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PPS Roadmap 2025 – Bayer's Vision and Strategy for the Future of Process and Plant Safety

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At Bayer process and plant safety has evolved over decades and remains a top priority. In 2020 the global Process and Plant Safety Department (PPS) jointly with Corporate Health & Safety (CHS) and divisional product supply representatives developed the PPS vision for the next four years. This task could not be achieved without understanding and addressing the major pain points of the divisional representatives with respect to process and plant safety. Therefore, an online survey and stakeholder interviews were organized resulting in a comprehensive status quo analysis. The results, which confirmed an overall high level of satisfaction with the performance of PPS, were analysed and provide a solid basis for five framework topics of the roadmap: safety performance, business driven innovation, risk-based approach, information sharing, and training. For each of these topics a cross functional and divisional team was formed to develop the concept of the "PPS Roadmap 2025". Finally, these five teams aligned and prioritized topics and goals, resulting in the creation of eleven workstreams to drive the implementation of the roadmap. This paper describes the "PPS Roadmap 2025" and the collaborative process between corporate functions and operating Divisions that led to its creation.

1. Introduction

1.1 Development of Bayer as a Company and Handling of Process Hazards

Since its inception in 1863, Bayer has continuously adjusted its portfolio and corporate structures. What started with two friends experimenting on their kitchen stove, eventually discovering how to make the dye fuchsine, evolved from dye manufacturing over an international chemical company into a life science business. Today, Bayer's core competencies are in the areas of health care and agriculture. In recent years significant divestments and acquisitions have been made that resulted in the current company profile. These changes over the company history also always had an effect on the production network and the associated process hazards. The largest spin-off in recent history was the polymer business, which became an independent entity as Covestro AG in 2015 and was floated on the stock exchange on October 16th, 2015, with Bayer completely selling all stocks over the following years. Covestro was and is active in the polyurethane and polycarbonate businesses as well as in coatings and adhesives. Its manufacturing sites were characterized by large worldscale plants, often continuous manufacturing with batch processes only in the polyether and coatings and adhesives business units. Also, a large portion of the products were based on phosgene chemistry with the associated process hazards that were handled carefully and responsibly. Also, many of the associated basic chemicals were often part of the integrated supply chain e.g., chlor-alkali electrolysis, different recycling routes for hydrochloric acid or generation of CO and hydrogen. All these processes are no longer part of Bayer's business.

Instead, Bayer acquired Monsanto, a leading supplier of seeds and traits as well as accompanying agrochemicals. Closure of the deal was in 2018 after regulatory approval of the deal. A post-merger integration project was set up to harmonize the internal regulatory landscape and provide a common framework for the chemical active ingredient production sites as well as the many seed breeding and treatment sites all over the world. Also, as part of the regulatory approval Bayer had to divest parts of its Crop Science business. Consequently, the former vegetable seed business as well as some active ingredients such as glufosinate and related products were sold to BASF.

Today, Bayer is a global life science company, consisting of three divisions: Consumer Health, Crop Science and Pharmaceuticals. All these changes led to a manufacturing network that can be characterized by these types of operations and sites (see Figure 1 for illustration):

- Active Ingredient (AI) production integrated chemical sites, where agrochemical active ingredients are
 produced in batch and sometimes continuous processes; often these operations fall under applicable major
 hazard prevention programs such as the European SEVESO-III-Directive, the German Major Accidents
 Ordinance (i.e. "StörfallV", German implementation of the SEVESO-III-Directive) or the U.S. OSHA
 regulations;
- Active Pharmaceutical Ingredient (API) production mostly batch processes, all under GMP conditions, providing APIs for Bayer's Consumer Health and Pharmaceuticals divisions; also, often subject to the above named hazard prevention programs;
- Formulation, Filling, Packaging (FFP) sites where finished products or intermediates are produced with the Als or APIs and other substances, mostly batch operations, characterized by a larger number of mechanical operations especially in the area of pharmaceutical "secondary manufacturing" with tabletting, blistering and packaging; oftentimes more discrete manufacturing with corresponding machines and package units than chemical reactors, distillation columns and the like;
- Seed Station sites a broad variety of operations where seeds are being bread, treated, prepared and/or packaged; sites can vary from the size of a farm to large industrial operations e.g., in case of seed processing sites for row crops like corn; relying heavily on mechanical unit operations, few if any chemical processing steps.

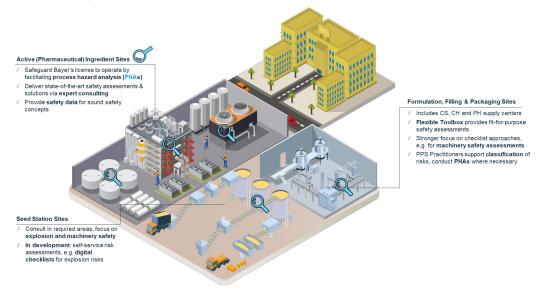


Figure 1: Typical types of operations and associated risk assessment methods

1.2 Organization and Roles and Responsibilities with Respect to Process and Plant Safety

Following the principle of "separation of powers" different roles and responsibilities have been assigned to different organizations within Bayer. This is best depicted by the triangle in Figure 2:

- **Product Supply (PS)**: these are the production areas of each of the three divisions Consumer Health, Crop Science and Pharmaceuticals, responsible for safe and reliable operations;
- Corporate Health, Safety and Environment (CHS) is responsible for governance and reporting;
- **Process and Plant Safety (PPS)** is part of the enabling function Engineering & Technology and responsible for PPS operations and expert advice.

Based on these roles and responsibilities different working relationships between the different parties ensue as is shown along the sides of the triangle. CHS and PPS jointly develop strategy & objectives and define a management system including a training program. This comprehensive process safety management system as well as the global Bayer TOPPS ("Top Performance in Process and Plant Safety") initiative were described by Gasche et al., 2016. Finally, the governance function CHS also closes the PDCA loop of the management system with audits and performance reviews. All parties come together in the so-called PPS Panel at the Industrial Operations Committee ("PPS Panel @ IOC") to set strategic direction and agree on initiatives of global and cross-divisional relevance (see centre of the triangle).

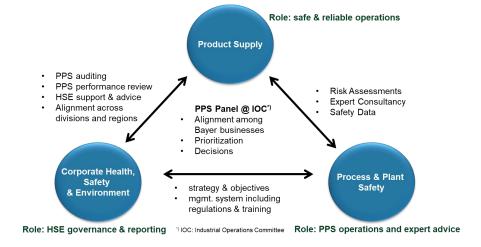


Figure 2: Split of roles & responsibilities between different stakeholders within the company

2. Determining the Status Quo

With the significant changes in portfolio during the past 5 years the organization was busy at first to digest these changes and ensure that no critical risks were unmitigated and that the regulatory and operational framework was consistent and ensured safe operations. As this phase came to an end in 2020, it was time to look ahead and set the frame for the next phase of development. But to do so, the status quo had to be determined to have a sound starting point. It was decided to combine a quantitative with a qualitative assessment. This should ensure that the "voice of the customer" was incorporated into the roadmap development that followed.

2.1 Stakeholder Interviews

The qualitative in-depth assessment was done with 15 interviews of key stakeholders. Interviewees were selected from senior management positions with different roles in the Product Supply organizations of the three divisions. Each structured interview was conducted by two interviewers from the CHS and PPS functions. This was done so that a lively discussion could ensue, and replies were properly documented, nevertheless. Results were captured digitally, some questions were the same as in the online survey (see following section), some were more open to allow for more differentiated replies and follow-up questions. The stakeholder interviews ensured high-level buy-in for the entire process and ensured that the PPS roadmap was well synchronized with other major relevant initiatives in the Product Supply organizations.

2.2 Online Survey

To make sure a larger portion of the global PPS community could express their satisfaction level and improvement ideas, 241 colleagues were invited to an online survey. These were selected from site and plant managers, HSE and PPS functions or technical or engineering roles at the various sites globally. A response rate of 68% over a period of 10 working days already demonstrated a high level of commitment to the topic.

2.3 Results

Overall feedback to both, the stakeholder interviews as well as the online survey, was very positive. The safety performance overall as well as the general satisfaction level with the central functions of CHS and PPS was well above 90%. This indicated that there was a solid base to build on and that apparently no major deficiency required immediate attention. Only when going a bit deeper, e.g., inquiring about the level of operational support for routine operations or projects, also some concerns were raised, more so in the online survey than in the stakeholder interviews (see Figure 4).

Participants were also asked to rank initiatives and ideas that were either already ongoing or had been proposed to the organization recently with respect to process and plant safety. The topic deemed most important was that of a risk-based approach to PPS. The idea here is to differentiate the methods and tools applied in risk identification and mitigation depending on the risk profile of an operation. Rather than "one size fits all", where in the past there were also examples of a full-blown HAZOP being applied to an off-the-shelf packaging line, the participants saw a need to focus scarce PPS resources where it matters most and provide other solutions and support in other areas.

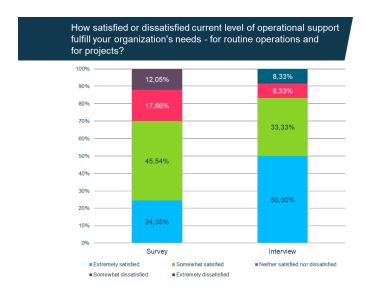


Figure 3: Satisfaction with operational support by CHS and PPS functions

The remaining questions covered the different areas of expertise and highlighted the conflicting targets of costs, operability, and regulatory requirements in the context of process and plant safety (see Figure 5). There was for example a clear request to maintain the high level of subject matter expertise for PPS. On the other hand, better understanding of the divisional business requirements was seen as an area of improvement: only when the economic and strategic situation of a division and its implications on the product supply organization is clear, planning of PPS resources or also alternative options in achieving a required safety level can be properly discussed and evaluated. Many free-text comments complemented the online survey and were evaluated, clustered, and presented back to the PPS Panel for final discussion and prioritization.



Figure 4: Process and Plant Safety requires a broad range of expertise and needs to ensure cost, operability and regulatory requirements

3. Roadmap Development

3.1 Defining the Vision of the PPS Roadmap 2025

Based on the survey results a program called "PPS Roadmap 2025" was developed jointly with participants from all organizations of the triangle in Figure 2. In this collaborative approach a target state was derived that served as the vision of the "to be state". It is described by these five key elements:

- 1. Data-driven and risk-based approach to PPS
- 2. PPS mindset to be strengthened into direction of competitiveness and operability of Divisions
- 3. Focusing on and ensuring PPS expertise in areas critical for Bayer
- 4. Agile understanding and response to divisional business requirements
- 5. Collaborative relationship between PPS and Operations

3.2 Framework

With this vision state in mind, the teams clustered results from the survey into five framework topics: performance, business-driven innovation, risk-based approach, information sharing, and training. For each of these framework topics a vision statement was formulated, and key objectives identified. For example, for the first framework topic "performance", the vision statement is:

"In 2025 Bayer is recognized for its process and plant safety performance contributing to the safest and healthiest place to work at."

From the vision statement key objectives can then be derived, which address the "WHAT?"; again, to use "performance" as an example, the key objectives were defined as:

- involvement and commitment of leadership,
- fostering collaboration and communication and
- reduction of process complexity.

In a next step, the teams looked at HOW this could be achieved and started to identify deliverables of the program, both short-term and long-term and assigned preliminary target dates to them (WHEN?).

With the vision defined and objectives and deliverables identified for each of the five framework topics, the implementation then could be structured in corresponding workstreams

3.3 Workstreams

Overall, eleven workstreams put actions and teams behind the framework concept. Taking the framework topic "business-driven innovation" as an example, associated workstreams address the topics "Digital Transformation" or "Externals@PPS". Figure 6 gives an overview of all workstreams associated with the five framework topics. Teams were assigned to each workstream, a steering committee was established with leaders from the PPS and CHS functions, and key results are being reported to the "PPS Panel @ IOC", where also fundamental decisions are being made (see Figure 2).

4. Implementation: Examples of Roadmap Projects

Implementation of the roadmap started after approval by the PPS Panel@IOC in spring of 2021. Some workstreams integrated already ongoing activities. For example, the workstream "regulation landscape" continued an effort that was already under way since the post-merger integration project after the Monsanto acquisition. While in the beginning focus was more on compliance and ensuring all regulatory requirements were properly met by joining the internal regulatory policies and procedures of the previously independent companies, now attention is shifting towards efficiency and simplification.

4.1 Use of External Partners "Externals@PPS"

Bayer has implemented several efficiency programs in the past few years to free up cash flow for investments in core areas of its Divisions (see annual report 2020, Schäfer (2021)). Part of these programs was to focus internal resources on activities that gave Bayer a competitive advantage in its businesses. This on the other hand meant to use external resources where they are available in the market in the quality required.

The workstreams "Externals@PPS" systematically screened different areas of activity in the scope of Process and Plant Safety for opportunities of external involvement. For each expert function such as pressure safety, consequence modelling or explosion safety a scope of work was defined, where necessary a market analysis performed together with procurement, and external providers screened. There were also core activities identified that were purposely kept in-house, e.g., parts of chemical & thermal safety, where close interaction with Bayer's R&D departments and sensitive handling of intellectual property is required and fast, integrated teams from PPS and R&D become a competitive advantage. Also, it is Bayer's philosophy to conduct HAZOP studies only with in-house moderators, called PPS Practitioners (see also Gasche et al., 2016), who follow a strict internal certification program to ensure consistent standards across all Divisions and regions. Nevertheless, also in the context of HAZOPs supporting activities can be done with external support, which then was incorporated into this workstream. The workstream already resulted in selection of some preferred suppliers who have been set up in the internal procurement systems with predefined scope of works. This significantly simplifies the ordering process for sites and plants for these types of services and ensures a consistent quality of deliverables.

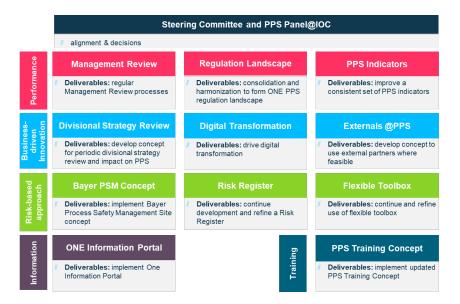


Figure 5: Five framework topics and eleven workstreams form the PPS Roadmap 2025

4.2 Digital Transformation in Context of Process and Plant Safety

This workstream, also called "Digital@PPS", combined some ongoing activities, and provided a holistic framework to better coordinate and prioritize activities. As a result, it is a mixture of projects and initiatives, some more addressing basic operational requirements such as the introduction of a new LIMS in the Safety Lab to achieve a vision of the "paperless lab", certified to GLP and ISO 17025. Another big project had been discussed for quite some time previous to the PPS Roadmap 2025 but now was tackled and became an important foundational infrastructure: the introduction of one global, cloud-based documentation system for all of Bayer's HAZOP studies. Again, a market study was performed, a beauty contest held and finally a supplier selected. The migration of old HAZOP studies into the new tool was addressed as a separate package and an engineering service provider selected to support this process. Meanwhile the cloud-based system has gone live after Bayer-specific configuration was implemented and tested on a development system. The project team is preparing for the first HAZOP studies by training PPS Practitioners as well as key users at the sites.

Besides these two major initiatives a range of other tools and solutions are being steered by this workstream. The maturity of these digital tools varies, some are more in a proof of concept or experimentation phase, others are also dedicated sub-projects like the introduction of digital checklists to simplify the generation of explosion prevention and protection documents (EPPD) for operations at seed sites or the use of augmented reality (AR) glasses for remote assistance. The later initiative got a special boost in the COVID pandemic, where travel to remote sites was no longer possible or very restricted and AR platforms allowed global experts to support local teams remotely.

5. Conclusions

Building on a long tradition in process and plant safety (PPS), Bayer has started on a journey towards a more digital, business-oriented approach to PPS with the PPS Roadmap 2025. Maintaining a leading position in process and plant safety while making the underlying processes and procedures more efficient requires a coordinated effort and is built on a thorough stakeholder analysis. This ensures also buy-in of all involved parties from the beginning. The roadmap is structured in five framework topics and eleven workstreams, which are coordinated by a sounding board and steered by the PPS Panel at the Industrial Operations Committee, where the central governance function, the enabling PPS function and senior management of Bayer's product supply organizations come together.

Reference

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