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Review of global process safety regulations: United States, European Union, United Kingdom, China, India

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ABSTRACT

Process safety regulations are an integral part of maintaining the safety of workers, the public, and the environment. Therefore, global regulations were analyzed to compare the extent of process safety regulations in the United States, European Union, United Kingdom, China, and India. The development of regulations is typically instigated by the occurrence of a significant process safety incident. However, the extent of the regulations and the quality of their enforcement varies greatly between countries. In general, the developed countries have better reporting procedures, enforcement of regulations, and emergency plans which increases the number of incidents reported. Developing countries are working to implement regulations, typically influenced by regulations from developed countries, but the regulations aren't currently enforced to the same extent. Overall, improvement in reporting & data collection procedures and increased communication between the government, companies and the public would help increase the effectiveness of process safety regulations.

1. Introduction

Process safety is an important issue that affects the global chemical and manufacturing industries. The development of process safety regulations has been continual as significant incidents occur, industry grows and new technology is developed. The regulations from five different regions were analyzed including the United States (US), European Union (EU), United Kingdom (UK), China, and India. These regions represent three developed regions (US, EU and UK) and two developing countries (China and India). Therefore, these countries are at different points in their industrial and process safety development which provides comparisons.

Each country has specific regulations that were implemented to regulate various industries. Many significant process safety incidents occurred throughout the 1970's to 1990's which instigated the development of process safety regulations in the developed countries. In the US, the two main regulations are the Occupational Health and Safety Administration (OSHA) Process Safety Management (PSM) implemented in 1992, and the Environmental Protection Agency (EPA) Risk Management Plan (RMP) implemented in 1996. The OSHA PSM focuses on the protection of workers within the facility, while the EPA RMP protects the public and environment. The main regulation in the EU is the Seveso Directive which covers all EU member states. Even though the UK is currently still part of the EU, it has unique process safety regulations/agencies including the Control of Major Accidents Hazards (COMAH) regulation and the Health & Safety Executive. The two developing countries, China and India, have also implemented process safety regulations. India's main regulation is the Factories Act, although it only applies to registered factories. Chinese regulations were implemented more recently than other countries, with the State Administration of Work Safety (SAWS) created ILO, 2005 and the SAWS PSM regulation passed in 2010. Each country also has specific environmental, protection of critical infrastructure and offshore safety regulations and trade associations which are involved in promoting process safety.

For each of the regions investigated, the findings are organized in terms of: background, significant incidents, regulations, environment, protection of critical infrastructure, offshore, related trade associations and performance in terms of fatality statistics. With the scope of this paper being process safety, the environment and offshore summaries are not comprehensive, but reflect key regulations and in particular those that address process safety.

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2. United States regulations

2.1. Background

In the United States, efforts to establish government safety regulations began in the 1800's. However, these efforts made little progress initially. The Federal Bureau of Labor was created in 1884 and went through many forms to become the Department of Labor in March 1913 (Grossman and MacLaury, 2017). This new department struggled to find direction and was initially focused on labor disputes and immigration (the Bureau of Immigration was separated from the Department of Labor in 1940) (MacLaury, 2017). However, in 1936, the Department of Labor passed the Walsh Healy Act which established the 8-h work day, defined healthy working conditions and allowed contract work under hazardous conditions to be banned (MacLaury, 2017). Throughout the next few decades, there was some growth in process safety programs particularly at the state level. However, these programs were not administered well and led to inconsistent results (Crowl and Louvar, 2011; Mentzer, 2016).

Therefore, the Occupational Safety and Health Act (OSHAct) was implemented in 1970 and was a major milestone in safety laws. This Act created the Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH). OSHA is responsible for creating regulations/standards and conducting inspections of workplaces, while NIOSH is generally responsible for researching hazards and developing safety criteria levels (Crowl and Louvar, 2011; DOL, 2016; Mentzer, 2016). Also in 1970, the Environmental Protection Agency (EPA) was created in response to a rising environmentalism movement. The EPA focuses on establishing and enforcing environmental protection regulations, researching impacts of environmental issues and implementing the components of the Clean Air Act (EPA, 2017a).

2.2. Incidents

Throughout the United States, several significant process safety incidents occurred during the past decades as shown in Table 1.

The occurrence of these process safety incidents (and others globally) led to the development of important process safety regulations in the United States.

- In August 1985, aldicarb oxide and methyl chloride were released from a Union Carbide facility in Institute, West Virginia. The release resulted in no deaths and was much smaller than the Union Carbide methyl isocyanate release in Bhopal, India (see India section). However, this release occurring so soon after the Bhopal release warned both government and industrial groups about the potential for serious incidents to occur even in developed countries (Macza, 2008).
- A vapor cloud explosion occurred at the Phillips Petroleum Complex in Pasadena, Texas in October 1989. The vapor cloud formed due to improper isolation of the process during maintenance and contained a mixture of ethylene, isobutene, hexane and hydrogen. The incident resulted in 23 deaths and 314 people injured (Crowl and Louvar, 2011; Macza, 2008).
- In March 2005, a vapor cloud explosion occurred at the BP refinery in Texas City, Texas. During the start-up of the isomerization unit, the splitter tower was overfilled to approximately 98 feet (should have been no more than 9 feet) and the level control systems failed to operate properly. Liquid then overfilled the blowdown drum that was part of the relief system and erupted from the top, which formed the vapor cloud. This vapor cloud exploded resulting in 15 fatalities, 180 injuries and billions of dollars in ultimate costs (Crowl and Louvar, 2011; CSB, 2017b).
- In December 2007, an explosion and fire occurred due to a runaway reaction at T2 Laboratories. The facility manufactured a gasoline additive through an exothermic reaction. The cooling process for the reaction vessel failed resulting in a runaway reaction and explosion. The explosion killed four people and injured 32 others. As a result of this incident, the American Institute of Chemical Engineers (AICHE) worked with the Accreditation Board for Engineering and Technology (ABET) to require study of process safety hazards in college level chemical engineering curricula (CSB, 2012; CSB, 2017c).
- In April 2010, an explosion occurred on the Deepwater Horizon drilling rig in the Gulf of Mexico releasing approximately 5 million barrels of oil. A “kick” occurred which caused oil and gas to enter the wellbore and eventually reach the rig where it ignited. However, the blowout preventer (BOP) failed to operate properly due to errors in wiring of the automated shear system and the buckling of the drill pipe which prevented the full closure of the pipe. The incident resulted in the death of 11 people and 17 injuries (CSB, 2017d).
- An explosion of 30 tons of ammonium nitrate occurred at the West Fertilizer Company in April 2013. This incident resulted in 15 deaths, over 260 injuries, and hundreds of millions of dollars in damage to buildings and property. The damage was more severe due to a lack of community awareness/emergency planning and a lack of zoning regulations to prevent other buildings being constructed near the site (CSB, 2017a).

Aftermath of BP Refinery Explosion in Texas City, Texas (CSB, 2017b)

Table 1
Significant incidents in the United States (Crowl and Louvar, 2011; CSB, 2012; CSB, 2017a; CSB, 2017b; CSB, 2017c; CSB, 2017d; Macza, 2008).

Date	Location	Description
August, 1985	Institute, West Virginia	Aldicarb oxide and methyl chloride released from Union Carbide Facility
October, 1989	Pasadena, Texas	Vapor cloud explosion and fire at Phillips Petroleum Chemical Complex
March, 2005	Texas City, Texas	Vapor cloud explosion at the BP refinery isomerization unit
December, 2007	Jacksonville, Florida	Runaway reaction resulted in an explosion and fire at T2 Laboratories
April, 2010	Gulf of Mexico (off the coast of Louisiana)	Explosion and oil release on the Deepwater Horizon Oil Rig
April, 2013	West, Texas	Explosion of ammonium nitrate at West Fertilizer Company

2.3. Regulations

2.3.1. OSHA PSM

After the Bhopal incident in 1984 and the Union Carbide release in Institute, West Virginia in 1985, OSHA instituted a new special emphasis program in 1986 to focus on preventing releases and protecting workers (Long, 2009). Also, the Clean Air Act Amendments (CAAA) were passed in November 1990 which authorized OSHA to create new process safety management regulations (Long, 2009; OSHA, 2000; Willey et al., 2005). The Clean Air Act Amendments of 1990 were vital in improving process safety regulations as they authorized OSHA to establish the PSM (section 304), created the Chemical Safety Board (section 112r6), developed a list of hazardous chemicals and their threshold values (section 112r3,4,5) and authorized the establishment of the RMP (section 112r7) (Willey et al., 2005). These steps resulted in OSHA passing the Process Safety Management of Highly Hazardous Chemicals Regulation (PSM) in February 1992. The goal of the PSM regulation (29 CFR, 1910.119) was to prevent future incidents by providing rules for the management of processes that use above specified threshold quantities of hazardous chemicals. There are 14 main sections in the PSM which includes (Crowl and Louvar, 2011; Mentzer, 2016):

- Employee Participation
- Process Safety Information
- Process Hazard Analysis
- Operating Procedures
- Training
- Pre-Startup Safety Review
- Contractors
- Mechanical Integrity
- Hot Work Permits
- Management of Change
- Incident Investigation
- Emergency Planning
- Compliance Audit
- Trade Secrets

Any facility that uses a specified quantity of more than 130 reactive, toxic or flammable materials is covered under the OSHA PSM regulation (OSHA, 2000). However, OSHA PSM does not cover federal waters, nuclear energy or the transportation industry (DOL, 2016). The nuclear energy sector is covered by the United States Nuclear Regulatory Commission (USNRC), while the transportation industry is covered by the Department of Transportation (DOT) (DOT, 2017; NRC, 2017). Through the OSHAct, workers are either covered directly by OSHA (federal program) or by a state plan that is approved by OSHA. Currently, six states/territories have plans that only cover public sector workers and 22 states/territories have plans that cover both private and public sector workers. These state plans must be “at least as effective as” the federal OSHA program, but have the authority to cover additional hazards or enforce stricter penalties (OSHA, 2017a). Each individual facility is responsible for the implementation of the OSHA PSM regulations at their facility and is required to comply with certain recordkeeping and reporting procedures (DOL, 2016). However, there are information and programs to help companies stay abreast of updates by the Department of Labor and OSHA. These resources include documentation of regulation information and step-by-step guidance to identify regulatory requirements for compliance (DOL, 2016; OSHA, 2017b). OSHA also has a bimonthly newsletter to notify facilities and employees of updates to OSHA programs and other process safety information.

OSHA assesses compliance with these regulations by conducting both programmed and unannounced inspections of facilities that are covered by OSHA regulations. To determine which facilities are inspected, OSHA ranks them in order of priority. Any facility judged for personnel to be in imminent danger of death or serious injury is a top priority. This is followed by facilities where worker complaints were filed and targeted inspections of high hazard industries (OSHA, 2016). Since 2010, OSHA has averaged around 37,000 inspections per year with about half of the inspections being unannounced. These inspections have led to approximately 65,000 to 96,000 violations per year with most violations being classified as “serious” (OSHA, 2017c). According to OSHA statistics for chemical manufacturing, the regulations most cited as lacking during inspections include (in order of number of occurrences) the Process Safety Management of Highly Hazardous Chemicals (PSM), respiratory protection, and control of hazardous energy (lockout/tagout) (OSHA, 2017d). The main four areas of PSM that are most commonly at fault when a serious incident occurs are Process Hazard Analysis, Operating Procedures, Mechanical Integrity and Management of Change (Mentzer, 2016). Also, there are several levels of violations that are penalized differently. A mandatory penalty of up to $12,471 is enforced for any safety violation that could cause serious harm. However, a facility could be penalized up to $124,709 for a willful violation which occurs when a facility intentionally violates the OSHA regulations or knows of the hazard and does nothing to prevent an incident. If an employee dies as a result of a willful violation the penalty could include a criminal trial and imprisonment. Finally, any repeat violation could be penalized by up to $124,709 and failure to implement any corrective action to fix violations could result in a penalty of $12,471 per day (DOL, 2016; OSHA, 2017e). However, there is an appeals process where the employer can discuss the identified violations and penalties and work out a settlement with OSHA to eliminate the hazard (OSHA, 2016).

2.3.2. EPA RMP (environment)

The Environmental Protection Agency (EPA) responded to the large number of process safety incidents in the 1970's and 1980's by creating process safety regulations to protect the surrounding community and the environment. The main EPA process safety regulation is the Risk Management Plan (RMP) which was passed in June 1996 after being authorized in the Clean Air Act Amendments of 1990 (Willey et al., 2005). RMP applies to any facility which uses above a specified threshold quantity of a regulated substance and focuses on protecting the off-site community and the environment. Also, the EPA RMP does apply to all state and local governments (EPA, 2017b). This is unlike the OSHA PSM regulation which only applies to state and local government workers if that state has an OSHA-approved state program. However, there are exemptions for the gasoline and crude oil industry, offshore facilities, transportation and explosives (Mentzer, 2016). Each facility is responsible for implementation of the EPA RMP regulations at their facility and the site plan must be updated every five years (EPA, 2016). However, the EPA does provide resources to help facilities determine if they are required to implement RMP and what they are required to do to be in compliance (EPA, 2017b). The RMP covers hazard assessment, prevention programs, emergency response programs and documentation (Crowl and Louvar, 2011). The hazard assessment section focuses on analysis of the off-site consequences of potential worst case and alternative release scenarios. The EPA provides guidelines for what must be covered in each release scenario analysis. Also, the distance affected by a worst case release is determined with dispersion modeling. The prevention program section has 11 elements (Crowl and Louvar, 2011):

- Process Safety Information
- Hazard Evaluation
- Standard Operating Procedures
- Training
- Pre-Startup Review
- Maintenance
- Management of Change
- Accident Investigations
- Emergency Response
- Safety Audits
- Risk Assessment

These sections were intentionally made similar to the OSHA PSM to reduce the burden on facilities, but there are some differences between the sections since the RMP focuses on the off-site community and environment (Crowl and Louvar, 2011). The emergency response program section involves training employees in emergency response procedures and coordinating with the community and emergency response agencies. Finally, the documentation section requires facilities to maintain proper documentation and make the documentation available to government authorities and the public (Crowl and Louvar, 2011).

The RMP has three different program levels which specify what needs to be covered for compliance in each of the four RMP sections. These levels are defined based on the facility's accident history, distance from the public and if the facility is subject to OSHA PSM (EPA, 2017b; Mentzer, 2016). Therefore, Program 1 is defined as facilities with no history of accidents that have affected areas off-site, where the worst case release distance does not reach the public and where emergency response has been coordinated with the local agencies. Program 3 is defined as facilities that are subject to OSHA PSM regulations and Program 2 is defined as facilities that don't fit in either Program 1 or 3. Thus requirements for compliance are lowest for Program 1 facilities and highest for Program 3 facilities (EPA, 2017b).

The EPA enforces the RMP by conducting audits and inspections of facilities. Facilities are chosen for audits/inspections if they meet any of a series of criteria including accident history for the facility/industry, location of the facility relative to the public, complaint by a member of the public and/or the amount of regulated substances used at the facility (EPA, 2017b). The purpose of the audits is to determine if the facility's RMP is in compliance. Inspections are also conducted which focus on the entire risk management program instead of just the RMP (EPA, 2017b). If the facility is not in compliance, then the inspector issues necessary revisions and a timetable to complete the revisions. Also, a facility can be fined up to $32,500 per day per violation. If the facility knowingly violated the regulations or provided false information, then they could be subject to additional fines or potentially jail time (EPA, 2017b). Finally, the EPA has an incentive program to encourage companies to voluntarily report noncompliance and correct process safety issues (EPA, 2017c).

2.3.3. Chemical Safety Board

The Chemical Safety Board (CSB) was established in January 1998 after being created as a part of the Clean Air Act Amendments (CAA) of 1990. Congress gave the CSB the authority to be independent of all other agencies, but the CSB does collaborate closely with other agencies including the EPA and OSHA (CSB, 2017e; Willey et al., 2005). The purpose of the CSB is to investigate process safety incidents and potential hazards to determine the root cause and to provide recommendations to government agencies and industry to prevent future incidents from occurring (CSB, 2017e).

2.3.4. Protection of critical infrastructure (anti-terrorism)

Security has become more of a concern in recent years which led to the implementation of the Chemical Facility Anti-Terrorism Standards (CFATS) in April 2007. CFATS is run by the Department of Homeland Security (DHS) which monitors facilities who store or handle over a specified quantity of certain materials (Crowl and Louvar, 2011). Facilities who use these materials are ranked based on risk and are required to complete a security vulnerability assessment (SVA) and a site security plan (SSP). The SSP includes measures for the deterrence, detection, delay, response and awareness of security threats (Crowl and Louvar, 2011). In 2014, CFATS was reauthorized for another four years. The CFATS Act of 2014 also included an Expedited Approval Program for Tiers 3 & 4 and improved reporting procedures for potential violations (DHS, 2016). The DHS inspects facilities to ensure compliance based on their ranking (higher risk facilities are inspected more frequently) or in response to any security concerns (DHS, 2017).

2.3.5. Offshore

In response to the Deepwater Horizon (Macondo) Blowout in April 2010, the Bureau of Safety and Environmental Enforcement (BSEE) was created and the Safety and Environmental Management System (SEMS) regulation was implemented (BSEE, 2017a). SEMS covers all offshore oil and gas operations in the United States outer continental shelf. The regulation was initially implemented in November 2010 and was largely based on the voluntary American Petroleum Institute's (API) Safety and Environmental Program for offshore operations (Mentzer, 2016). However, the SEMS rule made these safety practices mandatory. The SEMS regulation consists of 13 elements including hazard analysis, operating procedures, training, mechanical integrity, and audits (among other sections) (Mentzer, 2016). In June 2013, SEMS II was implemented as an update to the original regulation. Facilities were given one year to comply. This update focused on clarifying which operators have decision making authority and giving them the authority to stop work, establishing reporting procedures to report directly to the BSEE, and requiring that audits be conducted by independent third parties (BSEE, 2017b). Similar to other agencies, the BSEE conducts inspections of offshore facilities and issues citations and monetary penalties for any regulatory violations (BSEE, 2017c).

2.3.6. Industrial trade associations

Industrial groups responded quickly to the process safety incidents in the 1970's and 1980's by implementing programs to improve process safety. The American Institute of Chemical Engineers (AICHE) created the Center for Chemical Process Safety (CCPS) in March 1985. The mission of the CCPS is to promote process safety initiatives and improve understanding of process safety issues across all industries (CCPS, 2017a). This is achieved by establishing industry best practices, providing opportunities for collaboration between companies and improving process safety education (Willey et al., 2005). Also, the Community Awareness and Emergency Response (CAER) Program was begun in 1985 by the Chemical Manufacturer's Association (CMA) (later to become the American Chemistry Council) (Cooper, 1990). The goal of this program was to improve communication between facilities, emergency responders and the community, and to ensure that communities had emergency response plans. The CAER program later became part of the Responsible Care Program after the adoption of the Responsible Care program in 1988 (ACC, 2017a; Macza, 2008). Congress also responded to community concerns by creating mandatory emergency response programs through passing the Superfund Amendments and Reauthorization Act (SARA) in 1986. SARA comprises the Emergency Planning and Community Right-to-Know Act and requires any information regarding potential hazards to be made available to the public (especially Material Safety Data Sheets (MSDS)) (Cooper, 1990; Willey et al., 2005). Finally, various trade associations and other industry groups, such as the American Petroleum Institute (API) and the Organization Resources Counselors (ORC), worked to provide recommended best practices for employers (OSHA, 2017f). This cooperation between trade associations and government agencies continues as trade associations help to spread the word about new regulations and provide guidelines for how facilities should implement and comply with regulations.

2.3.7. Performance

Overall, process safety regulations in the United States cover a wide variety of process safety hazards which helps protect workers and the surrounding community. There has been a corresponding decrease in the fatal injury rate and number of fatal injuries per year in the manufacturing industry as seen in Fig. 1, although generally flat most recently (BLS, 2017). The sectors included in the manufacturing industry is defined by the North American Industry Classification System (NAICS) of 2012. Manufacturing includes food, chemical, plastic product, and metal manufacturing among others (BLS, 2017).

Also, the severity and frequency of safety incidents has decreased since the 1970's. OSHA reports that the worker illness and injury incident rate has dropped from 10.9 per 100 workers in 1972 to 3.0 per 100 workers in 2015 (OSHA, 2017g). Overall, fatal and non-fatal incident rates have decreased over the past few decades. Over the past decade various industries have also started to measure and report process safety incidents related to the loss of containment of hazardous substances. Such reporting is for specific industries, such as the ACC Responsible Care Program and the API RP 754 (ACC, 2017b; API, 2017). Such metrics reflect process safety performance vs. fatality rates that reflect both personnel and process safety incidents.

3. European Union regulations

3.1. Background

The European Union (EU) is a collection of member states who work together to develop collective economic and political policy. The development of the EU began with the creation of the European Coal and Steel Community (ECSC) by the treaty of Paris in 1951 to unite countries after the Second World War. Then, the European Economic Community (EEC) was created by the Treaty of Rome in 1957 to establish a common market and free movement of people, goods, capital and services (EP, 2017). In 1986, the Single European Act was signed which extended the powers of the Union and led to the creation of an internal market. Part of establishing the single market was the creation of minimum requirements for health and safety at work. Finally, the Maastricht Treaty signed in February 1992 officially created the European Union and the European Commission (EP, 2017). The European Parliament and Council of the European Union share legislative power, while the European Commission (EC) is responsible for managing and implementing policies, setting objectives and action priorities, and enforcing the law (EC, 2017a; EP, 2017). Finally, the European Agency for Safety and Health at Work (EU-OSHA) was founded in 1996 and is responsible for collecting, analyzing and sharing relevant information that can aid in protecting the safety and health of employees at work (EU-OSHA, 2017).

3.2. Incidents

Even with the development of personnel and process safety standards throughout the 20th and 21st centuries, significant process safety incidents still occurred in the EU as shown in Table 2. These incidents greatly influenced the development of process safety regulations.

Significant process safety incidents occurred in the early 1970's, which was one of the main catalysts for the development of the Seveso Directive in 1982.

- In Beek, Netherlands, the naphtha cracker was starting up at the Dutch State Mines (DSM) ethylene plant. Vapor escaped from the depropanizer due to the low temperature of the feed which caused embrittlement in the feed drum. The ignition and explosion of the vapor cloud resulted in 14 deaths and 107 injuries (HSE, 2017a).
- In Manfredonia, Italy, K_3AsO_3 and H_3AsO_3 were released after the explosion of one of the NH_3 washing columns at the ANIC petrochemical company. This resulted in arsenic contamination in a 15 km^2 area southeast and northwest of the plant (Liberti and Polemio, 2008).
- In Seveso, Italy, approximately 2 kg of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) was released from the trichlorophenol reactor which formed a vapor cloud. Although there were no direct human deaths reported from this release, thousands of animals in the area died and thousands of inhabitants of Seveso were at risk of being exposed. The map of the region shows the three zones based on the levels of soil contamination. Also, the residents and authorities were not informed that the plant was a potential risk or of the type of chemicals and production processes used at the facility (Bertazzi et al., 1998; Crowl and Louvar, 2011; De Marchi et al., 2017).

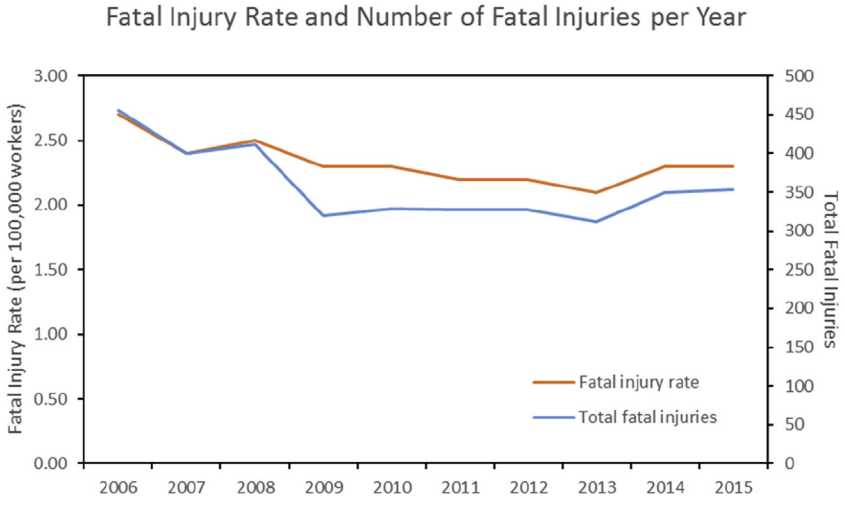
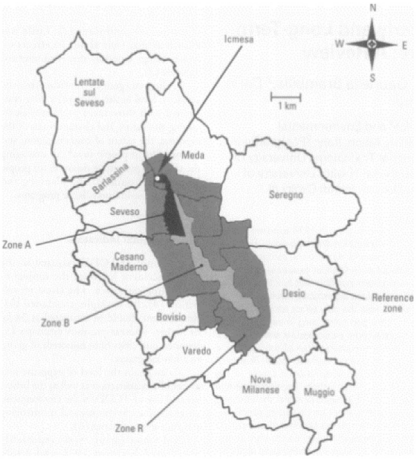


Fig. 1. Fatal injury rate and total fatal injuries per year for manufacturing industry (BLS, 2017).

Table 2
Significant incidents in the European Union (Brice, 2008; Crowl and Louvar, 2011; HSE, 2017a; Liberti and Polemio, 2008; Mihailidou et al., 2012).

Date	Location	Description
November, 1975	Beek, Netherlands	Vapor Cloud Explosion (VCE) during start-up of the naphtha cracker
September, 1976	Manfredonia, Italy	Arsenic Release
July, 1976	Seveso, Italy	Release of 2,3,4,8-tetrachlorodibenzo-p-dioxin (TCDD)
November, 1986	Basel, Switzerland	Chemicals washed into Rhine River
May, 2000	Enschede, Netherlands	Fireworks Fire and Explosion
September, 2001	Toulouse, France	Ammonium Nitrate Explosion



Zones of Contamination Levels Following TCDD Release (Bertazzi et al., 1998)

Even after the implementation of the Seveso Directive in 1982, severe process safety incidents continued to occur which led to updates to the Seveso Directive in 1996, 2003, and 2012. These incidents include the release of chemicals into the Rhine River after a fire at a chemical factory in Basel, Switzerland; the explosion at a fireworks warehouse in Enschede, Netherlands; and explosion of 300 tons of ammonium nitrate at fertilizer plant in Toulouse, France (Brice, 2008).

3.3. Regulations

3.3.1. Seveso Directive

The process safety incidents that occurred in the 1970's (particularly the release of TCDD in Seveso, Italy) led to the development of the first Seveso Directive (Directive 82/501/EEC) in 1982. This directive applied to chemical facilities across EU member states, but did not apply to nuclear or military facilities, mining, or the manufacture/storage of explosives and gunpowder (EEC, 1982). The key focus of this directive was on decreasing the frequency and severity of process safety incidents and standardizing regulations between EU member states (EEC, 1982; Peeters and Vanhoenacker, 2015). The directive provided a list of hazardous substances, but did not provide penalties for facilities that did not follow the directive (Holla, 2017; Peeters and Vanhoenacker, 2015). Process safety incidents continued to occur including the fire and release of pesticides into the Rhine River from a chemical factory in Basel, Switzerland (1986). Therefore, the Seveso Directive was updated in December 1996 creating the Seveso II Directive (Directive 96/82/EC) (EC, 1996). These updates created a classification system for substances that had been identified as hazardous and introduced land-use planning for siting facilities. Also, threshold amounts were determined for each substance and facilities were labeled as top or lower tier based on the amount of these substances used relative to established threshold values (Peeters and Vanhoenacker, 2015). Both top and lower tier facilities were required to submit a Major Accident Prevention Policy (MAPP) which describes the management system at the facility (Hawksley, 1999).

The Seveso II Directive was then updated in 2003 (Directive, 2003/105/EC) in response to incidents such as the fireworks factory explosion in Enschede, Netherlands (2000) and the ammonium nitrate explosion in Toulouse, France (2001). This update defined new reporting guidelines and new requirements for informing the public (EC, 2003; Holla, 2017). Finally, the Seveso Directive was updated again in July 2012 which created the Seveso III Directive (Directive, 2012/18/EU). More than 10,000 industrial facilities across all EU member states are covered by this directive (EC, 2017b; EU, 2012). The directive resulted in updates in the classification of dangerous chemicals and improvements to information collection systems, inspection processes, and the right to information for all citizens. The information that must be made available to the public includes emergency response plans and information regarding potential hazards at the facility (EC, 2016; EU, 2012; Peeters and Vanhoenacker, 2015). The requirements for compliance differ depending on the ranking of a facility as upper-tier or lower-tier. Upper tier sites carry out more dangerous processes and/or use more hazardous substances than lower tier sites. They are required to prepare a Major Accident Prevention Plan (MAPP) and have a safety management system, emergency plans and make information public. However, lower tier sites are now also required to submit a MAPP as part of the updated Seveso III Directive (EU, 2012). Each member state is responsible for enforcing the components of the regulation within its borders. The Seveso Directive recommends that each member state implement routine and non-routine inspections and impose penalties for noncompliance (EU, 2012).

3.3.2. EU Occupation Safety and Health Framework

The EU Occupation Safety and Health Framework directive (Directive 89/391/EEC) was implemented in June 1989 and is centered around managing safety and health, with emphasis on the responsibilities of employers, guidelines for the training of workers, and using risk assessments to improve company processes (EEC, 1989). The directive applies to both the public and private sectors and it is the responsibility of each EU member state to implement and enforce the directives in their country. Highlights from the guidelines of this directive include: the necessity to ensure that only workers that have been trained adequately can access designated areas and operate given processes, employers need to have at least one designated worker to oversee the prevention of occupational risks (a safety representative) and the need to have first aid, evacuation and fire-fighting plans. Notably, training timelines include but are not limited to initial hiring, upon a job transfer, or when new technology is added to the process. The deadline for implementation of these laws throughout the EU was December 1992 (EEC, 1989).

3.3.3. Environment

In September 1996, the EC adopted Directive 96/61/EC which focuses on integrated pollution prevention and control (the IPPC Directive). The IPPC Directive requires the monitoring of the operation of facilities with regard to air, water and soil emissions and requires facilities to have permits for their emissions. Also, Directive 97/11/EC was passed in March 1997 as an update to Directive 85/337/EEC for the assessment of the effects of certain public and private projects on the environment (Environment Impact Assessment (EIA) Directive). This EIA Directive covers both industrial projects and new infrastructure, and requires facilities to issue an environmental impact statement and communicate this information to the public. Similar to the IPPC Directive, the EIA Directive requires EU member states to provide permits to facilities (IMPEL, 1998).

3.3.4. Protection of critical infrastructure (anti-terrorism)

The EU is focused on the protection of critical infrastructure against damage from terrorism, natural disasters or criminal behavior. Critical infrastructure is defined as infrastructure that is important to society, where the loss of the infrastructure would have a negative impact on the EU member states (EC, 2017c). Therefore, the European Program for Critical Infrastructure Protection (EPCIP) was established. The Directive on European Critical Infrastructures (DIRECTIVE, 2008/114/EC) which was passed in December 2008 is an important part of this program. The directive makes each member state responsible for the protection of all critical infrastructure within their borders. The EC works to define and assess European Critical Infrastructures (ECI) that require protection (EC, 2008).

3.3.5. Offshore

In June 2013, the European Commission (EC) passed the European Offshore Directive (DIRECTIVE, 2013/30/EU). This was done in response to the Deepwater Horizon incident in the Gulf of Mexico in April 2010 (EC, 2017d). The directive requires that companies submit a Major Hazard Report (including risk assessment and emergency response plan) before construction of an offshore facility. Also, companies are required to make information available to the public regarding their offshore facilities and applicable safety measures. Finally, the EU member states have the authority to grant licenses to companies to operate offshore and to inspect companies to ensure they meet minimum technical, financial and safety standards (EC, 2017d). The European Union Offshore Oil and Gas Authorities Group (EUOAG) was created in January 2012 to provide a means for EU member companies to share best practices or other information regarding offshore standards/regulations (EC, 2017d).

3.3.6. Industrial trade associations

Industrial process safety organizations are important to the reduction in process safety hazards. The European Chemical Industry Council (CEFIC) is the primary trade association for the chemical industry of Europe. CEFIC is responsible for working with EU policymakers, facilitating communication within the industry (both local and international), and contributing to performance indicators and management models for process safety (CEFIC, 2017a). In 1992, CEFIC recommended the formation of the European Process Safety Center (EPSC). EPSC is an international collaboration of companies who share a common goal of eliminating process safety incidents. The main objectives of EPSC focus on collaboration, information sharing, influence, and outreach (EPSC, 2017).

3.3.7. Performance

Process safety regulations have been implemented and updated in the EU throughout the 20th and 21st centuries. In this time, the normalized incidence rates (per 100,000 employees) of fatal injuries at work in the EU-15 (not just manufacturing industry) has decreased, as shown in Fig. 2. The EU-15 consists of fifteen EU member states: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, Sweden, and the United Kingdom. The UK incident rate is consistently lower due to their early adoption and implementation of health and safety policy and formal risk assessments (HSE, 2016a).

4. United Kingdom regulations

4.1. Background

The United Kingdom (UK) follows many EU regulations but also has specific UK regulations. In July 1974, the Health and Safety at Work Act received Royal Assent which was a major step forward in process safety. This Act provided a new regulatory framework, encouraged the involvement of both employees and employers, and created the Health & Safety Commission (HSC) and Health & Safety Executive (HSE) (HSE, 2017b). The HSC is responsible for protecting the safety of both workers and the public and providing direction to the HSE. In general, the HSC proposes new laws and performs process safety research, while HSE assists the HSC and enforces the laws (HSE, 2004). In 1984, the UK implemented the Control of Industrial Major Accident Hazards Regulation (CIMAH) to comply with the Seveso I Directive of 1982 (Ansell et al., 1998; PE, 2000). Then, in 1985, the Reporting of Injuries, Diseases and Dangerous Occurrences Regulation (RIDDOR) was passed which requires companies to notify the authorities if an incident occurs (HSE, 2017b). The Control of Major Accident Hazards Regulation (COMAH) was implemented in 1999 in response to the Seveso II Directive of 1996 and replaced the CIMAH regulation (Ansell et al., 1998; HSE, 2017b).

4.2. Incidents

Several significant process safety incidents occurred in the United Kingdom in recent decades as shown in Table 3.

These process safety incidents and those occurring globally were influential in the development of process safety regulations in the United Kingdom.

- In Flixborough, England, a vapor cloud explosion occurred at the Nypro Limited facility. A temporary bypass pipe ruptured which released 30 tons of cyclohexane and created a large vapor cloud. The explosion resulted in 28 deaths and 89 injuries. This incident was a major factor in the creation of the Health and Safety at Work Act (Brice, 2008; Crowl and Louvar, 2011).
- On the Piper Alpha oil rig in the North Sea, multiple explosions and fires occurred due to the release of hydrocarbons during the ill-fated start-up of a pump that was down for maintenance. The magnitude of the incident was increased as the other nearby oil rigs continued producing, which fed more fuel to the fires on the Piper Alpha rig. This incident resulted in the deaths of 167 people and the total destruction of the platform (CCPS, 2005).
- In Hertfordshire, England, a tank was being filled with gasoline at the Buncefield oil storage depot. However, the independent high-level switch (IHLS) failed and the tank overflowed releasing over 250,000 L of gasoline which formed a vapor cloud. This vapor cloud then exploded which injured 40 people and resulted in fires that burnt for several days, but there were fortunately no fatalities (HSE, 2011).

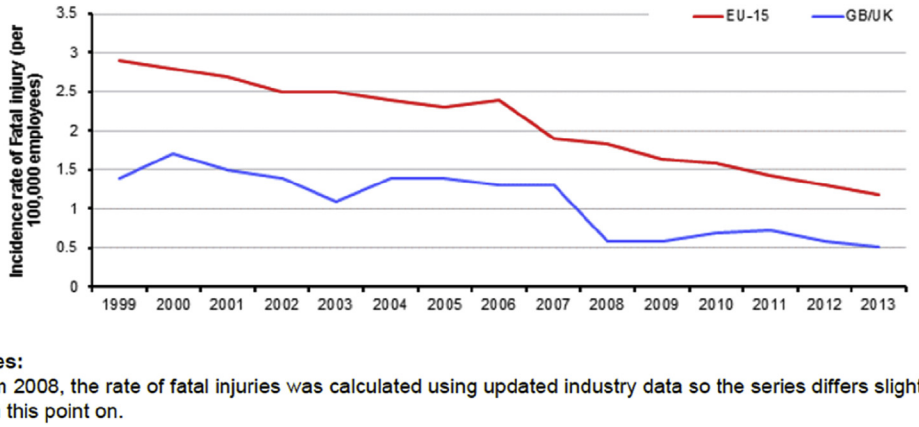


Fig. 2. Fatal incident rate for the EU-15 and GB/UK (HSE, 2016a).

Table 3
Significant incidents in the United Kingdom (Brice, 2008; CCPS, 2005; Crowl and Louvar, 2011; HSE, 2011).

Date	Location	Description
June, 1974	Flixborough, England	Explosion of vapor cloud of cyclohexane
July, 1988	Piper Alpha Oil Field, North Sea	Fires and explosions on the Piper Alpha Oil Rig
December, 2005	Hertfordshire, England	Explosion of vapor cloud of gasoline

4.3. Regulations

4.3.1. HSC, HSE, RIDDOR regulations

The HSC and HSE were both created by the Health and Safety Act of 1974. The HSC is responsible for the safety of both workers and the public through creating new laws, performing research and providing information and training. Also, the HSC established various advisory committees including the Advisory Committee on Major Hazards, Advisory Committee on Dangerous Substances, and the Advisory Committee on Toxic Substances among others. The HSE (along with local authorities) is responsible for the enforcement of the laws and assisting the HSC (HSE, 2004; HSE, 2017b). In 2008, the HSC and the HSE merged to form the Health & Safety Executive combining the functions of both organizations (HSE, 2017b).

RIDDOR requires that incidents be reported including workplace deaths and injuries, occupational diseases and dangerous occurrences that have a high likelihood to result in death or injury. After initial implementation in 1985, the RIDDOR regulation was updated in 1995 and 2013. The 2013 update simplified requirements regarding the types of injuries, diseases, and dangerous occurrences that are required to be reported (HSE, 2013).

4.3.2. CIMAH and COMAH

In response to the Seveso I Directive (Directive 82/501/EEC), the UK created the Control of Industrial Major Accident Hazards (CIMAH) Regulations in 1984. This regulation requires that companies identify hazards, implement the required control schemes, document the hazard control procedures, prepare an off-site emergency plan working with the Local Authority, and communicate the potential hazards to the public (HSE, 2017b). In 1999, the Control of Major Accidents Hazards (COMAH) regulation replaced CIMAH as the UK's method to implement the Seveso II Directive (Directive 96/82/EC). There are many differences between CIMAH and COMAH which include (see Table 4):

The Competent Authority is the agency that has the authority to review a company's documentation and ensure compliance (PE, 2000). Finally, the COMAH regulation was updated in June 2015 based on the Seveso III Directive (Directive, 2012/18/EC) that was passed in 2012. This revision included updates to the hazardous substances (adding sodium hypochlorite and low molecular weight gases among others) and additional requirements for public information and emergency planning (Cusco, 2015; HSE, 2017c). The COMAH regulation is enforced by HSE (for non-nuclear establishments) who appoints inspectors and can issue monetary or legal penalties for noncompliance (HSE, 2015).

4.3.3. Environment

As part of the COMAH regulation in 1999, the Environment Agency (EA) and the Scottish Environmental Protection Agency (SEPA) were added as competent authorities. These agencies work with each other and with the HSE to provide environmental regulations for the UK. SEPA is the competent authority for any land or water damage situations (SEPA, 2017). The EA regulates facilities to control environmental hazards and the disposal of chemicals under the EU Registration, Evaluation, Authorization and restriction of Chemicals (REACH) and Classification, Labelling and Packaging of Substances and Mixtures (CLP) regulations (EA, 2017). The REACH regulation was implemented in June 2007 and requires companies to register the substances used in their processes so the risks can be evaluated. The CLP regulation was implemented in January 2009 and created requirements for the labeling of chemicals to identify potential hazards (ECHA, 2017).

4.3.4. Protection of critical infrastructure (anti-terrorism)

The Center for the Protection of National Infrastructure (CPNI) is responsible for protecting the United Kingdom's critical national infrastructure from any threat including terrorism. Critical infrastructure is defined as the infrastructure that is required for the normal function of the country and whose loss would cause significant consequences (CPNI, 2017). The CPNI helps protect facilities through coordination with other government/law enforcement agencies and through the principles of deter, detect, and delay. These principles provide the basis for an emergency response plan to stop a potential attack, initiate the appropriate response, and reduce the effect of the attack (CPNI, 2017).

Table 4
Differences between CIMAH and COMAH (Ansell et al., 1998; PE, 2000).

CIMAH	COMAH
• Applied to facilities based on specific substances and quantities	• Applied to facilities based on categories of substances
• Lower-tier facilities only required to show safe operations and report any incidents	• Lower-tier facilities must prepare a MAPP and report to the Competent Authority (CA)
• Top-tier facilities required to prepare safety reports and emergency plans	• Top-tier facilities safety reports were expanded, focus on safety management systems, more public access to safety documents, expanded requirements for emergency plans, and requirements for restoration of environment after an incident
• No inspection systems	• Inspection systems are required
• No land-use planning requirements	• Includes land-use planning requirements
• Less focus on the environment (HSE was only Competent Authority)	• Increased environmental protection focus by including the Environment Agency and Scottish Environmental Protection Agency as Competent Authorities

4.3.5. Offshore

The Piper Alpha oil rig explosion had a major impact on offshore safety regulations. There was an investigation into the incident (known as the Lord Cullen Inquiry) which led to 106 recommendations for the oil and gas industry. By 1993, all recommendations were implemented across the UK by a variety of agencies including the HSE (OG-UK, 2008). The main recommendation from this investigation was the implementation of safety regulations that would require offshore facilities to be approved by the HSE before operation. This was known as the Offshore Installations (Safety Case) Regulations of 1992. This regulation requires operators to submit a safety case which describes the facilities safety plans (including emergency response plan) and how potential hazards would be controlled (OG-UK, 2008). The regulation was updated (ILO, 2005) and then updated again in response to the EU Offshore Directive (Directive, 2013/30/EU) in 2015 (HSE, 2017d). There were also other offshore regulations including the Offshore Installation and Pipeline Works (Management and Administration) Regulations (1995), the Offshore Installations (Prevention of Fire and Explosion, and Emergency Response, PFEER) Regulations (1995), and the Offshore Installations and Wells (Design and Construction) Regulations (1996) (OG-UK, 2008).

4.3.6. Industrial trade associations

There are several industrial groups that contribute to process safety development in the UK. The Chemical Industries Association (CIA) represents the chemical and pharmaceutical facilities in the UK. The CIA focuses on Responsible Care values and works to influence policy, train member companies and communicate actively with both companies and regulators (CIA, 2017). Also, the CIA represents the UK in CEFIC as a Federation Member (AFEM) (CEFIC, 2017b). In addition to the CIA, there are many industry specific associations that promote process safety. For example, the United Kingdom Petroleum Industry Association (UKPIA) and the Energy Institute both promote process safety in the energy industry (EI, 2017; UKPIA, 2017).

4.3.7. Performance

Throughout the late 20th and early 21st centuries, the United Kingdom focused on implementing process safety regulations to protect workers, the public and the environment. During this time, there was a decrease in the fatal incident rate (per 100,000 workers) for the manufacturing industry as seen in Fig. 3. The manufacturing industry is defined by the Standard Industrial Classification code (SIC) of 2007. Manufacturing includes the manufacture of a variety of products including food products, textiles, paper products, chemical products, pharmaceuticals, metals, electronic materials, among others (HSE, 2017e).

The workplace injury rate (per 100,000 workers) has also been decreasing since 2001 as shown in Fig. 4. The error bars on this figure represent 95% confidence intervals. By 2013/14, the 2001/02 incidence rate had decreased by approximately 40% (HSE, 2016b).

5. China regulations

5.1. Background

While China has a history of serious chemical accidents, regulations are continuing to be developed and implemented to prevent future incidents. The rapid industrial growth, particularly in recent decades, has contributed to challenges in process safety as facilities, technologies and processes are developing faster than safety regulations have been implemented. In 2002, the Work Safety Law was passed (Zhao et al., 2014). Also, the State Administration of Work Safety (SAWS) was established (ILO, 2005) and is focused on educating facilities regarding process safety, supervising/inspecting the implementation of process safety regulations and training procedures (ChinaCSR, 2017). In 2010, SAWS passed the PSM regulation (AQ/T 3034-2010) which consists of 12 elements and is modeled after the OSHA PSM Regulation (Zhao et al., 2014). Overall, China has passed about 300 chemical safety control regulations and over 600 national safety standards in the past 10 years (Zhao et al., 2013).

5.2. Incidents

During the past decade or so, several significant process safety incidents have occurred across China as shown in Table 5.

These process safety incidents and global incidents/regulations influenced the development of China's process safety regulations:

- In December 2003 in Chongqing, China, an underground gas well blowout occurred as it was being drilled resulting in an explosion and release of sour gas. The explosion and release of toxic sour gas caused 243 deaths, 9000 injuries and the evacuation of approximately 64,000 people (UNEP, 2017; Zhao et al., 2014).
- An explosion occurred at a petrochemical plant owned by China's National Petroleum Corporation in November 2005 in Jilin Province, China. Six people died in the explosion while dozens of others were injured and approximately 100 tons of chemicals (including benzene) were released into the Songhua River. Information about the incident was not released to the public or anyone downriver until two weeks after the incident. This incident and the gas well blowout in December 2003 led to the implementation of the Emergency Event Response Law of 2007 (EJAtlas, 2015; Guardian, 2005; Zhao et al., 2014).

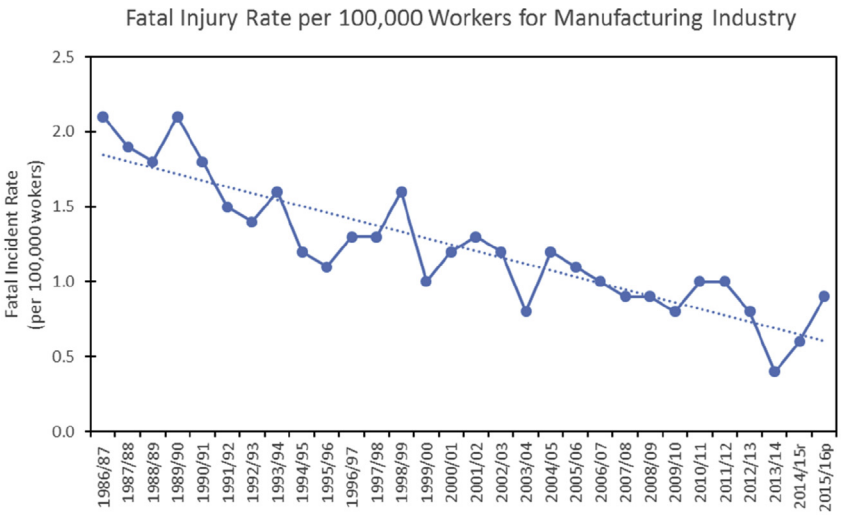


Fig. 3. Fatal injury rate per 100,000 workers in the manufacturing industry (HSE, 2017e).

Fig. 4. Workplace injury rate per 100,000 workers in the manufacturing industry (HSE, 2016b).

Table 5
Significant incidents in China (BBC, 2014; China, 2012; EJAtlas, 2015; Guardian, 2005; Kennedy, 2016; Mortimer, 2016; PHYS, 2011; UNEP, 2017; Watts, 2011; Zhao et al., 2013, 2014).

Date	Location	Description
December, 2003	Chongqing, China	Gas well blowout resulted in explosion and release of toxic sour gas
November, 2005	Jilin Province, China	Petrochemical plant explosion and release of chemicals into Songhua River
June, 2011	Bohai Bay, China	Penglai 19-3 oil spill
February, 2012	Hebei, China	Explosion at the Keeper Chemical facility
August, 2014	Jiangsu, China	Aluminum dust explosion at Zhongrong Metal Products Company
August, 2015	Tianjin, China	Explosion at Tianjin facility

- In June 2011, an oil spill occurred in the Penglai 19-3 oil field resulting in at least 5500 km^2 being contaminated by oil. This oil field is jointly operated by US based ConocoPhillips and the China National Offshore Oil Corporation. The leak was not acknowledged by the operating companies until 17 days after it had been detected (PHYS, 2011; Watts, 2011).
- In February 2012, an explosion occurred at the Keeper Chemical Factory. Changes had been made to the process, including a raw material change and increasing the temperature of the heat transfer oil without a management of change analysis being performed. The excess heat caused the explosion of ammonium nitrate in a reactor which then ignited another reactor. This incident resulted in 25 deaths, 46 injuries and destruction of the buildings on-site (China, 2012; Zhao et al., 2013, 2014).
- In August 2014, an aluminum dust explosion occurred at Zhongrong Metal Products Company in Jiangsu, China, a parts supplier for General Motors. This incident resulted in the deaths of 75 people and over 180 injuries (BBC, 2014).
- In August 2015, an explosion occurred at a storage facility in Tianjin when nitro-cotton self-ignited causing the ignition of other chemicals, including ammonium nitrate. The resulting explosion destroyed 300 buildings, killed 173 people and injured 800 others. Officials estimated that 11,300 tons of hazardous chemicals were stored at the facility and 49 people were jailed in connection with the incident including regulators and those associated with the facility (Kennedy, 2016; Mortimer, 2016).

Aftermath of facility following explosion in Tianjin, China (Mortimer, 2016)

5.3. Regulations

5.3.1. State Administration of Work Safety

In 2005, (ILO, 2005), China created the State Administration of Work Safety (SAWS). SAWS is China's main health and safety organization and is responsible for supervising associated local agencies, monitoring the implementation of process safety regulations, and education/training of facilities and local agencies (ChinaCSR, 2017; Wei et al., 2008). In 2010, SAWS passed the AQ/T 3034-2010 PSM Regulation which was the first process safety regulation passed by SAWS. This regulation is based on the US OSHA PSM regulation of 1992. The AQ/T 3034-2010 PSM regulation has 12 elements which are the same as the OSHA PSM except without the employee participation or trade secret sections (Zhao et al., 2014). Due to China's size, many local agencies have been established to help carry out inspections and oversee worker safety (Zhao et al., 2014). The various Occupational Health and Safety inspection agencies completed nearly 18 million inspections between 2006 and 2010. They report to have rectified about 95% of the hazards found during these inspections (ILO, 2012).

5.3.2. Chemical Industrial Parks

The Chinese government encourages small and medium-sized enterprises (SMEs) to move their plants into Chemical Industrial Parks (CIPs). CIPs are part of larger development areas (such as the Tianjin Economic and Technological Development Area, TEDA) that have been constructed in China since 1984 (Hauthal and Salonen, 2017). Having multiple facilities at the same location allows the SMEs to share resources for implementation of process safety and environmental management. Otherwise, many SMEs would not have the resources necessary to implement these policies and could be at higher risk of having an incident (Zhao et al., 2013, 2014). However, one downside is that the high concentration of companies could cause a small accident to escalate since it could set off other accidents in nearby companies. As of early 2014, about 30% of chemical companies are in these CIPs (Zhao et al., 2014).

5.3.3. Other regulations

The Law of the People's Republic of China on Work Safety was passed in November 2002 (ILO, 2012). This law specifies the rights for employees, incident response and inspection procedures, and other measures to reduce occupational incidents (ILO, 2012; Zhao et al., 2014). The Workplace Safety Law was amended in December 2014, which increased the scope of the law and the punishments for violating the law. For example, smaller companies are required to appoint personnel dedicated to safety instead of this only applying to larger companies. Also, the law increases fines from RMB100,000 ($15,980) to anywhere from RMB200,000 ($31,959) to RMB20,000,000 ($3,195,909) for a company that causes a serious incident (Xiong, 2015).

Also passed in 2002, was the Law of the People's Republic of China on the Prevention and Control of Occupational Diseases. This law focuses on the prevention of occupational disease and protection for workers diagnosed with occupational diseases (ILO, 2012).

The Regulations on Safe Management of Hazardous Chemicals in China was passed in March 2002 to define safety management procedures for the processing, transportation and storage of hazardous chemicals. The law was updated in March 2011 and the updates included requiring companies to have production/operating licenses and safe use permits, updating the registration of hazardous chemicals, and increasing penalties for violations (CIRS, 2014; ILO, 2012).

The Emergency Event Response Law was passed in 2007 in response to the gas well blowout in Chongqing, China (2003) and the petrochemical plant explosion/release of chemicals into Songhua River in Jilin Provence, China (2005). This law requires chemical plants to create an emergency response plan for any potential incidents. This is especially important due to the concentrated layout of CIPs (Zhao et al., 2014).

5.3.4. Environment

The first environmental protection related agency was created in October 1974 and was known as the Leading Team for Environmental Protection. The focus was writing environmental regulations and working with state and local groups to inspect facilities. This agency went through multiple organizational structures in the 1980's and then became the National Environmental Protection Agency in 1988. The agency achieved ministry level as part of the State Council in 2008 (MEP, 2016a). The Ministry of Environmental Protection has a variety of different departments that focus on different areas of the environment including monitoring, polices/laws/regulations, and environmental supervision/inspection, among others (MEP, 2016b). The main environmental protection regulation is the Environmental Protection Law of the People's Republic of China which was passed in 1989 and updated in 2014 (EU-China EGP, 2014). This law requires information disclosure/public participation, preparation of safety management system, permits and quotas for amounts of pollutants released, and penalties for noncompliance (EU-China EGP, 2014; Kaiman, 2014).

5.3.5. Protection of critical infrastructure (anti-terrorism)

As of early 2017, China doesn't have critical infrastructure protection (anti-terrorism) regulations. However, China did adopt United Nations (UN) Resolution 2341 in February 2017 which focuses on protection of critical infrastructure and international cooperation between the UN member countries (UN, 2017). China has also recently passed critical information infrastructure protection through passing the Internet Security Law of the People's Republic of China in November 2016. This law focuses on network operational and information security, warning systems, and penalties for noncompliance (NPC, 2016).

5.3.6. Offshore

The SAWS First Department of Work Safety Supervision is also called the Office of Offshore Oil Safety. This department is in charge of implementing the regulations, issuing permits for facilities, performing inspections of facilities, and responding to incidents

that occur, among others (ILO, 2012). The department responded to the Penglai 19-3 oil spill in the Bohai Bay in 2011, investigated the incident and ordered inspections of all offshore platforms and pipelines (PHYS, 2011).

5.3.7. Industrial trade associations

There are several industrial organizations that also contribute to improving process safety in China. An important industrial organization is the Center for Chemical Process Safety- China Section (CCPS-CS). The CCPS-CS was created in April 2007 and is focused on promoting process safety training/learning, advancing process safety in industry and providing informational resources for industry (CCPS-CS, 2017). Also, the China Petroleum and Chemical Industry Federation (CPCIF) promotes the Responsible Care Program with over 300 member companies across China (CPCIF, 2017; ILO, 2012).

5.3.8. Performance

During the 21st century, China has created and implemented process safety regulations. There is a lack of accessible data to show the number of process safety incidents and the fatalities & injuries resulting from these incidents. Fig. 5 is from a Notification of the Government Information Disclosure Request by Prof. Jinsong Zhao to the SAWS in 2012 (Zhao et al., 2013). This data shows that there has been a decrease in the number of incidents and fatalities per year between 2004 and 2011. Specifics behind this data are unclear.

6. India regulations

6.1. Background

India has a large industrial sector that is growing rapidly, which requires the development of process safety regulations. The development of these regulations began in 1948 with the passage of the Factories Act. However, few regulations were implemented following the Factories Act, until the release of methylisocyanate (MIC) in Bhopal, India in 1984 which resulted in the death of thousands of people (Crowl and Louvar, 2011). In response to this incident, India has been implementing more regulations including the Environment Protection Act of 1986, the Manufacture, Storage and Import of Hazardous Chemical Rules (MSIHC) of 1989, and the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules of 1996 (Karthikeyan, 2004).

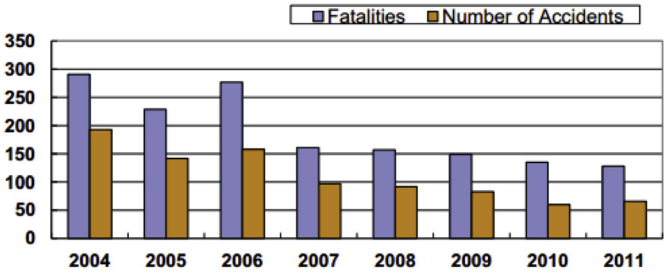


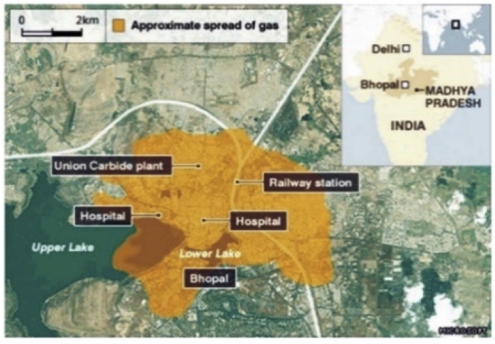
Fig. 5. Chemical accidents statistics in China from 2004 to 2012 (Zhao et al., 2013).

6.2. Incidents

Significant process safety incidents have occurred in India in the past few decades as shown in Table 6. The most prominent incident was the release of MIC in Bhopal. However, India continues to have serious process safety incidents even after Bhopal.

These process safety incidents (especially the release of methyl isocyanate (MIC) in Bhopal) have influenced the development of regulations.

- In December 1984 in Bhopal, India, a vapor cloud containing approximately 25 tons of MIC was released and spread throughout the nearby area. This occurred when water entered a MIC storage tank which caused a chemical reaction that caused the MIC to vaporize. Also, the scrubber and flare systems were not operational which allowed the MIC vapor to escape the plant. Nearby residents were exposed and over 2000 people were killed (Crowl and Louvar, 2011; Gupta & Nair, 2012).
- In November 1990 in Nagothane, India, propane and ethane leaked from a pipeline and formed a vapor cloud which exploded. Equipment at the gas treatment facility was damaged and 31 people were killed (Mannan and Lees, 2012).
- In June 2003, an explosion occurred at the Ranbaxy drug manufacturing facility in Mohali, India. The explosion occurred in the high pressure toluene distillation unit, but the cause of the explosion and resulting fire was not reported. Two people were killed and 19 injured in the explosion and fire (TOI, 2003).
- In October 2009, a leak of kerosene (SKO) and Motor Spirit (MS) occurred from a hammer blind valve on a transfer line at an Indian Oil Corporation Terminal. The leak continued for over an hour and approximately 1000 tons of MS escaped and subsequently exploded. The resulting fire consumed the plant and nearby buildings and 11 people were killed (IOC, 2017).



Spread of MIC vapor cloud in Bhopal (Gupta & Nair, 2012)

Table 6
Significant incidents in India (Crowl and Louvar, 2011; IOC, 2017; Karthikeyan, 2004; Mannan and Lees, 2012; TOI, 2003).

Date	Location	Description
December, 1984	Bhopal, India	Release of approximately 25 tons of methyl isocyanate
November, 1990	Nagothane, India	Explosion resulting from the leak of ethane and propane
June, 2003	Mohali, India	Explosion in toluene distillation unit at the Ranbaxy drug manufacturing facility
October, 2009	Jaipur, India	Indian Oil Corporation Terminal explosion and fire

6.3. Regulations

6.3.1. Factories Act

The Factories Act, India's first law on labor, health, and safety in industrialized areas, was enacted in 1948. There were small amendments to the Factory Act in 1949, 1950, 1951, 1954, 1970 and 1976 (Lok Sabha, 2016). However, after the MIC gas leak in Bhopal, India in 1984, the Factories Act was updated in 1987 to include a new chapter with specific regulations for workers in hazardous industries (Chapter IVA) among other updates (AMRC, 2017). Chapter IVA lists "Provisions Relating to Hazardous Processes" which includes the following elements (Factories, 2017):

1) Constitution of Site Appraisal Committees
2) Compulsory disclosure of information by the occupier
3) Specific responsibility of the occupier in relation to hazardous processes
4) Power of Central Government to appoint Inquiry Committee
5) Emergency Standards
6) Permissible limits of exposure of chemical and toxic substances
7) Workers' participation in safety management
8) Right of workers to warn about imminent danger

Therefore, the government can create Site Appraisal Committees and Inquiry Committees dedicated to inspecting hazardous processes in factories. Compulsory disclosure of information by the occupier requires the companies to disclose any information that may be related to a hazardous process and the workers must be involved and informed about safety management and potential hazards. Companies also need to assign the responsibility of safety to a specific person or "occupier" and have specific emergency plans in place (Factories, 2017).

The Factories Act only applies to a relatively small portion of the Indian workforce since facilities must be registered and have at least 10 workers for the Act to apply. It has been estimated that 94% of the overall Indian workforce is not covered by this Act (Gupta and Patel, 2017). Also, the funding for occupational health and safety services comes from the same budget as primary and curative health care. This results in a majority of the funding going to curative health care instead of occupational health (Gupta and Patel, 2017).

The Directorate General, Factory Advice Services and Labor Institutes (DGFASLI) is in charge of inspecting and implementing work safety policies. The DGFASLI is within the central government and appoints inspectors and chief inspectors at the state level. There is little to no standardized inspection strategies and the state inspectors have considerable autonomy on inspections. The inspections typically occur when a complaint is made and routine inspections are being reduced (ILO, 2017a). The DGFASLI reported that 16,921 hazardous facilities and 121,752 total facilities were inspected in 2011 (DGFASLI, 2017a). Also, the Asian Monitor Resource Center (AMRC) reported that in 2012, there was only one inspector for every 506 factories and that the entire DGFASLI staff only consisted of 263 people (Tevlin, 2012). This is a relatively small number compared to US OSHA who employees 2100 inspectors (OSHA, 2017g).

Penalties and fines for violations of the safety regulations are detailed in Chapter 10 of the Factories Act (ILO, 2017b). Generally, the occupier is the one who is deemed responsible if an incident occurs and they are penalized. The punishment for violations is around 100,000 rupees ($1529) and imprisonment up to two years. If the incident causes death, the occupier will be fined at least 25,000 rupees ($382). Penalties for obstructing the inspection process include imprisonment up to six months and a fine of 10,000 rupees ($155). Finally, if the occupier doesn't disclose information about possible hazards/safety measures, violates the right of workers to warn about imminent danger or doesn't fulfill their responsibilities for protection from hazardous processes, they could be sentenced to seven years in prison and fined 200,000 rupees ($3057) (ILO, 2017b).

6.3.2. New regulations implemented after Bhopal incident

Many regulations were passed/implemented in response to the MIC release in Bhopal in 1984. This includes the Manufacture, Storage and Import of Hazardous Chemical Rules (MSIHC) which were passed in 1989 and the Chemical Accidents (Emergency Planning, Preparedness and Response) Rules that were passed in 1996 (Karthikeyan, 2004). MSIHC was passed in 1989 as an addition to the Environmental Protection Act of 1986. The rules cover processes that use hazardous materials, the storage of hazardous materials, and the transport of nonflammable gas through pipelines (DGFASLI, 2017b). MSIHC Rules split factories into three different tiers (low, middle or high tier) based on the materials used by the facility. The tier designation specifies what requirements a facility must meet to comply with the regulation (DGFASLI, 2017b). The base requirements that apply to all tiers include the responsibilities of the "occupier" to identify and prevent major accidents and supply workers with necessary equipment, training and information. Also, facilities are required to provide notification if an incident occurs and prepare safety data sheets for chemicals. Middle and high tier facilities are required to create an on-site emergency plan and high tier facilities are required to prepare safety reports/audits (DGFASLI, 2017b; MOEF, 1989). The Chemical Accidents (Emergency Planning, Preparedness and Response) Rules, established in 1996, focus on the development of on-site and off-site emergency plans and the reduction in risks during the processing of hazardous chemicals (Karthikeyan, 2004).

6.3.3. Environment

The Ministry of Environment and Forests (MoEF) is a government agency focused on the conservation of the environment, protecting biodiversity, and reducing pollution (MOEF, 2015). In May 2014, the MoEF was renamed MoEFCC to encompass combating climate change as a top priority (ET, 2014). Also, the Environmental Protection Act was passed in May 1986 in response to the MIC release in Bhopal, India. This regulation is a broad regulation giving the government power to protect the environment and prevent future pollution (India, 2017). There are also other environmental laws that have been passed including the National Forest Policy (1988), National Conservation Strategy and Policy Statement on Environment and Development (1992), Policy Statement on Abatement of Pollution (1992), and National Environment Policy (2006) (MOEF, 2015).

6.3.4. Protection of critical infrastructure (anti-terrorism)

In January, 2014, a new government organization was created known as the National Critical Information Infrastructure Protection Center (NCIIPC). The NCIIPC was created by the 2008 amendment to the Information Technology Act of 2000 which called for the development of an agency to protect critical information infrastructure (NCIIPC, 2015; NCIIPC, 2017). The NCIIPC does this through five families of controls that are focused on protecting critical information infrastructure including (NCIIPC, 2015):

- Planning Controls – focused on design stage of infrastructure
- Implementation Controls – focused on translation of design to the implemented infrastructure
- Operational Controls – focused on controls during operation of infrastructure

- Disaster Recovery/Business Continuity Planning (BCP) Controls – focused on restoration and reduction of compromised infrastructure
- Reporting and Accounting Controls – focused on oversight of controls by management

6.3.5. Offshore (petroleum production)

India has a variety of regulations and agencies which focus on regulations for petroleum manufacturing. The Petroleum and Explosive Safety Organization (PESO) is responsible for preventing fires and explosions, and protecting both the public and property (PESO, 2006). Therefore, PESO manages a large range of regulations including the Explosives Act of 1884, Petroleum Act of 1934, Inflammable Substances Act of 1952, and the Petroleum Rules of 2002, among others. In general, these regulations cover guidelines for processing, transport and/or storage of materials and any licenses required for operations (MOP and NG, 2017a; PESO, 2006). Also, the Ministry of Petroleum and Natural Gas is involved in activities regarding petroleum production and the administration of relevant regulations (MOP and NG, 2017b). This includes the Petroleum and Natural Gas (Safety in Offshore Operations) Rules of 2008. These rules specify the facility requirements for record keeping/information collection and safety management. The safety management requirements include performing risk assessment to determine potential hazards, creation of a safety committee, and the preparation of an emergency response plan among others (MOP and NG, 2017c). Also, the Oil Industry Safety Directorate (OISD) is part of the Ministry of Petroleum and Natural Gas and focuses on the implementation of safety regulations. This includes performing audits of facilities, follow-ups after audits to determine if action items were implemented, and root cause investigations of any incidents that occur (OISD, 2017).

6.3.6. Industrial trade associations

An important trade association that has been dedicated to the growth of the chemical industry in India since 1938 is the Indian Chemical Council (ICC), formerly known as the Indian Chemical Manufacturers Association (ICMA) (ICC, 2009; ICC, 2016). The ICC is active in promoting process safety management and they have also been involved in promoting the Responsible Care Program (Karthikeyan, 2004). Responsible Care is a voluntary program for companies who commit to specific management practices including:

• Product Stewardship Code	• Process Safety Code
• Employee Health and Safety Code	• Pollution Prevention Code
• Emergency Response and Communication Code	• Distribution Code

As of July 2016, 40 companies have Responsible Care status and an additional 125 companies are working on the implementation of the management practices (ICC, 2016).

6.3.7. Performance

India has a history of process safety incidents including one of the most well-known incidents involving the release of MIC in Bhopal. The incident in Bhopal resulted in new regulations globally and in India and the updating of regulations such as the Factories Act. However, process safety incidents have continued to occur. According to the Government of India National Disaster Management Authority (NDMA), there have been 130 significant chemical incidents in the past decade. These incidents caused 259 deaths and 563 injuries (NDMA, 2017). However, the British Safety Council reports that the number of fatal and non-fatal injuries is much higher in the 324,761 registered factories in India. In 2009, there were said to be 1509 fatal injuries and 31,584 non-fatal injuries, which dropped to 1380 fatal injuries and 27,140 non-fatal injuries in 2011. Also, the British Safety Council reports that there are 506 factories for each factory inspector (Tevlin, 2012). Finally, The Hindu (India's National Newspaper) reports Ministry of Labor (MoL) statistics of 50,000 to 75,000 fatal accidents and 5 to 7.5 million non-fatal accidents for India's whole workforce (The Hindu, 2000). These statistics show the large range in reported process safety data for Indian industry. The lack of consistent data limits the learnings from process safety analysis and restricts the development of improved regulations and safety practices.

7. Overall learnings from incidents

While the scope of this study has focused on process safety related regulations and significant incidents in the US, EU, UK, China and India, in several instances specific detailed accident investigations have resulted in new regulations and upgraded industry operating practices, as discussed earlier. For example, the Lord Cullen report and recommendations on the Piper Alpha incident led to direct changes in how UK offshore oil & gas operations are managed and the Offshore Installations (Safety Case) Regulations of 1992 (OG-UK, 2008). The CSB investigation and Baker Panel Report of the BP Texas City refinery explosion of 2005 led to an OSHA National Emphasis Program for refineries and a series of API Recommended Practices, 752–756, addressing the siting of temporary and permanent buildings, process safety metrics, employee fatigue and other matters (API, 2016; Baker et al., 2007; CSB, 2017b). Also, in China, the Chongqing well blowout of 2003 and National Petroleum Corporation plant explosion of 2005 led to the implementation of the Emergency Event Response Law of 2007 (Zhao et al., 2014). More recently, the Bureau of Safety and Environmental Enforcement (BSEE) was created in the US and the process safety focused Safety and Environmental Management System (SEMS) regulation was implemented as a result of the 2010 Deepwater Horizon incident (BSEE, 2017a).

There has also been considerable work done relating to accident analysis & prevention and risk management. Marsh's periodic publication of 'The 100 Largest Losses' is a thorough source of information regarding major incidents in the hydrocarbon industries (MARSH, 2016). More broadly, Trevor Kletz's work in this area examines the causes of many industrial disasters and how they could have been prevented, such as 'What Went Wrong: Case Studies of Process Plant Disasters' (Kletz, 2009). Also, 'Chemical Process Safety, Learning from Case Histories', by Roy Sanders provides guidance for preventing process safety incidents based on learnings from past incidents in the hydrocarbon industry (Sanders, 2004). Lee's Loss Prevention in the Process Industries provides analyses of many significant incidents with recommended practices for prevention, and remains a key reference in the area of process safety (Mannan and Lees, 2012). Also, work by Mannan et al. of the Mary Kay O'Connor Process Safety Center have examined incidents for learnings and methods for prevention in terms of design and operation (Mannan et al., 2007; Yang et al., 2011). Some detailed incident analyses relate incidents to process safety practices, hazards analysis and risk management, such as Hopkins analyses of the Longford, BP Texas City and Deepwater Horizon incidents (Hopkins, 2000, 2008, 2012). Work by the Center for Chemical Process Safety, and books such *Guidelines for Risk Based Process Safety, 2007* provides their recommended four pillars and twenty elements that define the structure for a risk-based process safety management

system (CCPS, 2017b).

8. Analysis

The analysis of global process safety regulations has highlighted differences and similarities in the extent of regulations and the quality of implementation throughout the regions studied. The developed regions (including US, UK and EU) all have established regulations that are implemented nationally. However, in the developing countries (such as China and India) the regulations aren't as uniformly enforced and the focus on process safety is relatively more recent than for the developed countries.

Table 7 shows an overall comparison between the regions studied for each area of focus. In general, the US, EU, and UK have more developed regulations, however China and India are making progress in improving their regulations.

Regarding the development of process safety regulations, each country follows a similar trend. First, there is industrial growth with limited regulations, which leads to more frequent and more severe process safety incidents. In response to these incidents, new regulations are then introduced to prevent the occurrence of process safety incidents. Developing countries typically base new regulations on previous regulations in developed countries. For example, China's AQ/T 3034-2010 PSM regulation is very similar to US OSHA's PSM regulation. This allows developing countries to use learnings from developed countries and promotes faster implementation of regulations than if developing countries constructed their regulations from scratch. Also, government agencies and organizations acknowledge global incidents and create process safety regulations in response to these incidents. This results in most countries having regulations which cover similar hazards. For example, all countries analyzed have regulations that address environmental and offshore safety. However, countries differ regarding regulations on critical infrastructure protection (anti-terrorism). The US, EU and UK have defined critical infrastructure regulations or agencies, but China and India do not. Even so, China and India have implemented critical information infrastructure protection regulations since 2014. Countries also differ in the frequency of updates to their process safety regulations. The Seveso Directive (EU) has been updated three times since it was initially implemented in 1982. However, the OSHA PSM (US) and EPA RMP (US) have only experienced minor changes since their implementation, although efforts have been underway over the past few years to update these regulations (CSB, 2017f). In response to recent process safety incidents such as the explosion at the West Fertilizer Facility (April 2013), Executive Order 13650 was issued. This executive order was entitled "Improving Chemical Facility Safety and Security" and had five elements which required agencies to strengthen community awareness, improve federal coordination, enhance data management, modernize regulations and incorporate feedback when developing programs (OSHA, 2017h). Some progress has been made toward modernizing the process safety regulations based on the Executive Order, including gathering public input, publishing fact sheets and determining areas where the regulations could be improved (OSHA, 2017i). Updating these regulations is important to ensure that they properly address hazards associated with recent incidents and learnings, and keep up with the constantly developing chemical industry.

The implementation of regulations is highly variable between different countries. While all countries have provisions in their process safety regulations relating to inspections and penalties for noncompliance, these provisions are enforced to different extents. For example, in India, the DGFASLI has only 263 employees which is almost eight times fewer than the number of US OSHA inspectors. This reduces the effectiveness of the inspection program if facilities are rarely inspected and/or penalties not enforced.

The frequency and severity of incidents also varies depending on the country. As shown in Fig. 6, the number of process safety incidents peaked in the 1970's through 1990's for developed and developing countries. Throughout the early 1990's countries implemented process safety regulations in response to these incidents. The developed countries are shown to have more incidents which is likely due to better reporting procedures. However, incidents in developing countries tend to be more severe than those occurring in developed countries. Based on a summary of major severe incidents (defined as incidents that resulted in 25 deaths or more, 125 injured or more, 10,000 evacuated or more, or 10,000 people or more deprived of water) since 1917, all developed countries averaged 14 deaths per incident while developing

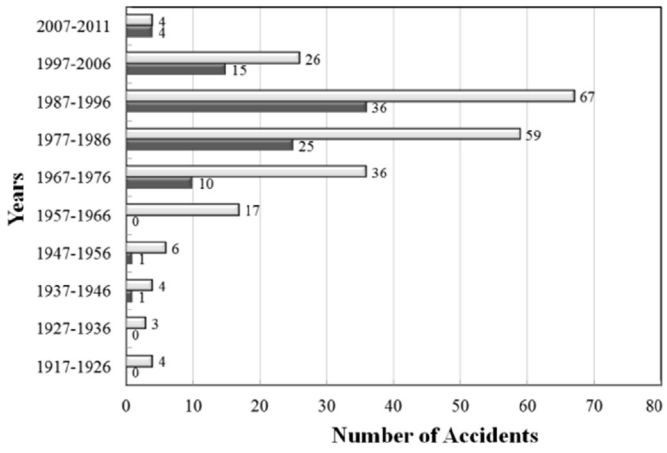


Fig. 6. Number of Incidents per Decade for Developed and Developing Countries. Developed countries are shown in white and developing countries are shown in black (Mihailidou et al., 2012).

Table 7
State of regulation development, implementation & compliance.

	United States	European Union	United Kingdom	China	India
Process Safety Regulations	A	A	A	B	C
Compliance Audit Process	A	A	A	B	C
Protection of Community & Environment	A	A	A	C	C
Protection of Critical Infrastructure	A	A	A	C	C
Offshore Process Safety	A	A	A	C	C
Metrics/Reporting – Fatalities	A	A	A	C	C
Metrics/Reporting – Loss of Containment Incidents	B	B	B	C	C

Key for Table:
A: Process in place with established implementation procedures.
B: Process in later phase of development and implementation.
C: Process largely non-existent or in early phase of development.

Table 8
Total Employment, Total Fatalities, and Fatality Rate per region from ILO 2001 data (Horiguchi, 2010; ILO, 2005).

Occupational Fatal Injury Rates (2001)			
Country (Country Code)	Total Employment	Total Fatalities	Fatality Rate (per 100,000 workers)
United Kingdom (GBR)	28,225,400	236	0.84
European Union (EU15)	162,712,925	5740	3.53
United States (USA)	135,073,000	6643	4.92
India (IND)	402,510,000	40,133	9.97
China (CHN)	733,705,100	90,295	12.31

countries averaged 254 deaths per incident (or 47 deaths per incident excluding the Bhopal, India incident). This is likely due to developed countries having improved emergency response plans and better enforcement of process safety regulations which reduces the magnitude of incidents (Mihailidou et al., 2012).

Also, the occupational fatality rates as reported by the International Labor Organization (ILO) differ between countries, as shown in Table 8. These fatality rates were determined from a single source which provides consistency for comparison. The EU data is an average of the countries which make up the EU-15. The developed countries have lower fatality rates than the developing countries since they have more enforcement of regulations and better emergency response/infrastructure. However, each country is making progress implementing process safety regulations to protect workers, the public, and the environment.

9. Recommendations

Of the countries analyzed, each is in a different stage in the implementation of process safety regulations and have areas of improvement which could help to reduce future incidents. In general, all countries need to improve documentation and data collection. Data is typically collected for major incidents, however many smaller incidents and/or near misses are not recorded. The data is also not collected consistently over a period of time due to changing or newly implemented data collection policies. Therefore, the learnings that can be achieved are greatly limited and the likelihood that more incidents will occur before preventive measures are implement is increased. Also, there is very little consistency in process safety statistics globally which makes comparisons between countries difficult. Each country defines their statistics differently including different definitions for lost time incidents, non-fatal injuries, and what constitutes the manufacturing/chemical industry, among others. Furthermore, there is minimal reporting of true process safety metrics resulting from the loss of containment of a hazardous substance. Instead, total fatalities are examined, which also reflect personnel safety related incidents, such as falls from height, electrocution, etc. Some international organizations, such as the ILO, compile data across countries, but missing or inconsistent data still hampers comparisons between countries.

Additionally, the regulations, incident details, and corresponding statistics need to be better communicated between the government, companies and the public. While this is universally true, it is particularly true in developing countries. This would help inform the public of potential hazards in their area and the necessary actions in case of an emergency. Also, more companies would be aware of required regulations which would improve the overall safety culture and reduce process safety incidents. This communication could be facilitated by active involvement of industrial trade associations. Next, it is important for countries to update their regulations or implement new regulations in response to the learnings from incidents and identification of new hazards. Finally, companies should maintain their familiarity with regulations in all countries where they operate and any updates to regulations. While this can be challenging to keep up with, especially for smaller companies, it is important to prevent future incidents and ensure compliance. Overall, countries need to continue their development of process safety regulations and prioritize the protection of workers, the public and the environment.

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