

Roche Position¹ on Waste Management

Background

Roche's business is to develop and offer high-quality medical and in-vitro diagnostic solutions for unmet medical needs. However, our products and operations also have the potential to negatively impact people and the environment.

Roche's operations generate wastes, some of which, if improperly handled, could cause harm to people and the environment. Roche has established an effective Safety, Security, Health and Environmental protection (SHE) management system, including internal guidelines, directives and auditing, to continuously reduce the potential for negative impacts of our business operations.

With regard to waste generation and waste disposal and management, Roche places a priority on avoiding waste generation. Furthermore, Roche is minimizing any potential adverse effects wastes might cause to the environment and communities where Roche wastes are ultimately managed, on Roche's employees. Waste streams arise from the many areas of the company's activities, e.g. manufacturing, R&D, logistics, utilities, facility management, warehousing, distribution and administration. Hazardous waste streams at Roche include materials from chemical, biological and physical processes. Roche also generates general wastes, including household type refuse, paper, cardboard, glass, plastics, green waste, scrap metal or uncontaminated building demolition debris. Waste handling principles valid for the Group globally are defined in the "Guidelines for the Assurance of Safety, Security Health and Environmental Protection (SHE) in the Roche Group" (see link at the end of this document). They preclude its affiliates from using landfills for disposing of chemical and other hazardous wastes (e.g. pharmaceuticals, byproducts or otherwise toxic or bio hazardous materials). Instead, Roche requires incineration to effect waste destruction.

Stakeholders' Expectations and Concerns

Waste Management encompasses many stakeholders including but not limited to:

- Community and Private Citizens;
- Ecological Receptors;
- Governmental Agencies and Regulators;
- Roche Affiliates and our Employees;
- Scientific Community

Each of the listed stakeholders has a unique interest in the disposal and handling of wastes. The interests and roles of each of these stakeholders are diverse, but not completely independent of the others. All of these stakeholders must partner in order to ensure risk mitigation measures are appropriately addressed and that all waste handling, transport and disposal measures are acceptable and in compliance with all applicable local legal and regulatory requirements.

¹ Pertains to SDGs 3, 6 and 12

Community and Private Citizens

Private citizens and the communities where they reside show a special interest in how wastes are managed in their communities. Releases of hazardous substances into the environment from mismanagement of wastes may potentially expose these stakeholders to these substances through various routes.

Ecological Receptors

Contaminated surface water, ground water or soils from mismanagement of wastes can also cause serious harm to a vast array of sensitive ecological receptors. Scientific advancements demonstrate the importance of the role that a healthy ecological system plays in the long term welfare and prosperity of our environment.

Another important topic is methane emissions (“greenhouse gas”) from waste decomposition in landfills and subsequent environmental impacts.

Governmental Agencies and Regulators

Governments and their regulating agencies have the mandate to protect their citizens and the environment. Regulators establish a set of laws and regulations to manage waste generation and disposal to prevent environmental risks and exposures that could potentially impact people or the environment in an adverse manner.

Roche Affiliates and Our Employees

Roche requires its affiliates to use resources responsibly and protect its employees from exposure to any potential wastes generated. Roche expects its affiliates to obey all applicable laws and regulations and to ensure all risks are identified and properly mitigated. Affiliates have the responsibility to being a good corporate citizen and neighbors to the communities surrounding them.

Scientific Community

Science plays a key role in the development of waste minimization and waste treatment technologies, and in developing processes for recycling to foster a circular economy. The scientific community is focusing on better and more sustainable ways to protect the environment and to identify ways to eliminate /minimize waste generation.

Roche Position

Roche has globally adopted the following principles and practices surrounding waste management (prioritized list):

- **Avoid** the use of environmentally harmful or toxic materials in manufacturing or other Roche operations, e.g. eliminating the use of chlorinated solvents, heavy metals etc.;
- **Reduce/minimize** the consumption of raw materials, resources in general (e.g. energy, water, etc.) and the amount of waste generated in all business processes;

- **Re-use**, e.g. by-products, packaging materials, etc.;
- **Recycle**, e.g. recovery and recycling of solvent mixtures, packaging materials, etc.;
- **Down-cycle** to a lower-value product
- **Thermally destroy** waste by incineration with state-of-the-art flue gas treatment. As incineration significantly reduces the volumes, toxicity, and reactivity of potentially harmful wastes, it is Roche's preferred disposal method for organic and hazardous waste;
 - **Thermal Destruction with heat recovery** (preferred) of the waste's energy content by incinerating, e.g. non-reusable wastes with high energy content;
 - **Thermal Destruction** without heat recovery; and
- **Landfill** only inert materials such as incineration residues and clean building rubble (free of PCBs, PAH coatings, asbestos, Pb paint, etc.) or other wastes not suitable for incineration. Roche requires incineration of combustible hazardous wastes in state-of-the-art incinerators wherever possible and also strives for incineration of general wastes.

Waste minimization and reduction measures are not only restricted to production processes, but are also evaluated and implemented across all other operations at Roche. Roche strives for eco-efficient and sustainable solutions which not only reduce the company's environmental footprint but also yield economic benefits, e.g. reduction in raw materials and disposal costs.

For Roche, unsafe waste handling and disposal practices represent an unacceptable risk to the environment; lead to environmental liabilities and ultimately impact the company's reputation and right to operate. Thus, before using waste vendors Roche SHE-professionals or third parties on behalf of Roche must do a thorough background investigation including a site-visit to review compliance with local and legal regulatory requirements, to check, whether Roche's minimum SHE standards are met and financial solvency requirements are fulfilled. Repeating waste vendor audits ensure that these vendors do not fall below Roche's expectations.

Country specific concerns about certain waste disposal technologies make it sometimes difficult for Roche affiliates to comply with our foresaid Group-wide waste management strategy. For example, incineration of wastes is not a waste management option in some countries due to negative public perception of incineration (concerns over adverse environmental impacts from suboptimal combustion (e.g. dioxin formation) or from the potential toxic effects of the resulting incinerator ash).

In many other countries where incineration is not outright banned, a shortage of incineration capacities may exist. Thus by default, landfilling wastes is either the only waste management option, or still the most common waste disposal practice in these countries. In such places Roche affiliates are supportive of any local actions towards a more favorable perception of incineration as the best form of waste management. In this case an affiliate might also consider making trans-boundary shipments of hazardous wastes to a state-of-the-art incineration plant in another country, if country-specific laws permit. Where such situations may occur, the legal requirements of the delivering and receiving countries have to be strictly followed. Furthermore, the environmental risks

and impacts resulting from the trans-boundary transportation of hazardous waste in such circumstances must be considered when making the over-all evaluation for managing wastes in this manner.

Outlook, Status, current Engagement and Initiatives

Roche has established goals intended to result in the continuous waste reduction for specific wastes. Roche has set corporate goals to reduce general wastes per employee by 10 % in 5 years, using 2015 as the baseline, and a 50% reduction in chemical waste to landfill in the same 5 years. Each and every Roche affiliate has been given the challenge to step up efforts to avoid, reduce or recycle general wastes. Affiliates have been tasked to increase recycling rates for general waste and when recycling is not possible, to incinerate general wastes for heat recovery as opposed to landfilling these types of wastes. Achievements will be closely tracked and correction measures will be implemented on the affiliate level. To measure and monitor performance and progress towards the goals, waste related data is collected as part of our annual SHE key figure reporting. This data is also used to inform questionnaires of rating agencies that assess our SHE performance.

Waste management actions and principles currently engaged by Roche affiliates include:

- **Documentation** of type, quality, quantity and treatment/disposal pathway of all wastes at each affiliate;
- **Tracking** of quality, quantity and treatment/disposal pathway of all wastes at each affiliate;
- **Segregation** of wastes preferably at the source. Commingling/mixing of different wastes must be avoided;
- **Pre-treatment of specific waste materials** to render them non-hazardous, e.g. decontaminating used diagnostic equipment, prior to final disposal;
- **Labeling:** Roche facilities must meet all international labeling requirements and regulations for dangerous goods/wastes, including any additional local/legal requirements that may apply;
- **Storage** facilities for hazardous, toxic, bio hazardous wastes (according to their hazard potential) and waste containing controlled substances must be properly designed, dedicated, and secured with restricted and controlled access. Adequate fire protection, fire water containment, smoke detection systems and emergency response provisions are necessary as well. Waste storage facilities must be designed especially for the type of waste that is to be aggregated;
- **Collection and shipment** for offsite disposal should be done on a regular schedule frequency so that wastes are not accumulating to large quantities on site;
- **Transportation** to waste treatment and disposal facilities must be organized under strictly controlled conditions for hazardous wastes and expired, returned or out-of-specification pharmaceutical products by officially licensed shippers. Returned products have to be ultimately destroyed and care must be taken to prevent these products from entering illegal or illicit supply channels;
- **Incineration** facilities must hold all required licences and meet the highest technical/destructive, safety, and regulatory standards.

Roche is also committed to an important international waste-related agreement: *The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal* is one of the few international waste treaties implemented by multiple countries. The Basel Convention is an international treaty including 75 countries that was designed to reduce the movements of hazardous waste between nations, and specifically to prevent transfer of hazardous waste from developed nations to less developed countries (LDCs). The Convention is also intended to minimize the amount and reduce the toxicity of the hazardous wastes generated by member countries. The intent of this measure is to further ensure the environmentally sound management of hazardous wastes. The Convention mission mandates the management/disposal of hazardous wastes to be as close as possible to the source of waste generation. The Basel Convention also has a mission to assist the LDC members in developing environmentally sound management practices of the hazardous and other wastes they generate.

Today, many countries discuss the potentially negative effects that releasing APIs may have on the environment. APIs primarily enter the environment through patient use and excretion. Additionally, some unused medicines may be improperly disposed of and thus may end up in the environment. Lastly, some API could be released into the environment via manufacturing processes. Despite precautions taken at manufacturing sites to prevent releases of APIs there is a remaining small risk for soils, ground water and surface water to become contaminated. Please also consult the *Roche Position on Pharmaceuticals in the Environment (PIE)* for further details (see link at the end of this document).

Drug “Take-Back” programs have been established in many countries. To avoid improper disposal of unused pharmaceuticals, Roche participates in take-back programs in various countries. Please refer to the *Roche Position on Product Stewardship* for further details (see link at the end of this document).

General practices in sustainable management of waste streams are becoming more and more important. As an example, the United Nations (UN) Sustainable Development Goals, especially goal #12 “Responsible Consumption and Production”, demand waste reduction, recycling and safe treatment of remaining waste streams, just as Roche supports them (see link at the end of this document).

Roche supports many initiatives or actively pursues change management related to new legislation such as:

- So called “Green Chemistry” principles (see reference to book below) are applied to reduce the raw material input, avoid or minimize the volumes of critical substances and minimize the consumption of resources in Roche’s future manufacturing processes. Roche joined the Green Chemistry Pharmaceutical Roundtable of the American Chemical Society (see link below) where member companies exchange information in a non-competitive environment, share experiences and try to influence other industries to adopt more environmentally benign processes.

- A systematic program to optimize chemical syntheses of new APIs - the Roche Environmental Awareness in Chemical Technology (REACT) - is under the lead of Roche's Research and Development department.
- On 29 October 2003, the European Commission adopted a proposal for a new EU regulatory framework for chemicals, called REACH ("Registration, Evaluation and Authorisation of Chemicals"). Under the EU REACH regulation (see link below), a priority list exists relating to substances of very high concern (SVHC). There is also a corresponding candidate list. Roche is in the process of phasing out the respective chemicals in accordance with the corresponding timelines.
- The concept of (and potential regulation for) "Circular Economy" is being discussed in the public. We actively try to implement the corresponding principles (see above) within the limitations we face because medicines and diagnostic reagents are consumed during use, and there can be a range of quality, regulatory and practical challenges associated with re-use of products and packaging.

Further Information:

- The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (1992); <http://www.basel.int/>
- Roche Guidelines for the Assurance of Safety, Security, Health and Environmental Protection; http://www.roche.com/cse-guidelines_assur_safety_env_protection.pdf
- Paul Anastas and John Warner, 'Green Chemistry: Theory and Practice', Oxford University Press, New York, 1998
- American Chemical Society Green Chemistry Institute Pharmaceutical Roundtable; <http://www.acs.org/content/acs/en/greenchemistry/industry-business/pharmaceutical.html>
- Roche position papers on several health and environmental topics: http://www.roche.com/sustainability/how_we_work/positions_policies_downloads.htm
- Roche Position on Product Stewardship: http://www.roche.com/position_product_stewardship.pdf
- Roche Position on Pharmaceuticals in the Environment (PIE): http://www.roche.com/pharmaceuticals_in_the_environment.pdf
- UN Sustainable Development Goals: <http://www.un.org/sustainabledevelopment/sustainable-development-goals/>
- Initiatives for Chemicals Management and Safety under the EU REACH regulation: http://ec.europa.eu/environment/chemicals/reach/chemicals_en.htm



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