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Aim and Scope

The Journal of Business Chemistry (JoBC) focuses on current developments and insights at the intersection of management and chemistry, biotechnology or pharmacy.

The JoBC provides an international forum for researchers and practitioners in companies, research institutes, public authorities, consultancies or NGOs to present and discuss current challenges as well as potential solutions in an interdisciplinary manner. Thus, the JoBC aims to foster the dialog between science and business, to support management practice in the chemical and pharmaceutical industry and to indicate where further research from academia is needed. The JoBC offers high quality publications with academic standards, a fast publishing process and global reach. With this multidisciplinary and boundary-spanning approach, the JoBC intends to become the leading journal for decision makers in the chemical and pharmaceutical industry.

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Letter from the Editors

Crises - come to stay ?

Crises have kept the world in turmoil since the beginning of 2020. Currently, there is no end in sight and the chemical industry is in crisis mode. Very high energy and raw-material costs slowed down global industrial production or significantly reduced it. In some cases, the high energy costs even made production unprofitable. The topic of supply security has moved to the forefront in the past months, especially in Germany which was highly dependent on Russian energy imports. But how can we best reach it? Delaying the coal phase-out, extending the operating times of nuclear power plants, importing LNG, accelerating the expansion of renewable energies - opinions differ widely. Likewise, there is the question of how the interplay between sustainability and crisis will develop - two key topics that are also reflected in the articles in this issue, albeit separately from each other.

The research paper "Improvising in a crisis: an empirical study of NPD teams in the field of chemistry and chemical engineering" deals with organizational crises which have the potential to threaten a company´s survival. While the focus in current crises is usually on communication with external stakeholders, Yassir M. Samra´s, Gary S. Lynn´s, and Richard R. Reilly´s research takes a different perspective. They investigate the role of new product development (NPD) teams in delivering a firm from an organizational crisis. The authors deal with the question of whether a perceived crisis by the NPD teams fosters successful new product development. The results, based on data from 55 firms in the chemical industry, indicate that a perceived crisis by the NPD team is positively correlated with project outcomes of speed and success, bringing about improvisation, but does not moderate the relationship between improvisation and NPD project outcomes.

The commentary "How chemicals can serve people sustainably without polluting the planet: through common objectives, integration, and more effective cooperation" written by Hans-Christian Stolzenberg, Christopher Blum and Anja Klauk points out the problem of global chemical pollution that is currently not yet sufficiently addressed. A brief overview of previous efforts to advance chemical management is given and the great importance of dialogue and collaborative efforts among all stakeholders and affected industries is emphasized.

Timo Flessner´s and Daniel Götz´s commentary "Current trends and challenges in the pharmaceutical industry - we are here to make a difference" gives an insight into current developments in the pharmaceutical industry. At first, the authors elaborate on megatrends and challenges e.g., the growing and aging population, increase of "prosperity" diseases or supply chain disruptions as the impact of the pandemic. Afterwards, they explain which opportunities arise and what needs to be taken into account.

Nora S. Griefahn´s commentary "Cradle to Cradle: Why we need to rethink the way we produce" presents an impulse to rethink how products are designed. "Cradle to cradle" is based on the concept of circular economy and places particular emphasis on the selection of suitable materials as all resources circulate either in a biological or technical cycle. Additionally, a short outlook on how "Cradle to Cradle" could be implemented in the chemical industry is given.

Please enjoy reading the third issue of the nineteenth volume of the Journal of Business Chemistry. We are grateful for the support of all authors and reviewers for this new issue. If you have any comments or suggestions, please do not hesitate to contact us at contact@businesschemistry.org. For more updates and insights on management issues in the chemical industry, follow us on LinkedIn: www.linkedin.com/company/jobc/.

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Research Paper

Yassir M. Samra*, Gary S. Lynn, Richard R. Reilly*****

Improvising in a crisis: an empirical study of NPD teams in the field of chemistry and chemical engineering

Organizational crises can ruin a firm's reputation and threaten its survival. The field of chemistry and chemical engineering has experienced this from the classic example of the Tylenol scare to Deepwater Horizon. In most cases, the firm is focused on communicating outwardly with external stakeholders but what about the rest of the firm? New product development (NPD) has delivered firms successfully from such financial peril and therefore can be instrumental in being a solution to a crisis. In this study, new product development teams are investigated to see their role in delivering a firm from an organizational crisis. Using an improvisational NPD approach towards dealing with a crisis, this study looks at teams at 55 firms that are associated with the field of chemistry and chemical engineering to determine whether a perceived crisis by the NPD team can be a motivating factor on the successful outcome of the new product being developed. The results indicate that a perceived crisis by the NPD team is positively correlated with project outcomes of speed and success, brings about improvisation, but does not moderate the relationship between improvisation and NPD project outcomes.

1 Introduction

Organizational crises happen infrequently but when they do, they threaten the survival of the firm. The history of organizational crises is primarily focused on firms associated with the fields of chemistry and chemical engineering. Notable crises where product tampering was suspect include Johnson & Johnson's Tylenol Scare (Pearson and Mitroff, 1993), Odwalla's E. coli outbreak (Choudhary, 2012), Coca-Cola's recall in Europe (Johnson and Pappas, 2003), and lead contamination of Nestle's Maggi noodles in India (Srivastava, 2019). In such cases, each firm suffered initially as they inspected and improved their products in question. Other firms such as Union Carbide's Bhopal gas leak (Weick, 1988), Exxon-Mobil's (then Exxon) Alaskan (Pearson and Mitroff, 1993) and BP's Gulf of Mexico oil spills (Halkos and Zisiado, 2020) brought about crisis management teams to quell the situation. In such cases, the firms kept operating, nonetheless. New product development teams within these firms were still working.

While crises may be debilitating, NPD can play a vital role to deliver the firm from a crisis. NPD team members perceiving a crisis, have the unique opportunity of taking on marginal risk since there's little left to chance since the crisis has done significant damage to the health of the firm. Along with

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proper management of the NPD process, a new product can be successfully launched, which becomes a solution to the situation (Akgün et al., 2006). For example, prior to Nintendo's Wii console, the firm had yielded considerable market share to Sony and Microsoft, putting the firm's survival in peril. In 2006, falling sales and a shrinking market share called for a drastic change. Nintendo developed and launched the first gaming console that involved the gamer using his/her body as a control for the avatar. This radical innovation revitalized Nintendo and made it a major player in its industry (Binns et al., 2014). While this example is not chemistry related, the example of Johnson & Johnson's NPD team bringing about a new way of coating and packaging Tylenol certainly is. Following this logic, this research suggests that NPD can be a solution and therefore a key outcome of a crisis.

The innovation literature relating to NPD provides insights into many best practices of successful NPD teams. The commonly adopted idea-to-launch process implies certain predictability or a somewhat measurable future. However, the environment is not always stable, which has been highlighted in past studies (e.g., Maltz and Kohli, 1996; Moorman and Miner, 1998). In a crisis, old rules generally do not apply (Starbuck et al., 1978). This study argues that because a crisis is an unplanned surprise event, an improvisational approach to NPD is more appropriate than a traditional one.

This research contributes to the field of crisis in different ways. Despite its importance, extant crisis management literature focuses on how firms deal with external stakeholders or how the management reassures employees. The focus is primarily on public relations and reestablishing trust or the firm's reputation. This research attempts to add that NPD teams can assist in delivering a firm from a crisis. Furthermore, since organizational crises are generally associated with firms where strict quality control measures are enacted (i.e., the use of chemicals), this study shows that a perceived crisis by an NPD team can help deliver a firm from the threatening level in such an environment. In addition, the NPD literature focuses on improvisation to improve project outcomes, but little exists on its use in a crisis.

2 Conceptual Framework

Crisis and crisis management

The dictionary defines a crisis as an unstable or crucial time in which a change is impending (www.merriam-webster.com). A classic definition of an organizational crisis is an unanticipated, threatening situation, that requires an immediate response to quell (Herman, 1963). Although the crisis is an actual event, it can be a measure of perception that the value of the organization is seriously threatened (Billings et al., 1980). Table 1 shows how different authors define the term crisis in organizational settings. Almost all agree that a crisis is a threatening situation to a firm's existence that necessitates a sense of urgency based on either a surprise event and/or an uncertain environment. This uncertainty

Table 1 Organizational crisis definitions.

Author	Urgency	Surprise	Threat/Danger to Existence	Uncertainty
Barnett & Pratt (2000)			X	
Billings et al (1980)	X	X	X	X
Heath (1995)	X		X	
Hermann (1963)	X	X	X	
Kim (1998)			X	
Pearson & Mitroff (1993)	X		X	X
Shrivastava et al (1988)			X	
Smart & Vertinsky (1984)	X			X
Starbuck et al (1978)	X	X	X	
Weick (1993)	X		X	
Weick (1988)			X	X

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creates a void of information available and thus confidence in decision-making is reduced (Plous, 1993).

Research also suggests that people may not make a distinction between crises that pose latent threats and those immediate (Barnett and Pratt, 2000). Whether a crisis exists may not be as critical, but if it exists in the minds of many people then its consequences will be real (Galtung, 1984). This is particularly crucial to organizations because they respond to the environment based on how they perceive it can be managed (White et al., 2003). Extant literature of crisis management has been done across various fields, such as consumer packaged goods (Johnson and Peppas, 2003), tourism (Hajibaba et al., 2016), pharmaceuticals (Priporas and Vangelinos, 2008), and automobiles (Fan et al., 2013). Crises can be initiated by various events, including product recall (www.cpsc.gov), economic recession (Fan et al., 2017), political and social change (Martins, 2015; Szántó, 1994), natural disaster (Quarentelli, 1988), and so forth.

Furthermore, Penrose (2000) asserts that firms perceive a crisis not only as a threat but as an opportunity. Successfully resolved crises involve the firm restoring its reputation and bringing back customers. Siomkos and Shrivastava (1993) find that firms need to face the crisis and not avoid it to survive. While they may have a financial burden, successful firms must be capable of dealing with the emotional fallout caused by a crisis. Mitroff et al. (1989) suggest that while most firms are not prepared for a crisis, those who are, often have key personnel that serve to help the firm navigate the crisis to emerge successfully. Effective crisis management involves detecting potential problems and mitigating the risk of what can and cannot be managed. Potential problems that can be fixed will result in no crisis occurrence; however, situations that cannot be planned for and threaten the firm can result in an actual crisis (Mitroff et al., 1987).

Once a crisis has emerged, it is up to the firm on how to manage it. Affected firms can have teams that interact with each other in an effort to bring about a positive change and become more sustainable. Since a crisis is something new, remaining silent during a crisis is not an appropriate strategy (Xu and Li, 2013). Considering that a crisis is often perceived as being threatening, any attempt to manage the situation is better than doing nothing. In fact, an attempt to manage the crisis likely results in a positive outcome as the current environment may have already had a negative impact on the firm.

Crisis and improvisation

From Table 1, some authors define an organizational crisis is a never-before-seen, surprising situation that can cripple a firm and as such, a normal reaction cannot be the answer to minimizing the damage (Starbuck et al., 1978). Therefore, a crisis requires a creative response to abate. The limited amount of time a crisis affords the affected firm, warrants an improvisational approach to the situation. To define improvisation, Barrett (1998) describes improvisation as coming up with novel responses without a set plan and Bastien and Hostager (1988) define improvisation as inventing and executing new ideas. This stream states that improvisation is a deviation from normal routines or behavior. This is synonymous with the definition of creativity (Amabile, 1996). An example of this is when an organization designs a creative marketing strategy (Moorman and Miner, 1998). The idea may be new and innovative, but it is not necessarily improvisational; improvisation is synonymous with creativity only under a time constraint or pressured situation. To better define improvisation, Crossan and Sorrenti (1991) define it as intuition guiding action in a spontaneous way. Cunha et al. (2001) define improvisation as the conception of action as it unfolds. Perry (1991) defines improvisation as formulating and implementing strategies in real time which is echoed by Weick (1993) as improvisation has no distinction in time between composition and performance. Moorman and Miners' (1998) definition of improvisation states that improvisation is when the planning and execution converge in time so that they occur simultaneously.

Therefore, the ability to accept real-time information as true and act upon it with little (or no) planning constitutes the act of improvising. This is sometimes referred to as managerial fire-fighting (Smart and Vertinsky, 1984) as an organization seeks to find alternative solutions to remedy the crisis. However, high-pressure environments are generally considered to be infertile grounds for improvisation (Cunha and Cunha, 2001) as they do not provide sufficient time to think creatively (Amabile, 1996). Weick (1993) asserts that when people are put under pressure, they respond in their most habituated ways which doesn't necessarily lead to positive outcomes. On the other hand, since a crisis is generally a new situation, requiring a new response, improvisation is the answer to dealing with the threatening situation.

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Crisis and new product development

Despite its threatening nature, a crisis can motivate firms to achieve superior performance. Chemically related firms are more prone to an organizational crisis as they attempt to ensure strict quality control measures. However, when a failure strikes, it can be devastating and threaten the firm's existence like in Union Carbide's case where, toxic gas was released into the atmosphere on the people of Bhopal, India. Over 3,000 people died soon afterwards and over 100,000 people have since been affected from breathing the gas. The firm paid millions in damages to the Indian government but the CEO at the time hadn't answered to criminal charges. On the other hand, Johnson & Johnson, after hearing that 5 people died from consuming their product, immediately initiated a nation-wide recall. This prompted the firm to ultimately create new packing for Tylenol and a few years later, after another death, the firm initiated another nation-wide recall before introducing new coatings to make their product even more tamper resistant. The two preceding examples, each dealing with the field of chemistry, show how firms can manage and mismanage a crisis (Samra, 2005).

NPD teams, while may not be directly fighting the crisis, can certainly respond to and help the firm emerge from it. In NPD, teams require not only a strategy for risk taking but also one for risk management to select the projects that have the most potential. The ability to manage risk throughout NPD is vital. It is suggested that NPD teams that can successfully do so are associated with positive project outcomes (Mu et al., 2009). However, research in the field of crisis tends to focus on how to prevent or recover from one (Lin et al., 2006). Effective teams in crisis settings contain members who know their role and engage in more concise behavior and interaction (Stachowski et al., 2009). In NPD, a crisis can be in the form of a sudden change in the environment such as a change in customer tastes after a new product has been launched, a new regulation imposed on firms in a particular industry, or a product recall. Information is often limited as the firm decides which direction it wishes to pursue. As such, NPD team members can experience stress and anxiety due to the threatening nature associated with a crisis and the lack of information as it unfolds. This can lead to inflexibility and poor decision-making by NPD teams as their level of anxiety increases during a crisis (Akgün et al., 2006). On the other hand, NPD team members who are familiar with their roles as well as those of their team members should exhibit more interaction and coordination in the NPD process, which can lead to a more favorable outcome.

While crises are generally addressed by senior management, lower-level organizational members – in this study, NPD team members – should also respond to such a threatening situation to assist in determining their firm's survival. An example of this is the case where a "crisis" was fabricated by the government of South Korea through imposition of new regulations designed to spark the Korean vehicle industry. While many executives did not see these new regulations as a significant crisis, employee perception of crisis was high. Because of it, Hyundai was able to design and develop a new Korean car, thereby moving from assembling foreign cars to a more integrated design and manufacturing firm (Kim, 1998). This case well reflects the role of NPD and engaged team members in crisis and how their perceived crisis can serve as a trigger for innovation.

Few studies have empirically explored the effects of crises on NPD. Akgün et al. (2006) examine the perception of crises by NPD team members and find that it is positively linked to creating new knowledge and processes but do not explore the direct effect of a crisis on project outcomes. In another study, Akgün et al. (2007) find that top management support positively moderates the relationship between perceived crisis and new product success. In both studies, the crisis was a measure of perception. Likewise, the term perceived crisis is adopted in this research to describe the extent to which people acknowledge a crisis and respond to it in the NPD process.

In summary, for a crisis to be managed, the NPD team and its members should be considered as an appropriate response vehicle as their decisions are not directly affected. In such a situation, the NPD team can manage the crisis by developing a successful new product.

Improvisation and new product development

Common formal processes in NPD tend to be associated with stable environments and with incrementally innovative products. In such times, NPD is predictable, and the technology associated with the new product is known. Therefore, this structured approach is very applicable,

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and the empirical results indicate its association with successful project outcomes (Cooper and Kleinschmidt, 1986, Shepherd and Ahmed, 2000). But NPD isn't always this easy. Changes in the environment and technology are ever present and a new approach to NPD is warranted. Cooper (1994) proposed fundamental changes to the structured approach to include one that is more flexible. Cooper and Kleinschmidt (1995) defined a flexible NPD process as one where stages and decision points could be skipped or combined. They empirically support that flexibility at the firm level is significantly associated with positive new product performance.

But proficiency throughout a specific NPD process is not a universal answer. Brown and Eisenhardt (1995) have found other factors that may contribute to the likelihood of new product success such as having senior management involvement and support, a clear vision, and team stability. Scholars have also suggested that sequential models may also be too general to fit the demands of some products and services. For instance, structured models may be inappropriate for products requiring extraordinary speed, secrecy, address specific problems, or entail short production runs (Gwynne, 1997, Donada et al., 2021). They have also been shown to be rigid, and as a consequence, may reduce flexibility (Rosenthal, 1992). Indeed, scholars have suggested that they may be too structured for quickly changing competitive environments (Cooper 1994; Hoopes and Postrel 1999). As a response to some of the drawbacks of earlier sequential approaches - namely: rigidity and speed, a new approach to NPD emerged. This new improvisational approach focused on giving teams the ability to think and execute faster to get products out to the market (Moorman and Miner, 1998).

Few industries remain stable yet those that are in constant change require a far more flexible approach to NPD. This new model elevates flexibility from adapting to a situation to improvisation which refers to the deliberate and substantive fusion of the design and execution of a novel production (Miner et al., 2001). The use of improvisation is ideal for new situations and is far more applicable to the field of crisis than any sequential approach.

In a widely cited study on new product development activities at two midsize firms, Moorman and Miner (1998) found that improvisation can be an effective tool when an organization faces environmental turbulence that requires action. One of the important findings of their research was that improvisation occurs with substantial regularity in the product development process. Also, it is important to mention that while improvisation may be attributed to start-up firms and small business environments, the two organizations in the authors' studies were two well-established organizations with formal structures, roles, and procedures.

Hypotheses: Crisis & Improvisation

In threatening situations, it is all too easy to rely on what one knows or what one has been trained to do (Barthol and Ku, 1959). This is seen in the airline industry where a captain does not rely on individual action but rather on the contingency plans that have been developed for the specific circumstance. Evaluation of pilot error accidents have found that the situation was (in some cases) worsened by relying on individual action (Anonymous, 2002). Heath (1995) proposes that the more an organization experiences disasters, the more routine will be their response. The situation of an airline's engine failure indeed threatens the lives of those on board, but prior planning for this circumstance (and others) can limit the damage (Quarantelli, 1988). Yet it is impossible to have a structured response for every contingency since the number of possible crises is virtually infinite (Weick, 1988). In this dangerously unfamiliar situation, some degree of trial and error is present and as Bateson asserts: "An explorer can never know what he is exploring until it has been explored" (Weick, 1988). Therefore, normal reactions to a crisis do not necessarily work because of the entirely new situation the organization is facing. In fact, Starbuck et al. (1978) claim that a situation cannot be deemed a crisis if normal behaviors produce improvements. Therefore, in returning to the airline example of engine failure, it is realized that this situation should not be a crisis for the airline crew but perhaps is perceived as a crisis to its passengers.

Another example of a crisis event was the infamous Mann Gulch fire (Weick, 1993) where many of the firefighters perished. At first, the team of firefighters attempted to pass the gulch and move towards a river that would lead them to safety. As the flames quickly approached, the team leader, Dodge, decided to change direction and attempt to lead his crew up a steep hill to avoid the approaching flames but was unsuccessful. After relying on logical solutions, the

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final act (of desperation) of Dodge (and to the amazement of his crew) was that he ordered his crew to abandon their firefighting tools and lit a fire in front of them and ordered them to lie in this ring of fire with him. No one heeded their superior's call and while they tried to outrun the fire, only two other members had survived unburned (a third survived but due to his burns, died the next day). It took 450 men and five days to get the 4,500-acre Mann Gulch fire under control, a fire that was originally classified as being between 10 to 99 acres. The Forestry Service held an inquiry and determined that had the crew obeyed Dodge's order to lie in the escape fire, they would have been saved.

The reason for a detailed description of this event is to illustrate that high-pressure environments are generally considered to be infertile grounds for improvisation (Cunha and Cunha, 2001) as they do not provide sufficient time to think creatively (Amabile, 1996). Weick (1993) asserts that when people are put under pressure, they respond in their most habituated ways. He continues by saying, "What we do not expect under life-threatening pressure is creativity" (Weick, 1993). Therefore, we can conclude that under times of crisis, the one thing we don't expect is improvisation, however if it is done, it can be very rewarding.

Few studies in the NPD literature have attempted to empirically establish an association between crisis and improvisation (Akgün et al., 2007, Samra et al., 2019). While several factors associated with new product success have been observed in turbulent environments, they have not been tested in crisis situations. It is important to understand the distinction between turbulence and crisis. The dictionary defines turbulence as a state of unrest or disturbance, while crisis is defined as an unstable or crucial time or state of affairs in which a decisive change is impending (www.merriam-webster.com), thereby implying that a crisis has a much higher degree of threat. Industries that are constantly turbulent and the successful firms in these industries have acclimated themselves to change (Brown and Eisenhardt, 1997) and therefore turbulence becomes part of their doing business. Crisis on the other hand can develop from a steady state. When a crisis does occur, the rules essentially get thrown out the window (Weick, 1993) and the NPD team must arrive at novel solutions quickly. Thus, as the literature accepts that improvisation can be a useful tool throughout NPD and a crisis, the following is hypothesis is presented:

Hypothesis 1: For a firm in crisis, higher threat levels as perceived by the NPD team will be positively associated with higher levels of improvisation by the NPD team.

Hypotheses: Crisis & Outcomes

Since a crisis is a threat to survival, urgent (re)action is necessary to abate the situation. An organization typically has neither the luxury nor the time to analyze several responses nor to develop a manner with which to execute them in hopes of delivering itself from the crisis; rather the crisis will worsen the situation if action is not swiftly taken.

In sports (particularly American football), there are countless moments when a team sits on the brink of elimination with little time left to score and manages to overcome enumerable odds to become victorious in the most unorthodox fashion (Katz, 2001). One may argue that in sports, the perception of a crisis is not as threatening as it might be in an organizational setting (lives aren't being lost and there's always next season). But the lesson is still the same; in a crisis, time is limited before the situation exacerbates and all is lost. A perceived crisis can be successfully resolved by immediately addressing the threatening nature in hopes of a successful resolution. A company can prepare only so much for a crisis, but it can never eliminate the possibility of one occurring. Therefore, if a crisis does exist, then a rapid response is required to quell the situation. If left unattended, the crisis can have further detrimental effects on the organization.

In NPD, crisis can be a good thing as it presents the NPD team with an opportunity to shine and deliver the organization from its (financial) peril. To do so, the NPD team must react immediately to the crisis and develop (and launch) this new product quickly. Formally stated:

Hypothesis 2a: For a firm in crisis, higher threat levels as perceived by the NPD team will be positively associated with speed to market.

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In addition, many NPD studies have shown a strong correlation between speed and success (Lynn et al., 1999; Cooper and Kleinschmidt, 1995; Samra, 2005). Therefore, if indeed a crisis is a good thing, then it will be positively correlated with both speed and success. Thus, the following is hypothesized:

Hypothesis 2b: For a firm in crisis, higher threat levels as perceived by the NPD team will be positively associated with higher levels of success in new product development and launch.

Hypotheses: Improvisation & Outcomes

With regard to the NPD literature, it has been empirically tested that proficiently using a structured approach will yield positive outcomes (Cooper and Kleinschmidt, 1986, Cooper and Kleinschmidt, 1987; Lynn et al., 1999; Millson and Wilemon, 2002; Shepherd and Ahmed, 2000). However, based on the preceding arguments, if this is the standard traditional approach to NPD, then it should not have any positive significance on the outcome of a new product in a crisis. On the other hand, there is support for the use of improvisation throughout new product development in uncertain and turbulent environments (Brown and Eisenhardt, 1997; Eisenhardt and Tabrizi, 1995). But a crisis is far more threatening in nature than a turbulent or uncertain environment because it contains not only an uncertainty factor but also the perception that the entire organization's survival is in question from this perilous situation. In fact, turbulent environments can be a part of the NPD team's industry (Eisenhardt and Tabrizi, 1995) as the more exposed the NPD team is to change, the more likely they will be able to adapt to rapid changes associated with turbulent environments.

As for uncertain environments, they are the midpoint between a turbulent environment (where changes can be anticipated) and crisis (where the threat level is extremely high and imminent). Uncertain environments are uncharted for NPD teams and differ from turbulent environments as they are not simply changes that the team can adapt to, rather, they are environments where the NPD team must decide if they wish to enter based on unavailable information. In a crisis, the company in question is in peril and it is imperative to respond to the situation at hand. The NPD team can still function in this newly created uncertain environment, but like the rest of the firm, it may feel threatened by the onset of the crisis. As successfully resolved crises require creative answers, the NPD team can improvise to be successful. As previously mentioned in the preceding hypothesis, both speed and success are highly correlated and since a crisis can occur at random to any organization and it is completely unpredictable and unrecognizable as a potential threat, the following hypotheses are presented:

Hypothesis 3a: A firm in high crisis will exhibit a stronger relationship between improvisation and speed in the NPD process than a firm in low/no crisis.

Hypothesis 3b: A firm in high crisis will exhibit a stronger relationship between improvisation and new product success than a firm in low/no crisis.

3 Research Design

Methodology

Figure 1 illustrates the overall picture of the relationship of the 3 variables: the level of perception of a crisis, improvisation, and project outcomes speed & success. Hypotheses 1 & 2 suggest that as the perception level of a crisis increases, so does the frequency of improvisation as well as the likelihood of both a faster and more successful product launch. To test this, a bivariate correlation matrix will indicate any support for these hypotheses. Hypotheses 3a & 3b will require using a hierarchical regression model with three blocks. The first two will contain the variables improvisation and crisis, respectively, while the third will contain a new variable that consists of the cross-product between improvisation and crisis. If a significant result is found in the third block, then a new dichotomous variable will be created to differentiate between a firm in high crisis and one in low crisis. Since the construct of crisis is one based on the perception by NPD team members, it is subjective. Different team members can rate the level of crisis differently from others even as the situation remains the same. Some members have prior knowledge or experience with a similar situation and therefore will not rate or perceive a threat as high as someone who lacks knowledge or experience with a similar situation.

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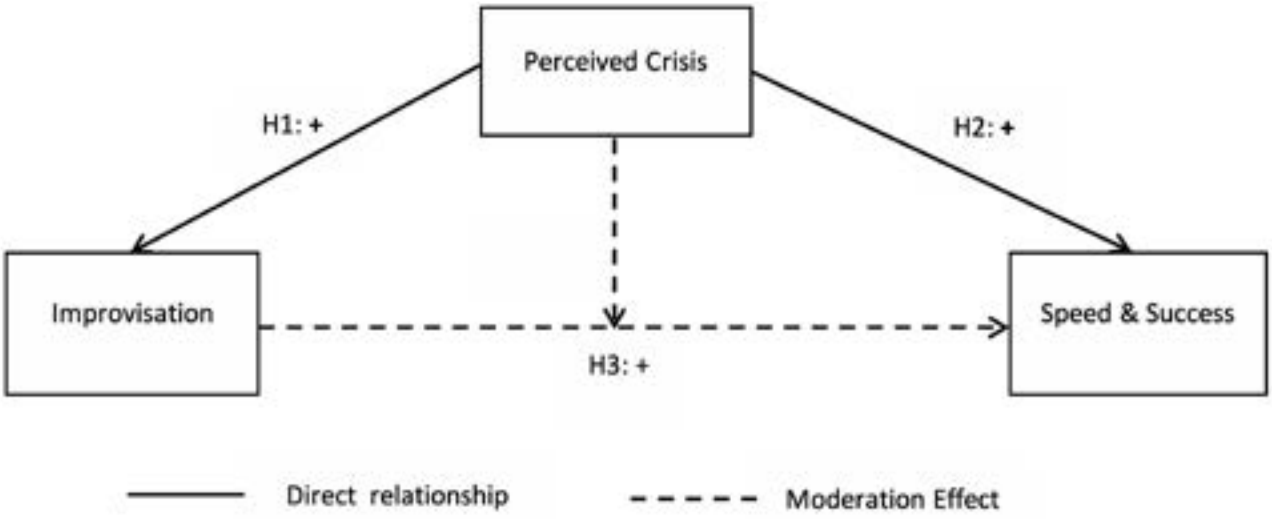

Figure 1 Conceptual Model.

For this study, a high crisis will be one where the NPD team member rates the situation higher than the median score of all respondents. Conversely, a low perception of crisis will be one where the NPD team member rates the situation as lower than the median score across all respondents. Finally, a new set of regressions should be able to empirically demonstrate that improvisation is more closely related to positive outcomes during a crisis than not.

Sample

To test our hypotheses, a questionnaire was developed based on previous research (Billings et al., 1980; Cooper 1994; Cooper, 2001; Kessler and Chakrabarti, 1999; Moorman and Miner, 1998; Schein, 1993). After designing and refining the questionnaire, a contact person in a variety of US based chemically related companies was selected to participate in this study. These firms were selected with the intention of identifying industries that are related to pharmaceuticals, petrochemicals, and chemical manufacturing. In other words, industries that can experience an organizational crisis like Johnson & Johnson, Coca-Cola, and British Petroleum, were the target. This would in turn make for a more natural response from the respondent on the perception of a crisis within the firm. The contact person in each company was asked to select a project manager or senior team member (respondents are primarily product/project managers, senior team members or department managers and directors) who was with the project from pre-prototype through launch. The project manager was asked to provide the product and industry that the firm operated in. Lukas and Ferrell (2000) and Podsakoff and Organ (1986) found that managers rely on their own self-reports and provide

Table 2 Industry of new product being developed.

Industry	Number of Firms	% of Sample
Chemicals	8	14.5
Coatings	4	7.3
Consumable goods	10	18.2
Lubricant Manufacturing	4	7.3
Natural Gas	1	1.8
Petrochemical Manufacturing	12	21.8
Pharmaceutical Drug Manufacturing	12	21.8
Plastics	4	7.3
Total	55	100%

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reliable and objective data. Also, Huber and Power (1985) note that simply averaging multi sources is less likely to be accurate than using a key informant. After the selection of the respondents, they were informed that their responses would remain anonymous and their responses will not be linked to a company or product name. This increased the motivation of informants to cooperate without fear of reprisals. To improve the accuracy of retrospective reports, recent projects were selected to eliminate the elapsed time between the events of interest and the collection of data. Of the 301 "contact people" asked to participate, 244 of them returned a questionnaire (an 81.1% response rate), of which 55 had sufficient data to be included in both the correlation and regression analyses. Industries ranged from the manufacturing of pharmaceutical drugs and other consumable packaged goods to plastics and the manufacturing of petrochemical related products such as fuel additives, lubricants, and other chemicals (see Table 2).

Measures

For this study, questions were measured on a Likert-type scale from 0 = strongly disagree to 10 = strongly agree. Table 3 provides a summary of the measures.

Table 3 Summary of Measures.

Dependent Variable	
Success	To operationalize new product success, six questions were asked referring to how well the project met volume, sales, profit, ROI, and market share expectations. All items loaded onto one factor and the mean was used as the variable. References: Cooper, 1994; Cooper, 2001
Speed	To operationalize speed, four questions were asked. Since a multi-company and multi-industry sample was used, the speed-to-market differences in the nature of projects were controlled by using relative measures. This approach and item content were similar to that of Kesslar and Chakrabarti (1999). Speed-to-market was assessed by comparing actual performance to pre-set schedules, company standards and similar competitive projects. Reference: Kessler and Chakrabarti, 1999
Independent Variables	
Improvisation	To operationalize improvisation, the following three questions were asked: (1) the team figured out the NPD process as it went along versus following a rigid well-defined plan, (2) the team improvised in developing the product versus strictly following the plan, and (3) the team improvised in commercializing this product versus strictly following the plan. Items were adapted from Moorman and Miner (1998). The mean of these items was used as the variable. Reference: Moorman and Miner, 1998
Moderating Factor	
Crisis	Three questions were asked to measure the perception level of crisis. Specifically, respondents were asked the level of crisis in within their organization, environment, and with their customers that their current project would help solve. References: Billings et al., 1980, Schein, 1993

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Measure Validity & Reliability

Before testing the proposed model, the structure and reliability of the constructs were assessed. To measure each construct, a factor analysis was performed (on the items asked in the questionnaire) along with a varimax rotation method and Kaiser normalization to validate the number of constructs used as well as to confirm whether the items mentioned for each construct were indeed capturing their respective construct (Tabachnick and Fidell, 2001). After the extraction of components with an eigenvalue > 1.00, four variables remained explaining 63.8% of the variance. A loading factor value of 0.5 and above in each component in the varimax rotated component matrix validated the items as acceptable measurements of the constructs.

Each variable in the model consisted of the average of the items in each component. To ensure the practicality of the measures, an Alpha reliability test was performed. All Cronbach's alphas (see Table 4) were above the minimum acceptable level of 0.7 as recommended by Nunally (1978).

4 Empirical Findings

Crisis and Improvisation

To determine if a crisis can present an opportunity, positive bivariate correlations between crisis and each of the two outcomes must be found. The results presented in Table 5 illustrate that indeed there is a positive correlation between crisis and improvisation, thus supporting H1. The results also show that crisis significantly correlates with both speed and success, thus supporting both H2a & H2b. Also, it is worth mentioning that speed was significantly related to success as they had a correlation coefficient that is consistent with past studies.

Hypotheses 3a & 3b sought to assess the degree to which predictor variable improvisation along with crisis explained the variance of project outcomes speed and success. To find support for the final two hypotheses, two regression models were used to assess the fit of the model and the impact of the predictor variable on both speed and success. In each case, the first variable in the model included the predictor variable improvisation. The next variable in the model was the moderating variable crisis. The final variable in the model included a cross-product between improvisation and crisis to determine any interaction effect between the two variables. If so, the results would indicate that improvisation may be better in times of crisis than in times of stability.

Speed to Market

The variable improvisation was found to have a non-significant impact on speed. The squared correlation ($R^2 = 0.000, p < 0.979$) was not significantly different from zero. This would mean that improvisation in NPD in these industries does not help speed the process of a new product launch. On the other hand, the variable crisis was found to have a significant impact on speed as the squared correlation ($R^2 = 0.157, p < 0.005$) was significantly different from zero. This result is like the previous analysis indicating that a perceived crisis is positively associated with improvisation (H1) and the speed (H2) with which a new product can be launched. The final block in the regression results indicates that there is no significant interaction between improvisation and crisis

Table 4 Measures and Reliability.

Predictor Variable	No. Items	Mean	Standard Deviation	Alpha
Predictor Variable *Improvisation*	3	5.56	2.21	0.76
Moderating Variable *Crisis*	3	4.58	2.32	0.74
Dependent Variables				
New Product Success	7	5.36	3.02	0.97
Speed to Market	4	5.44	2.64	0.85

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Table 5 Bivariate Correlations (N = 55).

	New Product Success	Speed to Market	Crisis	Improvisation
New Product Success	1			
Speed to Market	0.568**	1		
Crisis	0.197*	0.360**	1	
Improvisation	0.011	0.041	0.294**	1

* p < 0.05; ** p < 0.01

(R^2 = 0.161, Δ R^2 = 0.004, $p < 0.625$), thus demonstrating no support for H3a. This result indicates that there is no significant difference in the relationship of improvisation and speed based on the perception level of crisis in the selected industries where an NPD team was working on a project. In other words, the perception of a crisis does not moderate the relationship between an improvisational approach and the speed with which a NPD can launch a new product.

New Product Success

The variable improvisation was found to have a non-significant impact on success. In the selected industries, the amount of improvisation done by the NPD team does not significantly impact the outcome of the project. The squared correlation (R^2 = 0.001, $p < 0.833$) was not significantly different from zero. The variable crisis was found to have a marginally significant impact on success. This result is slightly different from H2b where it was shown that a perceived crisis has a significant association with a successfully developed new product. The squared correlation (R^2 = 0.046, $p < 0.063$) for crisis was partially significantly different from zero based on the p-value being under the standard of 0.1 for marginal significance. The final block in the regression results indicates that there is no significant interaction between improvisation and crisis (R^2 = 0.05, Δ R^2 = 0.004, $p < 0.604$), thus demonstrating no support for H3b.

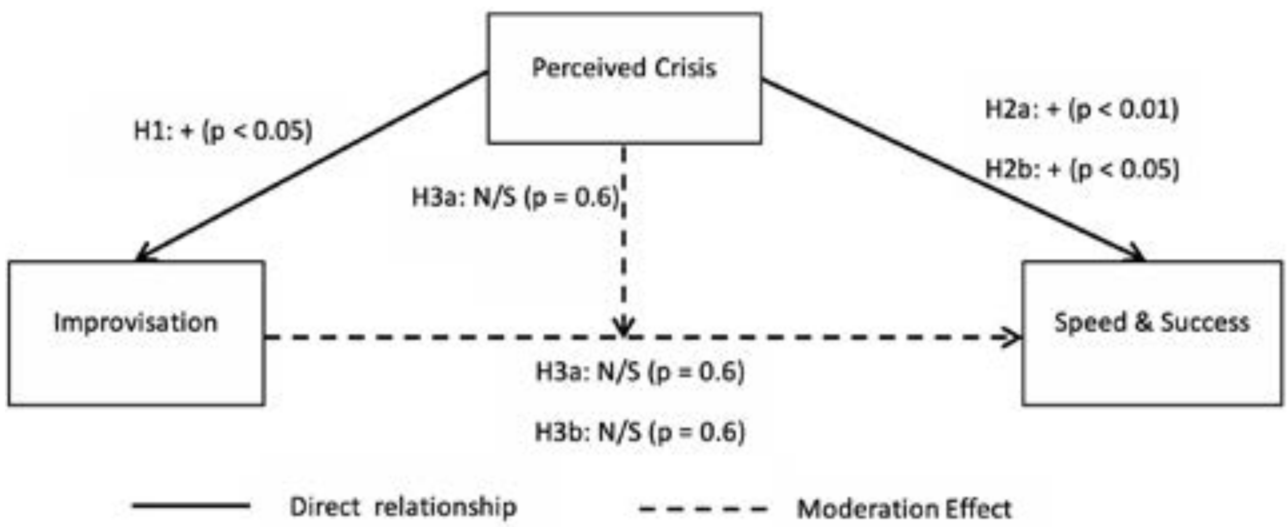

Figure 2 Results of Conceptual Model.

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5 Contributions and Implications

Theoretical Implications

First, few studies have addressed crisis and its effects on NPD. As stakeholders are increasingly alert to product safety, crisis management is undoubtedly becoming crucial to firms. This research fills a gap by examining how the perception of a crisis impacts the firm's NPD process. This study, to some extent, is in line with the dynamic capabilities theory, which suggests that successful firms should be able to adapt to a changing environment by using a combination of their competencies. In this research, the crisis is viewed as an impactful aspect of the environment and suggest that NPD can be an effective solution for a crisis.

Second, information sharing is viewed as a key success factor for NPD (Troy et al., 2008) and informal communication is a vehicle of sharing (Samra et al., 2019). As NPD team members become less formal during a crisis, they will rely less on the use of formal communication methods as this will increase NPD time, embrace informal communication which can lead to the NPD team improvising more during a crisis, and should speed up the NPD process.

Third, we find the existence of improvisation and successful outcomes brought out by a crisis but not linking the three together. This sheds light on simultaneous theoretical development of the conceptual framework. The moderating variable of crisis does have an impact on improvisation and project outcomes but in this study, improvisation cannot be linked with positive project outcomes. This creates a managerial dilemma which will be discussed in the next section.

Managerial Implications

The mixed effects of crisis perception on improvisations lead to a key question for mangers: what is to be done if improvisation won't help the NPD team succeed in a crisis?

First, improvisation is a default outcome of a crisis, suggesting that it cannot be completely avoided as a crisis requires something new and less formal. In the onset of a crisis, an NPD team will improvise and share information in an informal manner by communicating outside of formal channels. However, a balanced approach should exist. While NPD teams implement an improvisational approach, a moderate level of it may be ideal so that they can avoid errors on the account of a lack of a structured approach while not spending too much effort on a formal approach to get the job done. Too much improvisation will hinder the positive effect of perceived crisis on the NPD team as time is spent inefficiently and incorrect decisions are being made and/or executed without a formal process for consideration.

Second, if a team maintains a moderate level of improvisation, what else can a team do to facilitate a perceived crisis in the NPD process? One solution is that managers should consider incorporating a more structured process as the NPD team does not need to communicate to external shareholders when an organizational crisis occurs. They can focus on getting the project done successfully by ensuring that the quality of the new product meets required standards by the firm's industry.

Third, since external communication is typically done by public relations and/or senior management, it may help facilitate information sharing if top management is involved in the NPD process. A high degree of senior involvement and support can reduce the NPD team members' anxiety levels brought out by a crisis by reassuring the team of their role and providing resources for them to ensure that they are confident in their execution of the NPD process in a timelier manner. This could in turn, reduce the time needed for NPD and increase the likelihood of completing a project faster and more successfully.

6 Research Limitations & Future Research

This research is not without limitations.

First, while we studied multiple industries that deal with chemistry and chemical engineering, crises in different industries may play varying roles. In this regard, future research should examine the uniqueness of industry characteristics. NPD teams operating in industries that are used to product recalls due to sub-standard chemical composition in food quality or pharmaceuticals may have an advantage when it comes to a crisis as they are more ready to adapt to removing products from the retail space. On the other hand, firms in plastics and petrochemicals may have

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a more difficult time adapting. If a plastics manufacturer or oil refiner makes sub-standard products that are unreliable and break easily, this may not necessarily cause illness to the public. In other words, a sudden threatening event in one industry may have firms that are less surprised than others that are more likely to be impacted in more stable environments where firms in an industry operate under the axiom of "business as usual". Such firms in said industries may suffer much more during a crisis, thereby putting their survival at risk.

Second, model testing was based on survey responses. As such, it is recommended that researchers collect actual financial measures (e.g. revenue before, during, and after a crisis) to examine the impact of the new product that was developed and launched. Doing so will better show firms that successfully managed the crisis and those that didn't so that different factors can be considered for future study.

Third, conceptualization of crisis in this study focuses on utilizing NPD as a solution to the perceived threat of a crisis. Yet, the cause of the crisis may be the failure of the new product. For example, a new pharmaceutical drug that has adverse effects on patients can make the new product both the cause of the crisis as well as the result of one. Future studies can study specifically the consumables industry of food and pharmaceuticals from a longitudinal perspective.

7 Conclusion

Through empirical examination of outcomes of NPD (speed & success), its proposed antecedent (improvisation), and moderator (crisis), this study demonstrates associations between these variables. Generally, the data support the propositions of this research. Significant relationships were confirmed between crisis and improvisation, as well as crisis and outcomes (both speed and success); however, improvisation was not associated with positive outcomes of NPD. These findings increasingly confirm the theory that a crisis is not only something to avoid but can serve as an opportunity to shine and prosper.

The results also illustrate that while a crisis may lead to improvisation, this does not necessarily mean that team improvisation will have more of a significant impact on new product success under crisis conditions than not. The investigated industries for this study were limited to firms that are heavily involved with chemicals. Therefore, it can only be inferred that a crisis may lead the NPD team to improvise, however, the team performed other tasks associated with NPD that would lead to successful outcomes during a crisis.

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URN: urn:nbn:de:hbz:6-72059465724
DOI: 10.17879/72059465486

8 References

Akgün, A.E., Byrne, J.C., Lynn, G.S., & Keskin, H. (2007): Team stressors, management support, and project and process outcomes in new product development projects. Technovation, **27**(10), pp. 628-639.

Akgün, A. E., Lynn, G. S., & Byrne, J. C. (2006): Antecedents and consequences of unlearning in new product development teams. Journal of Product Innovation Management, **23**(1), pp. 73-88.

Amabile, T. M., (1996): Creativity in context. Boulder, CO: Westview Press.

Anonymous. (2002). Disaster Database, Disaster Prevention and Management. Bradford: **11**(4): 323-358.

Barnett, C. K. & Pratt, M. G. (2000): From threat-rigidity to flexibility: Toward a learning model of autogenic crisis in organizations. Journal of Organizational Change Management, **13**(1), pp. 74-88.

Barrett, F., (1998): Creativity and Improvisation in Jazz and Organizations: Implications for organizational learning. Organization Science, **9**(5), pp. 605-622.

Barthol, R.P. & Ku, N.D., (1959): Regression Under Stress to First Learned Behavior. Journal of Abnormal and Social Psychology, **59**, pp. 134-136.

Bastien, D.T. & Hostager, T.J., (1988): Jazz as a process of organizational innovation. Communication Research, **15**(5), pp. 582-602.

Billings, R.S., Milburn, T.W., & Schaalman, M. (1980): A model of crisis perception: A theoretical and empirical analysis. Administrative Science Quarterly, **25**(2), pp. 300-316.

Binns, A.J., Harreld, B., O'Reilly, C., & Tushman, M.L. (2014): The art of strategic renewal. MIT Sloan Management Review, **55**(2), pp. 21-23.

Brown, S. L., & Eisenhardt, K. M., (1997): The art of continuous change: Linking complexity theory and time-paced evolution in relentlessly shifting organizations. Administrative Science Quarterly, **42**(1), pp. 1-34.

Choudhary, A., (2012): Mission "Trust". Academy of Strategic Management Journal, **11**(1), pp. 101-113.

Cooper, R. G., (2001): Winning at new products, 3 rd edition. Perseus Publishing, Cambridge, Chap. 2, 10, pp 23-24, 250.

Cooper, R.G., (1994): Third-Generation new product processes. Journal of Product Innovation Management, **11**(1), pp. 3 - 14.

Cooper, R. G. & Kleinschmidt, E. J., (1986): An investigation into the new product process: steps, deficiencies, and impact. Journal of Product and Innovation Management, **3**(2), pp. 71-85.

Cooper, R. G. & Kleinschmidt, E. J., (1987): New products: What separates winners from losers, Journal of Product and Innovation Management, **4**, pp. 169-184.

Cooper, R. G. & Kleinschmidt, E. J., (1995): Benchmarking the firm's critical success factors in new product development, Journal of Product Innovation Management,**12**(5), pp. 374-391.

Crossan, M. M. & Sorrenti, M., (1997): Making sense of improvisation. Advances in Strategic Management, **14**, pp. 155-180.

Cunha, J.V. & Cunha, M. P., (2001): Brave new (paradoxical) world: Structure and improvisation in virtual teams, Strategic Change, **10**(6), pp. 337-347.

Cunha, M.P., Cunha, J.V., & Kamoche, K., (1999): Organizational improvisation: What, when, how, and why?. International Journal of Management Reviews, **1**, pp. 299-341.

Donada, C., Mothe, C., & Alegre, J., (2021): Managing skunkworks to achieve ambidexterity: The Robinson Crusoe effect. European Management Journal, **39**(2), pp. 214-225.

Eisenhardt, K. M., & Tabrizi, B. N., (1995): Accelerating adaptive processes: Product innovation in the global computer industry. Administrative Science Quarterly, **84**, pp. 84-110.

Vol. 19, Iss.3, October 2022
URN: urn:nbn:de:hbz:6-72059465724
DOI: 10.17879/72059465486

Fan, D., Li, Y., & Chen, L. (2017): Configuring Innovative Societies: The crossvergent role of cultural and institutional varieties, Technovation, **66–67**, pp. 43-56.

Fan, D., Geddes, D., & Flory, F. (2013): The Toyota recall crisis: Media impact on Toyota's corporate brand reputation. Corporate Reputation Review, **16**(2), pp. 99-117.

Financial Times (2012): Fiat in focus as industry crisis deepens, Oct. 29, 2012.

Galtung, J. (1984): On the dialectic between crisis and crisis perception. International Journal of Comparative Sociology, **25**(1-2), pp. 4-32.

Gwynne, P., (1997): Skunkworks, 1990s style. Research Technology Management, **40**(4), pp. 18 - 23.

Hajibaba, H., Boztuğ, Y., & Dolnicar, S. (2016): Preventing tourists from canceling in times of crises. Annals of Tourism Research, **60**(September), pp. 48-62.

Halkos, G. & Zisiado, A. (2020): Is investors' psychology affected due to a potential unexpected environmental disaster? Journal of Risk and Financial Management, **13**(7), pp. 151-174.

Heath, R., (1995): The Kobe earthquake: Some realities of strategic management of crises and disasters. Disaster Prevention and Management, **4**(5), pp. 11-21.

Herman, C. F. (1963): Some consequences of crisis which limit the viability of organizations. Administrative Science Quarterly, **8**(1), pp. 61-82.

Hoopes, D.G. & Postrel, S., (1999): Shared knowledge, "glitches", and product development performance. Strategic Management Journal, **20**, pp. 837-865.

Huber, G. P., & Power, D. J., (1985): Research notes and communications retrospective reports of strategic-level managers: Guidelines for increasing their Accuracy, Strategic Management Journal, **6**, pp. 171-180.

Johnson, V. & Peppas, S.C. (2003): Crisis management in Belgium: The case of Coca-Cola. Corporate Communications, **8**(1), pp. 18-22.

Katz, N., (2001): Sports teams as a model for workplace teams: Lessons and liabilities, Academy of Management Executive, **15**(3), pp. 56-69.

Kessler, E.H. and Chakrabarti A.K., (1999): Speeding up the pace of new product development, Journal of Product Innovation Management, **16**(3), pp. 231-247.

Kim, L. (1998): Crisis construction and organizational learning: Capability building in catchingup at Hyundai Motor. Organization Science, **9**(4), pp. 506-521.

Lin, Z., Zhao, X., Ismail, K.M., & Carley, K.M. (2006): Organizational design and restructuring in response to crises: Lessons from computational modeling and real-world cases. Organization Science, **17**(5), pp. 598-618.

Lukas, B. A, & Ferrell, O. C., (2000): The Effect of market orientation on product innovation, Journal of the Academy of Marketing Science, **28**(2), pp. 239-247.

Lynn, G. S., Abel, K. D., Valentine, W. S., & Wright, R. C., (1999): Key factors in increasing speed to market and improving new product success rates, Industrial Marketing Management, **28**, pp. 319-326.

Maltz, E. & Kohli, A. K. (1996): Market intelligence dissemination across functional boundaries. Journal of Marketing Research, **33**(1), pp. 47-61.

Martins, A. (2015): The Portuguese corporate tax reform and international trends: An assessment. International Journal of Law and Management, **57**(4), pp. 281-299.

Millson, M. R. & Wilemon, D., (2002): The impact of organizational integration and product development proficiency on market success, Industrial Marketing Management **31**, pp. 1-23.

Miner, A. S., Bassoff, P., & Moorman, C. (2001): Organizational improvisation and learning: A field study. Administrative Science Quarterly, **46**, pp. 304-337.

Mitroff, I., Pauchant, T., & Shrivastava, P. (1989): Can your company handle a crisis? Business and Health, **7**(5), pp. 41-44.

Vol. 19, Iss.3, October 2022
URN: urn:nbn:de:hbz:6-72059465724
DOI: 10.17879/72059465486

Mitroff, I, I., Shrivastava, P., & Udwadia, F. E. (1987): Effective crisis management. Academy of Management Executive, **1**(4), pp. 283-292.

Moorman, C., & Miner, A. S. (1998): The convergence of planning and execution: Improvisation in new product development. Journal of Marketing, **62**(3), pp. 1-20.

Mu, J., Peng, G., & Maclachlan, D.L. (2009): Effect of risk management strategy on NPD performance. Technnovation, **29**(3), pp. 170-180.

Pearson, C.M. & Mitroff, I.I. (1993): From crisis prone to crisis prepared: A framework for crisis management. Academy of Management Executive, **7**(1), pp. 48-59.

Penrose, J. M. (2000): The role of perception in crisis planning. Public Relations Review, **26**(2), pp. 155-171.

Perry, L.T., (1991): Strategic Improvising: How to formulate and implement competitive strategies in concert. Organization Dynamics, **19**(4), pp. 51-64.

Plous, S., (1993): The psychology of judgment and decision making, 1 st edition. McGraw-Hill, Inc., New York, Cambridge, Chap. 19, pp. 225.

Podsakoff, P. M., & Organ, D., (1986): Self-Reporting in organizational research: Problems and prospects, Journal of Management **12**(4), pp. 531-544.

Priporas, C. & Vangelinos, G. (2008): Crisis management in pharmaceuticals: Evidence from Greece. International Journal of Pharmaceutical and Healthcare Marketing, **2**(2), pp. 88-102.

Quarentelli, E. L. (1988): Disaster crisis management: A summary of research findings. Journal of Management Studies, **25**(4), pp. 373-385.

Rosenthal, S.R., (1992): Effective product design and development: How to cut lead time and increase customer satisfaction. Homewood, IL: Irwin Professional Publishing.

Samra Y M. (2005): Is new product development the solution to a crisis or is crisis the solution to new product development? Stevens Institute of Technology, Hoboken, NJ.

Samra, Y.M., Zhang, H., Lynn, G. S., & Reilly, R. R., (2019): Crisis management in new product development: A tale of two stories. Technovation, **88**(1), pp. 1-12.

Schein, E.H., (1993): How can organizations learn faster? The challenge of entering the green room. Sloan Management Review, **Winter**, pp.55-62.

Shepherd, C. & Ahmed, P. K., (2000): NPD Frameworks: A holistic examination. European Journal of Innovation Management, **3**(3): pp. 100-106.

Shrivastava, P., Mitroff, I.I., Miller, D., & Miglani, A. (1988): Understanding industrial crises. Journal of Management Studies, **25**(4), pp. 285-303.

Srivastava, R. (2019): Rebuliding a global brand under crisis – case of global brand Maggi. International Journal of Pharmaceutical and Healthcare Marketing, **13**(2), pp. 118-139.

Siomkos, G., & Shrivastava, P. (1993): Responding to product liability crises. Long Range Planning, **26**(5), pp. 72-79.

Smart, C. & Vertinsky, I., (1984): Strategy and the Environment: A study of corporate responses to crises, Strategic Management Journal, **5**(3), pp. 199-213.

Stachowski, A.A., Kaplan, S.A., & Waller, M.J. (2009): The benefits of flexible team interaction during crises. Journal of Applied Psychology, **94**(6), pp. 1536-1543.

Starbuck, W.H., Greve, A. & Hedberg, B., (1978): Responding to crisis: Theory and the experience of European business. Journal of Business Administration, **9**(2), pp. 112-137.

Szántó, B. (1994): Innovation in crisis: Hungary before and after the watershed of 1989. Technovation, **14**(9), pp. 601-611.

Tabachnick, B. G & Fidell, L. S., (2001): Using Multivariate Statistics, 4 th edition. Allyn & Bacon, Chap. 13, pp. 590-595, 614.

Troy, L. C., Hirunyawipada, T., & Paswan, A. K. (2008): Cross-functional integration and new product success: An empirical investigation of the findings. Journal of Marketing, **72**(6), pp. 132- 146.

Vol. 19, Iss.3, October 2022
URN: urn:nbn:de:hbz:6-72059465724
DOI: 10.17879/72059465486

Weick, K. E., (1988): Enacted Sense-making in crisis situations. Journal of Management Studies, **25**(4), pp. 305-317.

Weick, K. E. (1993): The collapse of sensemaking in organizations: The Mann Gulch disaster. Administrative Science Quarterly, **38**(4), pp. 628-652.

White, J. C., Varadarajan, P. R., & Dacin, P. A. (2003): Market situation interpretation and response: The role of cognitive style, organizational culture, and information use. Journal of Marketing, **67**(July), pp. 63-79.

www.cpsc.gov

www.merriam-webster.com

Xu, K. & Li, W. (2013), An ethical stakeholder approach to crisis communication: A case study of Foxconn's 2010 employee suicide crisis. Journal of Business Ethics, **117**(2), pp. 371-386.

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APPENDIX 1: QUESTIONNAIRE

Respondents were initially asked:

What industry was this product in? Please briefly describe this product:

For each of the variables, respondents were asked to rate the following questions based on the instructions below:

To what extent does each of the following statements correctly describe the selected project? Please rate each of the following items to indicate the extent to which you agree or disagree where **0 = STRONGLY DISAGREE, 10 = STRONGLY AGREE,** and the numbers between 0 and 10 indicate various degrees of agreement or disagreement.

APPENDIX 1A: Factor Analysis of Predictor Variable (loading factor)

Team Improvisation (0 = strongly disagree, 10 = strongly agree)

The team figured out the new product development process as it went along vs. following a rigid well-defined plan. (0.76)

The team improvised in developing this product vs. strictly following the plan. (0.84)

The team improvised in commercializing this product vs. strictly following the plan. (0.69)

Eigenvalue = 1.75

Percentage of variance explained = 7.00

APPENDIX 1B: Factor Analysis of Predictor & Moderating Variable (loading factor)

Crisis (0 = strongly disagree, 10 = strongly agree)

The team felt that there was a crisis in the company or division (lower sales, profits, etc.) to which this project would help solve. (0.704)

The team felt that there was a crisis in the environment (concerning competitors,
suppliers or legal regulations) that this project would help alleviate. (0.866)

The team felt that there was a crisis with customers or potential customers that this project would help solve. (0.743)

Eigenvalue = 1.60
Percentage of variance explained = 6.39

APPENDIX 1C: Factor Analysis of Dependent Variable (loading factor)

Speed to Market (0 = strongly disagree, 10 = strongly agree)

This project was developed and launched faster than the major competitor for a similar product. (0.794)

This project was completed in less time than what was considered normal and customary for our industry. (0.844)

This project was launched on or ahead of the original schedule developed at initial project go-ahead. (0.853)

Top management was pleased with the time it took the NPD team from specs to full commercialization. (0.813)

Eigenvalue = 2.31

Percentage of variance explained = 9.22

New Product Success (0 = strongly disagree, 10 = strongly agree)

This project met or exceeded volume expectations. 0.872

This project met or exceeded the 1 st year number expected to be produced and commercialized. 0.769
This project overall, met or exceeded sales expectations. 0.925

This project met or exceeded profit expectations. 0.897

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This project met or exceeded return on investment (ROI) expectations. 0.840

This project met or exceeded customer expectations. 0.825
This project met or exceeded market share expectations. 0.886

Eigenvalue = 7.98

Percentage of variance explained = 31.93

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Commentary

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How chemicals can serve people sustainably without polluting the planet: through common objectives, integration, and more effective cooperation

Introduction

Humans have mastered quite some crises. And we will need to master global ones in the near and distant future. Common sense and lessons learned along the way consistently attest to the fact that proper and resolute cooperation, towards clear joint objectives, is key for successful crisis management.

The Executive Director of the United Nations Environment Programme UNEP, Inger Andersen, has delivered strong messages about the challenge of the triple planetary crisis of climate change, biodiversity loss and pollution (Andersen, 2020). Public and policy attention are already high on the urgency to tackle climate change. By contrast, awareness about the significance of biodiversity loss and pollution has still to catch up. Both policymakers and the broader public will perceive the obvious role of chemicals in pollution. However, closer inspection reveals that chemicals are janiform, having a truly cross-sectional role: while chemicals are in many ways required for societal well-being, the ways chemicals are globally produced, used and disposed of, still contribute to all three aforementioned crises. Thinking ahead, it has become clear that many if not most solutions for sustainable development will require a much more conscious use of chemicals.

It is therefore urgent to advance common understanding of how the production and use of chemicals serve people, ensuring wellbeing and sustainable development globally without polluting the planet. This commentary intends to foster discussions on several pertinent aspects on the road to such common understanding and towards apt global goals for joint action.

A serious global pollution situation and chemical intensification goes on

The basic and comprehensive document expanding on global chemical pollution is the second edition of the Global Chemicals Outlook GCO-II (UNEP, 2019). It assesses progress towards the 2020 goal (see below), explores the linkages between chemicals and waste, provides scientific input, and proposes measures to reach relevant Sustainable Development Goals (SDGs) and targets up to and beyond 2020.

GCO II delivers key messages as follows: Opportunities to advance sustainable consumption, production and product innovation do exist, but global megatrends in chemical-intensive sectors like construction, agriculture, electronics, cause ongoing growth of global chemicals production, and still result in too much releases of hazardous substances and other pollutants. These releases are often just temporarily postponed by accumulation of hazardous substances in material stocks and products being disposed

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of one day, many still ending up in the environment. Aptly denoted as chemical intensification, chemical production capacity and turnover double every 15 years, the number of new chemicals increases, further diversity and spread of chemical uses and combinations are on the rise.

This intensification has a tangible impact on human health: According to the Lancet Commission on Pollution and Health (Fuller et al., 2022), pollution causes more than 9 million deaths each year globally. Evidence suggests there is no improvement in sight. A decline in death rates from household air and water pollution among people living in extreme poverty is offset by other pollution like ambient air pollution and toxic chemical pollution. Deaths due to these modern forms of pollution have increased by 66% since 2000. They are driven by industrialisation, uncontrolled urbanisation, population growth, fossil fuel combustion, and absence of an adequate national or international policy for the safe management of chemicals. Pollution remains a major global threat to health and prosperity, particularly in low- and middle-income countries (LMICs). Some 1.8 million deaths per year from pollution, of which 90% occur in LMICs, are attributable to lead and other chemicals. The figure is a conservative estimate and the real figure is likely higher. Intensified efforts geared towards mitigation and prevention are sorely needed, which implies adequate capacity building particularly in LMICs on institutional, regulatory, governance, implementation, and research levels. The push should be globally integrated and synergic.

Common objectives: High ambition agreed, reshaped, and still not sufficiently effective

A common chemicals 2020 goal was originally formulated in the 2002 Johannesburg World Summit's implementation plan. It now appears in reworded shape as target 12.4 of the 2030 Agenda for Sustainable Development:

"By 2020, achieve the environmentally sound management of chemicals and wastes throughout their lifecycles, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their impacts on human health and the environment."[2]

While this time-bound target is ambitious, both the GCO-II as well an independent evaluation of the Strategic Approach to International Chemicals Management SAICM[3] concluded that the international community missed the 2020 goal (SAICM, 2019). The critical analyses also pointed out that solutions do exist, which nevertheless urgently need to be implemented and scaled up with more ambitious worldwide action by all stakeholders ("business as usual is not an option").

At the UN level, there are at least some dedicated Multilateral Environmental Agreements (MEA) focussing on specified problems in the chemicals and waste cluster: the Stockholm, Basel, Rotterdam and Minamata Conventions and just a few more. Most recently a Plastics Convention is under preparation, with a full life-cycle approach stretching from design to production to circularity to reducing, managing and preventing waste. An essential basis for all chemicals management is the Globally Harmonized System GHS for classification and labelling of chemicals, i.e. substances and mixtures. SAICM includes a global agreement on specified issues of concern, such as lead in paint and highly hazardous pesticides.[4] While these are proven tools, effective implementation is still missing in many regions.

Prominent regional instruments include the European Union's CLP and REACH Regulations, the latter being a model for several countries in other regions, including South Korea and Türkiye. There are also flagship initiatives like the European Union's Zero Pollution Ambition with its Action Plan[5] and the recently launched European Partnership for the Assessment of Risks from Chemicals (PARC).[6]

While all these efforts are desperately needed, they are by no means sufficient to re-orient the machinery of chemicals and waste handling towards sustainability at the global level. The list of shortcomings in managing chemicals sustainably is endless: trade in products of unknown composition, wild waste dumping, regrettable substitution, resource extraction

[2] See https://sdgs.un.org/2030agenda, accessed 18 Sep 2022
[3] www.saicm.org, accessed 18 Sep 2022
[4] See http://saicm.org/Implementation/EmergingPolicyIssues/tabid/5524/language/en-US/Default.aspx, accessed 18 Sep 2022
[5] https://environment.ec.europa.eu/strategy/zero-pollution-action-plan_en, accessed 18 Sep 2022
[6] Further information available at https://www.anses.fr/en/content/european-partnership-assessment-risks-chemicals-parc

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from fossil raw materials, lack of institutional capacity, regulation, and effective cooperation, as well as major funding gaps. Those gaps cannot be closed by state budgets alone, including sources like the Global Environment Facility (GEF)[7] and thus also require significantly increased financial support from the private sector.

Overall, the GCO-II analysis of existing reporting schemes and indicators reveals a fragmented landscape of the mechanisms developed under multilateral treaties, SAICM and the 2030 Agenda for Sustainable Development and other regulatory and voluntary instruments. In spite of the availability of many proper instruments, tools and solutions, neither disrespecting all commendable existing efforts in chemicals and waste management, it still holds true that they fall short of the 2020 ambition.

Objectives towards sustainability: green and sustainable chemistry, chemicals and sustainable development

There is broad agreement that an overall policy concept and cohesive technical criteria are necessary to provide clear orientation if we want to reshape the way we produce, consume and use chemicals.

In 1998, Anastas and Warner have described a Green Chemistry[8] by twelve principles. These are not only important for the synthesis of chemicals, but have added urgency to the issue of responsible chemistry. In an International Workshop on Sustainable Chemistry 27-29 Jan 2004, UBA and OECD developed in-depth criteria for sustainable chemistry, combining ecological, social and economic attributes of sustainability in chemistry (UBA, 2009). More than ten years later, UNEP's Sustainable Chemistry Initiative developed ten objectives and guiding considerations for green and sustainable chemistry as part of the UNEP Green and Sustainable Framework Manual to inspire and guide relevant stakeholders (UNEP, 2020). They range from green molecular design to safeguarding that the use of chemicals to fulfil societal needs are void of pollution or other adverse impacts. In this respect, UNEP provides a blueprint for orienting chemistry innovations towards sustainability. Complementing the UNEP efforts, e.g. the International Sustainable Chemistry Collaborative Centre (ISC3)[9] pushed fulfilment of basically the same need for common understanding, by developing ten key characteristics of sustainable chemistry as result of a stakeholder process completed in 2020.[10] The ISC3's ten key characteristics extend the UNEP perspective by general sustainability principles such as sufficiency, consistency, efficiency, resilience. Precaution and respecting the planetary boundaries are core principles. Chemistry is addressed as a scientific and economic asset spanning its supply chains and whole life cycle. In consequence, the ten key characteristics seek to create new economic opportunities that are not purely economy-driven.

Additionally, various tools exist for accelerating and implementing sustainability on the ground. The assessment schemes collected in the Substitution and Alternatives Assessment Toolbox[11] of the OECD are mostly concerned with the avoidance and coping of hazardous properties. Some tools span a broader view on sustainability, like the UBA Guide on Sustainable Chemicals (UBA, 2016) and its corresponding IT tool SubSelect (UBA, 2020). Innovative and sustainability-oriented business models like chemical leasing[12] are complementing such tools in practice. Despite successful efforts, we believe it is overdue to mainstream and scale-up solutions for sustainable transformation.

For the strategic goal to advance Green and Sustainable Chemistry, three elements are important: At first, gaps need to be filled in terms of technical, management and political descriptions of Green and Sustainable Chemistry. Second, complementing the definitional efforts, existing and future building blocks on Green Chemistry and Sustainable Chemistry indicators, criteria and descriptions have to be structured and interlinked. Third, communication capabilities are needed to convey the ambitious topic appropriately among the technical, management and policy levels.

[7] Cf. https://www.thegef.org/what-we-do/topics/chemicals-and-waste, accessed 18 Sep 2022

[8] For reference and more information see https://www.acs.org/content/acs/en/greenchemistry/principles/12-principles-of-green-chemistry.html, accessed 18 Sep 2022

[9] www.isc3.org, accessed 18 Sep 2022

[10] https://www.isc3.org/page/sustainable-chemistry/who-we-are/key-characteristics-of-sustainable-chemistry, accessed 18 Sep 2022

[11] https://www.oecd.org/chemicalsafety/risk-management/substitution-of-hazardous-chemicals/, accessed 18 Sep 2022

[12] For more information see https://chemicalleasing.com, accessed 18 Sep 2022

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To illustrate the broad landscape of the necessary definitional work that needs to be accomplished, two initiatives are noteworthy: (1) As element of the EU Chemicals Strategy for Sustainability[13], the Safe and Sustainable by Design approach (SSbD) currently develops technical criteria and indicators (European Commission, Joint Research Centre, 2022). SSbD refers to the aforementioned guiding instruments and aims at steering innovation towards green industrial transition. In this regard, it strives to substitute or at least minimise production and use of substances of concern, as well as to minimise the impact on climate and the environment throughout the life cycle of chemicals and materials. However, its current structure just offers recommendations limited to research and innovation (including for SMEs) and is by no means a regulatory instrument. SSbD addresses the entire life cycle of a chemical or material, and also considers its functionality. However, evaluation of the product's sustainability is outside the scope. (2) As response of the Sustainable Chemistry Research and Development Act in the USA in 2019[14], efforts are underway to develop descriptive attributes of sustainable chemistry.

As another contribution to the reviving dynamic discussion, the German Environment Agency UBA held its second international sustainability transformation conference in November 2021, entitled "Socio-ecological Transformation: Production, Use and Management of Chemicals to serve People without Polluting the Planet". As a conclusion of the conference, UBA summarized six major objectives, all pertaining to the sustainable production and use of chemicals.[15] These objectives, all a condensation of Green and Sustainable Chemistry, have been re-iterated in the public discussion as priorities which all stakeholders and chemical-reliant sectors have to tackle, namely:

1. preference of low-hazard chemicals where possible,
2. limitation of the most hazardous chemicals to essential uses (while 1 and 2 in any case imply, but significantly disburden the resources needed for, the use of appropriate risk assessment methodology to confirm safe use conditions),
3. adequate conditions for circular economy with pollutant-free material flows,
4. a sustainable measure for chemicals demand including sustainable energy and resource consumption,
5. life-cycle climate neutrality of chemicals, and
6. clear sustainability criteria and indicators to enable transparent trade-off analyses as essential basis to deliver the necessary significant push in globally achieving the 2030 Agenda Sustainable Development Goals.

Cooperation across sectors at all levels from local to global is of particular relevance for effectively achieving any of these goals. Such bold and overarching endeavours inevitably need intense discussion. This journal alone published several pertinent contributions in its issues since June 2021 (Heck and Winters, 2021a; Gosalia, 2021; Franz and Kircher, 2021; Heck and Winters, 2021b; Paulus, 2021; Holthaus and Hemmati, 2022). Most recently in May and June 2022, the G7 ministerial meeting[16] and the Stockholm+50 conference[17] put noteworthy focus on the nexus of pollution, chemicals, and sustainable development. Yet urgency is needed to transform discussions and declarations into concerted and effective actions.

Integration for more effective cooperation: The SAICM multi-sector, multi-stakeholder approach to advance chemicals management with supporting UNEA resolutions

In the context of negotiations under the UN Strategic Approach to International Chemicals Management (SAICM), the fourth session of the International Conference to International Chemicals Management (ICCM4[18]) launched in 2015 an Intersessional Process (IP) "to prepare recommendations regarding the Strategic Approach [SAICM] and the sound management of chemicals and waste [SMCW] beyond 2020", inter alia "informed by the

[13] https://ec.europa.eu/environment/strategy/chemicals-strategy_en, accessed 18 Sep 2022
[14] https://www.congress.gov/bill/116th-congress/senate-bill/999, accessed 18 Sep 2022
[15] https://www.umweltbundesamt.de/en/press/pressinformation/chemicals-better-protection-of-environment-health, accessed 18 Sep 2022
[16] G7 Climate, Energy and Environment Ministers' Communiqué 27 May 2022: https://www.bmuv.de/fileadmin/Daten_BMU/Download_PDF/Europa___International/g7_climate_energy_environment_ministers_communique_bf.pdf, accessed 18 Sep 2022
[17] Stockholm+50: a healthy planet for the prosperity of all – our responsibility, our opportunity. https://www.stockholm50.global/, accessed 18 Sep 2022
[18] http://saicm.org/About/ICCM/ICCM4/tabid/5464/language/en-US/Default.aspx, accessed 18 Sep 2022

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2030 Agenda for Sustainable Development".[19] At ICCM4, the aforementioned sustainable chemistry considerations received their initial explicit reference, when Germany announced its plan to establish the ISC3 at a Special Event "ISC3 – Moving sustainable chemistry forward!".[20]

Gibson (2021) identifies SAICM with its unique characteristics and in its ongoing renewal process as an ideal case study. His analysis of SACIM's strengths and weaknesses as transnational public-private partnership (TPPP) explores how findings about actors, processes and context of SAICM are in line with prevailing theories on the effectiveness of such partnerships. This analysis has the potential to inspire the design of SAICM and SMCW beyond 2020. With regard to goal setting of the existing SAICM, Gibson (2021) concludes in his research, that "evidence paints a bleak picture", i.e. work needs to be done in particular on stringent goal setting, progress monitoring and reporting structures.

The SAICM IP has recently regained track with its postponed forth meeting (IP4) in Bucharest, Romania[21] - three years after the previous face-to-face meeting IP3. Finally, also with an expected delay of three years due to the pandemic, the ICCM5, 25-29 Sep 2023 in Bonn, Germany, will have to agree on four major threads: 1) a coherent and ambitious set of strategic objectives and targets, 2) adequate governance and effective mechanisms for implementation, 3) how to identify and tackle issues of concern, and 4) most challenging as ever, on finance. In a nutshell, SAICM's existing and already ambitious Overarching Policy Strategy (OPS)[22] has to be amended and reinvigorated in ways that seek to belatedly achieve the 2020 goal in combination with maximized contributions to the 2030 Agenda SDGs. This endeavour deserves utmost policy attention as well as best efforts of all stakeholders involved, because the ICCM5 outcome will be the next most relevant and global reference for how chemicals can serve people sustainably without polluting the planet.

In support of the future SAICM and all aspects of SMCW beyond 2020, the United Nations Environment Assembly UNEA 5.2 approved several future-oriented landmark resolutions in March 2022.[23] Most notable are Resolutions UNEP/EA.5/Res.7 on the Sound Management of Chemicals and Waste, and UNEP/EA.5/Res.8 on the establishment of a Science-Policy Panel to contribute further to the sound management of chemicals and waste and to prevent pollution. Further to this, and of major relevance with a view on how chemicals can serve people without polluting the planet, Resolution UNEP/EA.5/Res.11 on enhancing circular economy as a contribution to achieving sustainable consumption and production was adopted, as well as Resolution UNEP/EA.5/Res.14 to end plastic pollution. As to the latter, the way is paved to developing an international legally binding instrument in the coming years. Noting the challenge of the triple planetary crisis mentioned at this commentary's outset, a recent review even argues for a global binding chemicals and materials framework, as a third pillar of global governance on a par with the ones on climate and biodiversity (Steinhäuser et al., 2022) – certainly a long way to go.

Like the aforementioned holistic approaches of green and sustainable chemistry already implicate, the potential of more systematic integration is receiving new attention in several discussions. With a focus on SMCW, several IOMC[24] partner organisations sketch this out in their information document for IP4, referring to three core dimensions of integration: 1) establishing basic national chemicals management systems with adequate institutional, skill and regulatory capacities, 2) integrating chemicals and waste management in specific key industry sectors and product value chains, and 3) integrating these efforts within sustainable development.[25] With their recent perspective, Blumenthal et al. (2022) provide notable arguments in particular for integration of the first two dimensions. The third dimension of integration receives particular attention as potential success factor by

[19] Cf. ICCM4 Report, Decision IV/4 (http://saicm.org/Portals/12/documents/meetings/ICCM4/doc/K1606013_e.pdf, accessed 18 Sep 2022)

[20] http://saicm.org/Portals/12/Documents/meetings/ICCM4/ICCM4%20Side%20Events%20Schedule.pdf, accessed 18 Sep 2022

[21] http://saicm.org/Beyond2020/IntersessionalProcess/FourthIntersessionalmeeting/tabid/8226/language/en-US/Default.aspx, accessed 18 Sep 2022

[22] http://saicm.org/Portals/12/Documents/saicmtexts/New%20SAICM%20Text%20with%20ICCM%20resolutions_E.pdf, accessed 18 Sep 2022, OPS on pages 10-23

[23] https://www.unep.org/environmentassembly/unea-5.2/proceedings-report-ministerial-declaration-resolutions-and-decisions-unea-5.2, accessed 18 Sep 2022

[24] The Inter-Organization Programme for the Sound Management of Chemicals, run by nine Partner Organizations, see https://partnership.who.int/iomc, accessed 18 Sep 2022

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Gibson (2021) stating "the need to integrate the SDGs in a SAICM [and SMCW] Beyond 2020 agreement in order to develop active meta-governance".

As interim appraisal, it might still be impossible to draw reliable conclusions on how to mitigate the health and environmental impacts of chemical pollution and intensification: just capacity building and effective implementation, or much more resolute progress towards mainstreaming sustainability into all aspects of dealing with chemicals? Given the extent of key challenges to be tackled, we are convinced it is justified to fully consider both approaches in finding the most effective measures on the ground. Collaborative, evidence-driven and case-specific prioritisation will by all means be more promising than to play one off against the other.

Common objectives reloaded: The value of global goals and the challenge to develop and agree such goals for joint orientation

Obviously, several bold initiatives, like those described in the previous subsection, provide evidence for broad recognition of the challenges. While these initiatives spark and intensify discussions, there is a lack of a common understanding of how to boldly implement the goals on the ground, how cooperation gets most effective and how to get the necessary funding.

A global goal could be seen as a promising way to provide orientation; its value is best explained with the climate goal limiting global warming to the science-based numerical value of 1.5°. This goal is a reference in the public domain at all levels: It is the result of empirical studies on the relation between greenhouse gas emissions and climate change, on drivers for and impacts of climate change. In this way, a numerical figure for a very palpable physical variable presents a handy tool for setting targets, timelines and reduction goals which are to be addressed jointly by all stakeholders, like governments, industries of multiple sectors, farmers, academia, NGOs, to name just the key actors involved. So, overall, a global goal appears to be an ideal vehicle to stimulate discussion of trade-offs and adequate measures, agree on action and force implementation. Thus, the global 1.5° goal proves very beneficial to gain broad attention, for communication, and for basic orientation in managing activities and cooperation to address the climate crisis.

An UBA Thought Starter (Stolzenberg et al., 2021) sought to start a discussion on how it might be possible to find a commonly agreed extent of chemical intensity that respects all guard rails in a comprehensive understanding of sustainability. We believe that the basic idea, i.e. that chemical intensity could and should be sustainable, deserves much more attention and further in-depth development, since it well reflects the ambiguous nature of chemicals mentioned at the outset of this commentary. Even discussions about how to scale up circularity, at the same time overdue and progressive, do not yet explicitly address the obvious need to limit the per capita use of chemicals to a sustainable measure. Put in a nutshell, we need to additionally and seriously consider sufficiency.

This need is obvious, since chemicals production capacity is going to increase globally by a factor of 3.7 in absolute terms and 2.3 per capita, just in the forty years from 1990-2030.[26] Basically, the idea of a sustainable chemical intensity is inspired by the Doughnut Economy Approach (Raworth, 2017) seeking to find a corridor, confined by the essential needs of societal wellbeing and the planetary boundaries (Stolzenberg, 2021; Heck and Winters, 2021b). Admittedly, it will still require quite some research and discussions before this idea could be developed in ways how the 1.5° goal serves the implementation of climate protection. Major reasons are various: At first, it appears impossible to find a likewise plain and tangible measure for consequences of our use of chemicals; in contrast to myriad potential chemical pollution impacts, the link between greenhouse gas emissions and global warming is clear and therefore easy to explain. Secondly, a measure of chemical intensity has to consider a number of complex aspects. Like number and quantities of chemicals used, portions of chemicals with toxic and otherwise critical properties, extent of inextricably blending or entropy, and quite some more. At third, already less globally designed life-cycle-oriented measures for chemicals like carbon footprint or environmental footprint

[25] SAICM/IP.4/INF/18, Strengthening integrated chemicals and waste management: An IOMC contribution to the intersessional process on the "Strategic Approach and sound management of chemicals and waste beyond 2020". 17 pages, available at http://saicm.org/Portals/12/documents/meetings/IP4/2022/SAICM_IP4_INF_18_IOMC%20Integrated%20chemicals%20and%20waste%20management__.pdf

[26] UNEP, 2019: Global Chemicals Outlook II (full report, cf. figure 3.1 + related text)

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imply demanding data requirements and assumptions. These assumptions remain, as a matter of principle, debatable, whereas a global average temperature is not (apart from the models calculating it). For these reasons, the resulting proxy of chemical intensity might not clearly enough guide trade-off considerations, at least on a global level. If not yet as global goal, the basic idea of a sustainable chemical intensity could however firstly be applied to specific sectors, chemical uses or applications. Fantke and Illner (2019) undertook already a foray themed "Goods that are good enough" with a focus on consumer products, and concluded the "need to move from eco-efficiency indicating relative improvements to eco-effectiveness linking chemical-related impacts to absolute sustainability limits, considering entire chemical and product life cycles".

As to the world of chemical pollution, Persson et al. (2022) made a brave attempt to establish a planetary boundary for this "novel entity". However, for the time being the concept may not be fully usable for analytical purposes; for example, the model or concept behind the term "system", and in this connection the terms "function" and "process" that are used in various places in the publication would need to be clarified. Yet there are clear merits of this attempt in establishing a planetary boundary for pollution, namely that it alerts to the fact that more pollution is a dead end and that "business as usual is not an option", which closes the loop to the GCO-II (UNEP, 2019). After all, Persson et al. (2022) advanced the highly demanding discussion, namely whether establishing a planetary boundary for novel entities including pollution would be methodologically possible (cf. Diamond et al., 2015, Fenner and Scheringer, 2021).

While some clarity on carrying capacities for pollution can be achieved at local or regional levels, drawing a global picture is much more challenging. In particular it is difficult to locate and trace substances, mixtures and products on global markets, track their movements in environmental compartments, products and trade, and what impacts they have at the local, regional and global levels. Overall, it is challenging to establish cause-effect relations between chemical hazard and global pollution levels and impacts. It is also a fact that, due to the overall complexity of issues involved, even the vast amount of data and information which is available in dedicated databases, e.g. at OECD and ECHA, is insufficient to produce the necessary knowledge. So far, both the global goal and the knowledge where we are making progress require more clarity.

Bottom line

Chemical intensification and the multiplicity of its impacts are deeply threatening to both human health and our planet's capacity to absorb pollution. While a range of regulatory and non-regulatory tools are available at local, regional and also global scale, their overall governance is fragmented. Moreover, their existence as such is ineffective in making chemical intensity sustainable and abandon pollution. Gaps still exist in many respects, including insufficient state capacity, knowledge, risk management, regulation, sustainability-orientation and funding.

SAICM is not a regulatory tool on a par with conventions. Rather it is a cooperation framework which is dedicated to creating a worldwide community devoting attention and resources to SMCW, the sound management of chemicals and waste. In fact, this is the aim of the ongoing intersessional process and the ICCM5 conference in 2023. Just as much, the real implementation work is to be done between conferences. Since goal-oriented cooperation is a key lever of change, we believe that much more effort should be invested in effective multi-stakeholder and multi-sector partnerships across yet existing borders. In any such effort, industry and entrepreneurship are the protagonists, and their actors and sectors have to follow the economic paradigm. This implies needs like level-playing fields, respect of business confidentiality and an economy of scale, to name just a few important aspects. Thus, while cooperation initiatives and partnerships need to consider the specific needs of industry, any action will have to be embedded in a regulatory and conceptual frame ensuring a sustainable pathway. This in turn requires true dialogue and collaborative efforts among all affected stakeholders and sectors.

Despite all challenges to specify the details, we believe that necessary discussion of details must no longer prevent significant advancements in the right sustainable direction. Ultimately this means that resolute cooperation is key between regulators, industry with its sectors, academia, and civil society, to successfully re-orient the mega-machinery of production and consumption towards future-proof sustainability.

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References

Andersen, Inger (2020): The triple planetary crisis: Forging a new relationship between people and the earth. 14 July 2020, Statement prepared for delivery to the Sub-Committee, Committee of Permanent Representatives. Available at https://www.unep.org/news-and-stories/speech/triple-planetary-crisis-forging-new-relationship-between-people-and-earth, accessed 18 Sep 2022.

Blumenthal, J., Diamond, M.L., Hoffmann, M., Wang, Z. (2022): Time to Break the “Lock-In” Impediments to Chemicals Management. Environmental Science and Technology, **56**, pp. 6863-6870.

Development and Cooperation (2021): Chemicals Management Briefing, available at https://www.dandc.eu/en/briefings/global-challenge-making-chemicals-usage-sustainable, accessed 27 May 2022.

Diamond M.L., de Wit, C.A., Molander, S., Scheringer, M., Backhaus, T., Lohmann, R., Arvidsson, R., Bergman, Å., Hauschild, M., Holoubek, I., Persson, L., Suzuki, N., Vighi, M., Zetzsch, C. (2015): Exploring the planetary boundary for chemical pollution. Review, Environment International, **78**, pp. 8-15.

European Commission, Joint Research Centre, Caldeira, C., Farcal, R., Moretti, C., et al. (2022): Safe and sustainable by design chemicals and materials: review of safety and sustainability dimensions, aspects, methods, indicators, and tools. Publications Office of the European Union, https://data.europa.eu/doi/10.2760/879069.

Fantke, P., Illner, N. (2019): Goods that are good enough: Introducing an absolute sustainability perspective for managing chemicals in consumer products. Current Opinion in Green and Sustainable Chemistry, **15**, pp. 91–97.

Fenner, K., Scheringer, M. (2021): The need for chemical simplification as a logical consequence of ever-increasing chemical pollution. Viewpoint, Environmental Science & Technology, **55**, pp. 14470-14472.

Franz, A.W., Kircher, M. (2021): Options for CO2-neutral production of bulk chemicals. Journal of Business Chemistry, **18**, pp. 63-78.

Fuller, R., Landrigan, P.J., Balakrishnan, K., Bathan, G., Bose-O’Reilly, S., Brauer, M., Caravanos, J., Chiles, T., Cohen, A., Corra, L., Cropper, M., Ferraro, G., Hanna, J., Hanrahan, D., Hu, H., Hunter, D., Janata, G., Kupka, R., Lanphear, B., Lichtveld, M., Martin, K., Mustapha, A., Sanchez-Triana, E., Sandilya, K., Schaefli, L., Shaw, J., Seddon, J., Suk, W., Téllez-Rojo, M.M., Yan, C. (2022): Pollution and health: a progress update. Review, The Lancet Planetary Health, **6**, pp. e535-e547.

Gibson, G. (2021): The Strategic Approach to International Chemicals Management: A case study of transnational public-private partnerships in the chemicals sector. Journal of Business Chemistry, **18**, pp. 9-19.

Gosalia, A. (2021): Sustainability in Uncertainty? Journal of Business Chemistry, **18**, pp. 44-48.

Vol.19, Iss.3, October 2022
URN: urn:nbn:de:hbz:6-72059464571
DOI: 10.17879/72059463356

Heck, J. Winters, B. (2021a): Climate neutrality: 2050 or already earlier? Journal of Business Chemistry, **18**, p. 43

Heck, J., Winters, B. (2021b): Doughnuts not only for eating. Journal of Business Chemistry, **18**, p. 79.

Holthaus, A., Hemmati, M. (2022): Gender - an essential substance for sustainable chemistry. Journal of Business Chemistry, **19**, pp. 30-35.

Paulus, J. (2021): Is the EU Green Deal channelling a transition towards a sustainable chemical industry? Journal of Business Chemistry, **18**, pp. 96-104.

Persson, L., Carney Almroth, B.M., Collins, C.D., Cornell, S., de Wit, C.A., Diamond, M.L., Fantke, P., Hassellöv, M., MacLeod, M., Ryberg, M.W., Søgaard Jørgensen, P., Villarrubia-Gómez, P., Wang, Z., Zwicky Hauschild, M. (2022): Outside the Safe Operating Space of the Planetary Boundary for Novel Entities. Policy Analysis, Environmental Science & Technology, **56**, pp. 1510-1521.

Raworth, K. (2017): Doughnut Economy. Seven Ways to Think Like a 21st-Century Economist. Chelsea Green Publishing, 320 pages.

SAICM (2019): Independent Evaluation of the Strategic Approach to International Chemicals Management from 2006-2015, Documents SAICM/IP.3/9 (Executive Summary, 13 pages) and SAICM/IP.3/INF/3 (Final Report, 94 pages), available at http://saicm.org/Beyond2020/IntersessionalProcess/ThirdIntersessionalmeeting/tabid/8024/language/en-US/Default.aspx, accessed 18 Sep 2022.

Steinhäuser, K.G., von Gleich, A., Große Ophoff, M., Körner, W (2022): The Necessity of a Global Binding Framework for Sustainable Management of Chemicals and Materials—Interactions with Climate and Biodiversity. Sustainable Chemistry, **2022**, 3, pp. 205–237.

Stolzenberg, H.-C. (2021): Stop global trend of chemical intensification, available at https://www.dandc.eu/en/article/application-chemicals-must-become-safer-and-more-sustainable, accessed 18 Sep 2022.

Stolzenberg, H.-C., Blum, C., Klauk, A., Nuss, P., Vierke, L., Wieck, S. (2021): Towards sustainable chemical intensity - A global, inclusive goal for the sustainable use of chemicals is needed to safeguard both societal wellbeing and earth's life-sustaining capacity. UBA Thought Starter, 4 pages. Available at https://www.umweltbundesamt.de/en/publikationen/uba-fact-sheet-thought-starter-towards-chemical, accessed 18 Sep 2022.

UBA (2009): Sustainable Chemistry. Positions and Criteria of the Federal Environment Agency. German Environment Agency March 2009, 42 pages. Available at https://www.umweltbundesamt.de/publikationen/sustainable-chemistry, accessed 18 Sep 2022.

UBA (2016): Guide on Sustainable Chemicals. A decision tool for substance manufacturers, formulators and end users of chemicals. German Environment Agency Nov 2016, 72 pages. Available at https://www.umweltbundesamt.de/publikationen/guide-on-sustainable-chemicals, accessed 18 Sep 2022.

UBA (2020): SubSelect - Guide for the Selection of Sustainable Chemicals. Available at https://www.umweltbundesamt.de/en/document/subselect-guide-for-the-selection-of-sustainable, accessed 18 Sep 2022.

UNEA Resolution UNEP/EA.5/Res.7 (2022): Sound Management of Chemicals and Waste. Available at https://www.unep.org/environmentassembly/unea-5.2/proceedings-report-ministerial-declaration-resolutions-and-decisions-unea-5.2, accessed 18 Sep 2022.

UNEA Resolution UNEP/EA.5/Res.8 (2022): Science-Policy Panel to contribute further to the sound management of chemicals and waste and to prevent pollution. Available at https://www.unep.org/environmentassembly/unea-5.2/proceedings-report-ministerial-declaration-resolutions-and-decisions-unea-5.2, accessed 18 Sep 2022.

UNEA Resolution UNEP/EA.5/Res.11 (2022): Enhancing Circular Economy as a contribution to achieving sustainable consumption and production. Available at https://www.unep.org/environmentassembly/unea-5.2/proceedings-report-ministerial-declaration-resolutions-and-decisions-unea-5.2, accessed 18 Sep 2022.

Vol.19, Iss.3, October 2022
URN: urn:nbn:de:hbz:6-72059464571
DOI: 10.17879/72059463356

UNEA Resolution UNEP/EA.5/Res.14 (2022): End plastic pollution: Towards an international legally binding instrument. Available at https://www.unep.org/environmentassembly/unea-5.2/proceedings-report-ministerial-declaration-resolutions-and-decisions-unea-5.2, accessed 18 Sep 2022.

UNEP (2019): Global Chemicals Outlook II – From Legacies to Innovative Solutions: Implementing the 2030 Agenda for Sustainable Development. 700 pages. Available at https://www.unep.org/explore-topics/chemicals-waste/what-we-do/policy-and-governance/global-chemicals-outlook, accessed 18 Sep 2022.

UNEP (2020): Green and Sustainable Chemistry: Framework Manual. 106 pages. Accompanied by the infographic "Advancing the 10 Objectives and Guiding Considerations For Green and Sustainable Chemistry". Available at https://www.unep.org/explore-topics/chemicals-waste/what-we-do/policy-and-governance/green-and-sustainable-chemistry, accessed 18 Sep 2022.

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Commentary

Nora Sophie Griefahn*

Cradle to Cradle: Why we need to rethink the way we produce

More and more people are worried about harmful chemicals in our products. A survey by Statista from 2017 showed that 84% of the respondents fully agree or tend to agree with the statement "I am concerned about the health effects of chemicals in everyday products." (Statista, 2017). This concern about harmful ingredients does not only show in surveys but also in the products consumers choose to buy. The market share of natural cosmetics for example has constantly been increasing in the last few years (EHI Retail Institute GmbH, 2022). More and more products are marked as "natural" or even "free of chemicals". In its extreme form, an aversion to chemicals can even lead to an irrational fear of chemicals, also called chemophobia (Saleh et al., 2020).

Why we love good chemicals

Of course, it is a positive development that there is an increasing discussion about what ingredients are actually in our products and about harmful chemicals in general. However, what tends to get lost in the public discussion is the fact that everything is chemical. Every person, every product is based on and needs carbon, the basis of organic chemistry. When we think about an apple or a flower, most people will probably not see these items as chemical products, but in fact they are also made of chemical elements. Chemistry or chemicals are not by definition harmful, whereas "natural" does not always mean positive and healthy. Instead of this misleading separation, we should rather focus on a product's use scenario. In some scenarios the use of chemicals in a product might be completely harmless and even useful, whereas in other use cases, it might cause harm to us and the environment. This issue can be resolved when we start thinking about a product's use scenario from the very beginning: when we design a product. Thus, we need to rethink the way we design our products and the materials we choose to use.

However, when we talk about product design, material health is not the only issue. We live in a world with scarce resources and our current way of production and consumption is not at all sustainable: we take resources, make a product and after its usage, the product or parts of it become waste. In the case of plastic packaging materials, 44% of them go into thermal recovery instead of re-using the processed resources (Umweltbundesamt, 2019). And even the packaging materials that go into recycling lose quality during the recycling process due to their linear design. By doing this, we are wasting valuable finite resources and are at the same time producing a massive amount of waste. Thus, with this linear way of production we are creating damage to ourselves and the environment. Instead, we need to start thinking in a circular way (Ellen MacArthur Foundation, 2022).

A new product design with Cradle to Cradle

Cradle to Cradle design combines circularity and material health. Cradle to Cradle (C2C) aims for a consistent circular economy which, in contrast to other concepts, already begins with design and material selection, and which regards humans as potential beneficiaries. In a C2C world, all resources circulate in biological or technical spheres. Materials from the biosphere are returned to the natural cycle, while materials from the technosphere can be continuously reused - making the concept of waste obsolete. Instead of consuming finite resources, we use them for their defined use scenario. In this way, they can become nutrients for new products again and again. The prerequisite for this is that products are developed for cycles right from the start: Suitable for a specific use scenario, beneficial within their specific usage scenario for people and nature, and recyclable without loss of quality (Cradle to Cradle NGO, 2022).

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Material health and positive ingredients

In order to develop a better understanding of the C2C design concept in the context of chemistry, we need to take a closer look at the concepts of material health and the use scenario. Starting with a product's design is crucial when we want to develop truly circular products. During this design process we have to rethink the way we choose the materials and ingredients. A C2C product must always be designed for its defined use scenario. When it is inevitable that parts of the product end up in the environment during or after its usage, these parts have to be designed for the biosphere and be, for example, biodegradable. This is relevant for any product with abrasion such as tires or textiles. Harmful chemicals or other materials that cause damage to our health or harm the environment must not be part of these products. When a product's parts do not end up in the environment, it must be designed for the technical cycles in the technosphere. To do so, the product must be built in such a way that it can be completely dismantled without leaving any residue, and every material can be recycled by type. In this way, we are able to design beneficial and circular products that provide benefits for us and the environment, instead of harming it (Cradle to Cradle NGO, 2022).

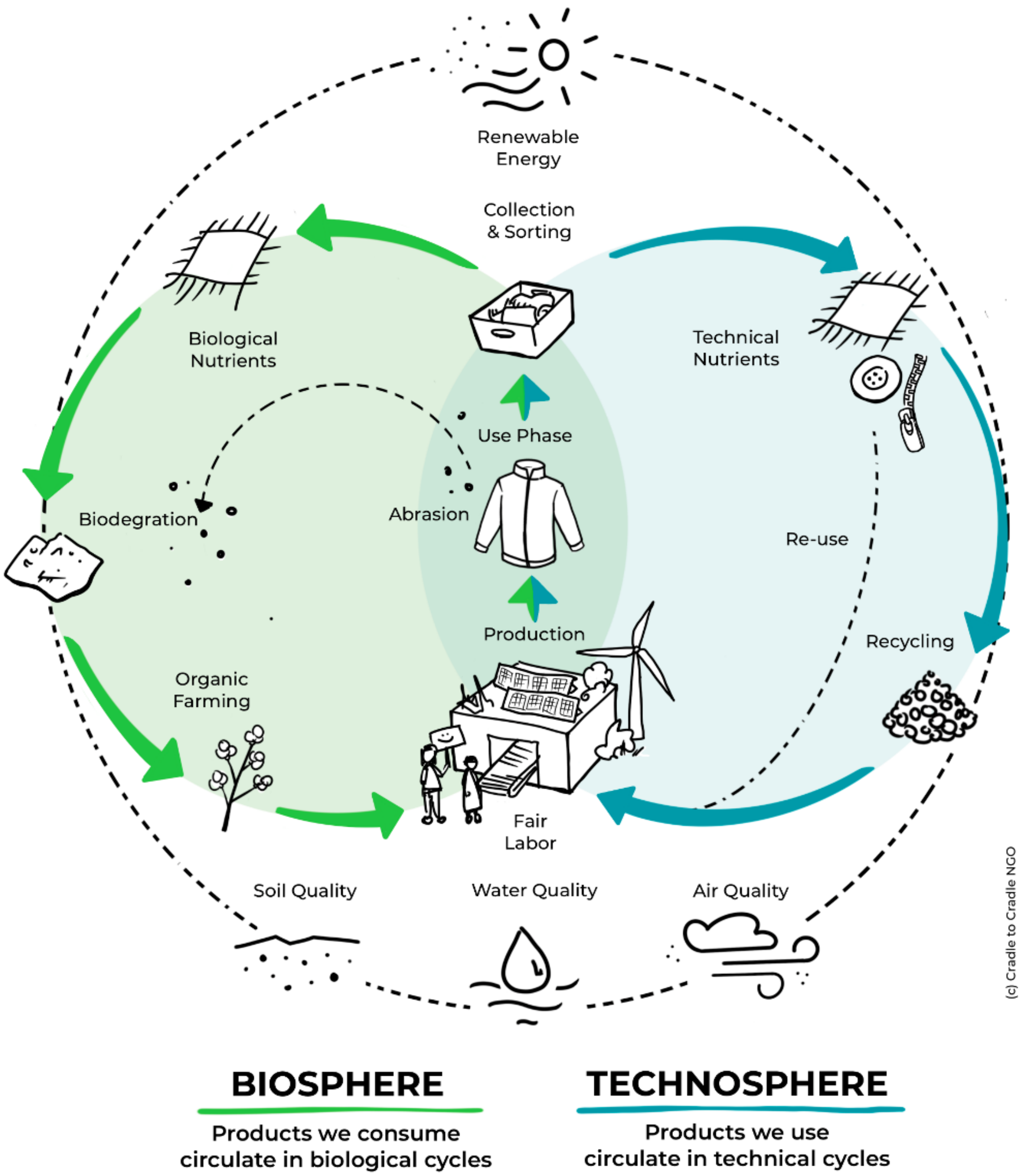

Figure 1 Biosphere and technosphere (Cradle to Cradle NGO).

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After defining the use scenario, we need to choose the appropriate materials and ingredients for the product. Right now, we often try to exclude harmful chemicals and cover our products with long lists of "free of's": free of microplastics, free of chemicals, free of aluminum salts. The problem with this approach is that excluding one ingredient does not mean that the rest of the product is harmless. In the 1990s, asbestos was used in brake pads for cars, but was then found out to be carcinogenic. Therefore, it was banned and a substitute, antimony sulfides, was used instead. However, later on, antimony sulfides were found out to be carcinogenic as well (von Uexküll et al., 2005). This shows that just by declaring a product free of something does not automatically mean that the product is beneficial or even harmless. A way to manage the process of deciding which materials should or should not be used are lists of banned substances, such as used by the Products Innovation Institute (Cradle to Cradle Products Innovations Institute, 2022). In their process of certifying C2C products, they combine lists of banned substances with lists of positively defined ingredients. Instead of only banning harmful materials, the products contain defined materials which are harmless or even beneficial for us and the environment. This goes along with the C2C school of thought: doing less bad is not enough, we need to be beneficial instead and create added value.

Why we need C2C in the chemical industry

The chemical industry is the basis and an imperative first step of production for a lot of other industries. Many products are dependent on materials produced by the chemical industry: colors for the textile industry, adhesives and sealants for building products or the automotive industry, synthetic materials for all kinds of plastic products, just to name a few (Accenture, 2017). If we want to achieve a circular economy starting by design, it is crucial that we start with the chemical industry. By doing this, we can set the course for all other industries. However, this is not only a nice-to-have for the chemical industry to become a little bit greener. Scarce resources and an unstable geo-political situation make the goal of a circular economy, based on the C2C principles, ecologically and economically necessary.

Implementing C2C in the chemical industry

But how can companies within the chemical industry start implementing circular business models and include C2C principles in their strategies? The starting point of a company's strategy needs to be a product's design. Trying to put an already existing product into a circular economy, is not going to solve our problems in the long-term. Instead, a product needs to be designed according to C2C principles right from the beginning, so it can truly be a part of a circular business model. To do so, companies need to invest into research and development to find circular alternatives for their materials. Process chemicals for example would be a good starting point for the chemical industry since they are used across industries and often responsible for water pollution during production. Additionally, cooperation is key for achieving a real circular economy. When companies work together with their customers and suppliers along the complete supply chain there is more potential for innovation and new ideas to rethink products in a circular way. Besides, the chemical industry needs to be open to different types of technology and materials. Just to name one example from the plastics industry, agricultural residues can be used for plastic alternatives (Traceless, 2022).

However, when companies within the chemical industry want to implement circular business models, they are facing barriers and challenges. Research and development of innovative materials and circular alternatives costs money which make some companies reluctant to invest in C2C solutions. In the long term, however, it pays off for companies to make these investments, both ecologically and economically.

Investment barriers are not the only challenges companies face when implementing C2C solutions and business models. Legal and political frameworks that encourage actions that are diametrically opposed to a circular economy pose another challenge on our way to a circular economy following C2C principles. When we take the plastics industry as an example again, it becomes obvious how indirect subsidies incentivize behavior which supports a linear way of production. As long as it is still cheaper to produce virgin plastic from crude oil in Germany, since it is exempt from energy tax, there is no incentive for the chemical industry to invest in plastics that are easy to recycle - regardless of the material (Wider Sense & Röchling Stiftung, 2020).

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Thus, it does not only need action from companies within the chemical industry, but also political action and the abolishment of subsidies that lead us in the wrong direction to achieve a circular economy according to C2C.

A circular use of carbon and phosphorus

However, Cradle to Cradle is not only a solution for circular and beneficial products but can also be applied to chemical elements such as carbon or phosphorus. Carbon is a good example of a resource we massively mismanage. In the form of CO2 in very high concentrations in our atmosphere, carbon is harmful and is accelerating the greenhouse gas effect. However, the goal of reducing CO2 emissions in order to fight climate change can only be an intermediate step. In the long term, we must see carbon - the basis of organic chemistry - for what it is: an important raw material that must be managed in cycles. Today, we extract oil from the earth, produce products from it that end up as waste, or burn it directly. In this way, too much carbon ends up in the atmosphere, where it accelerates climate change. A linear process and poor carbon management

A good example for circular carbon management is agriculture and soil. Humification processes incorporate carbon into the soil over the long term, making it the most important carbon store ahead of forests and oceans. However, this carbon is released during intensive use by conventional agriculture. We need to implement regenerative agriculture instead, which builds up humus and captures carbon and is more productive. This is not only smart carbon management but is also necessary to feed an increasing world population (Umweltbundesamt, 2022).

In addition, we need to promote negative emissions technologies such as biocarbons which we can use to recover CO2 from the atmosphere and use it for example for agriculture or in the plastics industry (Carbonauten, 2022). To do this, we need a science-based carbon management strategy that encompasses all sectors of the economy. In all these technologies recyclability must play a central role. Recovery and industrial applications must only use renewable energy that is produced in facilities that are able to circulate in the technosphere. Otherwise, we are merely postponing our problems instead of addressing interrelated problems in the long term.

Another good example which shows the potential of a circular use of resources is phosphorus. Phosphate (PO4) is found in minerals and is extracted in mines. It is essential for us humans since we need phosphorus for the energy metabolism in our cells and it is literally part of our DNA. Additionally, phosphorus is in high demand in agriculture since it is an indispensable nutrient for growing crops. At the moment, Germany is importing all of its phosphorus demand (approx. 120,000 tons of phosphorus per year) (Umweltbundesamt, 2019). However, the peak phosphorus, meaning the point of time at which the supply of phosphorus can no longer meet the increased demand, is expected to be reached between the years 2051 and 2092 (Umweltbundesamt, 2018). Thus, we are in desperate need of circular solutions to meet our phosphorus demand. Luckily, phosphate can also be found in high concentrations in urine, so it can be recovered either directly from urine or from sewage sludge instead of being repeatedly imported. The recovery rate within this process is quite high, so an estimated amount of 50,000 tons of phosphorus per year can theoretically be recovered (Umweltbundesamt, 2018).

How C2C can transform our economy

Phosphorus is only one example which shows how circular solutions can, among other benefits, make us less dependent on resource imports. In our complex political order full of global uncertainties and sometimes unstable value chains, circularity can be a reliable pillar. This reliability is important for the industry, also the chemical industry, which is highly dependent on imports.

However, circularity on its own is not enough to really transform our economy. In order to achieve a fully functioning circular economy following the principles of Cradle to Cradle, we do not only need circular products but also circular business models and reversed logistics on a global scale. Having circular products which are designed for their specific use scenario is an important step, but we also need appropriate logistics to allow products to circulate and to ensure that we have all the resources we need at the right place at the right time.

With this demand, the chance for a number of new business models emerges. Product-as-a-service models are a useful addition to C2C products: the manufacturer or another agent in the supply chain takes back the product from the

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consumer after its usage and can use the valuable resources for new products. These new business models must be accompanied by digitization. With digital material passports we can track at any time where valuable resources are currently located and what their market value is.

The transformation of our economy is not only necessary from a resource and climate point of view, but it is also a declared political goal to tackle the great problems of our time as well as preparing the European industries for the future. With the European Green Deal and the Circular Economy Action Plan the European Commission has set clear targets for a circular transformation of our economy and society. Within the Green Deal it is for example stated that all packaging needs to be recyclable or reusable by 2030 (European Commission, 2019). We urgently need the chemical industry to reach this goal.

In addition to this political imperative, it is important that the (chemical) industry begins to understand that a circular economy represents a great opportunity for the economy to ensure future competitiveness and to reconcile economy and ecology. Cradle to Cradle provides the blueprint for this as a design and innovation approach.

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DOI: 10.17879/72059462667

References

Accenture (2017): *Taking the European chemical industry into the circular economy*, available at https://cefic.org/app/uploads/2019/02/Accenture-Cefic-circular-economy-brochure.pdf, accessed 22 June 2022.

Carbonauten (2022): *Carbonauten*, available at https://carbonauten.com/, accessed 21 June 2022.

Cradle to Cradle NGO (2022): *Cradle to Cradle*, available at https://c2c.ngo/cradle-to-cradle/, accessed 16 June 2022.

Cradle to Cradle NGO (2022): *Umgestalten*, available at https://c2c.ngo/umgestalten/, accessed 16 June 2022.

Cradle to Cradle Products Innovations Institute (2022): *Cradle to Cradle Certified Restricted Substances List (RSL)*, available at https://www.c2ccertified.org/resources/detail/cradle-to-cradle-certified-restricted-substances-list-rsl, accessed 16 June 2022.

EHI Retail Institute GmbH (2022): *Umsatz mit Naturkosmetik in Deutschland in den Jahren 2007 bis 2018 (in Millionen Euro)*, available at https://www.handelsdaten.de/koerperpflege-und-gesundheit/umsatz-mit-naturkosmetik-deutschland-zeitreihe, accessed 15 June 2022.

Ellen MacArthur Foundation (2022): *We need to radically rethink the way we design*, available at https://ellenmacarthurfoundation.org/introduction-to-circular-design/we-need-to-radically-rethink-how-we-design, accessed 15 June 2022.

European Commission (2019): *The European Green Deal*, available at https://ec.europa.eu/info/sites/default/files/european-green-deal-communication_en.pdf, accessed 23 June 2022.

Saleh, R., Bearth, A., Siegrist, M. (2020), Addressing Chemophobia: Informational versus affect-based approaches, *Food and Chemical Toxicology*, 140, p. 1.

Statista (2017): *Meinung zu den Auswirkungen von in Alltagsprodukten vorhandenen Chemikalien 2017*, available at https://de.statista.com/statistik/daten/studie/782080/umfrage/meinung-zu-den-auswirkungen-von-in-alltagsprodukten-vorhandenen-chemikalien-in-der-eu/, accessed 15 June 2022.

Traceless (2022): *Traceless*, available at https://www.traceless.eu/materials, accessed 26 September 2022.

Umweltbundesamt (2018): *Klärschlammentsorgung in der Bundesrepublik Deutschland*, available at https://www.umweltbundesamt.de/sites/default/files/medien/376/publikationen/2018_10_08_uba_fb_klaerschlamm_bf_low.pdf, accessed 21 June 2022.

Umweltbundesamt (2019): *Aufkommen und Verwertung von Verpackungsabfällen in Deutschland im Jahr 2019*, available at https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2021-11-23_texte_148-2021_aufkommen-verwertung-verpackungsabfaelle-deutschland-2019_bf.pdf, accessed 23 September 2022.

Umweltbundesamt (2019): *Ökobilanzieller Vergleich der P-Rückgewinnung aus dem Abwasserstrom mit der Düngemittelproduktion aus Rohphosphaten unter Einbeziehung von Umweltfolgeschäden und deren Vermeidung*, available at https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2019-02-19_texte_13-2019_phorwaerts.pdf, accessed 21 June 2022.

Umweltbundesamt (2022): *Emissionen der Landnutzung, -änderung und Forstwirtschaft*, available at https://www.umweltbundesamt.de/daten/klima/treibhausgas-emissionen-in-deutschland/emissionen-der-landnutzung-aenderung#bedeutung-von-landnutzung-und-forstwirtschaft, accessed 21 June 2022.

Uexküll, O., Skerfving, S., Doyle, R., Braungart, M. (2005): *Antimony in brake pads - a carcinogenic component?*, Journal of Cleaner Production, 13 (1), pp. 19-31

Wider Sense & Röchling Stiftung (2020): *Polyproblem-Report*, available at https://polyproblem.org/wp-content/uploads/Polyproblem-_Wertsachen_Web-1.pdf, accessed 26 September 2022.

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Commentary

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Current trends and challenges in the pharmaceutical industry - we are here to make a difference

Introduction

The pharmaceutical industry is currently undergoing a major shift, driven primarily by groundbreaking new therapeutic approaches and a radical technological revolution. Issues such as the growing population of our planet, high unmet medical needs in various disease areas, and the rise of certain emerging markets to global players represent further challenges the industry must overcome.

On top of this, there is the lasting impact of the pandemic and the energy crisis caused by the war in Ukraine, which have led to supply chain disruptions and the need to adapt business and operating models to the "new normal". Finally, sustainability has stepped up from being a "feel-good topic" to being a business-critical success factor across the entire value chain. We need to act responsibly now to achieve challenging climate goals and safeguard our planet's resources for generations to come.

Against this backdrop, the pharmaceutical industry has to refocus and prepare for the future by establishing highly efficient and innovative R&D, agile marketing, and especially resilient and sustainable product supply organizations.

This commentary aims to reflect on a number of questions associated with industry trends and challenges. How do current trends impact our core business? How can we leverage our key strengths to unleash the full potential of our assets? How are we to deal with increasing regulatory requirements? Why should we make sustainability our top priority? How are we to rise to the challenges resulting from the pandemic and continue with renewed strength to make a difference for patients – now and in the future?

Megatrends and current challenges shaping the future of our industry

The effects of the pandemic are currently still very present in our daily routine, in both our working environment and our private lives. On top of this has come the terrible war in Ukraine, which has led to an unforeseen energy crisis, a rise in inflation, and higher raw material prices. Even without these global crises, the pharmaceutical industry was already undergoing a major transformation, driven primarily by the combination of radical inventions in the biology and biomedicine fields and digital innovations. This is still ongoing. Overall, we are facing a situation that makes one thing very obvious – we have to critically question our processes and long-established modes of (inter)action in the pharmaceutical industry to reorient and reinvent ourselves and be prepared for current challenges and those that lie ahead.

Amongst the most pressing global trends that will heavily affect our industry are the following:

- Our planet's growing and aging population – two billion people worldwide will be over the age of 60 by 2050, a doubling of this age group as compared to 2015.[1]
- The increase in "prosperity" diseases – for example, the number of people with diabetes is predicted to rise to 578 million by 2030, and to 700 million by 2045. (Datta, 2019)
- High unmet medical need for various indications – more than ten million patients globally suffer from Parkinson's disease, which is one of the fastest-growing diseases in terms of prevalence, disability, and mortality.[2]

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[1] For statistical data, see: https://www.who.int/news-room/fact-sheets/detail/ageing-and-health, accessed July 27th 2022

[2] For statistical data, see: https://www.parkinson.org/Understanding-Parkinsons/Statistics, accessed July 27th 2022.

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In line with our primary aim and purpose – improving patients' lives – we in the pharmaceutical industry need to switch gears and find ways to address these challenges. And we have already taken up the gauntlet. The combination of breakthrough discoveries in biological science (CRISPR-CAS was awarded the Nobel Prize in 2020) and the dynamic development of digital and computer science (from computing and automation to artificial intelligence) is propelling an unprecedented wave of innovation, referred to as the "biorevolution" (Chue et al., 2020). As a consequence, novel biological, biochemical, and biomedical applications are already improving our response to global challenges, with the best example being the recent pandemic. The speed at which scientists sequenced the coronavirus genome within weeks rather than months would not have been possible just a few years ago. In addition, new biochemical tools such as mRNA technology have reached maturity, enabling real-life applications such as the rapid introduction of mRNA-based vaccines to fight the pandemic. The development of smart devices, remote health monitoring, and precision medicines tailor-made to meet the need of individual patients are further examples of recent technological advances.

The rapid evolution of new technologies obviously opens up a range of unforeseen opportunities, especially for customers and patients. For example, we could unlock applications for biomedical tools that actually cure rather than just treat some of the most serious and deadly diseases such as cancer. As always, however, those opportunities are accompanied by challenges that need to be overcome first.

- Transforming Active Pharmaceutical Ingredient (API) portfolios from conventional small molecules to new chemical modalities and biomolecules requires an expansion of expertise and the establishment of new production technologies.
- End-to-end supply chains have been hit hard by the pandemic and must be turned into a future-proof setup with improved resilience.
- Sustainability has evolved into a huge, business-critical task that is increasingly relevant to keeping our license to operate.
- Artificial Intelligence opens up a vast array of options, but we still have some miles to go as an industry if we are to leverage the huge potential of digital solutions.

Further current challenges include reduced development timelines. One major focus of the pharmaceutical industry is to make new treatment options available to patients in need – as safely and yet as quickly as possible. In addition, new regulatory requirements and changes in reimbursement regimes are being driven forward. Speeding up development cycles raises the need to ramp up external innovation and partnerships, requiring new ways of thinking, for example by focusing on creative collaboration models with the clear goal of making full use of the knowledge capacity of other agile companies and start-ups.

Finally, the lasting impact of the pandemic has brought to the fore the need to transition to what is being called the "new normal", with remote working models (e.g. working from home, virtual audits, etc.) putting employees and new ways of working even more prominently at the center of attention. This is of crucial importance – not least because people and employees are the most valuable resource for companies to build on. Beyond the highly motivated workforces in the companies and organizations, we must put all patients in need at the heart of everything we do.

Selected challenges – dangers to our business or opportunities for growth?

Portfolio transformation – from conventional small molecules to new (chemical) modalities

As we have already pointed out, large parts of our industry are currently undergoing a portfolio transformation based on the increasing importance of new modalities. Over the past decade, the conventional drug discovery toolbox has been expanding continuously from traditional, small molecule APIs to new chemical modalities such as peptides, oligonucleotides, PROTACs, RNA-targeting therapeutics, antibody drug conjugates, and gene-editing approaches (Blanco et al., 2020).

While the transformational breakthroughs in bioscience offer invaluable opportunities for patients in need of new therapeutic approaches, the situation also poses challenges to the pharmaceutical industry. Firstly, we must extend our technological capabilities – including employees' knowledge, but specifically also engineering and manufacturing

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expertise – across the whole value chain from development to routine production on both a medium and a large scale.

Accepting that many key players in the pharmaceutical industry aim to build their future portfolio on new modalities to a significant extent, the question arises: "What about conventional small molecules and traditional organic chemistry – will they disappear?" Our clear answer is no! Instead, we are convinced they will continue to play a key role going forward. There will be many unsolved problems where chemical know-how, creativity and a deep knowledge of conventional process chemistry are of vital importance when it comes to uncovering the best methods of synthesis and scaling up, thus making next generation APIs accessible for patients (Nising and von Nussmaum, 2022). Chemical API manufacturing that applies state-of-the-art technology platforms in all necessary volumes will significantly contribute to driving economical and sustainable supply and growth.

However, even the small molecule business is currently undergoing a significant transformation. Most importantly, there has been a clear trend towards APIs that are structurally more complex. Among the main reasons for this progression over recent years are the lower druggability of several disease-specific targets and a narrow patent space due to increasing competition. Having said that, complexity in the small molecules API field is increasing in many directions. Increasing molecular complexity (i.e., higher molecular weights, moving toward more complex structural features such as macrocycles, greater number of stereogenic elements, etc.) often results in a higher step count in the initial synthetic approach. In addition, a broad range of production scales across the API portfolio – from small-scale APIs for treating rare diseases to chronic treatment of cardio-vascular indications typically characterized by high peak demands – often places additional pressure on the manufacturing and supply chain setup. Quite regularly, the volume variances in larger API portfolios range from just a few hundred grams to three-digit ton demands at peak sales. Special technologies in the areas of highly potent APIs, biocatalysis, electrochemistry, photochemistry, or unit operations such as ultrafiltration, lyophilization, and chromatography are often required to produce next-generation APIs and drug products at scale.

The rising complexity and the trend toward more complex clinical trials, sometimes involving a higher number of patients in earlier clinical phases and higher costs per patient, result in a significantly increased cost of goods pressure. Contrary to previous experiences, this is increasingly driven by API manufacturing. The need to support even shorter development timelines so as to bring life-saving medications to patients as quickly as possible often means the production process is less well developed at launch. This increases the need for post-launch changes or the development of "second-generation processes". It goes without saying that the very high quality standards for pharmaceutical products need to be safeguarded at all times.

In summary, there is an increase in the challenges for and expectations of pharmaceutical manufacturing organizations to supply innovative drugs in a fully reliable, cost-efficient, competitive, and sustainable way. At the same time, these reasons are offering opportunities to adapt traditional ways of working and make a difference in people's lives.

As an industry, we should always aim to establish first-in-class development and technology platforms with state-of-the-art, digitally transformed product supply networks. We must strive to be at the forefront of innovation and technological development. To safeguard the reliability of supply and commercial competitiveness, we firmly believe that strong in-house launch capabilities with a fully integrated interface between chemical and pharmaceutical development and product supply functions are key success factors for ensuring best-in-class supply of key brands to meet patients' needs and impact their lives for the better.

Resilient supply chains – impact during the pandemic and how we safeguard our future

The shock to supply and demand that arose out of the epidemic situation in China in January 2020 and the resulting global pandemic exposed vulnerabilities in the production strategies and supply chains used across many different industries. Concrete effects of the pandemic included:

- Lockdown and quarantine regulations affecting resource availability in production plants and distribution centers
- Temporary trade restrictions

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- Transport capacity shortages, especially air- and sea-freight containers
- Changed demands and stockpiling
- Shortages of many products, highlighting weaknesses in supply chains

The economic turmoil caused by the pandemic has exposed many vulnerabilities in supply chains. There has therefore recently been widespread speculation in policy circles and the popular press as to whether globalization is still a valuable guiding principle for the future. Will or should the experience of the pandemic lead to supply chains becoming more local again?

It is our firm view that it should not! Going back to a domestic setup will not solve the issues described above but would instead cause knock-on effects such as increased costs and capacity shortages, the rise of a global recession and decreased flexibility. We strongly believe that the key to success is a global supply network with strong regional footprints, relying on free trade and cooperation in industrial operations. If we are to overcome future crises with global impact, what we need are global and resilient supply chain solutions, globally diversified production and distribution networks, and global capacity reserves that offer flexible room to maneuver, among other things.

As the pharmaceutical industry, we should stand up for a transparent, rules-based system of trade, managed globally by international institutions. We must strive for resilience rather than isolation. At the same time, we should foster balanced and diversified global networks, including back-up systems within well-defined, segmented supply chains. Localization reduces the scope for fallback options and capacity reserves. In addition, we must further exploit the opportunities that Industry 4.0 offers for increasing supply chain transparency and improving risk management.

Digitalization is a key lever for optimizing supply chain processes and creating end-to-end transparency. Although "end-to-end" is regularly used as a buzzword, all too often we fail to look beyond the bounds of our own companies. The pandemic taught us that we must have a deep understanding (and ideally a real-time picture) of the entire value chain from 1st/2nd tier suppliers all the way downstream to distributors and pharmacies and ultimately the patient. We need to be able to receive early alerts when supplier problems arise and proactively manage demand signals. This includes merging suppliers and CMO partners on integrated platforms, increasing data transparency, cloud-based, real-time tracking of transports, and intelligent control tower solutions.

Digitalization and Industry 4.0 – a challenge that offers immeasurable chances for improvement

The ongoing automation of traditional manufacturing and industrial practices using modern smart technology based on cyber-physical systems (CPS) and dynamic data processing is commonly referred to as "Industry 4.0" (Arden et al., 2021). This is having a major impact on manufacturing in the chemical and pharmaceutical industry, too. While it seems obvious that digitalization offers a variety of options for improvement in production, the challenge we often face is keeping pace with the overwhelming speed at which digital solutions sometimes evolve in adjacent industries. To be honest, the traditional pharmaceutical industry (especially the big players) is not noted for its ability to adapt quickly to new technologies, and isn't typically known for being particularly agile and dynamic in this regard. Even so, we are facing the reality of having to digitize our processes and change data and business processes to achieve digital transformation. This is a must – even in a strongly regulated environment.

In the pharmaceutical industry, we have access to data from research studies, production campaigns and marketing and sales, for instance. Digital technologies such as machine learning and artificial intelligence (AI) have the ability to connect and leverage this data so as to uncover new insights and improve decision making. With the help of data and digital technologies, we are able to develop new solutions that better fit our patients' needs. This enables us to manufacture more efficiently in digital factories and reduce our own environmental footprint.

A clear vision for implementing digital solutions in API production is typically driven by advanced analytics technologies, alongside transforming the ongoing automation into smart manufacturing. It might seem natural to assume that, for the majority of mature products, the respective manufacturing processes have been exhaustively optimized over the years. It was therefore all the more surprising and highly motivating to learn that there

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is still potential to unleash by applying data science tools, even for long-established products. One thing is essential for the digital transformation – it has to be closely linked to the business by using digital insights to unlock additional value with relevant impact. It does not make sense to simply introduce technology just because it's all the rage. Doing so can bring with it a major risk of failure (Hotz, 2022). Taking this as a basic guiding principle for selecting meaningful use cases, it is advisable to follow a gradual process, starting with a plant readiness assessment (rating digital maturity), followed by a process improvement analysis (problem identification), clustering, and finally, prioritizing potential digitalization projects through the creation of implementation plans. In our experience, the key success factors of every advanced analytics project are best summarized as follows:

- 10% of the success is due to the algorithms identified
- 20% is based on successful application of new tools and improving the IT and computing landscape
- 70% can be attributed to sensitivity in the change management process, driven by the excitement and involvement of the interdisciplinary teams

Most importantly, "digital" must become an integral part of our thinking and mindset. In this context, it is worth pointing out that there is much to learn from next-generation employees – let's empower them to speak up, to share their views and knowledge and thus propel our digital transformation efforts in our industry to reach unprecedented speeds.

Sustainability – a challenge we must take seriously to safeguard our planet's resources

The scientific evidence could not be clearer. Global climate change caused by human activity is happening now and poses a growing threat to society. The pace of change and the evidence of harm have increased markedly over recent years. The time to significantly reduce greenhouse gas emissions is therefore now. Sustainability has quickly grown from a "feel-good" topic to a business-critical success factor. Society at large is increasingly aware of sustainability issues and has developed a strong desire for responsible action and change. As the pharmaceutical industry, we have a responsibility to deliver on the expectations of customers, policy makers, and investors. Most importantly, however, we should strive to push ourselves even beyond benchmarks and regulations imposed from the outside, since we are aware that it is us who can make a difference for the generations to come. API manufacturing organizations in particular have a huge lever when it comes to improving our industry's ecological balance (Flessner, 2022).

In order to improve our ecological footprint, we need to consider the following relevant aspects – science-based climate targets, water and waste reduction targets applying the principles of circularity, and the responsible use of substances, focusing on green chemistry. A strong basis for fulfilling challenging climate targets is typically a sound and forward-looking sustainability and green energy strategy. We need to aim for compliance with the carbon reduction ambitions defined by the European Green Deal as a business imperative. We should foster an even more intense dialog and partner up across divisions, companies, and even industries to reach the most challenging goals. Especially in the area of circularity, we strongly believe there are many opportunities beyond those currently being addressed. Once we enter into open discussions, we can come up with joint ideas that make the most of our creative potential and technological expertise.

Furthermore, sustainability must be a factor in everything we do, including hiring next-generation scientists and leaders with an eco-centered mindset to proactively design production and packaging processes, focusing our downstream distribution on reducing, recycling and/or reusing waste streams and optimizing our value streams across the entire value chain – from suppliers to customers and patients. Examples from API manufacturing include the recycling of starting materials, reagents or catalysts from production waste, with subsequent repurposing of the recovered material, and the use of biocatalytic platforms to replace the conventional chemical routes of synthesis with less resource-intense alternatives. Using raw materials from biogenic sources can further reduce our overall footprint.

We should also keep in mind that sustainability goes beyond waste treatment, circularity, and handling emissions. The final – but no less important – dimension is social responsibility. For example, it is well worth acknowledging the valuable impact of funding regional initiatives, engaging in the field of social innovation and hands-on support for science education. Both in the communities around our sites and in society as a whole, these efforts can bring about improvements and really make a difference.

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What actually makes the difference – people are our greatest asset

As the saying goes, "If you want to go fast, go alone. If you want to go far, go together!" A high level of commitment among employees is essential when it comes to achieving progress in our industry, mastering the challenges of today so as to be prepared for the future, and coming up with innovative solutions that address the needs of both our own generation and those to come – from sustainability to unmet medical need in a growing and aging population. To achieve this, we need to go from "command and control" to "agility and adaptability", with a key element of personal development and leadership being empowerment. In addition, we need to really live up to our commitment to inclusion and diversity. As employers, we must therefore take on the challenge of creating a working environment that values all people, supports them in their (self-)development and fosters creativity. On the other hand, it is up to every single employee to embrace a mindset based on a constant willingness to learn and adopt a culture of interaction.

Summary and conclusion – we are here to make a difference!

There are several key challenges that we need to take seriously to successfully shape the future of the pharmaceutical industry – the increasing cost pressure in production, the need to implement supply chain concepts with greater resilience, full commitment to driving sustainability, and the question of how to unleash the full potential of digital solutions in an industry that has historically not been very agile.

We need to act now to maintain the strong momentum of our industry and safeguard pharmaceutical companies as innovative and competitive global players with strong footprints in their home countries. If we approach this proactively, it is a big opportunity – but it might become a threat if we do not foster collaboration and joint action now. We must also not forget that it's all about the people, because every change needs strong commitment among staff, coworkers, and collaborators. Ultimately, this means we need to face and tackle the challenges for our industry together – across leading pharma companies, across the interface between industry and academia, and across colleagues with diverse backgrounds and opinions.

Our challenge to you today, therefore, is this – let's tackle it together. Let's team up and strengthen collaboration to shape the future of our industry together. Let's go hand in hand, using collaborative network approaches as a basis wherever feasible.

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References

Arden, N. S., Fisher, A. C., Tyner, K., Yu, L. X., Lee, S. L., Kopcha, M. (2021): Industry 4.0 for pharmaceutical manufacturing: Preparing for the smart factories of the future, *Int. Journal of Pharmaceutics*, 602, 120554, published online and available at https://www.sciencedirect.com/sdfe/reader/pii/S0378517321003598/pdf, accessed July 27th 2022.

Blanco, M. J., Gardinier, K. M. (2020): New Chemical Modalities and Strategic Thinking in Early Drug Discovery, *ACS Med. Chem. Lett.*, 11 (3), pp. 228-231.

Chui, M., Evers, M., Manyika, J., Zheng, A., Nisbet, T. (2020): *The Bio Revolution*, available at https://www.mckinsey.de/~/media/mckinsey/locations/europe%20and%20middle%20east/deutschland/news/presse/2020/2020-05-14%20mgi%20bio%20revolution/mgi-bio-revolution-report-may-2020_neu.pdf, accessed July 27th 2022.

Datta, J. (2019): *China, India and US home to the largest number of adults with diabetes: Intenrational Diabetes Foundation*, available at https://www.thehindubusinessline.com/news/variety/china-india-and-us-home-to-the-largest-number-of-adults-with-diabetes-international-diabetes-federation/article62235303.ece, accessed July 27th 2022.

Hotz, N. (2022): *Why Big Data Science & Data Analytics Projects Fail, referring to studies of Gartner and VentureBeat*, available at https://www.datascience-pm.com/project-failures/#:~:text=Indeed%2C%20the%20data%20science%20failure,outcomes%E2%80%9D%20(Gartner%2C%202019), accessed July 29th 2022.

Flessner, T (2022): Nachhaltigkeit in der Wirkstoffproduktion: Herausforderungen und Chancen, BIOspektrum, submitted.

Nising, C. F., von Nussbaum, F. (2022): Industrial Organic Synthesis in Life Sciences – Today and Tomorrow, *Eur. J. Org. Chem.*, published online and available at https://chemistry-europe.onlinelibrary.wiley.com/doi/epdf/10.1002/ejoc.202200252, accessed at July 27th 2022.

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