

Bayer's response on ChemSec's assessment 2023

In August 2023, Bayer responded to ChemSec's ChemScore draft assessment as follows:

General remarks sent to ChemSec

The Bayer team appreciates your interest in our company. Before digging into the details of your questionnaire, we would like to point out a few overarching remarks and suggestions concerning the underlying [methodology](#) of ChemSec's ChemScore considering our business activities:

Bayer is active in highly regulated markets in crop protection and in pharmaceuticals. Numerous studies need to be performed as basis for comprehensive scientific dossiers before a pesticide or a pharmaceutical substance can be approved (e.g. on EU-level) or a product can be registered on country-level and marketed – **this is different from other chemicals in scope of ChemSec and should be accurately reflected in the respective assessments.**

Each R&D project in crop protection must undergo comprehensive assessments of potential impacts on the health of humans and animals as well as impacts on the environment as defined by respective regulatory frameworks. To ensure the safe use of our crop protection products based on adequate research, we market only those crop protection products whose active ingredients are registered in at least one OECD country or, in the case of new active ingredients, for which an OECD data package has been compiled. The internationally agreed OECD methodology considers both the intrinsic hazard properties of a substance and its exposure into the environment. **Contradictory, ChemScore's methodology seems to exclusively focus on the hazard profile of the substances.**

The EU has the most complex and ambitious chemicals legislation in the world: REACH. Together with the CLP (Classification, Labelling and Packaging) for hazard assessment and communication, it constitutes a solid umbrella framework to regulate substances and mixtures. As a result of REACH, Europe has the most comprehensive knowledge database on chemical hazards and risks globally. This framework is complemented by a complex array of other use and product-specific policies.

We clearly have to distinguish between regulatory assessments following international standards and individual opinion. **ChemScore's assessment of the product portfolio mixes regulatory assessments and individual assessments.**

For FY 2022 Bayer's revenue generated in the US and EU countries was approx. 50%.

Assessment criteria ChemSec 1: Production of Hazardous Chemicals

Intermediates handled under strictly controlled conditions (SCC):

ChemSec's SIN List includes 9 substances on Bayer, that are used exclusively, without any exemption, as an intermediate under strictly controlled conditions (SCC) in all our facilities, including all subsidiaries. These substances also hold EU REACH registrations as intermediates, which requires that the substances are converted through further chemical reactions and handling takes place in enclosed industrial facilities, which means that no contact with any substance of concern occurs.

This applies to the following substances:

CAS #	Substance name
100-44-7	α -chlorotoluene
1634-04-04	Propane, 2-methoxy-2-methyl-
288-88-0	1H-1,2,4-Triazole
302-01-2	Hydrazine
360-64-5	Benzamide, 2-(trifluoromethyl)-
69045-84-7	Pyridine, 2,3-dichloro-5-(trifluoromethyl)-
76-05-1	Acetic acid, 2,2,2-trifluoro-
77-78-1	Sulfuric acid, dimethyl ester
96-18-4	1,2,3-trichloropropane

Assessment criteria ChemSec 2.3: *The company has a strict hazard-based and public commitment to not develop or market new chemicals or products with SVHC properties*

Bayer's response:

Please have a look at our Sustainability Report 2022, page 54 (verified with "limited assurance"): development of new pesticides requires assessments "including in-vitro and in-vivo studies (mammals) on acute, subchronic, chronic toxicity; mutagenicity, carcinogenicity, teratogenicity, reproduction; endocrine disruption, residues (e.g. plants, animals); dietary and nondietary risk assessments"

page 54/55: "As part of the testing process, chemical and biological crop protection products are examined early in the development phase with regard to their mode of action, their (eco)toxicological properties and the extent of potential residues in plants and the environment to ensure that we only continue to develop those products with the best safety profile. Development and in-licensing projects for crop protection products classified as World Health Organization (WHO) class 1a or 1b, or that do not meet the OECD (Organisation for Economic Cooperation and Development) Guidance for Pesticide Registration, will not be pursued. In all other cases further activities and refined risk assessments are performed. This enables selection and implementation of the right projects in a sustainable manner and makes the best use of available resources in research and development. Each R&D project must undergo a thorough safety assessment as defined by the respective regulatory environments following a risk-based approach that often exceeds these requirements – particularly in low- and middle-income countries (LMICs). This risk-based approach takes account of local agronomic use conditions in LMICs, especially common local application techniques that are not widespread in Europe or the United States (e.g. manual application of crop protection products in dense crop scenarios). For these scenarios, we have developed globally relevant exposure models that consider these actual use conditions. They are consistently applied before triggering development work for new products. R&D projects that we do not consider safe under the current use conditions will not be pursued further."

Sources: Sustainability Report 2022, pages 54/55 - all information published with "limited assurance"

Assessment criteria ChemSec 2.4. *Active marketing of self-proclaimed greener, eco-friendlier and more sustainable products*

Bayer's response:

This section is a bit more difficult to fill in: the pesticide products developed in the last decades by Bayer usually replace older products. But in many cases, older pesticide products once were developed by Bayer are now out of patent and therefore available as generic products manufactured and marketed by our competitors. Our more sustainable pesticide products therefore compete with cheaper generic products in the markets.

Bayer's products are labeled to be used in a safe and environmentally friendly way. Beyond existing labels, "we have contributed to the creation of a new label pictogram (see icon) designed by CropLife International and published by the Food and Agriculture Organization of the United Nations (FAO) to be used as a precautionary icon on labels for crop protection products to protect pollinators. The new label pictogram serves on the one hand to optimize global consistency in pollinator safety labeling, and on the other hand puts emphasis on the protection of wild pollinators beyond honeybees, and on pollinator habitats. We have started to adopt this label pictogram for Bayer's crop protection products."

Please have a look at our Sustainability Report 2022, page 63 (verified with "limited assurance")

As part of our Seeds Business, we are researching in more sustainable products like our "Smart corn System", see Sustainability Report 2022, page 40 (verified with "limited assurance"):

"One example of the possibilities offered by plant breeding innovations is our short-stature corn hybrids, planned to be commercialized in the coming years within the Smart Corn System. Through breeding, plant biotechnology and genome editing, we have succeeded in developing seed varieties that enable the growth of shorter corn plants that have the potential to not bend or break as easily as corn plants of regular height in the presence of strong winds or heavy rain. Losses in the United States due to bent plants amount to between 5% and 25% a year depending on the severity of weather events. Shortstature corn hybrids also have the potential to enable an optimized uptake of water and nutrients such as nitrogen."

Our Iberogast® are nature-based products and therefore marketed this way, see <https://www.iberogast.de/ueber-iberogast>

Assessment criteria ChemSec. 2.6. *Offering of circular end-products or processes, enabling circularity*

Bayer's response:

Pharmaceutical products and pesticides are highly regulated products and typically not allowed to be used more than one time.

Many of the bio-based materials (such as bioplastics) are made of corn starch, zein or soy protein/soy oil. With our seeds business in corn and soy, we aim to enable the large-scale production needed already today to provide enough quantity of the basic material for biobased products.

In our Pharmaceutical Business, we close the circle for our iodinated products, see Sustainability Report 2022, page 73 (verified with "limited assurance"): " through a returns program, we enable doctors' offices and hospitals to send remaining stock or unused supplies of the iodinated X-ray contrast agent Ultravist™ back to us. This in turn makes it possible to avoid unnecessary environmental discharges and properly reuse the iodine in an industrial cycle."

In our production processes, we use several technologies supporting the circular use of the production inputs, see Sustainability Report 2022, page 117 (verified with "limited assurance"):

"Whenever possible and within the framework of legal regulations, we make use of the opportunities in our divisions to recycle solvents, catalysts and intermediates and return them to the production process following treatment. Recycling plays an especially important role at Crop Science and is therefore a key criterion at the process development stage of active ingredient production.

In all divisions, production- and material-based recycling is aligned to the individual requirements of the production processes at the sites. Here are some examples:

// Material-based recycling of solvents from production is implemented at various active ingredient production sites.

// In 2022, a new facility for recycling an inorganic salt went on stream at a site in Germany. This substance is extracted from the production waste and returned to the production process as a raw material with a recycling rate of around 95%.

// Volumes of incineration waste are being reduced at a site in the United States using distillation. At the same time, occupational safety has improved because less manual intervention is required in the process.

// At a site in Germany, iodinated X-ray contrast agent from a returns program is being recycled. The recovered iodine is sold as a raw material because legal requirements prohibit it from being reused in pharmaceutical production.

// Plant residues (such as corncobs or rice husks) from seed production are used for animal feed or fuel.

// Employees and contractors at three sites in Argentina are being given extensive training that enables them to avoid the disposal of waste products at landfills. The waste streams are either reused, recycled, composted or incinerated.

// At a production site in Germany, a new process is currently being developed that should enable the recovery of the majority of a byproduct from a waste stream (mother liquor). This process is expected to lead to a much higher product yield and less incinerated waste.

Assessment criteria ChemSec. 2.7. *Using biobased/renewable resources (as input to their production/processes)*

Bayer's response:

For the production of our products, we use plant oil derivatives. See website [Strategic Sustainability Focus Areas | Bayer Global](#)

Palm Oil:"In terms of sustainable palm oil, we support the certified sustainable production of these raw materials as a purchaser of plant oil derivatives, which is especially important in Southeast Asia but also other regions. We are member of the "Roundtable on Sustainable Palm Oil" (RSPO), and since 2017 we are buying RSPO credits according to the quantities we use. In addition we at Bayer have decided to move from the RSOP credit system towards the RSPO Supply Chain Certification, the RSPO Mass Balance Certification. We understand the complexity of our value chains, therefore we drafted a trajectory for change targeting to achieve 50% Mass Balance certification in 2022, in 2023 60%, in 2024 70%, in 2025 80%, in 2026 90% and in 2027 almost 100% certified sustainable palm (kernel) oil. We invite all stakeholders to follow and support in this process."

For more information and for our purchasing of soy and timer, please see our "CDP Forests Report 2022" - rated "B"
<https://www.bayer.com/sites/default/files/Bayer-AG-CDP-Forest-2022.pdf>

Assessment criteria ChemSec. 2.8 Using or producing recycled feedstock

Bayer's response:

In our Pharmaceutical Business, we aim to close the circle for our iodinated products, see Sustainability Report 2022, page 73 (verified with "limited assurance"): " through a returns program, we enable doctors' offices and hospitals to send remaining stock or unused supplies of the iodinated X-ray contrast agent Ultravist™ back to us. This in turn makes it possible to avoid unnecessary environmental discharges and properly reuse the iodine in an industrial cycle." The iodine is offered to other companies as a recycled feedstock to be used in industrial products, as it is not allowed to use it in pharmaceutical products again.

In our production processes, we aim to use several technologies supporting the circular use of the production inputs, see Sustainability Report 2022, page 117 (verified with "limited assurance"):

"Whenever possible and within the framework of legal regulations, we make use of the opportunities in our divisions to recycle solvents, catalysts and intermediates and return them to the production process following treatment. Recycling plays an especially important role at Crop Science and is therefore a key criterion at the process development stage of active ingredient production.

In all divisions, production- and material-based recycling is aligned to the individual requirements of the production processes at the sites. Here are some examples:

// Material-based recycling of solvents from production is implemented at various active ingredient production sites.

// In 2022, a new facility for recycling an inorganic salt went on stream at a site in Germany. This substance is extracted from the production waste and returned to the production process as a raw material with a recycling rate of around 95%.

// Volumes of incineration waste are being reduced at a site in the United States using distillation. At the same time, occupational safety has improved because less manual intervention is required in the process.

// At a site in Germany, iodinated X-ray contrast agent from a returns program is being recycled. The recovered iodine is sold as a raw material because legal requirements prohibit it from being reused in pharmaceutical production.

// Plant residues (such as corn cobs or rice husks) from seed production are used for animal feed or fuel.

// Employees and contractors at three sites in Argentina are being given extensive training that enables them to avoid the disposal of waste products at landfills. The waste streams are either reused, recycled, composted or incinerated.

// At a production site in Germany, a new process is currently being developed that should enable the recovery of the majority of a byproduct from a waste stream (mother liquor). This process is expected to lead to a much higher product yield and less incinerated waste."

Assessment criteria ChemSec. 3.2. Company has a public strategy with (timed) phase-out plans for existing hazardous chemicals beyond regulatory compliance

Bayer's response:

Bayer already phased-out many pesticide products in the last decades - in line with international guidelines and local regulations. In countries without strict regulation, we go beyond the local level, as we apply the same standard like for our operations in OECD countries. This led to the phase-out of certain Bayer in these countries. But as many pesticides are out of patents, other chemical companies still sell these pesticides as generic products. See our Sustainability Report 2022, page 57 (verified with "limited assurance").

To effectively measure and reduce the environmental impact of pesticides used globally, we use our commitment of "Crop Protection Environmental Impact reduction:" Sustainability Report 2022, pages 43-45 (verified with "limited assurance"):

"To this end, Bayer adopted a methodology for crop protection environmental impact reduction (CP EIR) and made a commitment to reduce the environmental impact of our crop protection products. Specifically, we will reduce Bayer's global treated area weighted crop protection environmental impact per hectare by 30% by 2030 against a 2014 – 2018 average baseline. (...) Based on the data for the period 2017 to 2021, Bayer has reduced its global crop protection environmental impact by 14% against the 2014 – 2018 baseline. The reduction was mainly the result of changes in our crop protection product portfolio in recent years. At the same time, crop protection sales had risen by around 15% in 2021 (the last year in terms of the current reporting period) compared to 2018 (the previous year of baseline reporting)." Read more about the methodology, which was developed by the technical University of Denmark (PestLCI) and the UNEP-SETAC (USEtox®) in our Sustainability Report 2022, pages 43-45, verified with "limited assurance")

Also, in many countries counterfeit pesticides and illegal pesticides are in the markets, especially when there is a low level of regulation. This is an important aspect to effectively limit the use of hazardous pesticides globally. Read about our efforts in our Sustainability Report 2022, pages 49/50 (verified with "limited assurance").

Sustainability Report 2022, page 57 (verified with "limited assurance"):

"Self-commitment

Our crop protection products are classified according to their WHO acute toxicity class and this classification is maintained in our internal database. Internal processes ensure that no new product with a WHO class 1a or 1b category can be marketed. In addition, since 2012, we have no longer sold WHO Class 1a or 1b agricultural crop protection products despite continued formal authorization to do so. We also withdrew registrations on WHO Class 1a or 1b agricultural crop protection products.

Not all our crop protection products are registered in Europe. There are various reasons for this, e.g. different customer needs and agricultural practices outside Europe. These crop protection products are registered in accordance with national regulations outside Europe. Bayer complies with international regulations, e.g. the UN Rotterdam Convention concerning the export of such products that could be produced in Europe but are not registered in Europe, being registered instead in the importing country. In this context, Bayer committed itself to only selling crop protection products according to our OECD commitment. We regularly review the products we offer in emerging markets and developing countries with respect to the applicable specifications for ensuring the safety of our products and reducing the risks associated with their use. We voluntarily withdraw such products from the market if identified risks cannot be limited sufficiently. For more information on the safety of crop protection products, please see our website.

To ensure the safe use of our crop protection products based on adequate research, we made an important voluntary commitment in 2016 – we will market only those crop protection products whose active ingredients are registered in at least one OECD country or, in the case of new active ingredients, for which an OECD data package has been compiled. OECD data packages require the preparation of complete dossiers for crop protection products and their active ingredients in support of regulatory decisions in OECD countries. They include the findings of all test and study reports and other relevant information submitted by the company and other interested parties. The data needs to be made available to facilitate checking by regulatory authorities as a basis for decision-making with respect to the approval of individual active ingredients, the registration of crop protection products, the establishment of a maximum residue limit, or the determination of an import tolerance, as appropriate. The guidance contained in the OECD package can be used by regulatory authorities, where the evaluation of extensive data submissions is necessary. As part of our internal processes established to comply with this voluntary commitment, quarterly checks on all our crop protection products are conducted."

Assessment criteria ChemSec. 3.7. *Internal circular economy policy in place*

Bayer's response:

Our seeds business can be one of the key enablers for biobased products enabling circular economy.

But the principles of circular economy are not applicable to pharmaceutical and pesticide products.

We therefore ask ChemSec not to include this question in the assessment on Bayer.

Assessment criteria ChemSec. 3.8. *The company has key performance indicators (KPIs) covering circular economy targets*

Bayer's response:

Our seeds business can be one of the key enablers for biobased products enabling circular economy.

But the principles of circular economy are not applicable to pharmaceutical and pesticide products.

We therefore ask ChemSec not to include this question in the assessment on Bayer.

Nevertheless, we have in place a company target for our Consumer Health Division, please see Sustainability Report 2022, page 6 (verified with "limited assurance"), to "Transition all Consumer Health products to 100% recyclable or reusable packaging"