

Roche Position on Landfills / Contaminated Soil

Roche's Position

As a leading pharmaceutical and diagnostics company, Roche generates by-products during the synthesis of chemical and pharmaceutical substances, which ultimately have to be disposed of as chemical waste. Historically, the use of landfills has been commonly accepted and utilized as the method of disposal.

However, improved knowledge of geological characteristics and adverse impacts associated with chemical contamination of soil and groundwater through the disposal of waste - in particular hazardous waste - in landfills now represents a potential long-term risk for man and the environment. Experience shows that sooner or later all landfills and contaminated areas, even if equipped and secured with technologies presumed today to be ultimately safe, may eventually turn into a threat for its surroundings. Toxic emissions could seriously affect the soil, the ground- or drinking water and ultimately the health of residents.

Landfills containing these materials are under scrutiny today for potential hazards, resulting in the need for thorough risk analyses. Soil and groundwater that have been contaminated with chemicals are similarly being investigated. Depending on the results of these assessments, appropriate remediation measures have been or will need to be implemented.

Roche believes that existing landfills containing hazardous wastes threatening the environment should be addressed proactively, even if this entails applying solutions exceeding the individual country's legal framework. The issue should be resolved entirely and sustainably and no long-term continuous technical processes, i.e. pumping and treating of leachates from a contaminated site, should be required to keep the existing risk at bay.

Roche generates relatively low volumes of chemical products. In addition, Roche partially started to incinerate combustible chemical waste as early as 1954. Therefore, the total quantity of chemical waste generated and the company's share of chemical deposits in common landfill sites are generally small.

Roche applies high ethical and social standards in its efforts to protect the environment and thus accepts responsibility for all waste generated from its operations including that deposited in on-site or off-site landfills. This responsibility extends to the activities of the former Roche Vitamins and Fine Chemicals Division, as well as those of acquired businesses. We act as a responsible party at contaminated sites and landfills and accept

our individual share of liability, including at sites where landfilling was previously an accepted and legally approved disposal practice.

Roche is committed to a proactive, holistic, environmentally and socially responsible and integrated risk-based approach to determine the best course of action for contaminated sites and landfills. All activities developed and implemented must meet the following criteria:

- be legally compliant;
- consider the state of the art and apply best available techniques;
- reduce negative impacts to the environment;
- preclude additional risks as far as feasible;
- protect the health and ensure the safety of workers and the population;
- be conducted in an open and transparent context; and
- ultimately and sustainably minimize or where feasible eliminate the company's long-term liability.

Not only does Roche actively manage its historical contaminated sites issues, we also strive to avoid future liabilities. All hazardous, chemical, medical and potentially pathogenic wastes must be incinerated or otherwise treated to render them non-hazardous. Where no suitable waste thermal treatment plants exist or for special waste streams where incineration is not a feasible alternative (e.g. for PCB contaminated bulk concrete, soils containing heavy metals etc.), a disposal in carefully engineered and licensed landfills is indicated.

Our company policy on "Safety, Health and Environmental Protection in the Roche Group" outlines the use of landfills and permits general landfilling of waste only for non-hazardous and inert materials.

The global situation

Waste handling practices have dramatically evolved over time and many habits perceived to be acceptable in earlier times have turned out to be unsuitable from today's perspective.

Industrial activities often leave residues in the soil at the site in question. Therefore, critical concentrations of substances used at chemical manufacturing or processing facilities may be found in the ground. In addition, by its very nature the synthesis of chemical and pharmaceutical substances results not only in the desired compound, but also in by-products which ultimately have to be disposed of as chemical waste. Historically, landfilling was the commonly accepted disposal method in many countries

and still is today in many parts of the world. Strict procedures were legislated, as a result of which various private parties and local authorities made suitable plots of land available for a charge, often for joint use for municipal and industrial discharge, with sometimes many responsible parties involved.

In the last decades it became evident that many historical landfills caused an impact to the environment and the drinking water resource. Thus, the use of landfills for the disposal of chemical waste has mostly halted. In the majority of countries thermal treatment (high temperature incineration) is the preferred and often the only permitted disposal option for wastes, especially for those containing hazardous organic substances. Landfilling in these countries is acceptable only for wastes which are solid, immobile, non-reactive, non-toxic and odour-free. However, there are some countries where the thermal treatment of wastes has not been fully developed due to negative public perception, in particular regarding impacts from suboptimal combustion (e.g. dioxins) or incinerator ashes. Thus, in those countries, even hazardous waste landfilling is still permitted and common practice.

Contaminated sites today are subject to increased monitoring and thorough examination in order to evaluate their potential impacts and to initiate the suitable steps required for containment or remediation.

Yet a risk-based approach is not generally accepted and implemented worldwide. In some countries, political and non-governmental organizations are rejecting solutions based on sound science and are calling for more radical measures, i.e. complete excavation and incineration in all circumstances. Roche however strives to implement risk-based solutions covering all legal requirements, taking into account equally environmental, social and economic parameters and at the same time allowing the optimization of projects and implementing tailor-made solutions for every single site.

The situation at Roche

Roche has relatively low volumes of chemical production and chemical waste, however, prior to October 2003, activities of the Roche Group included the manufacturing of vitamins and fine chemicals. This high-volume production generated considerable amounts of chemical wastes, which were disposed of, at least in part, in landfills. Although the vitamins and fine chemicals business has been divested, Roche continues to maintain responsibility for these contaminated sites as well as for chemical waste landfills connected with this business. The same applies to other operations that have been divested owing to the changing portfolio of the Roche Group.



Roche has also assumed liability for a number of contaminated sites due to company acquisitions. Some of these sites have already been remediated, while others are being monitored, with additional measures currently under investigation. Adequate financial reserves have been set aside to cover the cost of any remediation deemed necessary in the future.

If Roche is identified as the sole party responsible for a contaminated site or landfill, an investigation can be promptly initiated and necessary remediation measures evaluated and implemented without delay and in compliance with the local regulatory framework.

If contaminated landfill sites are shared with other companies, collaboration is sought with all stakeholders and the authorities involved in order to identify solutions that are mutually acceptable and allow a holistic approach while satisfying regulatory requirements.

Each contaminated site has its own specifics and there are slight modifications to the investigation approach applied. As Roche becomes aware of a contaminated site, studies are initiated to evaluate any threats associated with the contamination. Depending on the outcome of a site investigation, including a thorough risk assessment and screening against the respective legal framework, steps are then taken to monitor, contain or, if necessary, remediate the site. As these issues are generally strictly governed by the individual country's legislation, the entire process is conducted in close collaboration with the competent authorities and in compliance with the current legislation. Roche's policy aims for a sustainable and ultimate course of action to eliminate long-term risks for the public and the environment. Hence Roche often engages in voluntary approaches that reach beyond the local legal framework.

Today Roche strives to minimise its environmental impact and applies responsible waste management practices to avoid future liabilities. Wherever possible the generation of wastes is avoided, otherwise reduced.

Wastes generated are subject to reuse and recycling, if applicable. Valorisation of wastes using state-of-the-art incineration involving heat recovery is Roche's preferred disposal option for wastes containing hazardous organic substances, Roche products (API's) as well as medical and potentially pathogenic wastes. Other solid wastes not suitable for incineration or recycling that contain heavy metals, asbestos and other hazardous constituents above regulatory and risk criteria levels must be disposed of in carefully engineered and licensed landfills. Any option selected should minimise our long term liability and meet all regulatory criteria. Furthermore, effective technical systems and handling procedures are designed to prevent direct emissions to soils and groundwater from our sites and operations.



More information

The topics of chemical waste, landfills and contaminated soil have been addressed numerous times in the annual Roche Group Reports:

http://www.roche.com/investors/annual_reports.htm.

Roche's Guidelines for the Assurance of Safety, Health and Environmental Protection in the Roche Group, including the Annex "SHE Principles and Procedures":

http://rochet.net.roche.com/cse-guidelines_assur_safety_env_protection.pdf

Contacts

Dr. Richard Huerzeler, Chief Remediation Officer (LSC)

richard.huerzeler@roche.com, +41 61 688 07 46, Basel / Switzerland

Dr. Peter Schnurrenberger, Chief SHE Officer (LS)

peter.schnurrenberger@roche.com, +41 61 688 52 13, Basel / Switzerland

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