Webinars: *From Theory to Practice:* Delivering PAS 2090-compliant Pharmaceutical LCAs

Wednesday 4th November 2026

Q&A

PAS 2090 methodology and application

Q1. Is PAS 2090 based on ISO14040 and ISO14044? If we implement the LCA as per PAS 2090, can we claim that we are following the methodology of ISO?

Yes, BS EN ISO 14044:2006+A2:2020 is a normative reference of PAS 2090.
The *PharmaLCA* software has undergone a third-party software evaluation by TÜV Süd based on the requirements of PAS 2090 as well as of ISO 14040/44.

Q2. Is an LCA PAS 2090-compliant if it only considers product carbon footprint or does it also need to consider more than 1 sustainability topic?

PAS 2090 is Life Cycle Assessment (LCA) standard based and therefore looks beyond carbon, however it is recognised that only a carbon footprint may be the goal of a study. PAS 2090 addresses this with the following text: “The selection of impact categories for the LCIA shall be consistent with the goal and scope of the study as specified in 4.1. The selected impact categories shall be drawn from those listed in Table 2 of the PEF Method and assessed and reported. Where a single impact category is assessed and reported, the report shall not be labelled as an LCA and instead shall be labelled as a single impact assessment. The report shall state that no conclusions shall be drawn in relation to the performance of this product with regard to other impacts.”

Q3. In the use cases presented, the functional unit is often taken treatment of one year. Is this time period a standard according to PAS 2090 or does it depend on the drug?

It depends on the medicine and the goal of the study. PAS 2090 does not prescribe a one-year functional unit for every pharmaceutical product. However, where a functional unit is used for the treatment of a chronic disease, PAS 2090 recommends 12 months as the default treatment period, starting from the first dose modelled, unless another period is appropriate and justified. For other treatment types, the relevant duration should reflect the defined therapeutic function and study scope.

Q4. It would be interesting to hear your thoughts on extrapolating activity data *e.g.* between products and/or production steps.

Data quality should be considered and any potential differences in drivers of activity data between products, sites or steps. For example, the same product could be made at two different sites and use significantly different energy values. It’s recognised that collecting data can be difficult for many sites and processes. PAS 2090 offers an approach to calculating the LCA of products that are multisite, with a hierarchy of what data is required for a PAS 2090-compliant LCA. Data selection should be in alignment with the goal of the study. This is addressed in PAS 2090:2025, Clause 4.4 (Geographical scope), particularly Note 1 and Table 1, with further guidance on modelling across multiple manufacturing sites and supply chains provided in Annex B.

Q5. Can the supplier LCA for a raw material be PAS 2090 compliant if based on modelling data only? (For example, where the supplier is scaling up and the raw material manufacturing plant is still under construction so measured data is not yet available)

PAS 2090 does not require all data to come from direct measurements. Its definition of primary data explicitly includes data derived through engineering models, material/product balances and stoichiometry, provided these relate to specific processes in the company's supply chain. Where suitable primary data are unavailable, PAS 2090 also allows secondary and proxy data, subject to its data selection and quality requirements. Therefore, modelling data for a facility under construction could be used, but the assumptions, data sources, representativeness and limitations would need to be documented and assessed against the goal and scope of the study.

Q6. How were the LCA data collected for packaging?

PAS 2090 has specific data requirements for packaging. Primary, secondary and tertiary packaging should include information on the amount and type of packaging material and its recycled content, with primary data used for the packaging raw materials. Where other information is unavailable, PAS 2090 allows secondary data to be selected using its data-selection hierarchy and provides default assumptions for tertiary packaging. Packaging manufacturing, packing/filling, transport where applicable and material end-of-life treatment are also addressed within the methodology.

The relevant requirements are primarily set out in PAS 2090 Clause 5.7 (Packaging), including the requirements and default assumptions for primary, secondary and tertiary packaging. These should be read alongside Clause 5.4 on data requirements and data selection, and the relevant end-of-life requirements in Clause 5.11.

For the Novo case study, when this question was asked during the webinar, the packaging defaults were developed as harmonised fallback assumptions for situations where product-specific primary data are unavailable. The tertiary-packaging quantities are based on defined reference configurations, such as a 400 kg pallet load and stated packaging weights/reuse rates, rather than being intended as representative averages for every pharmaceutical supply chain. Packaging material and conversion datasets are subsequently selected based on technological and geographical representativeness. Where company-, product- or supplier-specific primary data are available, these should be preferred.

Q7. What if my scope is only limited to API manufacturing, where would the packaging inputs go in which lifecycle stage? Additionally, if my API manufacturing feeds into drug manufacturing at a different plant, where would intersite and packaging be accounted - which stage would it be?

For an API-only assessment, transport between sites involved in drug-substance manufacturing is included within the drug-substance manufacturing stage. PAS 2090 requires the packaging weight associated with this intersite transport to be factored into the transport impacts and recommends modelling the production and disposal of that packaging for improved data quality. Where the finished API is subsequently transported from the drug-substance manufacturing site to a separate drug-product manufacturing site, that supply transport is included within the drug-product manufacturing stage.

Q8. How do you include the environmental impact of manufacturing wasted drugs (at use phase)? Is it together with the non-wasted drugs (*i.e.,* drug applied to the patient) in the manufacturing values or EoL or Use phase or is it not accounted?
Context: Losses/Waste at use phase, driven by different reasons (*e.g.* expiration date, maladministration), can be significant. As some numbers show most of the environmental impacts often come from manufacturing phases (*e.g.,* for carbon footprint).

This was a consideration in PAS 2090, and in Section 5.10 *Use stage modelling rules,* it states: “The impact of unused product during the use stage (*i.e.* related to the actual product amount required for the given treatment, expired products or consumer behaviour) or its end of life may be taken into account.”

It is not a requirement, and sometimes this data is difficult to gather for the pharmaceutical company who may be completing an LCA study. However, with the data, it can absolutely be included in a PAS 2090 LCA. The declared unit of a PAS 2090-aligned LCA is one product unit. Where unused product is included in the assessment, the amount manufactured to fulfil the declared or functional unit may include the additional product that is subsequently lost or unused. The associated impacts are therefore accounted for within the relevant drug substance, drug product, packaging and distribution stages, with disposal accounted for at end of life where applicable.

Q9. For the downstream impacts, how do you model (if at all) the impact of chemicals excreted by the body?

PAS 2090 addresses this within the end-of-life modelling of drug-derived compounds. Where freshwater ecotoxicity is assessed, the environmental impacts of the API, excipients and their derivatives can be characterised using the USEtox method, taking account of wastewater treatment and subsequent environmental release. Where not all metabolites or derived compounds are identified or specifically characterised, PAS 2090 allows an assumption that 100% of the initial compounds are excreted and that their ecotoxic impacts are represented

by those of the original API or excipient. The assumptions used should be transparently reported.

Q10. When we have a hotspot of 85%, why isn't that excluded and the remaining hotspots recalculated? An 85% impact is obviously significant but also overpowering the view on additional areas.

The 85% contributor should remain in the overall result because removing it would change the representation of the product's total environmental impact. However, it can be useful during interpretation to drill down into the remaining 15% separately to identify secondary improvement lever opportunities. *PharmaLCA* supports drill-down into individual life-cycle stages and processes for exactly this purpose.

***PharmaLCA* software functionality**

Q11. The BOM usually has information at multiple levels including packaging info. How can we model that in the AllocNow tool while filling the data for production process?

PharmaLCA was built with deep and multi-level value chains in mind. You can create a production process for each stage of the value chain and model each stage's manufacturing data (*e.g.* a separate step for packaging). This makes it easier to differentiate and identify drivers and hotspots.

Q12. Market-based data are left for the user to choose? Is there certain knowledge needed to pick the right emission factors?

Some judgement can still be required, particularly where there is no exact-match dataset and a proxy must be selected. PAS 2090 and its Technical Guidance provide a hierarchy and recommendations for dataset selection. *PharmaLCA* then narrows the available datasets according to context, including activity, sector and geography, so users are selecting from a smaller set of relevant options rather than searching an entire database. The software is designed to make this accessible to non-experts, but more complex assessments can still benefit from LCA expertise.

Q13. Does the utilities information come from ecoinvent or other databases included in the premium version of the tool?

Starter version of the PharmaLCA software comes with the BAFU database. *Professional* version of the PharmaLCA software comes with ecoinvent and optionally Carbon Minds.

Q14. Are there database options available for energy use factors for India location in application?

Yes, the databases in the Starter and in the Professional plan offer impacts for electricity in India.

Q15. Is it possible to assess regional or city-level water deprivation in a water footprint calculation, rather than relying strictly on country-level data?

Currently, the characterisation factors for elementary exchanges with the environment are location-agnostic.

Q16. Does the *Starter* plan allow to upload and use activities/processes from ecoinvent if we already have access to those? A follow up then is whether those manually added inputs can be used across the LCA model or do they need to be uploaded every time?

You can manually add environmental impacts, however an upload in bulk is not supported.

Q17. Which payment plan would you recommend for small companies with a single API?

We would recommend starting with *Starter,* which is free and supports unlimited modelling, PAS 2090 guidance, hotspot analysis, reporting and access to the BAFU database. Professional is more appropriate where the company needs integrated ecoinvent data, additional Carbon Minds datasets, multi-user collaboration, SSO or enhanced enterprise functionality.

***PharmaLCA* access and data security**

Q18. Who outside the user & their company colleagues are able to access/view the data entered into the tool? How can the user be sure that no confidential data is accessible to people outside of their team/company?

PharmaLCA keeps each company's data fully isolated from other customers, on ISO 27001 certified infrastructure and in line with GDPR. Users have the option to share data with other users of their own company only.

Q19. Can other companies see my results inside the software? How does it keep the data safe?

Data are strictly isolated per tenant/company. Only users within one company can share data. Role-based access control (RBAC) allows you to manage permissions across users within your company. Final results of an LCA study can be exported (PDF) and shared with external stakeholders.

Q20. Using the tool might lead us to "satisfy" our IT department in terms of (cyber) security and related IT General Controls applied to the platform (from user management over data backup *etc.*). Can standards be shared that were applied developing the software and/or is there a contact to get in touch with?

The application is developed based on ISO 27001. You can find some more details for sharing with your IT department on our website (https://www.pharmalca.com/features) and in the following document:
https://www.pharmalca.com/_files/ugd/63c7d2_ef2d90b6a43b4b03af9f5cc9d8175ca6.pdf

Comparability and external frameworks

Q21. As raw material suppliers, does PAS 2090 recognise other industrial guidance such as TfS for chemicals? This helps to use more information from suppliers whose LCA are already estimated and verified according to other sectorial guidance.

PAS 2090 explicitly references the Together for Sustainability (TfS) Product Carbon Footprint Guideline for the Chemical Industry and draws on it in several areas, including data quality, chemical modelling, cut-off criteria and energy/emission-factor selection. Supplier data developed using TfS can therefore be valuable input to a PAS 2090 assessment. However, the data still needs to be assessed against the specific requirements, scope and data-quality requirements of PAS 2090 rather than being assumed to be automatically PAS 2090 compliant.

Q22. How much do PAS 2090-based results diverge from those of peers using other LCA methods, and what would it take to make those footprints comparable?

In our experience, results may vary significantly depending on the scope of the assessment (product or treatment level), data quality and use of primary data behind LCAs. It is important to note that even if two PAS 2090-compliant LCAs are completed, they are not necessarily comparable, due to these differences (such as data quality and choice of primary data). ISO 14044 specifies requirements for comparability which is referenced in PAS 2090.

Q23. In practice, how are companies managing PAS 2090-compliant LCAs and submission to the French Healthcare systems' using score-carbon methodology? I would love to hear more about interoperability of the LCA Tool with French Score Carbone Médicament.

There is significant overlap in the underlying data required for PAS 2090 and the French Score Carbone Médicament, so much of the same inventory data can be reused. However, the methodologies are not fully interchangeable. The French CarbonScore assesses carbon only, whereas PAS 2090 can assess a broader range of environmental impacts. The French methodology is also more prescriptive in areas such as system boundaries, emission factors, allocation and modelling rules. Therefore, a PAS 2090 assessment can provide much of the underlying data needed for the French CarbonScore, but some data will need to be adapted or recalculated to meet the French methodology.

Q24. Is the *PharmaLCA* tool something we suggest to payers/authorities to be able to compare different medicines from different suppliers?

PAS 2090-compliant LCAs can provide consistent environmental information that is relevant to payers and procurement bodies, but PAS 2090 results should not automatically be used to directly compare medicines from different suppliers. PAS 2090 explicitly states that assessments conducted independently under the standard may differ in data sources, assumptions, supply-chain configurations and accuracy. Direct comparison requires the studies to have been specifically designed and conducted for comparative purposes in accordance with ISO 14044, including equivalent functional units and consideration of data quality and uncertainty.

The *PharmaLCA* software is not required to undertake a PAS 2090-compliant LCA. PAS 2090 defines the methodology and requirements for the assessment, which can be applied using different LCA tools and approaches.

PharmaLCA has been specifically designed to support implementation of PAS 2090 and make the process as straightforward and accessible as possible for users.

Q25. If we are looking to publish an EPD, which EPD programme operator is aligned with PAS 2090?

As a Consortium, we do not currently have any recommendations for specific EPD programme operators.

Implementation and use cases

Q26. Just for clarification: The two use cases are referring to products during (commercial) manufacturing processes or still during (clinical trial) development?

All three examples (Novo, GSK, Sanofi) were commercial products and processes. PAS 2090 is not specifically for commercial processes, but commercial processes generally have available the primary data required to meet the standard. However, PAS 2090 as a framework *can* be largely applicable to medicines in development and can even support LCA studies execution when information/data is not available.

Q27. From producers of generics I've heard criticism that the PAS2090 standard is too complex to be applied to generics. What would you respond?

PAS 2090 provides a common framework for assessing the environmental impacts of medicines, irrespective of whether they are generic or innovative. BSI has specifically stated that the standard is appropriate for all segments of the industry, including generic and innovative manufacturers and global suppliers. It accommodates organisations at different stages of data maturity and does not require primary data for activities outside a company's operational control.

We recognise that completing an LCA can still be complex, reflecting the complexity of the medicine value chain, particularly where companies have limited internal LCA expertise or supply-chain data. PAS 2090 therefore establishes data hierarchies, assumptions and modelling rules that allow secondary and proxy data to be used where appropriate. The accompanying Technical Guidance provides practical recommendations and examples to support implementation, while the *PharmaLCA* software translates the methodology into guided workflows for both LCA experts and non-experts.

Q28. As a raw material supplier, we have LCA data available for our materials. We would like to understand the assumptions and methodology behind your assessments?

Inventory data requirements are described in Sections 5.4-5.7 of PAS 2090 and are supported by the Technical Guidance, which provides further practical information.

The PharmaLCA Consortium

Q29. With the success of PAS2090 so far in mind, what is next on the roadmap for the Pharma LCA Consortium?

While PAS 2090 provides the foundation for harmonised environmental assessments, further collaboration is needed to support implementation, strengthen data and methodologies, and drive global uptake.

To support this next phase, the Consortium's mandate has been extended to 2028. Over this next phase, the Consortium is planning to:

- Support the update of PAS 2090 (led by BSI) and the associated Technical Guidance to ensure continued alignment with emerging best practices.
- Address key data and methodology challenges.
- Support user acceptance of the *PharmaLCA* software.
- Drive stakeholder uptake and alignment.

Q30. When is the planned Pharma Database noted on the consortium website due to be published and is there a cost associated with this?

The pharma database was published today [04/11/26], as part of the ecoinvent v3.13 release! Access requires an ecoinvent licence. Licence fees differ based on the license selected. More info here: https://support.ecoinvent.org/ecoinvent-version-3.13