WHITE PAPER

# Do We Need to Re-Define Process Safety?

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**The COVID-19 crisis has clearly shown how vulnerable humankind is to new, infectious micro-organisms and is prompting serious reflection on how we can best prepare for and respond to this type of threat. Process safety, originally developed to address and mitigate risks related to hazardous materials and energy sources in an industrial context, can prove useful against biological agents as well, especially as biomanufacturing expands its applications beyond its traditional niche. Faced with new challenges, the process safety framework is sufficiently robust to accommodate the necessary modifications and confront emerging risks.**

## Implications of a Precursor to COVID-19

The Marburg virus[1] first appeared at three locations in early August 1967: in Marburg an der Lahn and Frankfurt am Main in Germany and in Belgrade, Serbia. The virus was traced to a laboratory conducting research on African green monkeys (*Cercopithecus aethiops*) imported from Uganda, while its reservoir was ultimately found in bats of the *Rousettus* genus. In this first outbreak of the disease, which, like the related Ebola virus, causes hemorrhagic fever, 31 people were infected, and 7 died. There have been several outbreaks and sporadic cases reported since then in Angola, the Democratic Republic of the Congo, Kenya, South Africa and Uganda, where the disease has been much more virulent, with a fatality ratio of up to 88%.

Fast forward to mid-April 2020: I am writing this paper at home during the COVID-19-related lockdown. As of today, the novel coronavirus is responsible for nearly 200,000 fatalities worldwide[2], and its economic impact is forecast by the International Monetary Fund[3] to reach more than 6% of the Gross World Product (GWP), in excess of five trillion US dollars.

1 World Health Organization (April 2020). https://www.who.int/health-topics/marburg-virus-disease/#tab=tab_1

2 COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (April 24, 2020). https://coronavirus.jhu.edu/map.html

3 International Monetary Fund (April 2020). World Economic Outlook. Chapter 1. The great lockdown.

Once again, scientists seem to agree, the reservoir of SARS-CoV-2 (the virus causing COVID-19 disease) is in bats. It was first diagnosed in Wuhan, in the Chinese province of Hubei. Chinese authorities traced the infection to a now infamous wild animal market, which has been reported to be ground zero for the virus' transmission to humans, although the specifics of the first human infection are still being investigated. SARS-CoV-2 is particularly insidious due to its ease of transmission (including by asymptomatic carriers), a lack of herd immunity (the human body has never before been exposed), a long incubation period and a relatively high fatality rate. These circumstances have fostered its spread and resulted in the pandemic gripping the world today.

There has been some speculation in Western media about SARS-COV-2 accidentally leaking out of the Wuhan Institute of Virology. These allegations have been repeatedly denied by Chinese officials, and a study of the virus genome points to natural evolution[4]. We must acknowledge, though, that:

a) The 1967 Marburg incident proved that an outbreak can be caused by an infectious agent released in a laboratory setting. Safety measures in laboratories have greatly increased since then but, as we all know too well, there is no infallible safeguard.
b) The 2020 pandemic has proved that a local infectious episode can propagate to the entire world and end up causing tens of thousands of fatalities, not to mention having a devastating impact on the world's economy.

Therefore, and for the sake of argument, let us consider a Pandemic Induced by a Loss of Containment of a Biological Agent (PILOCBA) as a potential new class of industrial incident.

## Biomanufacturing is Gaining Ground across Industries

Humankind has been harnessing micro-organisms for its own benefit since prehistoric times. Beer, for example, is produced by yeast fermentation, and evidence shows its consumption dates back 10 millennia[5]. Other foods and beverages that humans have manufactured for thousands of years with the help of living organisms include bread, wine and cheese.

In the late 19th century, the anti-bacterial properties of some molds were identified, leading to the discovery of penicillin in 1928, and the development of the antibiotic industry. A number of the pharmaceutical products in use today are derived from micro-organisms, usually genetically modified.

Recent developments in biomanufacturing include the increased use of genetically modified micro-organisms in the production of a range of goods. Some applications include:

> **Bioremediation:** the use of living organisms to clean up hazardous chemical spills underground or in the sea.
> **Food manufacturing:** in meat replacement products and some other specialty items.
> **Biodesulfurization (BDS):** a new approach to removing sulfur from fuels, used in the chemical and petrochemical industries.
> **Microbiologically Induced Calcium Carbonate Precipitation (MICP):** for repairing cracks, preventing corrosion in concrete and other cementation applications.

In other words, biomanufacturing is extending out of the food and beverage and pharmaceutical industries and increasingly spreading to other fields.

## Expanding our Definition of Process Safety

At the 15th International Symposium on Loss Prevention and Safety Promotion in the Process Industries, DEKRA presented a paper entitled, "Industrial Accidents: Are More Serious Events than Bhopal Possible?"[6] The paper explained the underlying statistical distribution of major accidents, pointing to a potential distribution with a slope close to -1. In other words, for every 10 accidents with 10 fatalities, there is one accident with 100 fatalities; for every 10 accidents with 100 fatalities there is one with 1,000 fatalities, and so on.

Needless to say, the symposium took place in a pre-COVID-19 world, and yet we were already recognizing the possibility of an incident causing tens of thousands of fatalities and identifying bioengineering as a potential source of such a risk. To illustrate the implications of the current pandemic, Figure 1 (see page 3) shows a graph from the aforementioned paper, in which we have added an additional point, representing the number of fatalities due, so far, to COVID-19.

Note the position here of the PILOCBA point with respect to the regression of all industrial accidents: its probability is several orders of magnitude above the regression. According to the regression, we

4 J.Bowler (April 20,2020) https://www.sciencealert.com/here-s-what-scientists-think-of-the-coronavirus-was-made-in-a-lab-rumour.
5 The oldest evidence of beer production on record is residue found at the Raqefet Cave in the Carmel Mountains, near Haifa (Israel). Apparently, the semi-nomadic Natufians drank beer around ten millennia ago during ritual feasting at this location.
6 A. Trujillo (2016). Industrial Accidents: are more Serious Events than Bhopal Possible?. Chemical Engineering Transactions. Vol. 48.

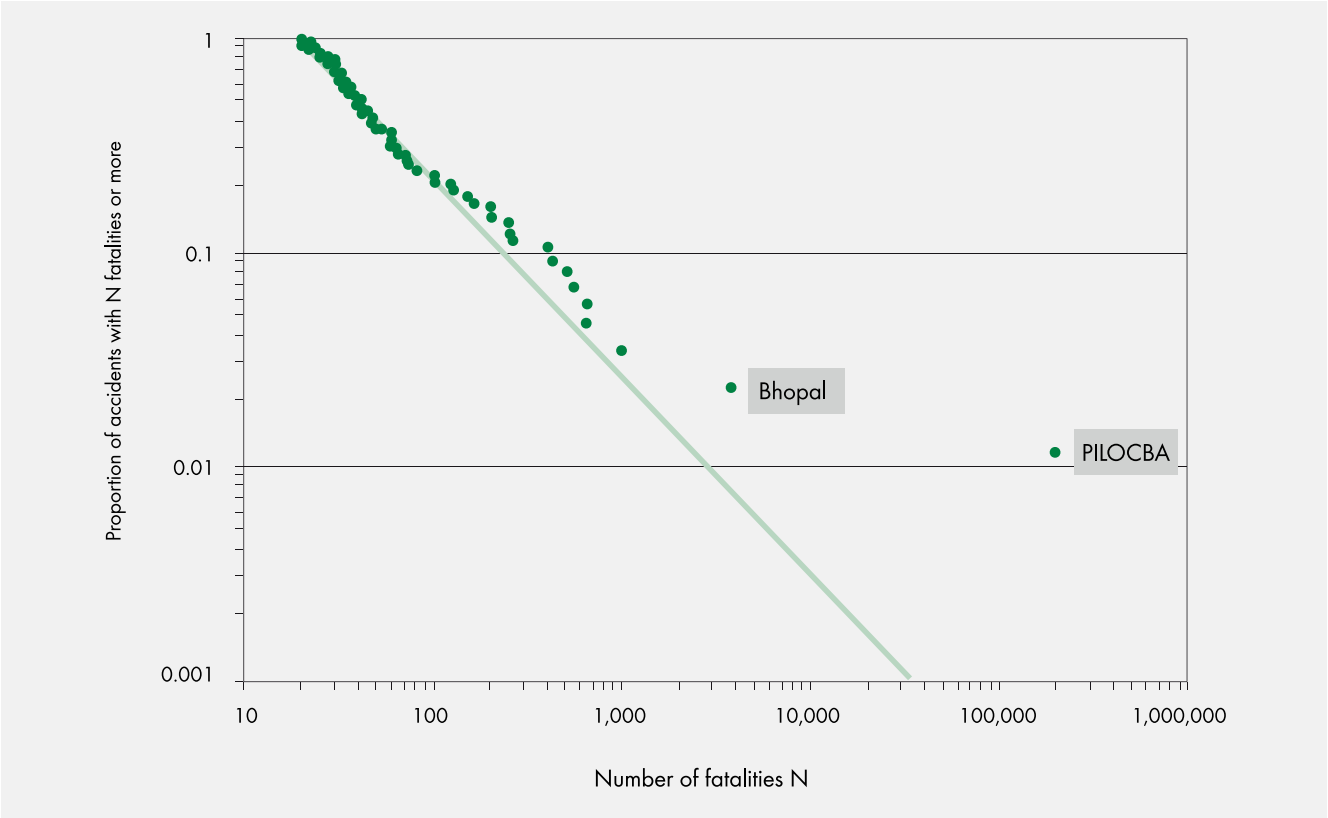


Figure 1: Number of fatalities in a PILOCBA versus the existing industrial trend

should observe one PILOCBA-class incident per every ten Bhopal incidents. Yet, we are observing one PILOCBA (once again, assuming for the sake of argument that COVID-19 were the result of a lab accident) after only one Bhopal. This may mean:

- We are ludicrously unlucky, as we live through an event with a minuscule probability;
- The risk associated with the event is disproportionately high: either the cause has high probability, or the safeguards are not sufficiently robust. If, as experts have deduced, COVID-19 is the result of natural causes and not an industrial incident, we must conclude that the probability of such a natural disaster is far higher than a similar man-made disaster. And, again in this case, sufficiently reliable safeguards should be in place.

This leads very naturally into process safety. Given that

a) Process safety is about preventing major accidents,
b) Biomanufacturing can cause major accidents on an unprecedented scale,

should we not start taking biomanufacturing into consideration when we define process safety?

The Center for Chemical Process Safety (CCPS) defines process safety as "*… a disciplined framework for managing the integrity of operating systems and processes handling hazardous substances by applying good design principles, engineering, and operating practices. It deals with the prevention and control of incidents that have the potential to release hazardous materials or energy. Such incidents can cause toxic effects, fire, or explosion and could ultimately result in serious injuries, property damage, lost production, and environmental impact.*"[7] To broaden our definition appropriately, we need only replace "hazardous substances" with "hazardous substances and biological agents," not forgetting of course, that biological agents can include things like prions (misfolded proteins), the culprits behind Creutzfeldt-Jakob disease (popularly known as "mad cow disease").

## Practical Responses from Process Safety

If we should decide to expand the definition of process safety to include a reference to risks related to biomanufacturing, what changes will occur in process safety? In particular, what aspects of current practices will need to be supplemented or modified?

7 CCPS (April 2020). https://www.aiche.org/ccps/process-safety-faqs#What%20is%20Process%20Safety

| Workstream | CCPS Element |
|---|---|
| 1. Capability | > Compliance with Standards<br>> Process Knowledge Management<br>> Process Safety Competency<br>> Training and Performance Assurance |
| 2. Incident Response | > Stakeholder Outreach<br>> Emergency Management<br>> Incident Investigation |
| 3. Risk Management | > Hazard Identification and Risk Analysis |
| 4. Asset Integrity | > Asset Integrity and Reliability<br>> Management of Change |
| 5. Accountability | > Measurement and Metrics<br>> Auditing<br>> Management Review and Continuous Improvement |
| 6. Operations | > Operating Procedures<br>> Safe Work Practices<br>> Operational Readiness<br>> Contractor Management<br>> Conduct of Operations – Operational Discipline |
| 7. Culture and Organization | > Process Safety Culture<br>> Workforce Involvement |

Table 1 Workstreams and CCPS elements

Table 1 shows the twenty elements identified by CCPS as essential for world-class process safety performance, grouped into seven workstreams according to DEKRA's Organizational Process Safety solution.

Every one of the elements and workstreams seems fully applicable to biomanufacturing. For instance, under "compliance with standards," it is clear that biomanufacturers will need to keep track of and comply with industry standards and applicable regulations. In terms of hazard identification and risk analysis, biomanufacturers must be able to identify the potential hazards of any new process and assess its risks. Indeed, each of the elements retains its validity for biomanufacturing, and taken together, the list is exhaustive.

While the basic framework for managing risks as set forth by the CCPS remains intact, there will be a need for:

> New tools and methodologies or adaptations of those that already exist. With some fine-tuning, we may be able to apply techniques such as HAZOP or quantitative risk analysis to biomanufacturing facilities. We will also need to develop consequence modeling in line with the new types of hazards. The Process Safety Management (PSM) structure will need to accommodate an entirely new class of hazards.

> A whole new cohort of process safety experts specializing in biological processes to complement our knowledge of chemical processes. Needless to say, appropriate competence development programs will be required.

## Process Safety Can Rise to New Challenges

Current circumstances have made us acutely aware of the need to confront growing risk. New bioengineering technologies are increasingly applied to manufacture a range of goods, even beyond food and pharmaceuticals. Genetically modified micro-organisms are also purposefully dispersed into the environment to help clean up chemical or oil spills. At the same time, the COVID-19 pandemic is demonstrating that human exposure to new micro-organisms (including engineered ones) can turn into a global catastrophe with unprecedented consequences.

We must remember, however, that risk of exposure to new hazards has always existed. In fact, humans developed process safety as a way to identify, assess and manage risks caused by hazardous materials, whether from familiar substances such as flammable dusts (sugar, flour) or those linked with hazardous industrial chemical reactions and new chemicals. Managing risk through technological and organizational means is the domain of process safety.

At DEKRA, we believe that the process safety framework is sufficiently robust and flexible to accommodate new risks as long as we have the foresight to acknowledge them. With the addition of new tools and adaptations as well as new specialists to provide relevant technical expertise, process safety can contribute to preventing incidents related to the expanding field of biomanufacturing and help mitigate associated risks.

**Learn how we can support your organization with our wide range of process safety services.**

## DR. ARTURO TRUJILLO

Dr. Arturo Trujillo is Global Director of Process Safety Consulting. His main areas of expertise are diverse types of process hazard analysis (HAZOP, What-if, HAZID), consequence analysis and quantitative risk analysis. He has facilitated more than 200 HAZOPs over the last 25 years, especially in the oil & gas, energy, chemicals and pharmaceutical industries.

## DEKRA Process Safety and Chemical Safety

The breadth and depth of expertise in process safety makes us globally recognised specialists and trusted advisors. We help our clients to understand and evaluate their risks, and work together to develop pragmatic solutions. Our value-adding and practical approach integrates specialist process safety management, engineering and testing. We seek to educate and grow client competence to provide sustainable performance improvement. Partnering with our clients we combine technical expertise with a passion for life preservation, harm reduction and asset protection. As a part of the world's leading expert organisation DEKRA, we are the global partner for a safe world.

### Process Safety Management (PSM) Programmes

> Design and creation of relevant PSM Programmes
> Support the implementation, monitoring, and sustainability of PSM Programmes
> Audit existing PSM Programmes, comparing with best practices around the world
> Correct and improve deficient Programmes

### Process Safety Information/Data (Laboratory Testing)

> Flammability/combustibility properties of dusts, gases, vapours, mists, and hybrid atmospheres
> Chemical reaction hazards and chemical process optimisation (reaction and adiabatic calorimetry RC1, ARC, VSP, Dewar)
> Thermal instability (DSC, DTA, and powder specific tests)
> Energetic materials, explosives, propellants, pyrotechnics to DOT, UN, etc. protocols
> Regulatory testing: REACH, UN, CLP, ADR, OSHA, DOT
> Electrostatic testing for powders, liquids, process equipment, liners, shoes, FIBCs

### Specialist Consulting (Technical/Engineering)

> Dust, gas, and vapour flash fire and explosion hazards
> Electrostatic hazards, problems, and applications
> Reactive chemical, self-heating, and thermal instability hazards
> Hazardous area classification
> Mechanical equipment ignition risk assessment
> Transport & classification of dangerous goods

We have offices throughout North America, Europe, and Asia.
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