In a Globalised World is Process Safety becoming harmonised?

Pat Swords BE CEng PPSE FIChemE, Principal Process and Environment, Health and Safety Consultant, PM Group, Killakee House, Belgard Square, Tallaght, Dublin 24, Ireland

Globalisation may be self-evident with regard to brands and products, but few realise the profound impacts the increasing harmonisation of standards, which facilitates this global trade, is having on the development and implementation of technical regulations, including those in the field of process safety. Regional differences will always remain, not least with respect to what is considered a tolerable risk, but significant strides have been made with regards to harmonising products, design standards and personnel competency.

Introduction

That we live in a globalised world is self-evident; the number of countries in which one cannot buy a Coca Cola or a McDonalds can be counted on the fingers of one hand. Yet process safety, which comprises the core principles upon which the design and operation of an industrial facility is based, still on the surface, seems to suffer from different interpretations, as imposed by regional and national preferences and practices, relating to regulatory interpretation. An example of this can be found in the F-Seveso Report (EU-VRi, 2008), a study financed by the EU Commission on the effectiveness of the Seveso II Directive on control of major accident hazards, which gave a clear conclusion:

- *The main weakness identified from the study: The great majority of the respondents indicate the implementation of the Seveso II Directive is not homogeneous within Europe and even in a given country. This represents a problem especially for multi-national companies operating in several Member States because most of them have internal safety standards or approaches, and they have to adapt them to each national context to fulfil the specific requirements (method for risk assessment, threshold for the quantification of the consequences…).*
- *A lot of recommendations were made to improve the harmonisation of implementation of the Seveso II Directive, and support the convergence of implementation practices in Europe, 68% of the industry respondents to the questionnaires and also a majority of the industry interviewees recommended the elaboration of a lot of guidance documents on the interpretation of the requirements (including, e.g. Risk Assessment approaches, SMS, Land-Use Planning) as well as for specific industrial sectors (e.g. metal treatment, storage in warehouses, etc…).*

The planet is a big place, with different languages, geographical conditions, social structures, etc. It is clearly unwise to expect a 'one size fits all' approach, not least as the field of process safety is about ensuring a low level of residual risk - but how low is low enough? The EU Commission's Major Accident Hazards Bureau guidance on the preparation of a safety report (JRC, 2005) made it clear in that the "*decision as to whether the residual risk is acceptable depends very much on national approaches and practices"*. This is an important point, if we consider the International Organisation for Standardisation (ISO) and the International Electrotechnical Commission (IEC), the worldwide federations of national standards bodies, then these have traditionally defined, such as through their ISO/IEC Guide 51:2014 "Safety aspects - Guidelines for their inclusion in standards" that:

- *Residual risk: Risk remaining after risk reduction measures have been implemented*
- *Safety: Freedom from risk which is not tolerable*
- *Tolerable risk: Level of risk that is accepted in a given context based on the current values of society*

Note: Within the above ISO/IEC guidance the terms "acceptable risk" and "tolerable risk" are considered to be synonymous. As societies differ, so too will the 'end goal' of process safety differ, as to achieving a residual risk, which is deemed tolerable. Not least as the same ISO/IEC guidance points out, as to how tolerable risk can be determined, not just by the current values of society, but also by:

- *The search for an optimal balance between the ideal of absolute safety and what is achievable;*
- *The demands to be met by a product or system;*
- *Factors such as suitability for purpose and cost effectiveness.*

To take the McDonalds analogy, then clearly their menu and pricing structures will show national and regional variations, but why should their delivery model have to be constantly re-invented to suit these same national and regional variations? So too for process safety, after all in an ideal world, an industrial facility should reflect what is the consensus on 'state of the art', while the regulatory structures should also reflect the same 'state of the art'. As the 'state of the art' is an evolving concept, it will change with time, as technology and societies evolve. So therefore maybe the globalisation challenge for process safety can be summarised, as to how we achieve on a global basis, consensus as to what is the current 'state of the art' and as to how we document it in order to implement it. In this regard 'times are a changing' and the following sections of this article focus on:

- The main drivers for harmonisation of process safety related requirements
- Their current and potential outcomes in different jurisdictions
- The development process behind international standardisation

- What can we reasonably expect in the future?

Technical Barriers to Trade Agreement

The benefits of global trade are self-evident; different geographical regions have particular characteristics and advantages, for example it makes sense to cattle ranch in Montana rather than in the densely populated areas of the China. However, the implementation of free trade is associated with inherent complexity; if you open up your markets to competition from elsewhere, is it going to be a 'race to the bottom' where the lowest common dominator applies? Equally local regulations cannot be allowed to be used as a form of selective trade barrier to gain a competitive advantage. As such then, global trade is inherently linked to the implementation of common standards. The World Trade Organisation's Technical Barriers to Trade Agreement (WTO, 1995) aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade.

- *Where technical regulations are required and relevant international standards exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.*

The scope of the above Agreement included technical regulations, standards and conformity assessment procedures related to products or processes and production methods. It is also clarified that for technical regulations compliance is mandatory, but for standards it is not mandatory. Furthermore, it was specified that Members shall specify technical regulations based on product requirements in terms of performance rather than design or descriptive characteristics.

ISO and IEC form the specialised system for worldwide standardisation. The following definitions are therefore of importance, as taken from the ISO/IEC Guide 2:2004 "Standardization and related activities - General vocabulary":

- *Standard: Document, established by consensus and approved by a recognised body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.*
- *Technical regulation: Regulation that provides technical requirements, either directly or by referring to or incorporating the content of a standard, technical specification or code of practice.*
- *State of the art: Developed stage of technical capability at a given time as regards products, processes and services, based on the relevant consolidated findings of science, technology and experience.*
- *Acknowledged rule of technology: Technical provision acknowledged by a majority of representative experts as reflecting the state of the art.*

In the European Union (EU) the technical regulations comprise the various Directives and Regulations, which are supported by European (EN) standards. Indeed, about twenty percent of all EN standards are developed following a standardisation request (mandate) from the EU Commission to the European Standardisation Organisations, to draw up and adopt EN standards in support of European policies and legislation. However, the use of standards remains voluntary, as in general the legislator refrains from making direct reference for a requirement to comply with a specific standard, as standards can and do go out of date or could provide a barrier to free trade. Instead, as is to be found with the 'New Approach' Directives, such as for machinery or equipment for explosive atmospheres, broad 'essential health and safety requirements' are specified along with references to the 'state of the art' or equivalent. Harmonised standards are also adopted, which provide a 'presumption of conformity' with specific aspects of the 'essential requirements', although their use remains voluntary and equivalent levels of safety can be provided.

The Commonwealth of Independent States (CIS) includes Russia and some of the former Soviet republics. There the same structure is now applied, in that technical regulations are mandatory, while the GOST standards prepared by the Interstate Council for Standardization, Metrology and Certification of the CIS, which support them, are voluntary. However, in China GB Standards apply (GB stands for Guobiao, or "National Standard"), where mandatory standards are prefixed "GB" and recommended standards are prefixed "GB/T". It is generally estimated that approximately 15% are mandatory standards, although voluntary standards can also be referenced by various regulations and legal acts, therefore in effect requiring compliance. For example the principal safety act, the "Law of the People's Republic of China on Work Safety" requires in Article 16 that: *"Production and business units shall have the conditions for work safety as specified by the provisions in this Law and relevant laws, administrative regulations and national standards or industrial specifications."*

Increasingly, in all of the above regions, previous regional and national standards are being replaced by ISO/IEC standards and thereby adopted into the regulatory framework. In the United States (US), both the Federal Code of Regulations and the Occupational Safety and Health Administration (OSHA) make use of relevant standards within their regulatory structure, although as is discussed later, the situation is not always so clearly defined. Increasingly these standards are national adaptations of ISO/IEC standards.

ISO and IEC also have a global reach, in that few countries are not members, associate members or affiliate countries; even North Korea is a full member of ISO and an associate member of IEC. In an increasingly complex technical world, it simply does not make sense for regulators in different countries, in particular those developing countries with limited resources, to

try and develop their own technical regulations 'from scratch'. As the ISO/IEC point out in their guidance document "Using and referencing ISO and IEC standards for technical regulations" (ISO/IEC, 2007):

- *Standards from ISO and IEC have the advantage of a broad geographical reach. Both of these organizations have a membership made up of national members the world over. This geographical reach is combined with a multi-stakeholder environment which ensures the representation of a wealth of technical views including those relating to social and economic interests. Different perspectives come from the national level and through a network of liaisons and cooperation with international governmental and non-governmental organizations. Therefore, the value of International Standards from ISO and IEC is that they are recognized, accepted and implemented around the globe. Regulators can save time and money by choosing ISO and IEC standards as solutions to policy and technical issues - solutions which have been agreed upon by a consensus reached with the involvement of all parties, including the regulators themselves.*

An example of a developing country is Ghana, where the Ghana Standards Authority is the member body of ISO and represents the affiliate country programme of the IEC. The mandate of the Authority includes: *"Promoting standards in public and industrial welfare, health and safety"*.

United Nations Agenda 21

As the website of the United Nations (UN) explains:

- *Agenda 21 is a comprehensive plan of action to be taken globally, nationally and locally by organizations of the United Nations System, Governments, and Major Groups in every area in which human impacts on the environment. Agenda 21, the Rio Declaration on Environment and Development, and the Statement of principles for the Sustainable Management of Forests were adopted by more than 178 Governments at the United Nations Conference on Environment and Development (UNCED) held in Rio de Janerio, Brazil, 3 to 14 June 1992.*

Section 19 of Agenda 21 related to the "Environmentally Sound Management of Toxic Chemicals including Prevention of Illegal Traffic in Toxic and Dangerous Products". Six programme areas were proposed:

a) Expanding and accelerating international assessment of chemical risks;

b) Harmonization of classification and labelling of chemicals;

c) Information exchange on toxic chemicals and chemical risks;

d) Establishment of risk reduction programmes;

e) Strengthening of national capabilities and capacities for management of chemicals;

f) Prevention of illegal international traffic in toxic and dangerous products.

If we consider progress on the first programme area (a) above, the International Programme on Chemical Safety (IPCS), established in 1980, is a joint programme of three Cooperating Organizations – the World Health Organisation (WHO), the International Labour Organisation (ILO) and the United Nations Environmental Programme (UNEP), implementing activities related to chemical safety. Note: WHO and the ILO are specific agencies of the UN, while WHO acts as the Executing Agency of the IPCS, whose main roles are to establish the scientific basis for safe use of chemicals, and to strengthen national capabilities and capacities for chemical safety.

With regards to the harmonisation of classification and labelling of chemicals, programme area (b) above, like many aspects of Agenda 21, the technical implementation has been primarily driven by the United Nations Economic Commission for Europe (UNECE) based in Geneva. Note: UNECE includes 56 Parties (countries) in Europe, North America and Asia, while the other four regional commissions of the UN tend to follow the technical lead of UNECE. The output of this programme is the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). UNECE published the first edition of the GHS Purple Book in 2003, which is amended every two years based on developments in scientific knowledge. While GHS provides a universal framework for all countries to follow, it is not compulsory, but is intended to be implemented by individual countries through their own legal instruments, recommendations, codes and guidelines, etc. By late 2016 the UNECE 'GHS implementation' webpage was showing GHS implementation in 72 countries.

In the European Union GHS implementation follows through Regulation (EC) No 1272/2008 (as amended) on classification, labelling and packaging of substances and mixtures, the so called CLP regulation, and Regulation (EC) 1907/2006 (as amended) concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency. In Russia GHS is implemented at national level through the Technical Regulation of Customs Union "On safety of chemical products", which is supported by a series of GOST standards. In China there are 28 GHS compulsory national standards (GB 30000-2013), while in the US OSHA's Hazard Communication Standard is aligned with GHS. The United Nations Institute for Training and Research (UNITAR), the ILO and the Organisation for Economic Co-operation and Development (OECD) are also working with developing countries, such as in Africa and Asia, to assist in the implementation of GHS. Finally, UNEP continues to work with primarily developing countries on the final four programme areas (c) to (f).

UNECE Convention on the Transboundary Effects of Industrial Accidents

This Convention was adopted in March 1992, entered into force in April 2000 and now has forty contracting Parties in the UNECE region. The requirements of the Convention, such as its list of qualifying quantities of dangerous substances in its

amended Annex I, bears strong similarities to the EU's Seveso III Directive and its 'top tier' thresholds. Indeed, the Convention is transposed into EU legislation by this Directive. However, the scope of the Convention is limited to activities, which are capable of causing transboundary effects. A key aspect of the Convention is the cooperation on research and development and the sharing of information and technology. As a result there is on-going dissemination of the experiences obtained to date on the implementation of the EU's Seveso legislation into the wider UNECE region. This occurs not only through the preparation of relevant guidance documentation, such as on land-use planning, but also through an Assistance Programme to enhance the capacities of countries of Eastern Europe, the Caucasus and Central Asia, and South-Eastern Europe in implementing the Convention. Note: The F-Seveso report, previously highlighted in Section 1.0, stressed the importance of "*a lot of guidance*" being available.

While naturally one has to acknowledge that the scope of the Convention is limited to transboundary accidents, that knowledge base does spread somewhat organically through to other industrial installations, which may not necessarily have transboundary implications. For example, to assist its member States in coordinating their efforts aimed at safeguarding industrial safety and exchanging relevant knowledge and experience, the Commonwealth of Independent States (CIS) created the CIS Interstate Council on Industrial Safety (ICIS). The secretariat of the UNECE Industrial Accidents Convention has been granted observer status at the ICIS, thereby aiding closer co-operation, which also emanates from the fact that eight of the nine ICIS countries, the exception being Russia, are already beneficiaries of the Convention's Assistance Programme. It is clear that the work programmes of the ICIS and UNECE are leading to greater harmonisation between countries of Eurasia and the Member States of the EU with respect to the prevention of industrial accidents.

International Social Security Association (ISSA)

The German Social Accident Insurance (DGUV), previously designated as the Berufsgenossenschaft (BG), is an institution, which dates back to the time of Bismarck. In most legal systems in the event of an industrial accident, it falls on the employee to essentially sue for damages in order to claim compensation. Under the system of Statutory Accident Insurers, such as in Germany with its DGUV and Switzerland with its SUVA, the employer pays into a central fund; this is drawn down upon in the event of an accident or occupational illness. The contribution which the employer pays is related to the number of employees and the risk profile of the sector. In order to maintain this risk profile as low as possible, the Statutory Accident Insurers, in co-operation with industry and commerce, not only produce a comprehensive set of technical guidance, but also implement inspection and enforcement measures.

Unlike systems where there is an adversarial system of litigation following an accident or occupational illness, with the net result that the authorities shy away from issuing specific guidance, the Statutory Accident Insurers have promoted an extensive programme of prevention in co-operation with the specific branches of industry. The International Social Security Association (ISSA) in Geneva not only co-operates with the ILO, a specialised agency of the UN, but it also draws heavily on the technical knowledge of the Statutory Accident Insurers in Germany and Switzerland. The ISSA is a worldwide Association, bringing together nearly 350 organisations in more than 150 countries, focusing on, amongst others, the concept of prevention and its integral component, that of risk management. It has a number of preventative sections, such as for the 'Chemical Industry' and 'Machine and System Safety'. These produce a series of clear and comprehensive multilingual guidance documents addressing such issues as explosion protection, risk assessment, chemical safety, machinery safety, etc., which are available as free downloads on the ISSA website. As many of the ISSA members are developing countries, this provides an effective means of disseminating established best practice in industrial safety to a wider reach.

Practical Implementation of these Drivers towards Harmonisation

A Common Technical Language?

The whole concept of free trade and related regulatory structures is at its most developed within the Member States of the European Union. Certainly when one considers aspects of process safety which are more product related, such as machinery and ATEX (explosive atmospheres), then it is increasingly obvious that throughout the Member States both industry and regulators are using the same 'hymn sheet', i.e. the range of detailed European Standards, many of which are now, as noted previously, also ISO/IEC standards. However, as Section 2.0 pointed out, International Standards relate not just to products, but also to processes, while even for products the technical regulations should be performance related. A good example of 'process related' standardisation is the whole area of functional safety, which as the IEC explains:

- *Systems comprised of electrical and/or electronic elements have been used for many years to perform safety functions in most application sectors. Computer-based systems (generically referred to as programmable electronic systems) are being used in all application sectors to perform non-safety functions and, increasingly, to perform safety functions. Functional safety is a concept applicable across all industry sectors. It is fundamental to the enabling of complex technology used for safety-related systems. It provides the assurance that the safety-related systems will offer the necessary risk reduction required to achieve safety for the equipment.*

Functional safety is defined within the IEC 61508 series of standards and the related IEC 61511 series of standards for the process industry sector, while for machinery IEC 62061 and the ISO 13849 range of standards apply. Within the EU and on a global basis, essentially nobody uses anything else, so we really do have a global 'common language' in this regard. In many respects one could also point out that functional safety was a relatively new technology sector, which only really achieved definition with the development of these IEC/ISO standards.

What is less successful in terms of a common language is the usage of the IEC range of standards for risk assessment techniques, which are also in many cases also ISO standards and adopted as EN standards. Examples are IEC/ISO 31010:2009 "Risk management - Risk assessment techniques" and ISO 31000:2009 "Risk management - Principles and

guidelines", while specific IEC standards also exist for Hazard and Operability studies (HAZOPs), Fault Tree Analysis, Failure Mode and Effects Analysis (FMEA), etc. Therefore, we should, in theory, be using a common language for such risk assessments, but we aren't. In many respects people in Europe are still hanging on to older guidance documents related to risk assessment techniques, such as company standards, industry guidance documents, etc. If we go back to the F-Seveso Report and industry's 'wish list' 'of a lot of guidance documents', then this situation is definitely improving. However, if industry also wants to see the main problem it identified being solved, i.e. the non-homogeneous implementation of the Seveso legislation, then it too has a role to play in adapting to the new harmonised approach, as it is documented in the various technical standards, which help to define the 'state of the art'.

In many respects, economies in transition are proving to be faster responders in this regard. In both the Russian Federation and China there has been a very deliberate focus to get rid of old standards, many mandatory, which belonged to the old planned economy, and replace them, as quickly as possible, with new ISO/IEC standards and related technical regulations. In essence, the broom has gone in with a big clear out. Equally in the developing world, where in effect previous regulation and standardisation was poorly developed, it simply makes sense, as much as possible, to make the jump to what is now internationally recognised as 'state of the art', not least as it provides an incentive for industrial development. Indeed, the Technical Barriers to Trade Agreement (WTO, 1995) has specific sections related to technical assistance to developing country members, plus in its Article 12: "Special and Differential Treatment of Developing Country Members", clarifies:

- *12.3 Members shall, in the preparation and application of technical regulations, standards and conformity assessment procedures, take account of the special development, financial and trade needs of developing country Members, with a view to ensuring that such technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to exports from developing country Members.*
- *12.4 Members recognize that, although international standards, guides or recommendations may exist, in their particular technological and socio-economic conditions, developing country Members adopt certain technical regulations, standards or conformity assessment procedures aimed at preserving indigenous technology and production methods and processes compatible with their development needs. Members therefore recognize that developing country Members should not be expected to use international standards as a basis for their technical regulations or standards, including test methods, which are not appropriate to their development, financial and trade needs.*

Consensus Standards – The US Approach

The US has really to be looked at as a special case, as it has its own very large internal economy and in many respects an established way of doing things, which is somewhat divergent from elsewhere - a clear example being its lack of metrification. However, at the same time the US is a firm advocate that unjustifiable barriers to trade, such as standards-related measures which are outdated, overly burdensome, discriminatory, or otherwise inappropriate, must be broken down in order not to reduce competition, stifle innovation, and create unnecessary obstacles to trade. However, such issues cut both ways, how good is the US at adapting to new International Standards? The Trade Agreements Act of 1979 prohibits Federal agencies from engaging in any standards-related activity that creates unnecessary obstacles to trade and directs them to consider the use of international standards in rulemaking. The National Technology Transfer and Advancement Act of 1996 states that federal agencies and departments shall:

- *Use technical standards developed or adopted by voluntary consensus standards bodies if compliance would not be inconsistent with applicable law or otherwise impracticable; and consult with voluntary, private sector, consensus standards bodies and shall, when such participation is in the public interest and is compatible with agency and departmental missions, authorities, priorities, and budget resources, participate in the development of technical standards.*

Indeed, this position was strengthened by the Office of Management and Budget, Executive Office of the President in its Circular A-119 of January 2016. However, this is all well and good in theory; practice is somewhat different, as OSHA explains:

- *Before OSHA can issue a standard, it must go through an extensive and lengthy process that includes substantial public engagement, notice and comment periods. This is known as OSHA's "rulemaking process."*

OSHA can "*by rule promulgate as an occupational safety or health standard any national consensus standard*". The latter including those of the American National Standards Institute (ANSI), which is the US representative of ISO/IEC. However, as OSHA itself points out, it's a 'lengthy process', i.e. the pace of adaption of the 'rule book' is desperately slow. However, OSHA has the power to cite companies for non-compliance with the provisions of relevant consensus standards, regardless of whether or not they have gone through "incorporation by reference". This can be understood within the legal context of the General Duty Clause 5(a)(1) of the OSH Act:

- *Even in areas where OSHA has not set forth a standard addressing a specific hazard, employers are responsible for complying with the OSH Act's "general duty" clause. The general duty clause [Section 5(a)(1)] states that each employer "shall furnish . . . a place of employment which is free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."*

Essentially by this means, the content of consensus standards can 'de facto' become a requirement to be complied with, as OSHA further explains:

- *The General Duty Clause, Section 5(a)(1) of the OSH Act, can be used to cite employers that fail to keep a workplace free of hazards, but only where there is no OSHA standard that applies to the particular hazard involved. In evaluating such situations, the hazard must be recognized (by industry or the employer), must have caused or be likely to cause death or serious physical harm, and a feasible means to correct the hazard must be available. Consensus standards may be used to provide a feasible means of abatement and establish employer and industry knowledge.*

Indeed, even where OSHA specifically references a national consensus standard as a guideline, such as when listed in a specific OSHA Regulation / Standard, OSHA acknowledges there may be other means of compliance.

- *Employers who comply with the requirements of an industry consensus standard rather than a specific OSHA standard, where such compliance deviates from the OSHA requirements but provides for a more conservative safeguarding concept, are categorized as having created a de minimis violation of the specific OSHA standard. (A de minimis violation is a violation of an OSHA standard that has no direct or immediate relationship to safety or health. Such de minimis violations require no correction and result in no penalty.)*
- *OSHA encourages employers to abide by the more current industry consensus standards since those standards are more likely to be abreast of the state of the art than an applicable OSHA standard may be. Furthermore, the industry consensus standards will usually discuss a variety of techniques for averting exposure to the identified hazards of the machine or process.*

Naturally for those having to navigate this minefield, it is complex; if you ignore valid consensus standards, are you negligent? A point which is leading to considerable debate in the US, as one US industry blog put it (Titus, 2013):

- *We don't have a "Machinery Directive" like in Europe listing all the standards for legal compliance. So, industry experts often recommend that U.S. companies identify all consensus standards relative to their business. Then, define and document every reason for adopting or rejecting any consensus standard, particularly if any standard is recommended in writing by anyone. And, keep current records documenting all considerations and solutions. A documented risk assessment and your mitigation plan decisions could become a very key document. Simply said, to be safe, don't most folks in the U.S. assume that consensus standards are legal requirements for machine safety?*

While it may be a somewhat messy process lacking legal clarity, 'times are a changing' in the US also, as industry there adapts to the use of International standards defining the 'state of the art'.

Common Law versus Civil Law structures

Globally there are two different legal systems, which have different approaches resulting in a different focus, as to how the area of technical regulation is addressed. In the English speaking world there is 'common law', such as in the UK, US, Ireland and Commonwealth countries, while the countries of mainland Europe, and those associated with them, have a different 'civil law' system. There are merits and disadvantages to each system, which others have discussed in detail elsewhere. However, with 'common law', there is a principle of 'precedent' as a 'rule of law' established for the first time by a court for a particular type of case and thereafter referred to in deciding similar cases. In 'common law' jurisdictions, technical regulations and other associated documentation tend to be more general in nature rather than prescriptive, while the final interpretation on what is required, may well have to wait, until the judges interpret and set the relevant precedent.

'Civil law' systems are inherently prescriptive and the role of the Courts and their case law is considered to be secondary and subordinate to statutory law, which judges must follow. In such countries, there is a far greater degree of technical regulations, guidance documents and other standards, which are considered to give legal effect.

'State of the Art' - The German and now EU Approach

The particular the case of Germany stands out, not least as it is the largest and most technically developed EU Member State, but because there is also a rapid pace of codification of technical regulations, guidance, codes of practice and standards. The overarching occupational and product safety legislation in Germany requires compliance with 'Stand der Technik', i.e. 'state of the art' technology. In many respects Germany is, with regards implementation of process safety, very much at the opposite end of the spectrum to the US, as it has a very prescriptive 'civil law' approach.

This concept of 'state of the art' is defined, with some slight tweaks, within various German legislative structures relating to emissions control, chemical agents, plant safety, Seveso compliance, etc. However, within their technical regulations for hazardous substances, which help implement the EU's Chemical Agents Directive (98/24/EC as amended) and aspects of the EU's ATEX legislation, there is a specific regulation TRGS 460 on the "Recommended course of action for determining the state of the art", which is also available as an English translation (BAuA, 2013). As this clarifies:

- *"State of the art" is an indeterminate legal concept with historical roots in engineering sciences. It is an essential and accepted element of the lexicon of German engineering tradition. Currently, it appears to be generally accepted that the "state of the art" does not offer stakeholders a quantifiable target but rather a criterion or assessment aid for defining measures or specifying requirements.*

As it goes on to then clarify with respect to a pivotal ruling of the German Federal Constitutional Court (BVerfG, 1978) in relation to nuclear power:

- *"... given the complex and multifaceted problems presented by technical issues and processes, it is not generally possible for [the legislature] to define in detail all of the safety-related requirements that the respective systems or items are to meet. In fields [...] where constant innovations are likely due to rapid technical development, the legislature would also have to bring these up to date on an ongoing basis if it had in fact laid down a detailed regulation."*

As a result the legislature makes use of 'indirect reference' by specifying compliance with the concept of 'state of the art', which in general is defined in German legislative acts, such as their Hazardous Substances Ordinance, as:

- *The state of the art is that state of development of progressive techniques, equipment and modes of operation which makes the practical suitability of measures for controlling emissions and for ensuring the employees' safety of health. In determining the state of the art, particular consideration shall be given to comparable techniques, equipment and modes of operation which have been successfully tested in practical operation.*

Indeed, the above definition is not dissimilar to that, already highlighted in Section 2.0, in the ISO/IEC Guide 2:2004. While as also pointed in Section 2.0, the EU legislator also makes use of this definition of 'state of the art' with respect to compliance with the various 'essential requirements' of 'New Approach' Directives, such as for equipment for explosive atmospheres, machinery, etc. While those Directives don't specifically define 'state of the art' it is clear from the comprehensive supporting guidance from the EU Commission, that it includes as a minimum the relevant harmonised standards, plus where such standards are not yet developed or out of date, the consensus on good engineering practice. Therefore, at both German and EU level the 'state of the art' is a dynamic concept, which to a certain extent is technology forcing. Indeed, the EU Commission's guidance is very clear in that as the 'state of the art' develops and it is possible to meet the objectives in the 'essential requirements' of the Directives more closely, a manufacturer must upgrade his design accordingly. However, the 'state of the art' also reflects the balance between technical considerations, economic costs and risk reduction.

For an existing production facility, it is simply not possible to modernise to every development in the 'state of the art', although there is a general requirement in the EU's Framework Directive on Occupational Safety and Health (89/391/EEC) to "adapt to technical progress". Proportionality in this regard is key - is the level of risk reduction, which could be achieved, proportionate to the costs involved? TRGS 460 also clarifies: *"it should be checked in each case whether the success achieved through adaptation is proportionate to the respective costs".*

While both the German and EU approaches to the 'state of the art' are similar, the German interpretation of the 'generally accepted rules of technology' is extremely broad, far broader than the EU's harmonised standards. As a minimum it comprises technical regulations, DIN standards of which many are now adopted from ISO/IEC, publications of the Statutory Accident Insurers, VDI/VDE standards, etc. Note: VDI is the German Association of Engineers and VDE the German Association of Electrical Engineers, both which have a mandate in Germany to prepare technical standards, which are available in both German and English. Culturally the Germanic world is renowned for its love of rules and regulations, but even there questions are raised in relation to *"Normenflut und Gesetzeslawine"*, the flood of standards and avalanche of laws. However, with regard to technology being a dynamic process, as Germany is a major manufacturing base, in which 'Made in Germany' is a big brand, there is as highlighted previously, a very rapid development in regulations, guidance and standards, thus providing a degree of 'first mover advantage' to that manufacturing base. This is also enhanced by the co-operative approach of their Statutory Accident Insurers, such that with regard to process safety and the development of new standards in this area, Germany is very much the leading nation. In simple terms VDI standards often form the basis of subsequent EN standards, which in turn form the basis of subsequent ISO/IEC standards.

Explosive Atmospheres – An Example of a now Harmonised Approach

Clearly for example China has not formally adopted the EU's ATEX legislation. However, the technical standards in both jurisdictions are now essentially the same, in China many being mandatory CB codes. So in practice there is little difference. It is also interesting to look back at the history of how this developed. In the 50s and 60s the German Statutory Accident Insurers for the chemical industry (BG Chemie) developed their explosion protection regulations (EX-RL), which to this day are in a state of continuous development. When for instance one considers the EU Commission's guidance to the ATEX 'worker protection' Directive 1999/92/EC (EU Commission, 2003) and the key type-A standard harmonised to both the ATEX 'equipment' Directive and the Machinery Directive, EN 1127-1 "Explosive atmospheres: Explosion prevention and protection: Basic concepts and methodology", the similarities to EX-RL are obvious. EX-RL also has a comprehensive set of examples of hazardous area classifications, to date only available in German, which is now referenced in IEC 60079-10-1:2015 "Explosive atmospheres: Classification of areas: Explosive gas atmospheres" as an applicable national and industry standard in this regard.

The IEC 60079 range of standards now defines all the electrical requirements related to explosive atmospheres. In the European Economic Area ATEX certification of equipment applies, but globally for Ex rated electrical equipment there is the IECEx Conformity Assessment System; two different conformity systems, but both using the same electrical standards. For non-electrical equipment, there is since early 2016 a new ISO/IEC 80079 range of standards, which support the ATEX conformity scheme for non-electrical equipment and other conformity schemes, such as by IECEx. Therefore, we have reached the situation where there is now a common regulatory framework for equipment used in environments with an explosive atmosphere. Even in the US, with its traditional approach to hazardous area classification, the new IECEx model is being run in parallel, both being recognised by the National Electrical Code (NFPA 70). In Russia and the CIS the IECEx system is fully implemented through GOST standards and certification schemes, while even prior to the adoption of the new

ISO/IEC 80079 range of standards, the previous EN standards for non-electrical equipment in explosive atmospheres had been adopted in Russia as GOST standards and in China as GB Codes.

So are there future developments? Process Control Engineering relates to the use of process control technology to either prevent or reduce the occurrence of hazardous explosive atmospheres or the presence of ignition sources or to mitigate the harmful effects of an explosion. In practical terms, we are all familiar with the concept of using an inert gas to reduce or eliminate a zone or the use of gas detectors to implement a shutdown of non-rated equipment when the Lower Explosion Limit is approached. However, how many of us are aware of designing the necessary reliability for such systems, i.e. functional safety? To date ISO/IEC standards have not been developed specifically for this area, while the EU's guidance on Directive 1999/92/EC (EU Commission, 2003) only outlines the requirements for Process Control Engineering and the associated EN standards in this area only address functional safety in the context of protective systems (EN 15233:2007) and safety devices (EN 50495:2010).

For a broader design code, for such as designing an inerting system, one has to turn to Germany and recent developments there. VDI/VDE 2180 Blatt 6:2013 "Safeguarding of industrial process plants by means of process control engineering (PCE) - Application of functional safety in the context of explosion protection" and the supporting NAMUR NE 138:2013 ""Hazardous Potentially Explosive Atmospheres – Process Control Equipment in the Context of Explosion Protection Measures" provide good guidance in this regard. However, not to be outdone, in early 2016 the German Ministry of Labour adopted a technical regulation TRGS 725 on "hazardous explosive atmospheres – measurement, control and regulation in the scope of explosion protection measures", although unlike the two previous standards it is only in German, which is a pity as it brings a lot of clarity to the subject. No doubt in time these German technical developments in terms of 'state of the art' will find their way into new ISO/IEC standards in the area of Process Control Engineering.

Global Competency?

Referring back to the ISO/IEC Guide 2:2004 "Standardization and related activities - General vocabulary" then this guide defines:

- *Fitness for purpose: Ability of a product, process or service to serve a defined purpose under specific conditions*

This is just reinforcing the point, which the same guide clarifies: *"Important benefits of standardization are improvement of the suitability of products, processes and services for their intended purposes, prevention of barriers to trade and facilitation of technological cooperation."* So are process safety related skills not a service, which has to be fit for purpose and subject to a degree of standardisation? In more blunt terms, do you have the competency to do your job in multi-country environment and if so show me? Indeed, the demonstration of the latter often comes back to cultural tendencies and legal structure. In the English speaking world professional competency is generally not formalised. As a result one could end up having to explain in a common law Court that one has the recognition of one's peers, but it's a long way from the formalised structures in other civil law countries. Michael Palin was right in his wonderful travel programmes of the nineties in Eastern Europe: "Never argue with a guy with a rubber stamp" - conversely you are not going to get far in such environments without the appropriate rubber stamp.

In Germany a section of their overarching legislation on emissions control and process plant safety (§ 29a BImSchG) specifies that the competent authority can request the plant operator, to undergo a formal safety inspection, by an officially recognised competent person for this task. There the subject matter expert (Sachverständiger) must demonstrate the necessary competency and have also met the applicable State certification requirements. In Germany implementation of environmental and safety legislation is at the provincial (Länder) level, where the Länder authorities are responsible the certification of such competency. Indeed, there is an even a guideline dating originally to 1995, which has been prepared by the committee at Länder level (LAI) for the official publication of a register of subject matter experts, designated as competent for these safety inspections. This guideline defines the necessary professional training and practical experience, the requirement for independence, the form of official interview, etc. Once this procedure has been passed, the relevant subject matter experts are published on the official register for a period not exceeding eight years, plus they are legally required to produce annual reports in relation to their activities. This registration can be renewed with a new application procedure, while this official register is now available as an on-line database called ReSyMeSa. Note; the LAI guideline points out that it does not discriminate against applicants from other Member States.

The lack of an equivalent level of professional competency in process safety in the English speaking world has been recognised by the Institution of Chemical Engineers (IChemE), who has now established a register for Professional Process Safety Engineers. While this is still very much at its initial stages, industry has been very supportive of the whole scheme. Naturally one would ask, as to if there is or will be, a globally based competency certification scheme? ISO/IEC 17024:2012 "Conformity assessment -- General requirements for bodies operating certification of persons" establishes the structures for assessment of such competency. While coming back to the leading area of global harmonisation, namely explosive atmospheres, there is actually such a scheme up and running; the IECEx Certified Persons Scheme. In a similar manner to the IECEx system for conformity and certification of products, IECEx will issue a Certificate of Personnel Competency, a system, which just like for products, is administered by designated notified bodies and the person, once officially registered, is similarly displayed on the designated section of the IECEx website.

There are ten modules (units) under this scheme. However, many process safety specialists will only be concerned with the first two: (i) "Apply basic principles of protection in explosive atmospheres" and (ii) "Perform classification of hazardous areas". Additional units can be added to a registration as required, such as "Design electrical installations in or associated

with explosive atmospheres". Like it or not people are often the weakest link in the safety chain and this has to be addressed, a factor which many are recognising in industry. As a result there is a growing multitude of private organisations, some also notified bodies, running various training courses which provide their own level of certification, such as related to Functional Safety. However, while these fall short of a global registration procedure, such as run by IECEx above, it does appear from their website, that IEC are also planning to establish a normative basis for the competence of persons with regard to the IEC 61508 range of standards on functional safety.

Trends – Winners and Losers

The growing harmonisation in defining what is an appropriate 'state of the art' for the multitude of challenges, which occur in the field of process safety, can only be of benefit, particularly if it is also linked to an equivalent harmonisation in the recognition of professional competency. It's an old adage, but 'why re-invent the wheel'? As to who are the winners? Well for starters industry, particularly industrial concerns which operate multiple facilities in different geographical locations. Why should what has been proven successful in one location have to be changed? So too for professionals in this field, it takes considerable learning and relevant professional experience before one can be considered as competent in process safety, not least as this field is inherently related to managing to a tolerable level, the risks inherent with high hazard facilities. Judgemental skills are required; it will never be black or white and a residual risk will always remain. Why for instance should one's professional opportunities be restricted to one of sixteen Länder in Germany, far better to have the 'world as your oyster'?

In this regard, there is a worldwide shortage of experienced process safety specialists and that is not going to change in the medium term. While successful industries can afford to hire on the competitive market place, it is more difficult for the public sector and there is no doubt that in many jurisdictions regulatory agencies are struggling with the complexity of regulating high hazard industries. This has a knock on effect on the ability of this regulated industry sector to react and respond to the dynamic pace in which technology and the market place changes; lost opportunities can occur. On the other hand, greater definition in the appropriate 'state of the art' greatly facilitates regulatory agencies with being able to complete their tasks.

While there are a lot of winners in a more globally harmonised approach, and in this regard one would not be presumptuous in including in this bracket society at large, there are also losers. In the past doing business 'abroad', particularly in emerging economies and / or those recently freed from the constraints of a planned economy, was fraught with obstacles related to local regulations, which took both time and money to overcome. At the same time, it was also a nice 'little earner' for those, who could correctly interpret those local regulations in the local language. This situation is radically changing, where compliance with technical regulations is now increasingly based on a multitude of EN or IEC/ISO standards. EN standards are published in English, French or Germany, which is well and good if your national standards authority also has the resources to complete a translation into the local language, but this is not always the case, often it is simply a lead sheet in the local language. The 'little earner' is increasingly hard to justify, not least as the foreigner may now actually know more of what is actually required than the local so called 'expert'. Maybe after all Mark Twain was right; "an expert is an ordinary fellow from another town".

Some Personal Observations and Conclusions

To reiterate why re-invent the wheel? While one can't do the stealing in 'beg, borrow or steal', the concept is clear, there is no shame in replicating, with a few tweaks and upgrades as required, what has proved to be successful elsewhere. Simple concept, but we are not doing it. Society can learn a lot from history, but in practice learns very little. Equally the field of process safety is sculpted by the fact that there are no new accidents, just repeats of previous ones. For many there is a cultural mind set to be overcome, if improvements are to be made, but at the same time greater harmonisation in defining in an international context the current 'state of the art', can only help with progress.

It was previously mentioned, Germany is at the polar end of the spectrum from the US and this is a concept which is worthy of further clarification. Each country and cultural approach has its strengths and weaknesses, while as per the previous theme, it is useful to borrow what is good, and if possible, move on when it is not so good. The EU has a Framework Directive on Occupational Safety and Health, while twenty 'individual' or 'daughter' Directives follow providing greater clarity on such as chemical agents, explosive atmospheres, work equipment, etc. There are also in relation to product safety some 27 'New Approach' Directives addressing the conformity procedures for machinery, equipment for explosive atmosphere, pressure equipment, etc. The two strands on occupational safety and product safety then overlap, as the Directive on 'work equipment' (2009/104/EC) requires that equipment be compliant with the relevant 'New Approach' Directives. It is in essence a clear hierarchy or pyramid, in which the essential requirements are defined in the top layer and the supporting information on what is the suitable 'state of the art', follows from further guidance, technical regulations, standards, etc., some of which are Member State specific. Once one recognises and understands this pyramid structure and how the different levels interact and interface, there is a general realisation that it is actually a very sensible approach for an inherently complex task. Indeed, if we go back to Section 2.0, the EU's approach is very much in line with the Technical Barriers to Trade Agreement, in that 'technical regulations', in this case the Directives, should be based on performance requirements rather than design or descriptive characteristics. In other words, establish the overarching requirements and leave the details to the technical standards and other documentation.

For those used to that approach, the US structures can be somewhat frustrating, because as previously explained their technical regulations, where they are established, are usually based on direct adoptions of technical standards. These standards are by nature somewhat in-depth and prescriptive, but at the same time, as the ISO/IEC guidance clarifies, standardization may have one or more specific aims, to make a product, process or service fit for its purpose. However, the

applicable administrative provisions, with which compliance is mandatory, have to be defined in specific technical regulations, which it is generally assumed, not least by those preparing standards, would complement and supplement those standards. As a result certain ineffectiveness can occur, due to a failure to establish the overarching principles and objectives. For example, OSHA requires by means of its Occupational Safety and Health Standard 1910.119 on "Process safety management of highly hazardous chemicals" that:

- *The employer shall perform an initial process hazard analysis (hazard evaluation) on processes covered by this standard.*

So what does one do if your process is not covered by this OSHA standard, which a lot aren't? The same OSHA standard then goes on to provide a nice list of risk assessment techniques, which can be used, such as HAZOP, FMEA, etc. So what next, what does one benchmark the outcome of that risk assessment against? The European system may not be perfect and have all the answers, but the core requirements are clearly defined. The Principles of Prevention of the Framework Directive on Occupational Safety and Health are applicable in all circumstances and require for example, both the evaluation of risks which cannot be avoided and the combatting of risk at source. The Directive on Chemical Agents further clarifies on this theme, as to how the quantity of chemical agents present at the workplace should be reduced to the minimum required for the type of work concerned. Both ATEX Directives on 'equipment' (2014/34/EU) and 'worker protection' (1999/92/EC) also state that the first principle is to take measures to prevent the formation of explosive atmospheres. In contrast, while OSHA's standard does clarify that: *"The employer shall document that equipment complies with recognized and generally accepted good engineering practices"*, it establishes little in terms of the hierarchy of objectives to be achieved, rather defines a set of documentation to be produced.

Many US multinationals then develop their own corporate standards to 'fill the gap' and then proceed to implement and audit their overseas affiliates to this same Process Safety Management Standard. It is a somewhat less than comprehensive approach, as the focus tends to be on the completion of the process hazard analysis exercise itself, rather than on what the fundamentals supporting the design basis were. The Germanic way, on the other hand, is for all parties concerned namely, industry, regulators, academia, insurers, etc. to 'beaver away' together on defining what is the 'state of the art'. For example, the German Statutory Accident Insurers has a very nice guidance BGI 5151 on safe working in the pharmaceutical industry, unfortunately only in German. However, the equivalent one on safe working in laboratories, BGI/GUV-I 850-0, is available in English on the internet and provides an example of the type of clear guidance, which is literally 'churned out' by the German Statutory Accident Insurers. As a result German industry in a given sector, such as pharmaceuticals, will have a single common approach; while with the equivalent US approach, each major corporation will have its own set of standards / guidelines. The Swiss approach mirrors the German, such as the "TRCI Tank Farm Guidelines for the Chemical Industry" prepared by the Basel Chemical Industry and both listed as Engineering Rules by the Swiss Federal Office for the Environment (BAFU) and available in English on their website.

There is also a limitation in the US corporate approach, in that it lacks a 'social contract', as they developed their corporate standards themselves without involving a wider community, not least those with a regulatory function. The latter is a position the likes of ISO/IEC, as highlighted previously, are keen to avoid. Developing standards and guidelines in isolation has limited value. If for instance a corporation moves into a developing country and bases its approach around corporate standards, is this going to necessarily fulfil the expectation of the local regulatory bodies, which as a starting point are likely to be on a learning curve anyhow? On the other hand, if everything is benchmarked against recognised international standards, then as explained previously, there are few countries without a National Standards Authority somehow affiliated to and receiving support from IEC/ISO. Indeed, similarly as regards those of us in Europe, we tend to be focused towards Brussels, without realising that if one actually checks the number of International Agencies in Geneva, ranging from UNECE to ISO and IEC, there is actually another and wider dimension out there.

All too often as a HAZOP chairman, a recurrent failure observed in the English speaking world, is that the design team fail to give adequate recognition to the simple fact that they are not the first doing this type of design; designs evolve from previous established technologies. However, expectations are that everything has to be analysed from first principles, as otherwise it's not a proper 'HAZOP', and this HAZOP then suffices as the project 'risk documentation', such as for compliance with their Process Safety Management Standards. The Germans on the other hand for decades ran an extremely successful process industry sector, with little or no HAZOPs, relying instead on endless references to endless German technical documents, which defined the 'state of the art'. Somewhere in the middle lies a balance.

For example, the typical 'English' HAZOP would come up with a prompt relating to low pH, something with regard to "suitable PPE" would then be written down. In reality not only are clear legislative principles defined in 'daughter' Directives related to chemical agents and Personal Protective Equipment (PPE), but since the advent of the EU's REACH legislation, 'downstream users' are required to follow the guidance in the 'exposure scenarios' provided in the extended Safety Data Sheet. Therefore a prescriptive approach is already defined in EU technical regulations, which needs to be followed. However, when at a later stage a corporate or regulator auditor tries to establish the basis on which the facility is actually designed, such as what is exactly suitable in terms of PPE and why, they can't? HAZOP reports are by their nature disjointed, as a HAZOP is only a structured methodology for identifying risks and operability problems with the original design, such that they can be rectified later, in other words, it's a 'reactive' approach to those weaknesses identified. Conversely, with an 'active' approach the design team would have established in plain language beforehand, what 'what good is'; namely the established and documented 'state of the art', and how they were going to implement it. A 'reactive' approach is not only highly inefficient, but it leads to repeats of past accidents. We need to do things better and the first step is acknowledging the benefits, which increasing harmonisation and documentation of process safety is bringing.

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