

Roche's Position¹ on Landfills / Contaminated Soil

Background

Landfills and their Impact on the Environment

Since the beginning of civilization, land disposal has been used by humankind as a primary means of discarding waste materials. As society advanced into the industrial and the modern technological ages, a plethora of new hazardous materials have been created in this advancement, which are increasingly toxic, mobile and persistent. Despite this fact, landfills have been used in the legacy of waste management of hazardous materials. Only in recent decades has society become aware of the inherent dangers posed by the disposing of waste hazardous materials in traditional uncontrolled landfills and the long-term liabilities posed even by well-engineered landfills. Most important is the understanding of the detrimental impacts that landfills cause to the subsurface environment, most particularly groundwater resources. Groundwater is a critical resource closely interconnected with many important surface based aquatic environments such as lakes, rivers and wetlands. Groundwater serves as a source of water supply to these sensitive ecological systems and as a water supply source for human consumption. Landfills also occupy large tracts of land that would be better suited to support other more beneficial purposes. As society's awareness to the dangers of landfilling increased, it has become apparent that disposing of hazardous materials in traditional uncontrolled landfills is not acceptable. Until recent times, landfills were not constructed with protective measures to prevent many wastes from leaching downward through the soils, contaminating both the subsurface soils and the groundwater under the landfill. Unfortunately, even with the current state-of-the-art standards of current landfill design, in time these modern landfills or leachate collection systems may fail and may ultimately leak mobile contaminants into the underlying soils and groundwater. Today, scientists are more acutely aware of the close interaction between surface and groundwater, and the dynamics of groundwater flow as part of the greater hydrologic cycle. Groundwater systems are not static, but can flow great distances below the surface, often carrying and spreading any pollutants that may have leached downward from a landfill into an aquifer. In recent decades, there have been enormous advancements in the geological, hydrogeological, and geochemical sciences that have done much to reveal the extent of the landfill problem. Moreover, these same advances in geological sciences play a pivotal role in remedying damage to subsurface environment.

Industrial Handling of Hazardous Materials

Landfills were not the only historic source releasing hazardous materials into the environment. In the past, older industrial sites were often not equipped with either the infrastructure or the containment practices to protect against leaks or spills of hazardous materials into the soils or groundwater underlying some sites. As a result, many historic manufacturing sites have soils and groundwater contamination that need to be addressed.

Today society is aware of these resulting environmental impacts. In many developed regions, laws and regulations have been adopted to incorporate protective infrastructure, monitoring and practices to minimize or eliminate the likelihood of releasing hazardous materials into the environment.

¹ 1 Pertains to SDGs 3, 6 and 12



In the majority of countries, thermal treatment (high temperature incineration) with energy recovery is the preferred and often the only permitted disposal option for wastes containing hazardous organic substances. Landfilling chemical wastes in these countries is generally limited to solid wastes streams that are immobile and non-reactive and which cannot be destroyed. However, there are some countries, where the thermal treatment of wastes containing hazardous organic substances is not possible, either because thermal treatment facilities are not commercially available or local regulatory authorities do not permit thermal treatment. Thus, in those countries, even hazardous organic chemical waste landfilling may remain a common practice.

Roche's Historic Situation

In the past, Roche and its affiliates have used landfills as a means of disposing of their chemical and solid wastes. These wastes often included waste production by-products, intermediates, off-specification active pharmaceutical products, and spent manufacturing feedstocks such as solvents, hazardous and non-hazardous substances. While Roche did historically landfill some of its organic chemical wastes, we have actively sought a more suitable alternative to manage these wastes. As early as 1954, Roche began incinerating some combustible organic wastes. Since the 1950s, Roche has advocated incineration as its preferred method of destroying organic hazardous wastes. In the decades since the 1950s, Roche's relative use of waste incineration has increased, while the amount of hazardous wastes landfilled by Roche has significantly decreased. Today, all Roche global affiliates are directed not to landfill the following chemical wastes:

1. Organic chemical wastes
2. Mobile Wastes (leachable to groundwater)
3. Reactive wastes
4. Chemical Wastes that can either be destroyed by thermal or other means and
5. Wastes where beneficial use is feasible.

Currently there is a corporate initiative to reduce all remaining chemical wastes to landfill by 50% within 5 years using 2015 as the baseline (excluding construction and remediation wastes). Roche affiliates are required to incinerate organic chemical wastes in state of the art incinerators. Roche believes that high temperature incineration is the only existing widespread technology today that ensures the complete destruction of hazardous organic wastes.

In recent years, many countries have enacted laws and initiated efforts to clean-up old contaminated landfills and industrial sites. Many governments now require corporations to contribute to the clean-up of these old waste sites as a Potentially Responsible Party (PRP). Along with many other companies, Roche too participates as a PRP in the clean-up of a number of contaminated sites under government oversight. Roche believes that it is the company's social and ethical duty to protect the environment, our neighboring communities in which we operate and to assume the responsibility for cleaning up contamination resulting from our past practices. Some sites that Roche has completed remedial clean-ups include former landfills, and a number of Roche's historic manufacturing sites, some of which have ceased operations.



Stakeholder's Expectations and Concerns

Stakeholders with a common interest in addressing contamination resulting from the practice of landfilling and the historic release of hazardous substances into the environment include:

- Community and Private Citizens;
- Ecological Receptors;
- Governmental Agencies and Regulators;
- Roche affiliates and employees;
- Scientific Community

Each of the listed stakeholders has a unique interest in the past practices of landfilling hazardous wastes and the clean-up of hazardous materials at contaminated landfills, or at industrial sites. The interests and roles of each stakeholder are diverse, but not completely independent of the others. All of these stakeholders must cooperate and compromise in order to ensure risk mitigation measures are appropriately addressed and that all remedial actions and measures are acceptable and in compliance with all applicable local legal and regulatory requirements.

Community and Private Citizens

Private Citizens and the communities where they reside show a special interest in how contaminated industrial sites are remediated. Releases of hazardous substances into the environment from historic landfills or manufacturing operations may potentially expose these stakeholders to these substances through various routes. For example, communities who draw their potable water supplies from contaminated aquifers may be exposed to these contaminants. Citizens near sites where contaminated groundwater is present may be exposed to these volatile contaminants through vapor intrusion. Unprotected contaminated soils may also pose a risk of direct contact exposure. Communities have a stake in the clean-up of a contaminated landfill or industrial site that could compromise their health, safety and wellbeing. In addition, communities are aware of impacts to critical ecological systems near their community.

Ecological Receptors

Contaminated groundwater or soils and impacted surface waters/sediments 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.

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 prevent releases of contaminants that could potentially affect people or the environment in an adverse manner. Governments also are tasked with restoring compromised environments using scientifically based standards that protect both human health and sensitive ecological receptors.



Industries charged with cleaning up contaminated sites must work with governments to ensure that the clean-up efforts meet the legal and environmental standards established to be protective of human health and the environment, and in addition are responsible to oversee the clean-up efforts.

Roche affiliates and Our Employees

Roche requires our affiliates to use resources responsibly and protect our employees from exposure to any potentially harmful substances. Roche affiliates must also remediate contamination caused by historic releases at their sites or at other sites impacted by the affiliates past waste disposal/treatment practices. When remediating contamination, affiliates must adhere to the Sustainable Remediation principles outlined within this Position Paper. 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 technologies and remedial treatment measures used to examine, monitor and remediate contaminated sites, including the development or implementation of novel approaches to environmental risk assessment, clean-up and remediation work as well as the restoration of ecological systems.

Roche Position

Roche's position on the use of landfills and addressing contaminated sites is straightforward. Ultimately, Roche contends that there are no environmentally acceptable landfills for chemical/hazardous waste. Roche has instructed its affiliates to avoid using landfills as a means of disposal for all chemicals, and other forms of hazardous wastes (see also "Roche's Guidelines for the Assurance of Safety, Security Health and Environmental (SHE) Protection in Roche Group": <https://www.roche.com/dam/jcr:5b95a6fa-f1a8-4c00-9219-86e5b8d70e82/en/she-guidelines.pdf>).

This general principle avoids future risks and liabilities associated with landfilling hazardous wastes, including chemical wastes, unusable by-products, off-specification Active Pharmaceutical Ingredients (APIs), pathological wastes, medical wastes, etc. Therefore, Roche requires incineration to effect waste destruction. When conducting the clean-up of contaminated landfills, former or current contaminated Roche affiliate sites, it is our policy to treat contaminated resources, soils and/or groundwater, and to put them back clean in the place from where they originated, whenever possible. While many companies use the "dig and haul" (landfill disposal) approach to "remediating" contaminated soils, Roche does not advocate this.

This only results in moving contaminated soils from one place to another, which Roche believes is not a sustainable practice. Roche always considers technically feasible sustainable solutions. Landfilling is the absolute last option considered by Roche for the disposal of remediation wastes (e.g. certain types of heavy metals; co-contaminated soils; contaminated concrete and demolition debris; radioactive materials; or if no suitable hazardous chemicals incineration plant is available in the country and the waste cannot be sent to another country).



Under any circumstance where an affiliate must use a landfill for waste disposal, Roche requires that affiliate to use only state of the art landfills (including avoidance of water infiltration; leachate collection, monitoring and treatment; groundwater monitoring). Before the landfill can be used, it has to be confirmed by audit that the landfill meets the most rigorous state of the art standards for landfill design and construction. Furthermore, the affiliate must ensure that the landfill is properly licensed to operate by the appropriate government agency or regulatory authority.

Regardless of the technological improvements incorporated into modern landfill design, Roche believes that over enough time, even the most modern landfills may eventually degrade, and potentially release contaminants into the subsurface environment. Landfills are not temporary structures, and once they have been built, and filled with waste materials, these structures could remain in place in perpetuity. As a general guidance Roche Group SHE requests its affiliates not only refrain from landfilling hazardous organic waste but rather extend this practice to “General” household-type of wastes as well (see also “Roche’s Global Position on Waste Management”: http://www.roche.com/position_waste_management.pdf)

Outlook, Status, current Engagement and Initiatives

Roche’s Vision of Sustainable Remediation

Wherever Roche may be completing remedial activities, Roche is committed to applying the aforementioned principals consistently across all its affiliate sites, whether currently active, newly acquired or formerly owned and operated by a Roche affiliate. In circumstances where Roche participates as a partial responsible party (RP), Roche fully accepts its individual share of liability. Such liabilities typically include older waste disposal sites created at a time when it was legal to dispose of hazardous wastes in landfills whose design did not meet today’s rigorous protective standards. For such multi-party sites, Roche works actively within the Responsible Party technical management groups to ensure that Roche’s most demanding standards are met as far as possible.

Roche’s position of Sustainable Remediation reflects a risk based evaluation of suitable measures that employ the following principles and practices:

- **Commitment:** Roche is committed to a proactive, holistic, environmentally and socially responsible risk integrated approach to determine the best course of remedial action for each individual contaminated site and landfill. This may go beyond the applicable legal clean-up requirements;
- **Investigation:** Each site must be thoroughly investigated to identify all the contaminants and areas of concern. Roche insists that only the most advanced yet reliable investigative methods and technologies be used;
- **Identification, Evaluation, and Risk Control:** All environmental and human health risks must be identified, fully evaluated and reduced and controlled as far as feasible;
- **Compliance:** Roche expects all remedial work to be wholly compliant with applicable laws, regulations and standards;



- **Evaluation:** Roche will evaluate and implement the most effective remedial solutions including the use of state of the art technologies, taking into account the potential side effects of the remediation on human health and the environment;
- **Remedy:** Roche will select technically feasible remedies that will manage and control all unacceptable risks to the public, and that lead to the least overall negative environmental impact. Avoidance of long-term liability is a driver in remedy selection;
- **Protection:** We strive for an optimal protection of our employees conducting the remedial work, residents and all other stakeholders who could be negatively impacted in their safety and health;
- **Stakeholder Involvement:** Roche will work closely and proactively with all stakeholders, such as a neighboring community, or a government agency to address their concerns; and
- **Transparency:** Roche will conduct all remedial activities in an open and transparent manner, in close collaboration with the neighboring community members, employees and local environmental regulatory agencies.

Roche's view of sustainable remediation takes an all-inclusive approach that considers all aspects of the remedial project, and evaluates its clean-up objectives against the overall long-term impacts the project might have, such as energy consumption and CO₂ emissions that result from a remedial approach. For example, long term pump and treat systems often do not eliminate risks, but use a lot of energy. Pump and treat energy sources contribute to greenhouse gasses and thus this remedial solution has a greater overall adverse impact on the environment than benefit. Thus, it is Roche's policy not to use long-term continuous technical processes to keep existing contamination risks at bay.

In some areas of the world, risk-based approaches for remediation are not always accepted. In some countries, political and non-governmental organizations (NGOs) reject science-based remedial solutions and are calling for more radical measures, for example, complete excavation and incineration in all clean-up circumstances. However, when and where possible Roche strives to implement sensible risk-based solutions that fulfill all legal requirements while balancing all environmental, social and economic factors in order to optimize every project with tailor-made site-specific solutions.

As an essential sustainable policy value, Roche not only actively seeks to remedy historically contaminated sites, but for current locations implements practices and policies to protect against creating future liabilities. Roche manufacturing and other operational affiliate sites implement protective infrastructure, polices and management systems that are designed to prevent releases of critical substances into the environment and to minimize or eliminate waste generation. In addition, Roche also seeks to innovate its manufacturing processes so smaller amounts of hazardous substances are necessary to make a lifesaving product.

Treatment and Waste Management Facilities

For external treatment of remediation wastes, Roche thoroughly evaluates all suitable treatment options for efficacy before the technology is utilized. Roche must approve any incinerators or other active treatment options used to destroy or remove contaminants, before these can be used.



In addition, for any circumstances where a landfill might have to be used, Roche will evaluate and approve the landfill beforehand. Any landfill used by Roche must, at a minimum, use state of the art design technology concerning lining, waste segregation/compatibility, leachate prevention, leachate collection, leachate treatment, methane extraction, groundwater monitoring and protection. Any landfill used by a Roche affiliate must, at a minimum, operate in compliance with all applicable laws and regulations and must have the proper permits or licenses to operate. Each remediation site is different and technical experts are retained to identify and evaluate ideal remedial treatment alternatives through bench and pilot tests for efficacy.

For More Information

Each year Roche addresses chemical waste management, landfills, and contaminated soils in its annual Roche Group Reports. These reports can be found at the following link:

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

Roche's Guidelines for the Assurance of Safety, Security Health and the Environmental (SHE) Protection in the Roche Group, including the Annex "SHE Principles and Procedures" are obtained at the following link:

<https://www.roche.com/dam/jcr:5b95a6fa-f1a8-4c00-9219-86e5b8d70e82/en/she-guidelines.pdf>

Other Roche Position Papers, among those the Roche Position on Waste Management, can be found using this link:

http://www.roche.com/sustainability/how_we_work/positions_policies_downloads.htm

Contacts

Dr. Richard Huerzeler, Chief Environment and Remediation Officer; richard.huerzeler@roche.com, +41 61 688 07 46, Basel, Switzerland

Mr. Robert Baldisserotto, Head of Remediation Management, Group SHE; robert.baldisserotto@roche.com, +1 973 890 2238, Little Falls, NJ / USA

This updated position paper was proposed by the Corporate Sustainability Committee and adopted by the Corporate Executive Committee on April 21, 2017 and entered into force the same day.

It was reviewed in April 2020.