3 (8%)</p>		
<p>Other (Oil Hydraulics, Defense Systems,etc.)</p>	<p>0.5 (3%)</p>		 <p>呼吸調整器 ライトテックDS13 融剤回収装置 ライトテック-3X</p>

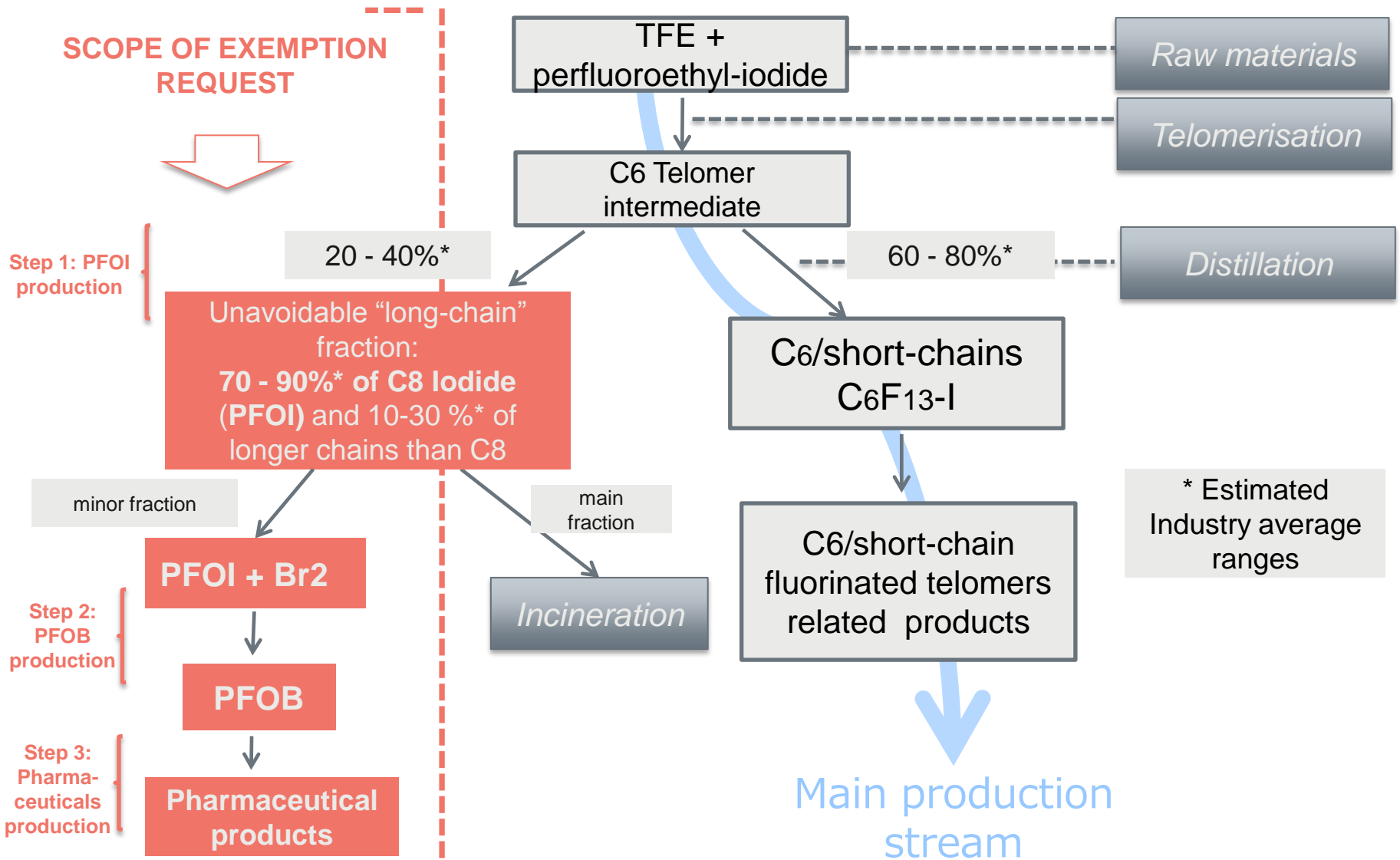
Sales Breakdown by Global Region

Ratio of Overseas Sales 75% (fiscal 2015:consolidated)



Production process related to the exemption request

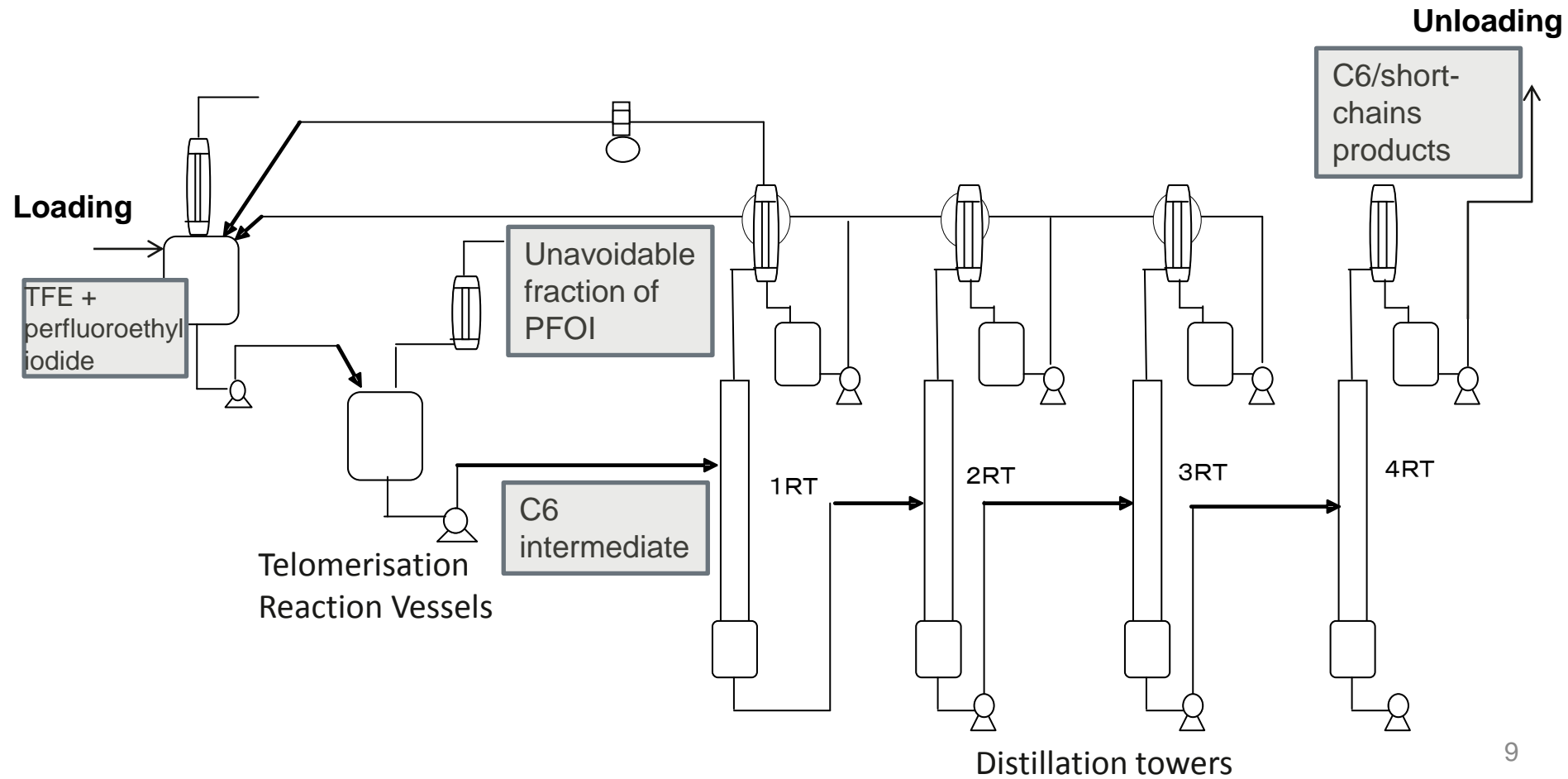
Overview of scope of exemption request



Step 1: PFOI as unavoidable by-product from C6/short-chain alternatives production

- PFOI (Perfluorooctyl iodide) is considered as a substance that can degrade into PFOA, i.e. a PFOA related substance
- A fraction of PFOI is unavoidably/unintentionally produced during the production of short-chain fluorotelomers (“C6 telomerisation process”) which are the main alternatives to C8-based fluorotelomers
- This production takes place at one single site in Japan

Step 1: Production process



Step 1: Emissions control measures

Substance PFOI (Perfluorooctyl iodide, CAS number: 507-63-1)

PFOI Manufacturing at Daikin industries

Loading	All materials are loaded via closed automatic charging
Process	Exhaust gas is removed with alkali tower, and its liquid is then incinerated
Workers	Safety equipment: protective gloves, gas mask (see picture) Training: preparation of procedure manual and periodical OJT
PFOA related substance	PFOI is absorbed by activated carbon, and exhaust gas is removed with alkali tower



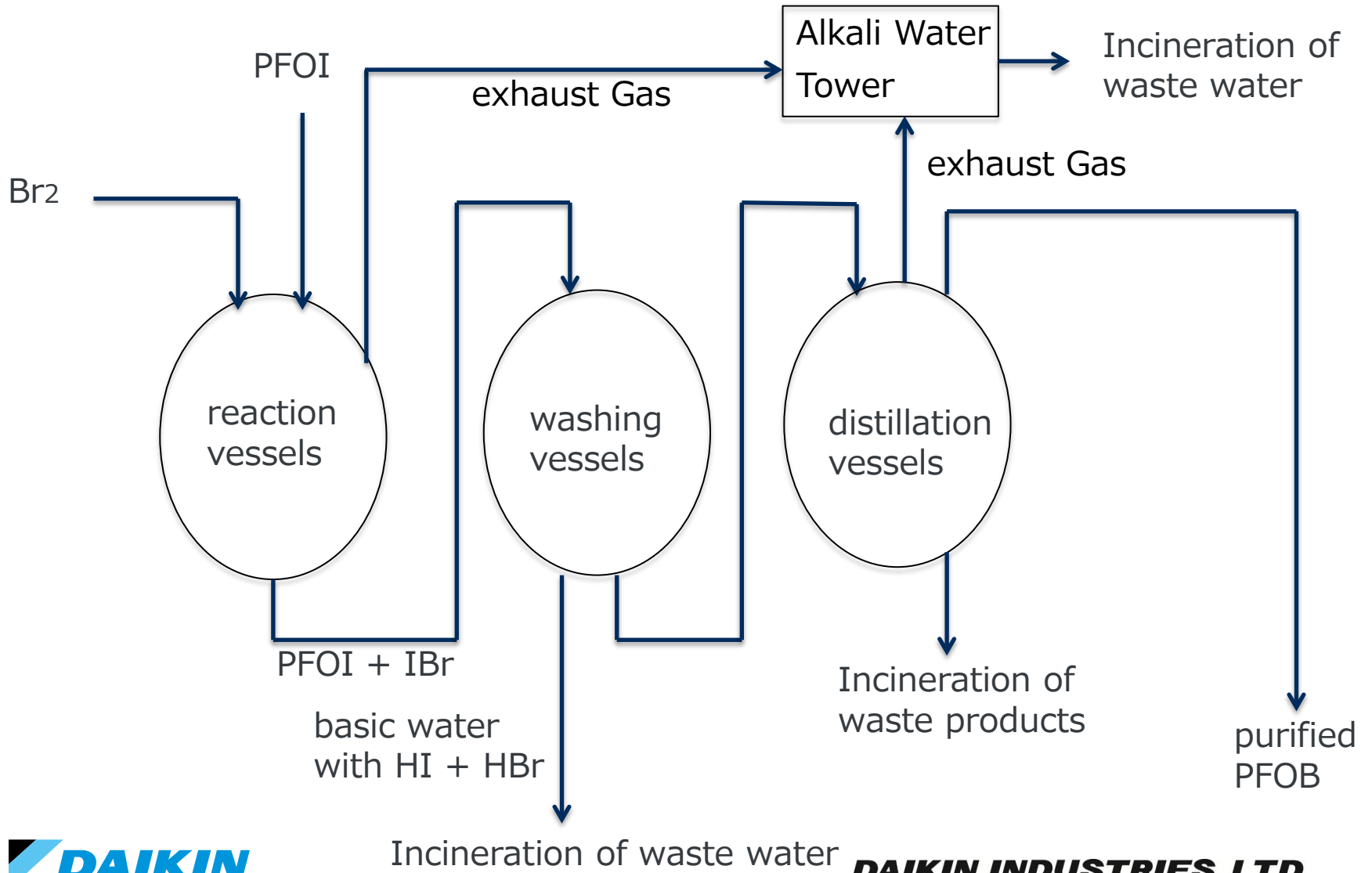
PFOI transportation to PFOB manufacturer

Unloading	Unloaded to chemical drum by loading tubes equipped with ventilation system Exhaust gas is removed with activated carbon and then absorbed with alkali tower, waste water incinerated
Workers	Safety equipment: protective mask Training: preparation of procedure manual and periodical OJT

Step 2: Reprocessing of PFOI into PFOB

- PFOB (Perfluorooctyl bromide): a Perfluorocarbon (PFC) with limited GWP (e.g. not covered by the EU F-Gases Regulation, not covered by the Montreal Protocol), not a PFOA-related substance
- PFOI is used as intermediate to produce PFOB
- PFOI residual amount in PFOB in the range of 100-200 ppm, ongoing R&D to further take down PFOI residual amount
- PFOB production occurs in one single site in Japan (different site than PFOI production)

Step 2: Reprocessing of PFOI into PFOB

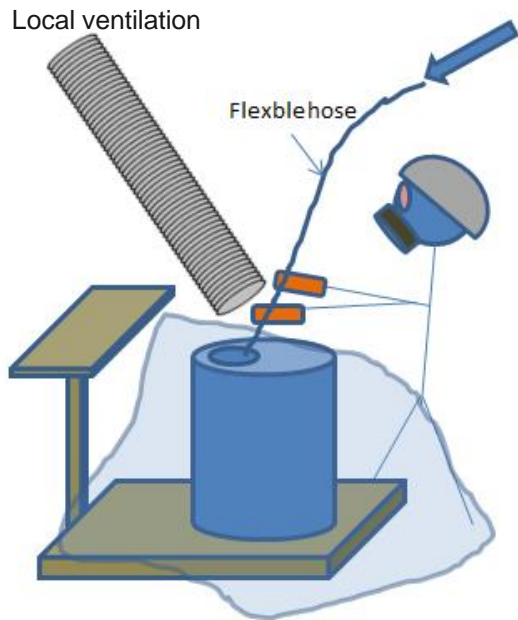


Step 2: Emissions control measures

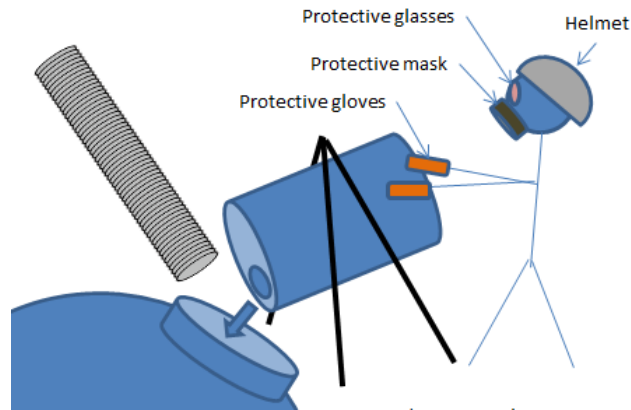
Substance	PFOB (Perfluorooctylbromide, CAS number: 423-55-2)
PFOB Manufacturing	
Loading	Ventilated with wash-column. Empty drum is dried by local ventilation and disposed at specialised firm Waste water/solvent is incinerated externally (outsourcing)
Process	The reaction mixture is treated into alkali (basic) water solution, after separation the waste water is incinerated externally, PFOB is purified by fine distillation
Workers	Safety equipment: protective gloves and mask, local ventilation Training: Exercise to wear line hose mask and respirator – every six months
PFOA	PFOA that may be produced during the reaction is removed when PFOB is washed with basic water, waste water is then incinerated

Step 2: Emissions control measures

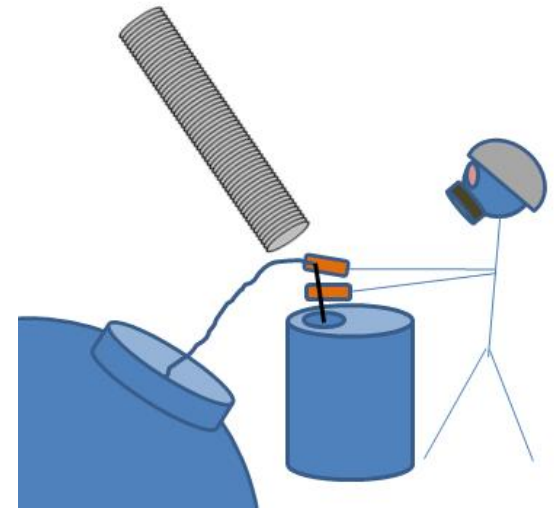
Filling materials to drums



Loading of PFOI to reactor



Loading of Br₂ to reactor under reduced pressure



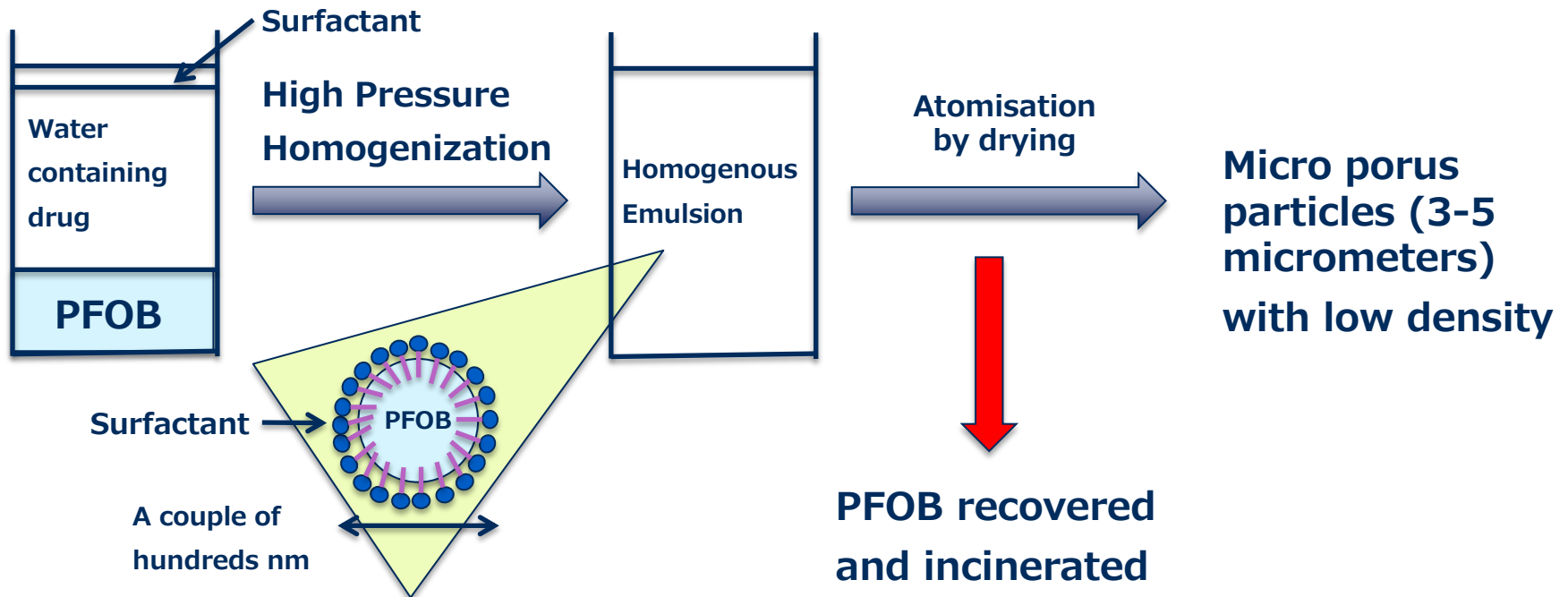
Step 3: Use of PFOB in pharmaceuticals production

- PFOB is used as processing aid (solvent) to produce “micro-porus” pharmaceutical products
- **Technical function:**
 - Allows to obtain a drug which is very small and porous that can deliver the active substance in a smaller amount of dry powder to the lesion (lung) more effectively in a short time via inhalation
- **Applications:** Respiratory therapeutics for lung/pulmonary diseases, ongoing research on additional pharmaceutical applications
 - PFOB-based technology may allow pharmaceutical companies to develop more effective treatments via inhalation for a wider scope of clinical applications
- Drug delivered via metered-dose inhalers. Inhalers disposed after use.
- PFOI may be present in final drug as residue. Daikin would estimate the figure to be in the range of a few ppm
- Production currently takes place on two sites in the US

Step 3: Use of PFOB in pharmaceuticals production

- The use of PFOB is the result of years of research by the pharmaceutical industry
- At present, no alternatives to PFOB is available to meet product performance
- Improved life quality and health status of patients
- Indicative references:
 - “Cosuspensions of Microcrystals and Engineered Microparticles for Uniform and Efficient Delivery of Respiratory therapeutics from Pressurized Metered Dose Inhalers”, Reinhard Vehring et al, Langmuir, 2012, 28, 15015 – 15023, <https://www.ncbi.nlm.nih.gov/pubmed/22985189>
 - Impact of COPD on daily lives of sufferers; “COPD uncovered: an international survey on the impact of chronic obstructive pulmonary disease (COPD) on a working age population” Fletcher et al. BMC Public Health 2011, 11, 612, <https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-11-612>
 - “Efficacy and Safety of Glycopyrrolate/Formoterol Metered Dose Inhaler Formulated Using Co-suspension Delivery technology in Patients With COPD” Fernaondo J. Martinez et al. CHEST 151#2, February 2017, <https://www.ncbi.nlm.nih.gov/labs/articles/27916620/>
 - Development of an Inhaled Dry-Powder Formulation of Tobramycin Using PulmoSphere Technology, David E. Geller, M.D.,¹ Jeffry Weers, Ph.D.,² and Silvia Heuerding, Ph.D., JOURNAL OF AEROSOL MEDICINE AND PULMONARY DRUG DELIVERY, Volume 24, Number 4, 2011, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3146747/pdf/jamp.2010.0855.pdf>
 - Pharmaceutical Particle Engineering via Spray Drying (Reinhard Vehring, 2008) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2292490/>

Step 3: Production process



Step 3: Emissions control measures

Substance	PFOB (Perfluorooctylbromide, CAS number: 423-55-2)
PFOB transportation to Pharmaceutical manufacturers	
Packaging	Stainless steel drum with PTFE gasket
Safety	Torque of drum lid, capping and sealing
PFOB use at Pharmaceutical manufacturers	
Process	PFOB recovered either from exhaust gases or water is incinerated
Workers	Safety equipment: protective mask, gloves and clothing, local ventilation

Exemption request

Exemption request under the Stockholm Convention

- *Production of pharmaceutical chemicals* is mentioned in paragraphs 69 and 186 of the draft *Risk Management Evaluation* report.
- PFOI is used as intermediate in the production of PFOB. Use of PFOB as processing aid is essential for the production of more effective pharmaceuticals for various clinical applications
- Strict emissions control/minimisation at all steps of production.

An exemption is needed for **PFOI reprocessing into PFOB**
for the production of pharmaceuticals