



GHb Reagent Business Continuity Plan

to ensure steady supply

TOSOH CORPORATION

GHb Reagents Business Continuity Plan

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Corporate Mission

Tosoh's corporate mission is "to contribute to society through the chemistry of innovation." Good management is essential to the mission. It requires a commitment to superior products and regard for the environment, safety, and health. Emissions must be minimal and the characteristics of chemical substances understood. These are our responsibilities as we supply products that benefit society.

Our continued viability as a chemical company is premised on the reliable manufacture of safe products. It also hinges on our being a member of society overall. We must proactively communicate with the communities where we operate, earn community trust, and provide communities a sense of security.

Basic Principles Regarding the Environment, Safety and Health

In all of its business activities, Tosoh Corporation will contribute to the advancement of society through continuous innovation in the field of chemistry, leading ultimately to the supply of products and services that bring customer satisfaction. At the same time, Tosoh will continue to regard environmental protection, safety and health as top management priorities.

Action Policies

Basic Stance

- Promote initiatives based on awareness of the need to comply with laws and regulations and self-responsibility
- Establish targets, formulate action plans and implement actions with the participation of all concerned
- Reflect audit results in future action plans

Environmental Protection Initiatives

- Conserve energy and resources through the use of the smallest possible quantities of resources to obtain the greatest possible benefits
- Lower emissions and waste through improved manufacturing processes and operational management

Safety Assurance Initiatives

- Accident prevention and disaster response through facility safety management
- Maintain and manage emergency response capabilities through safety drills
- Eliminate accidents and disaster effects through analysis of case studies Product-related

Environmental and Safety Assurance Initiatives

- Allowing consideration for the environment, safety and health to guide the product design and development of manufacturing processes
- Undertake prior assessment during development of new products and processes
- Ensure product safety through total quality management

Communication Initiatives

- Provide safety management-related information for products and chemical substances
- Enhance public confidence through dialogue concerning business activities

Increased Focus Towards Business Continuity

In the past, Tosoh established disaster prevention measures with earthquakes and tsunami in mind. However, in line with the Japanese government's revisions in the scope of damages expected from major disasters, we have bolstered efforts to include having a well-prepared business continuity plan (BCP) in addition to disaster prevention measures.

An essential step to producing a BCP is the listing up of elements critical to stable product supply using business impact analysis, risk assessment, and other tools. Recovery times are then estimated for each element. Through such an analysis, we have determined that extensive damage to Tosoh's production facilities results in the longest recovery time and that natural disasters are the most likely cause of such an occurrence. With its major operations situated in Japan, Tosoh therefore needs to consider a massive earthquake and associated tsunami as the major risks to its operations. Consequently, we have taken these considerations into account in developing our BCP.



Aerial photo of Nanyo Complex (Shunan City, Yamaguchi Prefecture, Japan)

Group-Wide Measures

1) Safety Reform Activities

Tosoh is targeting safety assurance in its operations based on five measures set out in the guidelines of an industrial safety action plan. The Japan Petrochemical Industry Association formulated the plan as an “industry-wide measure” in July 2013. Furthermore, Tosoh’s Safety Reform Committee has produced and publicly announced safety reform guidelines. In accordance with one of those guidelines, “continuous reform and improvement,” the company is taking various steps to boost safety. Plants are steadily correcting defects and problems as discovered using specially appropriated “safety measures improvement budgets.” At the same time, Tosoh’s production facilities are consistently identifying and reviewing their safety protocols to eradicate accidents and occupational accidents from the leakage of hazardous substances.

2) Responsible Care Activities

Responsible Care (RC) is a global, voluntary initiative by the chemical industry. It aims to encourage manufacturers and handlers of chemical substances to conduct their operations taking environmental protection and safety into consideration. Its scope covers the entire lifecycle of chemical substances from development to disposal.

In fiscal 2016, our RC activities are being implemented under six categories guided by an overarching priority. Specifically, we are carrying out diverse RC-related measures throughout the company, such as strengthening and expanding education programs, revising manuals, and identifying safety risks. The company also has substantially increased its facility maintenance budgets. Under the category of Safety and Disaster Prevention, we strengthen equipment management and plant maintenance measures in order to overcome challenges presented in fiscal 2015, as well as implementing medium to long-term plans for dealing with earthquakes and tsunamis.

And strong management of logistic facilities and product transportation is essential to improving the degree of customer satisfaction. Consequently, we are also maintaining close communications with logistics services companies and considering ways to optimize and to prevent transportation problems.

Safety Reform Guidelines

Objectives

- To be a safe chemical manufacturer where incidents and accidents such as the 2011 fire and explosion are not repeated and are prevented from occurring in the first place
- To be a safe workplace for our employees
- To be a trusted and contributing member of the local community and society overall

BASIS OF SAFETY ASSURANCE DECLARATION

• Commitment by the President

The president recognizes that safety is the foundation of sound business operations and will therefore allocate the necessary management resources to ensure safety and will share his resolve regarding safety with all employees.

• Cultivation of a Culture of Safety

In carrying out general inspections of safety activities, each employee will independently strive to make his or her actions highly effective.

• Disclosure and Use of Information

Our operations will promptly and diligently share accurate information on emergency and safety-related situations with their surrounding communities. They will also make sure to effectively utilize all safety- and incident-related information.

• Comprehensive Education and Training

Tosoh will implement comprehensive technology and safety training and ensure that its training is flexible to suit the different needs and proficiencies of its employees.

• Continuous Reform and Innovation

Establishing sound safety practices is not a one-time activity. We will work to keep employees from forgetting accidents and incidents and will review and revise our safety practices regularly.

Fiscal 2016 RC Activities

Priority: Ensure that all Tosoh Group employees are safe in their performance of basic functions through the continued, group-wide promotion of RC activities and realize a workplace where communication begins with “hello”

Safety and Disaster Prevention and Occupational Safety and Health	<ul style="list-style-type: none"> • Promote safety and security activities with shared investment by all staff in aiming for no incidents and no accidents resulting in lost work time • (Each employee must think about and act on safety reform with an understanding of basic operation and compliance with rules, communication, management, facility administration, and so on.) • Push earthquake and tsunami countermeasures (From an understanding of administration trends, we must review the suitability of our planning and enact countermeasures.)
Environmental Conservation	<ul style="list-style-type: none"> • Continue to manage emissions of PRTR substances while maintaining stable operation • Reduce industrial waste for final disposal (RC target: 1,768 mt/yr) • Promote disposal of equipment containing PCBs (Tosoh plans to begin disposing of small equipment containing low concentrations of PCB.)
Chemical and Product Safety	<ul style="list-style-type: none"> • Continue to comply with regulations regarding SDS • Continue to comply with foreign laws and regulations (In the year ahead, we will comply with Korea’s K-REACH and with Taiwan’s Toxic Substance Control Act and will continue to comply with the EU’s REACH regulation.)
Quality Assurance	<ul style="list-style-type: none"> • Promote the inspection and strengthening of the quality assurance system to prevent future complaints • Establish Logistics Conference as additional fact-finding entity to Logistics RC Promotion Committee in effort to reduce logistics-related complaints
Logistics Safety	<ul style="list-style-type: none"> • Clarify root of problems and enact countermeasures to prevent future occurrences
Public Dialogue	<ul style="list-style-type: none"> • Continue to promote linkages with the community • Share information to promote risk communication

Preparation for Earthquakes and Other Natural Disasters

1) Laws and Ordinances

Based on the 2011 Great East Japan Earthquake, Japan's Central Disaster Prevention Council and other disaster prevention bodies have been optimizing measures for major earthquakes. Tosoh also has aligned its disaster prevention measures for facilities with any changes in legal requirements, including the Construction Standards, High-Pressure Gas Safety, and Fire Service Acts. When an earthquake of a certain scale occurs, for the sake of safety, plant operations are carefully halted with the exception of certain facilities, such as electric power plants. Each facility has set up a working group to consider measures to deal with major earthquakes. Their work has involved confirming the earthquake resistance of facilities, etc.; estimating flooding damage from a tsunami and determining countermeasures; and discussing disaster response measures from the point of view of giving top priority to saving lives. We expect that even if our two independent electric power plants are completely stopped, they can be operating again within two weeks.

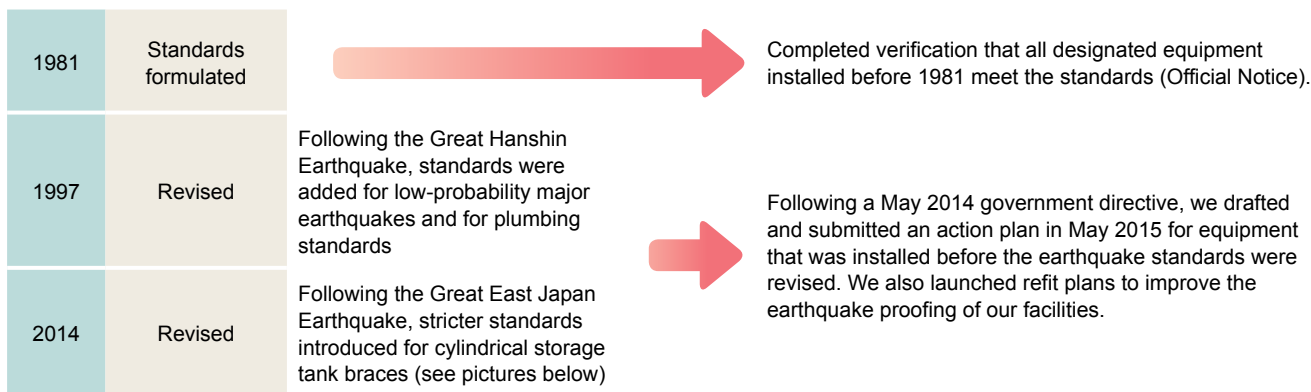
2) Logistics

The Logistics RC Promotion Committee meets once every two months to discuss verification of incidents, share information, and take steps to prevent reoccurrence of incidents and spread safety information horizontally. The committee comprises representatives of the shipper, Tosoh Corporation, and of the main logistics contractor, Tosoh Logistics Corporation, and other associated logistics companies. Among other measures taken to alert people about safety measures, regular patrols are made of product shipping areas and education and monitoring programs are carried out for cooperating companies. To be prepared for emergencies when shipping harmful liquid substances other than oil, Tosoh has concluded a Contract for Hazardous and Noxious Substances (HNS) Response Resource Deployment and Emergency Response with the Marine Disaster Prevention Center.

3) Information Technology

Responsible for Tosoh Group IT systems, Tosoh Information Systems Corporation backs up data and has prepared recovery procedures for IT systems in the event of a disaster.

■ Compliance with Earthquake-Resistance Design Standards for Designated Equipment Under the High-Pressure Gas Safety Law



■ Compliance with Fire Service Act



Shaking of the liquid surface in a floating roof tank during the 2003 Tokachi-Oki Earthquake was the cause of an oil refinery fire after the earthquake. As a result, the strength standard was raised for floating roof tanks. Tosoh is steadily progressing with refurbishing to meet that standard.

4) Capital Investment for Safety

Since fiscal 2013, Tosoh has increased its budgets for safety reform throughout the company. Besides ensuring the continuous improvement of defaults and problems found with facilities through these “safety reform budgets”, the company is also revising its facilities maintenance plans to eradicate accidents from the leakage of hazardous substances and occupational accidents.

	Capital Investments (millions of yen)		
	FY 2013	FY 2014	FY 2015
Facility improvements	1,176	965	3,404
Labor safety and work place improvements	192	176	536
Disaster prevention measures for earthquakes and other natural disasters	148	368	99
Others	36	45	168
Total	1,552	1,554	4,207

Yamaguchi Prefecture Natural Disaster Risk Analysis

1) Relatively Low Risk

A country with many active faults, the risk of an earthquake happening in Japan is high because of their frequency. Surrounded by ocean, the potential for earthquake-related tsunami also is high—and fires from either of these types of natural disasters must be considered a possibility.

However, because Yamaguchi Prefecture, the site of the Glycohemoglobin Analytical Columns, Elution Buffer and Hemolysis & Wash Solution plants, is a long distance from any major faults, it is a low risk region for earthquakes in Japan. While no records remain of the type of major earthquake that occurs once every couple of centuries, we do know that according to statistics for the past 90 years since recording of seismic activity began, there has been only one earthquake of intensity of 5 or over. Therefore, statistically, Yamaguchi Prefecture can be said to be a relatively low risk region for earthquake related disasters in Japan (see below table).

Magnitude and Intensity of Earthquakes

Magnitude measures the size or scale of an earthquake at source. Intensity, on the other hand, measures the strength of shaking caused by the earthquake at a specific location at the time of the earthquake.

The relationship between magnitude and intensity is that intensity, even for small earthquakes, depends directly on the distance from the epicenter—the closer the land is to the epicenter the greater the shaking or intensity. Conversely, the farther away the ground is, the less it shakes and the lower the intensity, even in the event of a large earthquake.

■ Table 1. Earthquake frequency and intensity by region

Prefecture	Level of earthquake intensity										Total frequency
	1	2	3	4	5	5.0 to 5.4	5.5 to 5.9	6.0 to 6.4	6.5 to 7	Unknown	
Fukushima	7,150	3,419	1,159	251	43	9	2	1	0	0	12,034
Tokyo	3,161	1,244	357	62	6	1	1	0	0	0	4,832
Kanagawa	2,720	1,205	411	93	8	3	1	0	0	0	4,441
Toyama	292	132	49	10	2	0	0	0	0	0	485
Mie	1,335	499	152	37	5	1	1	0	0	0	2,030
Osaka	796	216	64	19	2	0	0	0	0	0	1,097
Hiroshima	955	530	172	18	11	1	1	0	0	12	1,700
Yamaguchi	439	191	70	23	6	1	0	0	0	0	730
Fukuoka	670	288	77	15	0	1	1	0	0	0	1,052

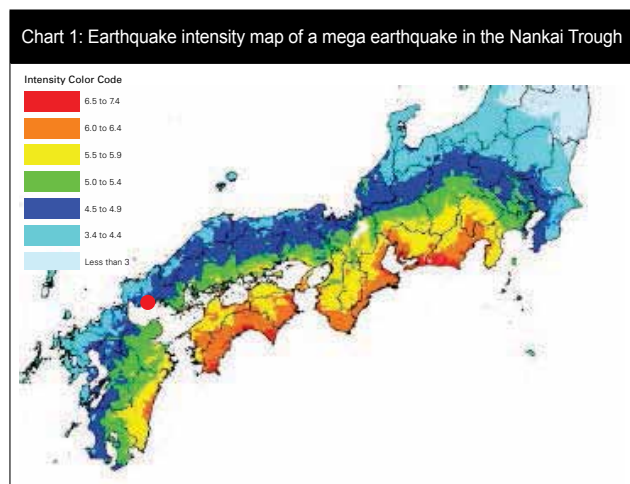
Source: The earthquake database of the Japan Meteorological Agency for the period from January 1, 1923 to September 30, 2015 (Tokyo data includes a portion of that for Chiyoda Ward).

2) Nankai Trough Earthquake

Historically, Japan is an earthquake prone country. Consequently, buildings are designed with earthquake resistance in mind and flood control measures to cope with tsunami are in place. However, after experiencing the 2011 Great East Japan Earthquake, the country has begun to revise its measures by expanding their scope to include a once in a thousand years mega earthquake and revising them based on the maximum expected damage from the largest possible earthquake or tsunami.

When considering possible future earthquakes in the region of Tosoh's Glycohemoglobin Analytical Columns, Elution Buffer and Hemolysis & Wash Solution plant, a Nankai Trough earthquake is expected to cause the greatest damage. This is an earthquake that occurs in the subduction zone of the Nankai Trough where the Philippine Sea Plate slides under the Eurasian Plate. Reports in March and August of 2012 by a working group set up following the Great East Japan Earthquake by the Cabinet Office to discuss a model of a mega earthquake in the Nankai Trough indicated that a large-scale revision of previous damage estimates was needed. A distribution map of maximum earthquake intensities based on their findings is shown in Chart 1.

Their estimates are based on an earthquake with a magnitude of 8 to 9. Regions near the epicenter are expected to experience an intensity of 7.0 to 7.4. Given its distance from the source and its ground base, the maximum intensity that would be felt in Shunan*, Yamaguchi Prefecture is estimated to be from 5.5 to 5.9. (*Shunan is the name of the city where Nanyo Complex is located)



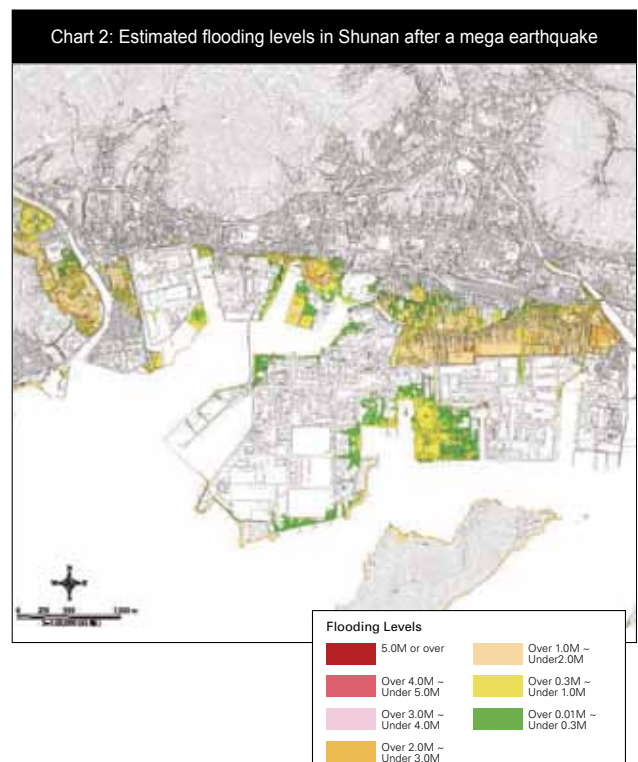
● : Nanyo plant

Corresponding Area	Current Distribution Map	Central Disaster Prevention Council (2003)
Intensity of 5.5 to 5.9	Approx. 71,000 km ²	Approx. 24,000 km ²
Intensity of 6.0 to 6.4	Approx. 29,000 km ²	Approx. 6,000 km ²
Intensity of 6.5 to 7.4	Approx. 4,000 km ²	Approx. 400 km ²

Source: Cabinet Office's working group on a Nankai Trough mega earthquake (First report, announced August 29, 2012)

3) Flooding Damage Estimates

Based on the revision of earthquake-related flooding damage estimates, local governments are providing estimates of flooding damage estimates for different regions. The flooding damage estimate for Shunan is shown in Chart 2. Yamaguchi Prefecture faces the Seto Inland Sea and does not have a complicated, irregular shoreline. As a result, the damage from tsunami is expected to be relatively light. Some sections of Tosoh's operations are estimated to experience a maximum flooding level of under 0.3 meters, but the land on which the columns, eluent and hemolysis cleaning solution manufacturing facilities stand is expected to have less than 0.1 meter of flooding.



Source: Yamaguchi Prefecture Tsunami Flooding Estimates (announced on December 24, 2013 by Yamaguchi Prefecture)

Business Continuity Plan

Measures Taken By Tosoh Bioscience Division

The Bioscience division having utilized technology for high-speed liquid chromatography technology today offers dedicated instruments (HLC-723 series of glycohemoglobin analyzers) and reagents (columns, elution buffer, hemolysis & wash solutions) for the measurement of hemoglobin A1c in blood (HbA1c).

The aforementioned reagents are classified as pharmaceuticals for in vitro diagnostics, and are mainly used hospitals, clinics, and other medical institutions. They are essential products for health care and thus there is great demand for stable supplies.

Tosoh's glycohemoglobin analytical instruments are designed to demonstrate a level of ability and quality of data through the matching of its dedicated reagents with its analyzers where substitutes cannot be used. On the other hand, there is a need for a business continuity plan that addresses the possibility of restricted supply due to natural disasters, acts of terrorism, accidents and other unforeseeable occurrences.

Therefore, in addition to Tosoh's group wide measures, the Bioscience division has independently developed measures for ensuring stable supply.

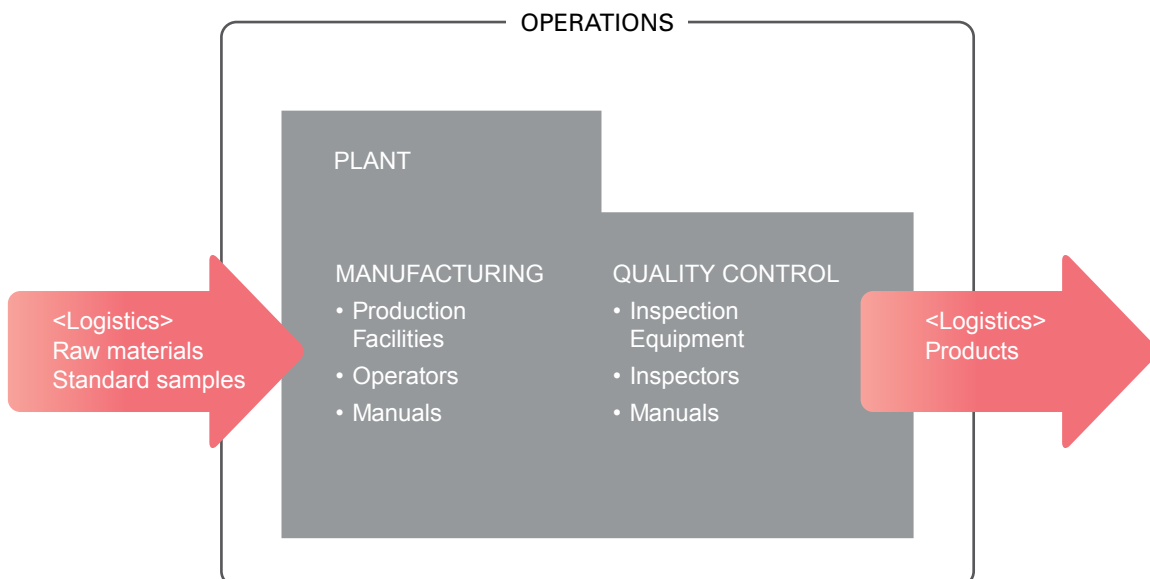
1) HLC-723 Series and Dedicated Reagents

The Bioscience division commenced development and production of liquid chromatography columns in 1971 and applied this technology to the clinical diagnostics field. In 1982, the division launched the HLC-723GHb I, a dedicated analyzer for the measuring of HbA1c, a critical marker for diabetes testing. Answering the needs of the market, the division continued to improve analyzer performance in measurement accuracy, (shorter) time, and operability. In 2014, the division released in Japan its 10th generation HLC-723 model, the G11. Dedicated reagents were also developed and manufactured for various models along the way.

Today, columns, elution buffer, and hemolysis & wash solutions are manufactured at a dedicated facility, the GP plant, constructed in 2011 at Tosoh's Shunan, Yamaguchi Prefecture based Nanyo Complex. Here, quality management is performed, with the Nanyo Complex having obtained ISO9001. And the Bioscience division has obtained ISO13485, a demand for health care instruments.

2) Critical Elements for Dedicated Reagents Manufacturing and their Flow

Based on a business impact analysis and risk assessment, the Bioscience division has examined the work process flow for its reagents, from the procurement of raw materials to the shipment and delivery of the final product. Within that process, the division has listed up critical elements and has considered such measures essential to business continuity as recovery from stoppages in raw materials supply, utilities and logistics; depletion of internally produced raw materials; and damage to manufacturing facilities.



3) Recovery Period

As a result of doing a risk analysis of the GP plant, the division found that the risk event that would require the longest recovery period was damage to the plants caused by a natural disaster, such as an earthquake or tsunami. As mentioned previously, the plants have been constructed with earthquake resistance adequate for the maximum expected earthquake intensity in the region. Moreover, the largest expected scale of flooding from a tsunami would not cause the collapse of the plants. Therefore, it can be said that a natural disaster would not cause damage on the level of total plant destruction. However, it must be assumed that instruments and equipment would be ruined. After closer investigation, it was decided that the maximum period that could be required to recover operations was three months.

Tosoh is working on a group-wide BCP involving safety measures that reduce the likelihood of damage and promote a rapid recovery of services in the event of an emergency. Furthermore, the Bioscience Division is taking additional measures, such as maintaining a strategic inventory of product to ensure that Glycohemoglobin Analytical Columns, Elution Buffer and Hemolysis & Wash Solution supplies continue to flow during the recovery period and ensuring that stable supplies of raw materials for manufacturing are available to maintain continuity of business operations under emergency situations.



Glycohemoglobin analytical columns, elution buffer and hemolysis & wash solution plant



Analytical column (Variant Analysis Mode)



Elution buffers (Variant Analysis Mode) and hemolysis & wash solutions

Summary

1) Earthquake-Resistant Plant Design

Geographically as well as historically, Japan is a country of frequent earthquakes. Consequently, since ancient times, buildings have been designed to withstand them. In modern times, this is enforced legally through the Building Standards Act, with building being required to meet the earthquake-resistance standard deemed necessary in any area. As a matter of course, these standards apply to Tosoh's plants.

The GP plant is constructed so as to withstand damage from an earthquake intensity of up to 6.4. Since the maximum expected intensity in the region is 5.9, it can be said that the plant has satisfactory earthquake resistance.

2) Strategic Product Inventories

As mentioned previously, should some unforeseen event occur affecting the GP plant, it is estimated that the maximum recovery period would be three months. However, we consider it our responsibility to continue to supply customers during the recovery period.

For columns, elution buffer and hemolysis & wash solutions, we currently keep more than three months' worth of inventory. These levels are maintained at our Japanese and our overseas sales companies in order to continue supplying customers while recovery is ongoing.

3) Continuity of Raw Material Supply

Even if problems do not occur at the GP plant, the Bioscience division needs to be prepared for any unforeseen event occurring at one of its raw material manufactures that would disrupt supply. When selecting a raw material supplier, we take into consideration not only their ability to provide a quality guarantee but also their ability to maintain stable supply. In addition, we regularly evaluate their qualifications as a supplier and initiate inspections as necessary.

Due to the impact a disruption in raw material supply can have on production, we are moving forward with dual supplier sourcing of such essential materials for column parts, elution buffer, hemolysis & wash solutions, and reagents.

4) Dispersion of Manufacturing

As a drastic measure taken to stably supply our dedicated reagents, we are currently considering the dispersion of our manufacturing operations. Manufacturing of hemolysis & wash solutions is already ongoing at our sales companies in the U.S. and in Europe. In the future, elution buffer and columns are also planned for consideration.

Conclusion

As we believe it is our responsibility to keep hospitals and other medical institutions stably supplied with dedicated reagents for glycohemoglobin analytical columns, in addition to developing better products, Tosoh will continue to raise product quality, and, with a business continuity plan, further its commitments to stable supply so as to meet the needs of our customers' product life cycles.

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