

Roche's Position¹ on Landfills / Contaminated Soil

Background

Landfills and their Role in Impairing 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 through the industrial, and into the modern technological ages, the many materials used in this forward progress have become increasingly toxic, so too are the types of wastes generated by this development. Despite this fact, landfills continued to be used as a legacy of waste management. Only in recent decades have people become aware of the inherent dangers posed by the disposing of toxic wastes in traditional uncontrolled 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 that is closely interconnected with many important surface based ecological 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 could be better used to support other more beneficial purposes. As people's awareness to the dangers of landfilling has increased it has become apparent that this form of waste disposal is no longer acceptable.

Until recent times, landfills were not constructed with protective measures to prevent the critical constituents they contained 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 to which landfills must be constructed, in time these landfills will fail and will leak contaminants into the underlying soils and groundwater.

Today scientists are more sharply 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 means by which hazardous substances were historically released into the environment. Hazardous substances used at numerous historic manufacturing sites were discovered to have been released into the soils and groundwater underlying many of these sites. As the industrial age progressed, many new chemicals were created that were used to manufacture many of the technological items that improved people's lives. 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. In the past, older industrial sites oftentimes were not equipped with either the infrastructure or safety practices to protect against leaks or spills of dangerous materials into the environment. Thus the soils and aquifer systems that lie below the surface of these sites may have become contaminated. Today both governments and citizens are aware of this potential harm. In many developed regions, laws and regulations have been passed to require modern industries to incorporate protective infrastructure, monitoring, and to incorporate practices that greatly reduce the likelihood of releasing harmful substances into the environment.

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, especially for those containing hazardous organic substances. Landfilling in these countries is acceptable only for wastes which are solid, immobile, non-reactive and odor-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 the impacts from suboptimal combustion (e.g. dioxin formation) or incinerator ashes. Thus, in those countries, even hazardous waste landfilling is still permitted and common practice.

Roche's Historic Situation

Like many industries through the past, Roche, and its affiliated companies, 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 feed-stocks such as solvents, hazardous and non-hazardous substances. Comparatively, the types and amounts of wastes Roche historically generated and disposed of in landfills were small when measured against other industries.

While Roche did historically landfill some of its organic chemical wastes, we have actively sought a more suitable alternative to manage our chemical wastes. As early as 1954, Roche began incinerating combustible organic wastes. Since the 1950s Roche has advocated incineration as its preferred method of destroying hazardous wastes. In the decades since the 1950s Roche's relative use of incineration has increased, while the overall amount of hazardous wastes landfilled by Roche has dropped significantly. Today Roche affiliates around the globe are directed not to landfill any organic chemical wastes or potentially harmful substances. Currently there is a corporate initiative to reduce all remaining chemical wastes to landfill by 50% within 5 years using 2015 as the baseline. Roche Affiliates are directed 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 potentially impacted by 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 our Employees; and the
- 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 of these stakeholders 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 vested interest 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 impact people or the environment in an adverse manner. Governments also are charged 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 affiliate's 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 safe landfills. 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 the Roche Group": http://www.roche.com/cse-guidelines_assur_safety_env_protection.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 have the potential to eventually degrade, and 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 RP 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's 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 remedial solutions based on sound science 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 hazardous 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. Any incinerators, or other active treatment options used to destroy, or remove contaminants must be approved by Roche before they 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:

http://www.roche.com/cse-guidelines_assur_safety_env_protection.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

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