Major Accident Hazard in Bioprocess Facilities: A Challenge To Sustainable Industrial Development

K A Johari and A Ramli,

Faculty of Chemical & Natural Resources Engineering, , Universiti Malaysia Pahang, 26300 Gambang, Pahang, Malaysia.

Abstract. Sustainable components of renewable biological resources in Malaysia provide the prospect for the growth of the bioeconomy via research, innovation and commercialisation. Malaysia is one of the few Asian countries that has most of its bio safety regulations and guidelines in place. In spite of the government is driving the sector in full force, there are still missing links and challenges. Some recent accidents involving the bioprocess raised concern on the safety of such technologies inclusive one incident happened in a bioprocess facility that has been selected as a case study. The facility selected is one of the Bioeconomy Transformation Programme (BTP) Trigger Projects in Malaysia. Holistic risk assessment is needed in order to identify and potential hazard related to bioprocess. With the usage of hazardous substances in the process, the approach towards risk assessment and accident prevention is crucial. Mechanical integrity and process safety related aspect is among the area need to be explored.

1. Introduction
Bioprocess or biotechnological process is a process that uses living organisms or its component, in order to make or modify desired product [1]. Meanwhile, bioprocess or biochemical engineering combine biotechnology and chemical engineering to make or modify desired product. The range and application is quite enormous, from waste water treatment to agriculture, food, feed, pharmaceuticals, paper, polymer and energy production [2]. The implementation of these ground-breaking processes and technologies in the industry [3-5] can increase the potential of the facilities where bioprocesses are carried out [2]. Generally, bioprocesses are deeming to pose less risk compared to conventional chemical processes. However, several major accidents happened in this industry in recent years [2,7-8]. Moreover, in some of the accident scenarios not identified in the risk assessment which may be considered as exceptional [9]. Such trend may be considered as warning signs of the emerging risk issue, something that unusual as defined by International Risk Governance Council (IRGC) [10]. Furthermore, this phenomenon may suggest that some limitations may be present during the risk assessment process [2].

In a bioprocess facility, both biological hazards and conventional chemical hazards may be present. However, the holistic techniques for risk assessment in this industry are not available [7-8]. Only few studies attempted to apply conventional methods for risk assessment such as to bioprocesses [11-14]. At this time, there is no uniform risk assessment methodology to approach bioprocess facility and existing approach for bioprocess mostly concentrate on the protection of workers from exposure to biological agents [15]. The prospect of risk management and accident prevention approach for bioprocess are huge especially with hazardous substances involvement in the process. In case of any incident, the consequences towards people, environment and asset are severe. Thus, it can be a challenge to sustainable industrial development.
2. Bioeconomy Transformation Programme

Lead by Ministry of Science, Technology and Innovation (MOSTI), National Biotechnology Policy (NBP) was launched in 2005 with the aimed to established biotechnology as the key contributor to Malaysia economic growth. In 2012, Bioeconomy Transformation Programme (BTP) was launched to complement the National Biotechnology Policy and accelerate the country’s bioeconomy development. Sustainable components of renewable biological resources in the country provide the prospect for the growth of the bioeconomy via research, innovation and commercialisation. The BTP is expected to be one of the strategies to transform Malaysia into a high income nation with activities focusing on biotechnology. BTP targets to secure RM48 billion (USD10.9) of Gross National Income (GNI), create 170,000 new job opportunities and capture an investment of RM50 billion (USD11.4) by the year 2020. [16]. In 2016, the Malaysian Biotechnology Corporation was renamed to Malaysian Bioeconomy Corporation. Already moving into the third phase of the NBP, the main objective is that Malaysian player to ply their trade globally. Furthermore, Malaysia has established biosafety related regulations and guidelines, among few Asian countries that have done the same. However, there may be a need to review all the regulations and guidelines especially related with risk assessment.

3. CIMAH Regulation 1996

The Department of Occupational Safety and Health (DOSH) of Malaysia which was formerly known as The Factories and Machinery Department (FMD) of Malaysia spearhead the regulations on the Major Hazard Installation (MHI) operations of in the country. The ultimate goal is ensure the safe operation of the installation. Earlier, Factory Machinery Act 1967 focusing on conventional standard setting and enforcement on factories operations. In May 1991, the incident involving firework factory, the Bright Sparklers at Sungai Buloh, Selangor was one of the worst technological catastrophe in the country. The factory was located only 30 feet away from residential areas and was built on a piece of land designated for agricultural use. The explosion took 22 lives, 103 others sustained injuries of varying degrees of seriousness, one person was reported missing and many surrounding homes and factory buildings were destroyed. Over 1000 residents near the surrounding area were evacuated from their homes.

This incident triggered and accelerated the enactment and implementation of the Occupational Safety and Health Act in 1994 (OSHA 1994) regulation followed by the establishment of the Control of Industrial Major Accident Hazards (CIMAH) Regulations in 1996. The regulation which has being enforce since February 1996 requires the owner of the major hazard installation to notify the status of the premise, prepare emergency plan and notify major accident that occur in their premises.

There are two major concerns in the regulations, which are type of hazardous substance and quantity of hazardous substance. Above a certain amount or inventory (threshold quantity), is believed to be potentially a major accident that threaten the safety and health of workers on-site or to the public surrounding the installation. Industrial activities are classified into Major Hazard Installation, Non Major Hazard installation and No-Threshold Quantity. Installations having hazardous substance equal or higher than the threshold quantity (TQ) are classified as Major Hazard Installation (MHI), whereas those that contain the material in between 10% threshold quantity and threshold quantity are categorized as Non-Major Hazard Installation (NMHI) and installations with less than or equal to ten percent of threshold quantity are called Non-Threshold Category (NTR).As required by the CIMAH regulations, the MHI must submit a Safety Report and on site Emergency Response Plan (ERP) to The Director General of DOSH. The objectives of the safety report are:

i. To identify the nature and scale of the use of dangerous substance at the installation.
ii. To give an account of the arrangements for safe operation of the installation, for control of serious deviations that could lead to a major accident and for emergency procedures at the site.
iii. To identify the type, relative likelihood and consequences of major accidents.
iv. To demonstrate that the manufacturer has identified the major hazard potential of his activities and has provided appropriate controls.

The DOSH requires that the information of the safety report must include:

i. Hazardous substances: name/quantity, hazards, purity/impurity.
ii. Installation: a map of the site: a scale plan of site showing locations and quantities of hazardous substances; process description and conditions; number of persons on site; nature of land use and population in the vicinity, and the nearest emergency services.

iii. Management System: staffing arrangements (person in charge, responsible for safety, to set emergency procedures); safe operation; design, construction, testing, operation, inspection and maintenance; staff/worker training programs.

iv. Risk Assessment: description of potential sources, conditions and events; diagram to show features for accident control; description of measures taken to prevent, control and minimize the consequences; prevailing meteorological conditions; and consequences to the surroundings in the form of appropriate risk measures.

Other requirements imposed on manufacturers under MHI are to keep an up to date report and plan, to inform local authority and help them to prepare off-site ERP, inform the public and DOSH about any major accident. The obligations of manufacturers under the NMHI category are notification of an industrial activity, preparation and submission of Demonstration Operation Document and Emergency Response Plan (ERP) to DOSH in case the Director General requests, for them and to keep an up to date report and plan and inform DOSH of any major accident. In order to maintain the standard and quality of the safety report submitted to DOSH, its Major Hazard Division registers consultants as “Competent Persons” to approve the reports. Originally they were it called ‘register persons’ a term used by other government agencies for one who has been appointed by an authority to approve a report such as the report of Environmental Impact Assessment (EIA). The Criteria used to register a Competent person by DOSH is mainly based on academic qualifications and experience in the area. Such a person is required to possess a Bachelor of Science or Engineering and also meet other criteria such as adequate knowledge, skill expertise and experiences in area related to the content of safety report. Although the competent person approves the safety report, it still requires to be reviewed by the DOSH. The manufacturer is also asked to present the report to the DOSH officers. Any unsatisfactory report due to the inadequacy or discrepancy of the information must be corrected before the manufacturer can resubmit the report to the DOSH. For a satisfactory report, the DOSH will acknowledge the acceptance by sending a letter to the manufacturer.

Table 1. Distribution of Major Hazard Installations in Malaysia. Source: Department of Occupational Safety and Health (DOSH), Malaysia

| Location                        | Number of Major Hazard Installation |
|--------------------------------|-------------------------------------|
| Kedah                          | 11                                  |
| Pulau Pinang                   | 22                                  |
| Perak                          | 24                                  |
| Selangor                       | 72                                  |
| W. P. Kuala Lumpur/ Putrajaya  | 7                                   |
| Negeri Sembilan                | 18                                  |
| Melaka                         | 10                                  |
| Johor                          | 49                                  |
| Pahang                         | 21                                  |
| Terengganu                     | 31                                  |
| Kelantan                       | 3                                   |
| W.P. Labuan                    | 6                                   |
| Sarawak                        | 20                                  |
| Sabah                          | 22                                  |

Up to 14 March 2017, there are 316 Major Hazard Installations (MHI) in Malaysia as shown in Table 2. The highest number of MHI is 72 which are located in Selangor followed 49 in Johor and 31 in Terengganu.
4. Case study: The bioprocess of L-Methionine production facility

Livestock requires minimum 10 essential amino acids for biological function and L-Methionine is the first limiting amino acid in livestock growth. Amino acids is part of proteins essential for body development in case of poultry. However, since L-Methionine cannot be produced naturally, it has to be supplied from secondary sources. The process developed by this facility utilises a combination of applied chemical and biochemical processes (fermentation and enzymatic conversion) to produce L-Methionine (L-MET) safe for the target animals when used as a feed additive to meet their requirements [17].

The process commences with production of O-acetyl-L-homoserine (OAHS) through fermentation process, where OAHS is an L-MET precursor which is a natural metabolic product and does not contain any sulphur. The OAHS is then converted to become L-MET by enzymatic reaction with an equimolar of Methyl Mercaptan (or commonly known as Methanethiol or MeSH). The process is a unique process which are sulphur incorporation and methylation, are deleted from the equation. MeSH is already in the methylated sulphur form and hence, sulphur incorporation and methylation can be achieved simultaneously via one enzymatic reaction. The overall process can be simplified into 3 biochemical process stages: (a) fermentation, (b) enzymatic conversion and (c) purification and isolation of the product (production of Co-Product). The net reaction of these two products is as follows:

\[
\text{OAHS} + \text{MeSH} \rightarrow \text{L-MET} + \text{Acetate}
\]

The final step is the purification of L-MET which also led to production of Co-Products, namely Ammonium Acetate (AMA), Ammonium Sulphate (AMS), Dried Cell Mass and Liquid Fertiliser (LF).
This facility has been classified as Major Hazard Installation (MHI) in accordance to Regulation 12 (a) or 12 (b) Occupational Safety and Health Regulations (Control of Industrial Major Accident Hazard) 1996. Ammonia with the quantity of 151 m$^3$ is the hazardous substance exceeding Threshold Quantity. In this facility, Ammonia is used for cell growth, nitrogen source for OAHS and pH control in fermentation process. Other than that, it is used to produce AMA. Operated since 2015, there has been an incident involving ammonia leakage in October 2016. At 7:30 a.m. the ammonia detector triggered and operation personnel went to investigate the alarm. It was found out that ammonia was leaked from emergency shut off valve. Meanwhile, the water spray system at the ammonia storage area has been activated for protection. The waste water was sent to the Waste Water Treatment Plant. Engineering team replaced the valve immediately and it was completed at 4 p.m.

5. Major accident involving bioprocess facility
Back in August 5, 2009, there was a major incident related to ammonia storage in a bioprocess facility in China. The report was produced by United Nation Environment Programme in 2014 as part of chemical accident reporting in China. During unloading activity, the unloading metal tube of a tank truck loaded with 30 ton liquid ammonia suddenly ruptured and caused liquid ammonia leakage. The emergency cut-off valve at the rear of the tank failed to work. The facility responded to the incident and notified local government and police concurrently. The police officers controlled the incident site while the firefighters dilute the leaking liquid ammonia with water. It took about 1 hour and 30 minutes before the leakage under control. However, there was another issue. The nearby river has been polluted with liquid ammonia. 8-ton hydrochloric acid solution was used to neutralize the ammonia polluted water. As a result of the incident at the bioprocess facility, 21 persons hospitalized and 88 persons get outpatient treatment due to irritating reactions. The incident is the evidence that holistic risk management is needed for bioprocess facilities especially on bulk chemical storage.

6. Ammonia leakage incident in Malaysia
In recent years, several accidents involving ammonia leakage reported by newspaper and social media. Such accidents may be considered as early warnings of an emerging risk issue.

| Year | Location | Death | Injury |
|------|----------|-------|--------|
| 2002 | Terengganu | 1     | 1      |
| 2009 | Selangor  | 6     | 5      |
| 2012 | Terengganu | 24    |        |
| 2016 | Sabah     | 2     | 3      |
| 2018 | Selangor  | 2     | 18     |

In the L-Methionine production facility, ammonia is stored in 2 pressure vessels. Maximum storage capacity is 151 m$^3$. Therefore, this bioprocess facility provide the same threat as other industrial facility. The ammonia storage area is protected with water spray system. It consists of water spray nozzles, linear detector and control panel, deluge valve and piping. During detection of fire by linear detector, releasing system will be activated and the deluge valves will open to release the water to the protected area.

7. Discussion
The facility selected as a case study was just started operation in 2015 when the first recorded incident at the ammonia storage facility happened in October 2016. This incident is one of threat to sustainable bioprocess industry. In this case, mechanical integrity is one of the aspect that need to be considered. In European countries, the Seveso Directives related legislations require the owner of facility where hazardous chemicals are handled, to put into practice a safety management system, which will incorporate mechanical integrity. Risk-Based Inspection (RBI) is one of the common method used in
process industry. The essential implementation of RBI is to optimize the inspection intervals instead of fixed frequencies that were required by long-established time based approach. By having sufficient risk assessment in RBI, inspection times and modes can be determined.

The concern of ageing industrial facilities has been growing in recent years. However, managing ageing facilities may be difficult due the nature of the physical and chemical mechanisms that need to be studied, the treatment of life cycle information and data acquisition on real conditions. A recent review have shown that maintenance is major root of 184 major accidents in the process industry in the US and Europe during the period 2000-2011 [20]. Therefore, preventive maintenance is the key to prevent major accident. A standard preventive maintenance consists of inspections of components which are to corrosion or erosion, and parts replacement. Other than that, safety related equipment such as Pressure Safety Valve (PSV) must be tested and recertified at regular intervals, usually once per year [21].

It is important not to discriminate small bioprocess facility without taking into consideration the quantities of hazardous materials, which is essential in major hazard legislations. However, the implementation of safety management system and preventive maintenance program may be weak. Thus, as a result the risk may be took too lightly [19]. Other than that, dynamic risk assessment towards process need to be explore further.

8. Conclusion

The losses of containment from major accident hazard facilities which contained hazardous substances may caused severe consequences for people, environment and asset. Not to forget, bioprocess facilities pose the same threat that conventional process has.

9. References

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