Bayer's response on ChemSec's assessment 2025

In August 2025, 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 would also like to highlight that for the purposes of REACH and chemicals regulations in general, persistence thresholds have been chosen not on the basis of persistence alone, but on a combination of persistence and other substance properties. This means that a substance deemed to be persistent is only considered to be hazardous if it is at the same time persistent, bioaccumulative and toxic (PBT substance), or at the same time persistent, mobile and toxic (PMT substance). Therefore, fulfilling the persistence criterion on its own does not constitute a hazard to human health or environment. This is not reflected in ChemScore's methodology.

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 2024 Bayer's revenue generated in the US and EU countries was approx. 56%.

Additional comments on ChemSec assessment criteria Category 2. Phase-out persistent chemicals

Persistence is a property indicating presence of a substance in the environment for a prolonged period. In legal terms, persistence is typically defined by a half-life of a substance, i.e., the time required for a quantity of substance to reduce to half of its initial value. For example, Annex XIII of REACH Regulation setting out the criteria for Article 57d notes that a substance fulfils the persistence criterion when the degradation half-life in fresh water is higher than 40 days, or when the degradation half-life in soil is higher than 120 days.

For the purposes of REACH and chemicals regulations in general, persistence thresholds have been chosen not on the basis of persistence alone, but a combination of persistence and other substance properties, such as bioaccumulation (build-up of a substance over time in a living organism), mobility (ability of a substance to move through the environment), or toxicity (the degree to which a substance can cause harm to humans or animals). This means that a substance deemed to be persistent is only considered to be hazardous if it is at the same time persistent, bioaccumulative and toxic (PBT substance), or at the same time persistent, mobile and toxic (PMT substance). Therefore, fulfilling the persistence criterion on its own does not constitute a hazard to human health or environment.

It is also worth noting that in some cases persistence may be necessary for a particular substance to perform its function. For example, persistence of pharmaceuticals in the environment may be linked to how a medicine should be metabolised in the human body in order to be effective. In cases where a pharmaceutical product is deemed to be persistent in the environment, an assessment to conclude on its PBT/PMT properties will be conducted during a market authorisation process in line with the criteria identical to those defined under REACH regulation.

We remain committed to minimising any environmental impact across our portfolio, including use and production of potential PBT and PMT substances.

Additional comments on ChemSec assessment criteria Category 4. Increase share of safer solutions

We disagree with the very subjective (and therefore unfortunately not transparent) definition of "safer solutions" as applied by ChemSec for the ChemScore. We reiterate, that products which are subject to stringent regulations and approval need to be assessed differently than those which can be brought to the market without limitation. An approval process (e.g. for pharmaceutical products) implies a societal consensus on what is needed and what is safe to use - which is carried out by authorities.

Our upcoming pharmaceutical products in R&D phases like:

- Elinzanetant (targeting vasomotor symptoms VMS, also known as hot flashes during menopause) is proposed to be a safer solution to hormonal products in that area;

- cell & gene therapy target e.g. Parkinson's disease (where currently a comparable treatment is not available);

- our chemoproteomics platform technology enables us to unlock a large number of traditionally unaddressable oncological targets with the aid of precision cancer therapeutics;

- and many more as described in our Annual Report 2024, pages 44ff. must be understood as "safer solutions" if they have the potential to replace an existing pharmaceutical product in a certain area of treatment (a prerequisite for the approval) - or will be the only treatment (and therefore the safest solution by means).

Also, in the case of pesticides/crop protection products, only products with more beneficial safety profiles than existing products for a specific use case will be granted approval.

Most of our finished products, whether pharmaceuticals or crop protection products, are subject to very stringent regulations prescribing specific and extensive approval and registration procedures. Our products cannot be sold on the market until they have been approved by a competent authority, or an official registration has been granted. As a condition of their approval, the prescribed efficacy and safety of the individual products must always be demonstrated as proven. Therefore, our substances and finished products undergo extensive assessment and testing to ensure product efficacy and safety. We examine possible health and environmental effects along the entire value chain – from the research and development stage up to products that are already available on the market – and use this to derive appropriate mitigation measures. These can vary from revised application recommendations to the substitution of a substance. The substitution of chemicals is basically a continuous task for the chemical and pharmaceutical industries in generating new or substantially improved products and processes. This is integral to our commitment to Responsible Care™. For more information, please see Bayer's Impact Report 2024, pages 52ff.

Taking this into consideration, there are serious concerns with a concept called "safer solutions" that is defined subjectively and that comes along with a risk of undermining existing testing, approval, and registration procedures that form the backbone of very stringent regulatory requirements in the industries we are operating in.