UNDP

Sustainable Procurement Index for Health (SPIH)

User Guidance

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Ove Arup & Partners International Ltd 8 Fitzroy Street London W1T 4BJ United Kingdom www.arup.com

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		Name	Anna Tuddenham Terry Ellis	· ·	Callum Newman
		Signature	A. Middenham	ahm kum.	ahm kum.
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			Prepared by	Checked by	Approved by
		Name	Anna Tuddenham	Callum Newman	Callum Newman
		Signature	A. Tuddenham	ahm kum.	ahm kam.
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Acronyms

Acronyms	Full term
ACS	American Chemical Society
ADEME	Agence de l'Environnement et de la Maîtrise de l'Energie
ANSI	American National Standards Institute
APIs	Active Pharmaceutical Ingredients
BBP	Benzylbutylphthalate
BCF	Bioconcentration Factor
BIFMA	Business and Institutional Furniture Manufacturers Association
BPA	Bisphenol A
BPB	Bisphenol B
BPE	Bisphenol E
BPF	Bisphenol F
BPS	Bisphenol S
BSCI	British Society for Cardiovascular Imaging
CASRN	CAS Registry Number
CC14	Carbon tetrachloride
CDP	Carbon Disclosure Project
CHMP	Committee for medicinal products for human use
CMRs	Carcinogens, mutagens, and reproductive toxicants
CO	Carbon Monoxide
CPA	Clean Production Action
DBP	Dibutylphthalate
DCE	1,2-dichloroethane
DCHP	Di-cyclohexyl phthalate
DEHP	Di(2-ethylhexyl) phthalate
DIBP	Di-isobutyl phthalate
DIDP	Disodecyl phthalate
DINP	Diisononyl phthalate
DMAc	Dinscholyf philatate
DMAC	Dimethylatetamde
DME	Dimethylformamide
DnHP	Di-n-hexyl phthalate
DNPP	Di-n-pentyl phthalate
EDS	Endocrine-disrupting substances
EINECS	European Inventory of Existing Chemical Substances
EMA	European Medical Agency
EMS	Environmental Management System
ENCORD	European Network of Construction Companies for Research and
ENCORD	Development
EPA	Environmental Protection Agency
EPD	Environmental Protection Agency Environmental Product Declaration
EPRA	European Public Real Estate Association
ETI EU	Ethical Trading Initiative European Union
FPP	Finished pharmaceutical product
FSC	Forest Stewardship Council Green Chemical Institute
GCI	
GHG	Greenhouse Gases
GHLR	Gender, human and labour rights
GPIH	Green Procurement Index Health
GPP	Green Public Procurement
GRI	Global Reporting Initiative

Acronyms	Full term			
HCWH	Health Care Without Harm			
IFO	International Finance Cooperation			
ILO	International Labour Organisation			
ISEAL	International Social and Environmental Accreditation and Labelling			
LCA	Life Cycle Assessment			
LGBTQI+	Lesbian, gay, bisexual, transgender, queer and intersex			
MRSL	Manufacturing Restricted Substances List			
NGO	Non-Governmental Organisation			
NH3	Ammonia			
NMP	n-methyl-2-pyrrolidone			
NOEC	No-observed effect concentration			
NOx	Nitrous Oxide			
OECD	Organisation for Economic Cooperation and Development			
РАНО	Pan American Health Organisation			
PBT	Persistent, Biochemical and Toxic			
PFAS	Polyfluoroalkyl Substances			
PM	Particulate Matter			
PMI	Process Mass Intensity			
PVC	Polyvinyl chloride			
РОР	Persistent Organic Pollutant			
RSL	Restricted Substances List			
SBT	Science Based Target			
SDGs	Sustainable Development Goals			
SHiPP	Sustainable Healthcare in Public Procurement			
SIDA	Swedish International Development and Cooperation Agency			
SPDM	São Paulo Association for the Development of Medicine			
SPHS	Sustainable Procurement in the Health Sector			
SPIH	Sustainable Procurement Index for Health			
SO2	Sulphur dioxide			
STOT RE	Specific target organ toxicity - repeat exposure			
TEA	Triethylamine			
UN	United Nations			
UNEP	United Nations Environment Programme			
UNFPA	United Nations Population Fund			
UNDP	United Nations Development Programme			
UNW-PSAF	UN Women Private Sector Framework			
VfU	Verein fur Umweltmanagement			
VOCs	Volatile Organic Compounds			
WHO	World Health Organisation			

1 Introduction and context

1.1 SHiPP programme

The Sustainable Health in Procurement Project (SHiPP) is an initiative developed by the United Nations Development Programme (UNDP), in collaboration with Health Care Without Harm (HCWH) and funded by the Swedish International Development and Cooperation Agency (SIDA). The project results are contributing towards reducing harm to people and the environment caused by the manufacture, use and disposal of medical products, and by the implementation of health programmes.

SHiPP is a four-year project aiming to promote sustainable procurement in the health sector, in the United Nations (UN) Agencies, and in key project countries through the reduction of toxicity of chemicals and materials in health products, the reduction of greenhouse gases in the supply chain, and the conservation of resources.

The key objectives of SHiPP are to:

- Develop universally applicable criteria and standards for sustainable manufacturing, distribution and content of products procured by the health sector;
- Strengthen capacity for sustainable procurement in the health sector in ten project countries;
- Strengthen capacity for sustainable production, supply and disposal of health care products in at least ten project countries; and
- Strengthen the understanding and application of appropriate indicators and monitoring and evaluation processes that help promote accountability for sustainable procurement in the health sector.

The Sustainable Health in Procurement Project enabled the development of the Sustainable Procurement Index for Health (SPIH).

1.2 From Green to Sustainable Procurement Index for Health (SPIH)

The healthcare sector plays a central role in human development. However, the sector itself, and particularly its procurement practices, can an also have negative sustainability impacts.

The environmental burden caused by the health sector is not inconsequential. In light of this, the Green Procurement Index for Health (GPIH) Roadmap¹, was developed, which aimed to specify and harmonise green procurement criteria, and develop a monitoring tool to enable continuous improvement of green

¹ UNDP (2015) 'Green Procurement Index Health (GPIH): Phase 1: 2015 Project Report', (online). Available at: <u>https://issuu.com/informal_int_task_team_sphs/docs/gpih_booklet-report-2015</u>. Accessed 25/08/2021.

procurement practices. This was developed in 2015 with support of the UNDP Innovation Facility (UN Innovation Fund in New York), and conceptualised with Sustainable Procurement in the Health Sector (SPHS) members. In particular, the United Nations Population Fund (UNFPA) financially supported the project which resulted in the concrete roadmap for the index development.

However, the Green Procurement Index focused mainly on environmental dimensions. The Sustainable Procurement Index for Health (SPIH) has been developed to look more broadly at sustainability – to be a globally established, recognised and adaptable measurement tool for policy makers, manufacturers, suppliers, procurers, and healthcare facilities end users. The new guidance document brings on board added focus on gender equality, human and labour rights and anti-corruption. This tool will provide an incentive for entities to improve not only their environmental, but also the social sustainability record. No such measurement tool currently exists to monitor (I) Greenhouse gas emissions, (II) resource depletion (water, energy and material consumption), (III) chemical/toxic impact on human health and the environment (IV) human, labour rights and gender equality.

1.3 Acknowledgements

The UNDP/Arup project team would like to thank our subconsultants, Ergon and Clean Production Action, and other technical experts who provided valuable content, comments and feedback on the SPIH and user guidance document, as well as key stakeholders (buyers, suppliers, manufacturers) who participated in the piloting and training exercise online.

Full acknowledgements are set out in Appendix A3.

2.1 What is the SPIH?

The SPIH has been designed to accelerate sustainable procurement in the health sector, by:

- Supporting the decision making of buyers, and providing certainty to suppliers during the procurement process;
- Providing a consistent, robust and transparent method, that clearly communicates expectations for supply chain performance;
- Being proportionate and relevant, respecting the materiality and capability in the supply chain; and
- Not just focusing on risk but providing clear pathways for stakeholders to improve their performance.

To achieve these aims, the SPIH is a structured set of questions and criteria, organised around a set of key sustainability themes which can be used to identify the sustainability credentials of a supplier and its products. It consists of a set of modules, each containing a range of questions which are worth a number of points. Depending on the number of points scored in each module, an overall score for the supplier can be determined.

The SPIH can be used in many different ways, but it has primarily been designed to support the decision-making process as part of a procurement event (i.e. as part of the criteria for selecting a supplier). However, it can be used in other ways – some of these use cases are set out in Section 2.4

2.2 Who is the SPIH for?

The SPIH has been designed for use during the procurement process primarily with buyers and suppliers in mind. Their role and interaction with the SPIH can be described as follows:

- Suppliers suppliers should complete the appropriate SPIH Tool (general or pharmaceutical) for the product selected. Using the SPIH Tool will enable suppliers to position products in the market and show they are satisfying the sustainability standards required; receive more consistency from buyers on sustainability requirements; and have a clearer picture of expectations relating to sustainability performance now and in the future.
- **Buyers/Procurers buyers/procurers should review the SPIH tool completed by a supplier for the product selected.** Using the SPIH Tool will provide buyers/procurers with the information available to make decisions during procurement that relate to the four pillars of the index (GHG emissions; resource depletion; chemicals; and gender, human and

labour rights); and to have mechanisms to choose suppliers based on key criteria.

Additional key stakeholders that might use, or benefit from use of, the SPIH include:

- Wholesalers: who operate as both a buyer and supplier and may be required to answer the SPIH, or could ask their suppliers to do the same;
- UN and Non-Government Organisations (non-buyer role): who could provide the evidence to support robust policy positions, and make the case for sustainability; integrate the SPIH with broader programmes of work, support the conditions within which sustainability can be embedded within a product/organisation, and specifically within procurement activity through provision of tools and guidance; develop knowledge to support all stakeholders involved in sustainable procurement;
- **Regulatory agencies and policy makers:** who could set top-level policy on sustainability for the organisation as a whole in line with the range of healthcare priorities; influence whether the SPIH is adopted and in which circumstances;
- **Research bodies:** who could support best practice in achieving sustainable development; provide new ideas and innovations at both company and product level; provide knowledge transfer to the market; and
- Other standards bodies: who could develop robust standards/guidance that helps achieve specific goals; develop products that support standards users in achieving their goals; provide an independent view and rigour in demonstrating performance.

2.3 What products or services are targeted?

The General SPIH Tool targets general healthcare commodities, such as medical gloves.

The Pharmaceutical SPIH Tool targets pharmaceutical products only, such as malaria medication. It has specific tailored criteria.

The criteria should be applied to the main manufacturer/vendor of the product or service being provided. This means that in the case of a wholesaler or distributor being engaged by a buyer, they should answer the SPIH from the perspective of their supplier.

2.4 When can the SPIH be used?

2.4.1 Use during a procurement event

The SPIH has been developed for use within specific procurement activities (buying events). *Figure 1* gives an overview of how the SPIH could be applied:



Figure 1: The SPIH's position in the procurement process.

The SPIH Tool can be included in a tender event as a scored or non-scored element as follows:

- Scored approach:
 - Set a weighting for sustainability (alongside cost, quality etc.) and award more points for achievement of higher levels in the SPIH;
 - Set a weighting for sustainability (alongside cost, quality etc.) and set a minimum pass threshold e.g. Level 1 must be achieved. (Note, you could simply require the supplier to only complete Level 1 requirements for example);
- Non-scored approach:
 - Advised where you feel small or local suppliers might be disadvantaged at this time, but you would like to give signalling to the market that this will be coming into consideration in the future. It would still be mandatory to complete the SPIH and may instead lead to the development of an improvement plan for the winning bidder.

To drive better outcomes in the long term, it is crucial to communicate to your potential supply chain in advance the approach you might take to including the SPIH within your procurement process. This will give suppliers the opportunity to prepare and invest in improvement activity which will deliver more sustainable outcomes.

An example of the scored approach is set out in Box 1.

Example of scored approach

A procurement event is developed which includes sustainability as part of the evaluation criteria, using the SPIH. The weighting used is 45% quality, 40% commercial and 15% sustainability. The 15% for sustainability is based on performance in the SPIH, where meeting level 3 gives the full 15%, level 2 awards 10% and Level 1 awards 5%. This places sustainability as a competitive aspect of the procurement event.

Box 1 Example of scored approach

2.4.2 Use as a monitoring tool

The SPIH can be used as a monitoring tool for supplier/contract performance. In this case, an existing supplier or a new supplier could be appointed on the basis that it will improve its sustainability-related credentials over a certain timescale.

This would be achieved through the supplier completing the SPIH initially, identifying potential areas for improvement with the buyer, and then developing a plan to address those areas. Periodically, the SPIH could be updated to track any improvements, measured by the level achieved in the SPIH Tool.

2.4.3 Use in pre-qualification

The SPIH can be used in pre-qualification. In this case, a buyer would include in the pre-qualification criteria that the SPIH Tool is completed by the supplier to enable them to bid for the contract. In the first instance, a buyer might only dictate that the Tool is completed and ask for voluntary disclosure of the level achieved. Once suppliers are more familiar with the Tool, the buyer might then choose to make disclosure mandatory to bid and/or for a certain level to be achieved.

Note on evidence

Many of the criteria in the SPIH require that some form of evidence is available to support the answers given by the supplier.

When specifying the use of the SPIH, buyers should consider what is proportionate to expect the supplier to provide. The buyer should consider the relative size of the contract or supplier relationship, as well as factors such as reputational risk in deciding on the level of scrutiny to give to reviewing the supplier's response to the SPIH.

For the most important circumstances, the buyer could request full disclosure; in other circumstances the supplier could be required to provide evidence 'on request'. Buyers could consider this as a factor during any heatmapping activity that considers the sustainability risks and opportunities in their supply chain.

Box 2 Note on evidence

Note on confidentiality

Some of the evidence that might support responses to the SPIH may contain confidential or proprietary information about the supplier and its operations. Where the SPIH is used in procurement activity, this information should be bound by the same rules as other information might be treated (e.g. price information). There is no requirement to publish all of the information associated with an SPIH response, although note that there are some specific criteria in the SPIH which refer to public disclosure of information.

Box 3 Note on confidentiality

2.4.4 Use in capacity building

The SPIH can be used as a tool for capacity building. In this case, organisations and/or institutions would use the SPIH Tool to help develop sustainability standards.

2.5 How can the SPIH be used?

This user guide contains all the information for you to use to implement the SPIH for yourself. You can use the information and criteria set out and integrate this within your eProcurement platform, or as part of your standard tender documentation as you see fit.

An Excel-based tool has also been provided which sets out all the criteria in an easy-to-use form that you can use – further details on the tool are set out in Section 5. You can use this tool as part of your tender documentation, which provides the full set of criteria.

Adapting the SPIH

There are circumstances where certain aspects of the SPIH need not be included and/or are not relevant. This provides flexibility and is important to ensure a proportional approach can be taken when applying the SPIH. However, this should not be undertaken in an arbitrary way. A filtering system has been built in to support rationalisation of the indicator set to fit specific circumstances. This includes:

- Intrinsic factors such as product category, value of contract, etc.; and
- Extrinsic factors such as geography (e.g. using Global Slavery Index).

Filtering will take place at the beginning of the assessment by the buyer, to define which modules should be completed by the supplier. For example, if the product being assessed is not a pharmaceutical, then the pharmaceutical product modules will be excluded.

Box 4 Adapting the SPIH

It is recommended that all the criteria are answered (organised in modules – see Section 3.4) as the SPIH has been designed to cover the most relevant sustainability themes for healthcare and provides a balanced approach to its scoring methodology. In addition, having a consistent set of criteria enables better comparison, benchmarking and monitoring of supplier's sustainability credentials.

However, it is recognised that there may be circumstances where an adapted version of the SPIH is appropriate. Buyers are free to do this, but in the case that any modifications are made, the buyer should clearly indicate that it is using a modified version of the SPIH and specifically which modules or criteria have been excluded, removed or changed.

2.6 Continual improvement

One of the key objectives of the SPIH is to help move the market towards greater sustainability in delivering healthcare. However, as the expectations of

stakeholders change and evolve, it is key that the SPIH has a framework within which it can change and adapt over time. Equally, innovation and investment are encouraged when there is certainty between buyers and suppliers – when it is clear there will be a requirement in the future to win work, suppliers will invest in the measures to keep them competitive. Buyers within the UN and elsewhere have the leverage to help influence this type of behaviour if the signals are clearly made.

It is important that the SPIH and its constituent parts are not static over the next decade. It is proposed therefore, that within the modular structure there is a mechanism by which, over time, modules can change, and/or standards can move between levels within the SPIH. How this is decided is a question for the long-term governance of the SPIH, but mechanically, the structure of the SPIH has been designed so that each part has the capability of being linked to different time frames.

As a simple example, in 2021 the requirement for recycled content of a product might by 15%, but by 2025 it could be 50%. Equally, modules might be moved so that, for example, the more product-specific criteria appear at lower levels of the SPIH. A conceptual illustration of this is set out in Figure 2.



Figure 2: Conceptual illustration of how requirements could become progressively tougher over time.

2.7 Summary

The box below summarises the information presented in this section.

• What: The SPIH Tool has been designed to accelerate sustainable procurement in the health sector. The SPIH is a structured set of questions and criteria, organised around a set of key sustainability themes which can be used to identify the sustainability

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credentials of a supplier and its products. It consists of a set of modules, each containing a range of questions.

- Who: The SPIH has been designed for use during the procurement process, primarily for buyers and suppliers.
- What product/services are targeted: The General SPIH Tool targets general healthcare commodities, such as medical gloves. The Pharmaceutical SPIH Tool targets pharmaceutical products only, such as malaria medication. It has specific tailored criteria.
- When: The SPIH Tool has several uses during a procurement event, as a monitoring tool, in pre-qualification, and/or in capacity building.
- How: This user guide contains all the information for you to use to implement the SPIH for yourself. You can use the information and criteria set out and integrate this within your eProcurement platform, or as part of your standard tender documentation as you see fit.
- Continual improvement: One of the key objectives of the SPIH is to help move the market towards greater sustainability in delivering healthcare. It is important that the SPIH and its constituent parts are not static over the next decade.

Box 5 Section 2 summary

3 Overview of structure and scoring methodologies

3.1 Scope

The SPIH should be applied to the actual product or service that is being purchased, and the main manufacturer of that product. In the case where the products are provided by wholesalers or distributors, the wholesaler or distributor should endeavour to gather responses to the organisational questions from the original manufacturer.

3.2 Four key themes

The SPIH contains four themes, each with several sub-themes within them. The four themes are key SHiPP priorities, recognised to increasingly cause environmental risks to human health. The main themes are:

- GHG emissions
 - Resource depletion
 - Chemicals and toxicity
 - Gender, human and labour rights.

The sub-themes within each topic centre on aspects of regulation, governance, management and reporting of various aspects associated with those themes.

3.3 Levels

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B

To ensure that the SPIH does not provide a significant barrier to entry for users in the target SHiPP countries, whilst also encouraging and rewarding better performance, the SPIH is designed around three levels of criteria. These levels reflect progressively challenging levels of performance. An example of this for the GHG topic is presented in *Figure 3*.

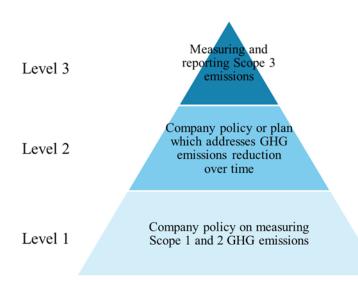


Figure 3: Concept for a tiered approach to the indicators; the example shown is for GHG emissions. Scope 1 refers to direct emissions from owned or controlled sources. Scope 2 refers to indirect emissions from the generation of purchased electricity, steam, heating and cooling consumed by the reporting company. Scope 3 includes all other indirect emissions that occur in a company's value chain (GHG Protocol Corporate Accounting and Reporting Standard. Available at: https://ghgprotocol.org/corporate-standard).

- At Level 1, there are 'foundational' level requirements which provide a relatively simple but still meaningful set of criteria that signal whether a supplier is at least fulfilling the basics (or alternatively, legal or internationally accepted norms) and mainly focused on the organisational aspects of the supplier;
- Level 2 adds further stretching criteria for organisations and adds criteria focused on the product; and
- Level 3 add the most stretching criteria for organisations and for products.

3.4 Modules

Within each of the three levels is a set of modules aligned to the four sustainability themes of the SPIH. This is represented conceptually using boxes in Figure 4 and Figure 5.

Each module contains several criteria which are organised by sub-themes. Each criterion has a defined set of potential responses, with each response leading to a point score. The points for each response in the module are used to determine the overall module score.

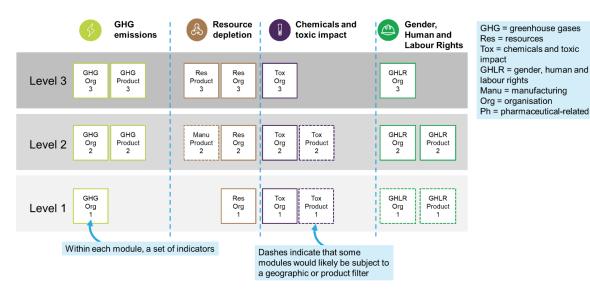
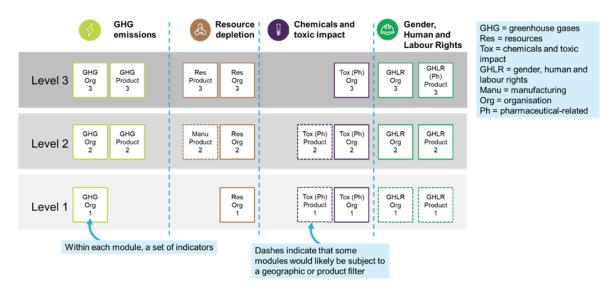
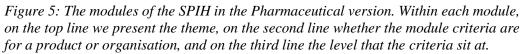


Figure 4: The modules of the SPIH in the General version. Within each module, on the top line we present the theme, on the second line whether the module criteria are for a product or organisation, and on the third line the level that the criteria sit at.





3.5 Module scoring

The scoring mechanism for the SPIH operates according to thresholds. It is based on the following concepts:

- Each module is weighted equally;
- Within each module, there are questions, and these are weighted;
- Each question has a score associated with it;

- To pass a module, you must exceed the pass threshold of 50%, which is dictated by the existing SPHS platform's design. The numerical value of the 50% threshold is calculated by calculating each criteria's weighting (%) multiplied by the maximum score achievable for that criteria, summing this for all criteria, and then dividing by two;
- To pass an overall SPIH level, you must pass all the modules within a level (see *Figure 6*).

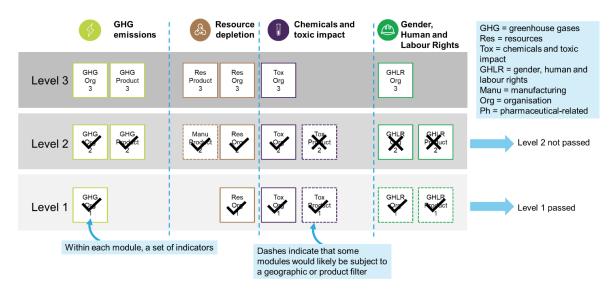


Figure 6: Scoring. The supplier assessed here has passed all the modules in level 1 and therefore has achieved level 1. Moving to level 2, as the supplier has not passed three of the modules in level 2, the supplier does not achieve level 2.

It is important to note that some modules will be specific to certain product types e.g. if the product being assessed is a pharmaceutical, then the pharmaceutical product modules (1-3) would be used in place of the standard product modules, or specific situations. Thus, not all modules will necessarily be assessed.

It is crucial for the successful implementation of the SPIH that the criteria and scoring approach is transparent to the supply chain. In this way expectations are clearly communicated to stakeholders, and there is understanding both of performance requirements and the direction these will transition to over time.

3.6 Summary

The box below summarises the information presented in this section.

- Scope: The SPIH should be applied to the actual product or service that is being purchased, and the main manufacturer of that product.
- Key themes: The SPIH contains four themes, each with several sub-themes within them. These are GHG emissions; resource depletion; chemicals and toxicity; and gender, human and labour rights.
- Levels: To ensure that the SPIH does not provide a significant barrier to entry for smaller producers or users in low capacity contexts, whilst also encouraging and

rewarding better performance, the SPIH is designed around three levels of criteria (Level 1, 2 and 3). Levels reflect progressively challenging levels of performance.

- Modules: Within each of the three levels is a set of modules aligned to the four themes of the SPIH.
- Module scoring: The scoring mechanism for the SPIH operates according to thresholds. To pass a module, you must exceed the pass threshold of 50%. To pass an overall SPIH level, you must pass all the modules within a level.

Box 6 Section 3 summary

4 Technical chapters for each theme – General Products version

4.1 Greenhouse gases (GHGs)

The GHG section of the SPIH contains five modules, as set out in the table below. These modules aim to establish the supplier's capacity to understand, manage and reduce GHG emissions in its own operations and within its supply chain.

As established in Health Care Without Harm's report "Health Care's Climate Footprint", healthcare represents 4.4% of global emissions, with 71% of these emissions associated with emissions in the healthcare supply chain, from delivery of services, and manufacture and use of healthcare products. Therefore, measuring and managing GHG emissions is a key priority action area for the healthcare sector, and it should strive to reduce its impacts in line with the Paris Agreement.

To support climate action, the themes covered in the SPIH GHG modules include:

- Reporting of GHG emissions, including scope of emissions considered and disclosure
- Supplier policy on GHG reduction
- Governance
- Targets for GHG reduction
- Consideration of all emissions associated with the manufacture of the product
- Any certifications achieved

The structure of the modules for the GHG theme is as follows:

Theme	Level	Scope	Relevance	Questions	Max score	Pass score
GHG emissions	1	Organisation	All organisations	2	20.00	10.00
GHG emissions	2	Organisation	All organisations	4	30.00	15.00
GHG emissions	3	Organisation	All organisations	4	30.00	15.00
GHG emissions	2	Product	All products	3	20.00	10.00
GHG emissions	3	Product	All products	3	20.00	10.00

The full details of the modules follow in this section.

GHG – Level 1 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance	
Scope	Do you measure	50%	No	0			
	your Scope 1 & 2 GHG footprint?			Yes, following a recognised methodology [from list in Appendix A2]	10	Link / documenting that the company reports in accordance with the relevant standard	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated. Scope 1 and 2 emissions should be clearly stated.
			Yes, following another methodology	10	Link / document evidencing that company reports to a different standard that meets minimum criteria (including Scope 1 and 2 and using recent data)	Your footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated and include details on the which company activities are included, emission factors used. Scope 1 and 2 emissions should be clearly stated.	
Reporting	Do you report your		No	0	N/A		
	GHG footprint?		The results are published internally	10	Published results	Screenshot evidence of how they are reported should be provided, and this should clearly show Scope 1 and 2 emissions and be less than three years old.	
		They are provided 10 Publis on request	Published results	A report/data should be provided which details Scope 1 and 2 emissions clearly and be less than three years old.			
			Yes, published on our website	30	Link to published report	The weblink should be accessible. The reporting should clearly state Scope 1 and 2 emissions and be less than three years old.	

GHG – Level 2 – Organisation

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Laws and	Are there any	0%	No	0	N/A	
regulations	regulations national laws or regulations which you have to follow related to GHGs?		Yes, there are legally binding GHG targets which have implications for the organisation	0	N/A	This question is for information only and can help identify whether there is a regulatory framework which may promote GHG reduction in the healthcare sector.
			Yes, there are legally binding net zero GHG targets which have implications for the organisation	0	N/A	This question is for information only and can help identify whether there is a regulatory framework which may promote GHG reduction in the healthcare sector.
Policy	Does your company		No	0	N/A	
	have a policy or plan which addresses GHG emissions reduction?		No, but currently developing one	10	Policy document	Some evidence should be presented to prove that this is in development. This may be from an internal memo or email, news article, company report or similar.
			Yes, as part of a broader policy or plan	20	Policy document	A copy of the policy or plan should be provided. Actions and intent for GHG emissions reduction should be clearly stated.
		Yes, a specific policy or plan	30	Policy document	A copy of the policy or plan should be provided.	

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Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Governance	Do you have a	25%	No	0	N/A	
	person responsible for GHG-related matters?		Yes, at the operational level	15	Name and job title of the person(s) responsible.	Name and job title of the person should be provided.
			Yes, at the operational level and the senior/board level	30	Name and job title of the person(s) responsible.	Name and job titles of the persons should be provided.
Targets	Do you have a	25%	No	0	N/A	
	carbon reduction plan in place for your Scope 1 and 2 emissions?	an in place for your cope 1 and 2	Yes, applicable for the next 5 years or less	15	Carbon reduction plan for at least Scope 1 and 2 for next ≤5 years	The plan should document specific actions that the organisation has put in place, and may include aspects such as energy efficiency, renewable energy, reducing process emissions or training and skills development, applicable for the next five years. It may also quantify the potential benefits and set targets.
				Carbon reduction plan for at least Scope 1 and 2 for next >5 years	As above but should include actions that go beyond the next five years.	
Targets	Have you published	25%	No	0	N/A	
	your targets and reduction plan?		10	Internal memo, email, news article, report or similar, to demonstrate that this is the case.	Some evidence should be presented to prove that this is the case. This may be from an internal memo or email, news article, company report or similar.	
			Yes, they are published on our website	30	Link to published targets and reduction plan	The weblink should be accessible.

GHG – Level 3 – Organisation

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Scope 3	Does your company	25%	No	0	N/A	
	measure and report on Scope 3 emissions?	Scope 3 issions?	Yes, but only business travel	10	Scope 3 emissions report	These should be included as part of the GHG emissions report and clearly identified and be less than three years old. This should be consistent with the GHG Protocol's definition of Scope 3, Category 6 (business travel).
			Yes, including business travel and upstream emissions	20	Scope 3 emissions report	In addition to the above, upstream emissions should include those associated with the extraction of raw materials and services (i.e. the supplier's supply chain) consistent with GHG Protocol's definition of Scope 3, Categories 1 and 2 (purchased goods and services, capital goods).
			Yes, including business travel, upstream emissions and downstream emissions (including logistics)	30	Scope 3 emissions report	In addition to the above, downstream emissions should include those associated with logistics and use of sold products, consistent with GHG Protocol's definition of Scope 3, Categories 9 (downstream transportation and distribution) and, where relevant 11 and 12 (use of sold products and end of life treatment).
Disclosure	Do you report to a	25%	No	0	N/A	
	voluntary GHG reporting mechanism?		Yes	30	List [from list in Appendix A2]	Evidence of participation should be provided. This may be a weblink or email confirming participation. The most recent reporting should be more than three years old.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Targets	Do you have a	25%	No	0	N/A	
	carbon reduction target in place for your Scope 3?		Part of scope 3	15	Evidence of target, and explanation of which parts of scope 3 it applies to	This may be documented as part of a carbon reduction plan or policy. The target should identify which aspects of scope 3 are included.
			All of scope 3 30 E		Evidence of target	This may be documented as part of a carbon reduction plan or policy. Note that not all categories of Scope 3 may apply to a specific company. Those categories which have scoped out should be documented with an appropriate explanation.
Targets	Have you adopted		No	0	N/A	
so ta th A	science-based targets (in line with the Paris Agreement) for your organisation?		Yes, covering scope 1 and 2 emissions	15	Evidence of SBT target	If the targets have been verified by a third party (e.g., Science Based Targets Initiative) then a relevant weblink or documentation should be provided. If not, then evidence should be provided which should clearly set out the method used, and which climate scenarios have been used to establish the SBT. This should at least be in line with the 'well below 2 degrees' scenario.
			Yes, covering scope 1, 2 and 3 emissions	30	Evidence of SBT target	As above, but applicable to all relevant emission Scopes.

GHG – Level 2 – Product

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Scope 3	Do you measure the	30%	No	0	N/A	
	emissions from business travel, including logistics?		Yes, following a recognised methodology [from list in Appendix A2]	20	List	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated. Scope 3 business travel and logistics emissions should be clearly stated.
			Yes, following another methodology	10	Evidence of calculations for Scope 3 emissions	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated and include details on the which company activities are included, emission factors used. Scope 3 business travel and logistics emissions should be clearly stated.
Scope 3	Do you measure the emissions from your product supply chain?	40%	No	0	N/A	
			Yes, following a recognised methodology [from list in Appendix A2]	20	List	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated. Scope 3 purchased goods and services emissions should be clearly stated.
			Yes, following another methodology	10	Evidence of calculations for Scope 3 emissions	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated and include details on the which company activities are included, emission factors used. Scope 3 purchased goods and services emissions should be clearly stated.
Scope 3	Do you manage the emissions from your product supply chain?	30%	Yes, we require our Tier 1 suppliers to: have a policy and have a carbon target	20	Evidence of targets	Documentation should be available from the supplier which demonstrates that it requires this of its own supply chain, for example a pre-qualification questionnaire or sustainable procurement policy document.
			No	0	N/A	

GHG – Level 3 – Product

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Product	Do you have a	33.33%	No	0	N/A	
certification detailed understanding of your product's carbon footprint?		Yes, undertaken an LCA of product	20	LCA assessment report or claim	An LCA report should be provided. This should represent the specific product being sourced or the family of products to which is belongs. The LCA should clearly represent (and justify) the relevant aspects of the product lifecycle that have been included in the assessment. Impacts on greenhouse gas emissions should be included. The methodology used should be clearly stated. The LCA study should be less than 5 years old.	
Product	Have you achieved product-level certification?	33.33%	No	0	N/A	
certification			Yes, produced an EPD or similar third- party reviewed product declaration	20	Evidence of EPD / Declaration	A certificate, approval or formal letter of certification should be provided. This should clearly refer to the product being sourced or the family of products to which it belongs. The relevant methodology should be stated and/or the Product Category Rules which have been used. The certification should be less than 5 years old.
			Yes, achieved a recognised standard for product [from a selected list relevant to GHG]	30	Evidence of achieving standard	A certificate, approval or formal letter of certification should be provided. This should clearly refer to the product being sourced or the family of products to which it belongs. The relevant methodology should be stated. The certification should be less than 5 years old.
Product	Do you collect data	33.33%	No	0	N/A	
certification	from the supply chain on emissions that you use to inform decision making?		Yes	10	Description of data collected	The evidence might include an explanation of what has been done as part of a GHG report, or a typical data collection form. It should include which data is requested from the supplier's supplier, for example Scope 1 and 2 emissions or product-level LCA or similar.

4.2 **Resource depletion**

The resource section of the SPIH contains five modules, as set out in the table below. These modules aim to establish the supplier's capacity to understand, manage and reduce resource use (energy, water, materials) in its own operations and within its supply chain.

The depletion of resources is recognised as harming the health of human beings and the planet directly and indirectly. Therefore, reducing resource use is a key priority action area for the healthcare sector and it should strive to reduce the use of resources.

To support action on reducing resource use, the themes covered in the SPIH resource depletion modules include:

- Supplier policy on resource efficiency
- Governance
- Third party / supplier review
- Consideration of all resource use associated with the manufacture of the product

Theme	Level	Scope	Relevance	Questions	Max score	Pass score
Resource depletion	1	Organisation	All organisations	2	30.00	15.00
Resource depletion	2	Organisation	All organisations	3	20.00	10.00
Resource depletion	3	Organisation	All organisations	3	20.00	10.00
Resource depletion	2	Manufacturing	All products	13	20.00	10.00
Resource depletion	1	Organisation	All products	3	20.00	10.00

The structure of the modules for the resource depletion theme is as follows:

The full details of the modules follow in this section.

Resource depletion – Level 1 – Organisation

Maximum Score	30
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Laws and regulations	Are there any national laws or	0%	No	0	N/A	
	regulations which you have to follow related to resource efficiency?		Yes, there are legally binding resource efficiency targets which have implications for the organisation	0	N/A	This question is for information only and can help identify whether there is a regulatory framework which may promote resource efficiency in the healthcare sector.
			Yes, there are ambitious legally binding resource efficiency targets which have implications for the organisation	0	N/A	This question is for information only and can help identify whether there is a regulatory framework which may promote resource efficiency in the healthcare sector.
Policy	Do you have environmental policies or plans in place which address key resource efficiency aspects relevant to your business?	50%	No	0	N/A	
			No, but currently developing one	10	Environmental Policies / Plans	Some evidence should be presented to prove that this is in development. This may be from an internal memo or email, news article, company report or similar.
			Yes, as part of a broader policy or plan	20	Environmental Policies / Plans	A copy of the policy or plan should be provided. Actions and intent for resource efficiency should be clearly stated.
			Yes, a specific policy or plan	30	Environmental Policies / Plans	A copy of the policy or plan should be provided.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Governance	Do you have a person responsible for key resource depletion aspects relevant to your business?	50%	No	0	N/A	
			Yes, at the operational level	10		Name and job title of the person should be provided.
			Yes, at the operational level and the senior/board level	30		Name and job titles of the persons should be provided.

Resource depletion - Level 2 - Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Governance	Do you have an	33.33%	No	0	N/A	
	environmental management system in place?		Yes, in compliance with ISO14001	20	Certificate of compliance	A copy of the certificate should be provided. It should be less than three years old.
			Yes, following another standard	20	Certificate of compliance or copy of the EMS	A copy of the certificate should be provided. It should clearly state the approach taken to environmental management and/or the scheme/system that it is compliant to. The evidence should be less than three years old.
Monitoring	Do you monitor resource	33.33%	No	0	N/A	
	use at an organisational level (water, energy, etc)?		Yes	20	Evidence of monitoring	A monitoring report for key environmental impacts should be produced, and/or a copy of a monitoring protocol. This should cover environmental issues relevant to the product being supplied, typically including water, waste and energy. The monitoring information should be less than three years old.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Strategy	Do you have a plan	33.33%	No	0	N/A	
	which addresses the key relevant aspects of environmental impacts/resource efficiency relevant to your business and tracks progress against its actions?		Yes, tracking progress using key criteria from ISO14001 and GRI	20	Plan document	A copy of the plan should be provided.
			Yes, tracking progress using other criteria	20	Link / document evidencing that company reports to a different standard that meets minimum criteria (including Scope 1 and 2 and using recent data)	A copy of the plan or link to the plan should be provided. If a weblink is provided, it should be accessible.
Innovation	What improvements have you made in your environmental performance or resource consumption in the last two years?	0%	Free text	0	N/A	Narrative description of positive outcomes should be provided to give context on steps the organisation is taking to promote resource efficiency.

Resource depletion – Level 3 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Third party review	Has your environmental management system been independently reviewed?	50%	No	0	N/A	
			Yes, our environmental management system is independently reviewed	20	Third party verification certificate	A certificate, approval or formal letter of certification should be provided. This should clearly refer to company supplying the product or service. The relevant standard should be stated. The certification should be less than three years old.
Supplier	Do you monitor the	25%	No	0	N/A	
review	environmental performance of your suppliers?		Yes, we actively monitor the environmental performance of our suppliers (% of suppliers with their own Environmental Policy)	20	Evidence of monitoring suppliers' performance	Information on what monitoring is undertaken should be provided, and any data on performance. This might include information on whether their suppliers have their own policy, their energy, water or waste performance or any other relevant aspects. A copy of the monitoring form or information request might alternatively be provided.
Reporting	Do you report to a voluntary scheme to disclose your environmental performance?	ry scheme to e your mental ance?	No	0	N/A	
			Yes, we report to a recognised voluntary scheme	20	Link to CDP Water security score / report	A copy of or link to the CDP Water Security report should be provided.
			Yes, we report to another voluntary scheme	10	Link to GRI Reporting standards score / report	A copy of or link to the GRI Reporting standards score or the report should be provided.

Resource depletion - Level 2 - Manufacturing

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Recycled content of product	Have you calculated the recycled content of the product?	7.69%	No	0	N/A	
			Yes, each product has <50% post- consumer recycled content	10	Evidence of the levels of recycled content	Evidence should be provided to support the claim of recycled content of the product. This might include information on the composition of the product, evidence on the origin of the materials and any specific label/labelling scheme that is relevant for the product.
			Yes, each product has ≥50 and ≤100% post-consumer recycled content	20	Evidence of the levels of recycled content	Evidence should be provided to support the claim of recycled content of the product. This might include information on the composition of the product, evidence on the origin of the materials and any specific label/labelling scheme that is relevant for the product.
Recycled	Recycled Are major content of components of the product product recyclable?		No	0	N/A	
			Yes	20	Evidence that supports that the main components can be recycled	Evidence should be provided supporting the claim that the product can potentially be recycled (or refurbished). This should apply to at least 80% of the mass of the product.
Waste and	Does the manufacturer operate a take-back programme?	7.69% ck	No	0	N/A	
circular economy			Yes	20	Details of programme and agreement	Details of the take back programme should be provided, which describe how the programme works and how it can be accessed.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
manufacturing v r	Do you undertake wastewater management and monitoring?	7.69%	No	0	N/A	
			Yes, we assess water quality monitoring data (e.g. PNECs)	20	Evidence of monitoring	A monitoring plan should be provided which documents how and when wastewater quality is measured, the instrumentation used and how it is reported. This might be a specific plan or part of a broader environmental management system. Further evidence of monitoring data would provide increased confidence.
			Yes, we assess other data	10	Evidence of monitoring	A monitoring plan should be provided which documents how and when wastewater quality is measured, the instrumentation used and how it is reported. This might be a specific plan or part of a broader environmental management system. Further evidence of monitoring data would provide increased confidence.
Energy use in	Have you calculated the % use of renewable energy in final manufacturing stage?	ergy in	No	0	N/A	
I I			Yes, each product has <50% renewable energy used in final manufacturing stage	10	Evidence of renewable energy purchasing and use in manufacturing process	Evidence might include information of on-site renewable energy generation amounts showing the proportion contributed to the total, as well as utility bills/documentation showing the use of a renewable energy electricity tariff is similar. Note this information might also be presented as part of the GHG emissions report. Confidence is increased when the evidence is directly representative of the place of manufacturer, as opposed to a whole-company average. The evidence should be less than three years old.
			Yes, each product has ≥50 and ≤100% renewable energy used in final manufacturing stage	20	Evidence of renewable energy purchasing and use in manufacturing process	Evidence might include information of on-site renewable energy generation amounts showing the proportion contributed to the total, as well as utility bills/documentation showing the use of a renewable energy electricity tariff is similar. Note this information might also be presented as part of the GHG emissions report. Confidence is increased when the evidence is directly representative of the place of manufacturer, as opposed to a whole-company average. The evidence should be less than three years old.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Energy use in		7.69%	No	0	N/A	
manufacturing	in line with ISO50001 or similar energy management approach?		Yes, in line with ISO5001	20	Evidence of ISO5001 certification	A copy of the certificate should be provided. It should clearly state the facility(s) included, which should include the main place of manufacture of the product or location from which services are provided. The evidence should be less than three years old.
			Yes, in line with another energy management approach	10	Evidence of alternative EMS	A copy of the management plan should be provided. It should clearly state the facility(s) included, which should include the main place of manufacture of the product or location from which services are provided. It should set out how energy use is monitored and improvement activities that are being put in place to minimise energy use. The evidence should be less than three years old.
Water use in	Have you quantified	1 7.69%	No	0	N/A	
manufacturing	manufacturing water use at final manufacturing stage?		Yes	20	Evidence of calculation	A report/data should be provided setting out calculations of water use at final manufacturing stage and be less than three years old.
Water use in	Do you use any	ter conservation	No	0	N/A	
manufacturing	ing water conservation technologies?		Yes	20	Evidence of technologies/measures	Evidence should be provided to support the claim that water conservation technologies are used. This could be in the form of photographs.
Packaging	Have you calculated	7.69%	No	0	N/A	
	the recycled content of the product packaging?	he product	Yes, each product has <50% recycled packaging content	10	Evidence of the recycled packaging content	Evidence should be provided to support the claim of recycled content of the packaging. This might include information on the composition of the packaging, evidence on the origin of the materials and any specific label/labelling scheme that is relevant for the packaging.
			Yes, each product has ≥50 and ≤100% recycled packaging content	20	Evidence of the recycled packaging content	Evidence should be provided to support the claim of recycled content of the packaging. This might include information on the composition of the packaging, evidence on the origin of the materials and any specific label/labelling scheme that is relevant for the packaging.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Packaging	Is the product	7.69%	No	0	N/A	
	packaged without PVC and polystyrene?		Yes	20	Evidence of materials contained within packaging.	
Transport	Do you have a	7.69%	No	0	N/A	
	mitigation strategy in place to minimise the impact of product distribution?		Yes	20	Link to strategy	A copy of the strategy should be provided.
Land use	Have you assessed	7.69%	No	0	N/A	
	the risks associated with sourcing the main raw materials in your products from potentially vulnerable ecosystems?		Yes	20	Link to risk review	A copy of the risk assessment should be provided.
Air pollution	Do you quantify the	7.69%	No	0	N/A	
	release of harmful pollutants such as		Yes	20	Evidence of monitoring	Evidence of compliance in relation to relevant permits.
	sulphur dioxide (SO2), nitrogen oxides (NOx), particulate matter (PM), ammonia (NH3) carbon monoxide (CO) and volatile organic compounds (VOCs)?		N/A	20	Please confirm that this issue is not relevant to you	Evidence of auditing in the past 3 years demonstrating that this is not relevant.

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4.3 Chemicals

The Chemicals section of the SPIH contains modules for all products used in health care (excluding pharmaceutical products), as set out in the table below. These modules aim to establish the capacity of suppliers to understand, manage and reduce the use of toxic chemicals in products, operations, and supply chains.

Toxic chemicals impair the health of people and planet by causing adverse health outcomes, polluting drinking, ground, and surface waters, and polluting the air. As such toxic chemicals in products and supply chains are impediments to achieving many UN SDGs, including #3 Good Health and Well-Being, #6 Clean Water and Sanitation, and #12 Responsible Consumption and Production. Therefore, measuring and managing toxic chemicals is a key priority action area for the healthcare sector and it should strive to reduce its impacts of these chemicals.

To support action in substituting toxic chemicals in products and manufacturing operations with safer alternatives, the themes covered in the SPIH Chemicals modules include:

- Corporate chemicals management policies, procedures, and practices
- Restricted substances lists (RSLs) and manufacturing RSLs (MRSLs)
- Certifications achieved
- Progress to green chemistry for the pharmaceutical industry, including solvents, reagents, and process mass intensity

Theme	Level	Scope	Relevance	Questions	Max score	Pass score
Chemicals and toxic impact	1	Organisation	All organisations	3	20.00	10.00
Chemicals and toxic impact	2	Organisation	All organisations	4	20.00	10.00
Chemicals and toxic impact	3	Organisation	All organisations	3	20.00	10.00
Chemicals and toxic impact	1	Product	All products	1	20.00	10.00
Chemicals and toxic impact	2	Product	All products	2	20.00	10.00

The structure of the modules for the chemicals theme is as follows:

The full details of the modules follow in this section.

Chemicals – Level 1 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Corporate	Does your	50%	No	0	N/A	
Chemicals Management Policies, Procedures, and Practices	company have an organisational Restricted Substances List (RSL) posted on website that includes all substances restricted by the European Union (EU) and relevant to your products?		Yes	20	Documentation on company's website that includes chemicals on the RSL.	Company must demonstrate it has an RSL that includes relevant EU listed chemicals, including: a) Cosmetics Directive : Carcinogens, mutagens, and reproductive toxicants (CMRs) restricted from personal care products ² b) Medical Devices Directive : medical devices cannot contain substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR 1A/1B) or endocrine-disrupting substances (EDS) in amounts over 0.1% w/w without justification ³ c) REACH list of restricted substances ⁴ d) RoHS Directive for list of restricted substances in electrical and electronic equipment ⁵ Notes: a) The EU listed chemicals are only applied to relevant products in the company. For example, Cosmetics Directive listed chemicals would only apply to cosmetic products and not medical devices (unless also covered by the Medical Devices Directive); b) to answer "yes" to this question the company must have an RSL but

² https://ec.europa.eu/growth/sectors/cosmetics/products/cmr-

substances en#:~:text=EU%20cosmetics%20legislation%20contains%20provisions,apart%20from%20in%20exceptional%20cases.

³ <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20170505</u>.

⁴ https://echa.europa.eu/substances-restricted-under-reach

⁵ <u>https://www.rohsguide.com/</u>

For results from past Chemical Footprint Project Surveys, including scores and responses of participating companies see¹⁰

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
						it does not need to be fully implemented (that occurs at Level 2); and c) for guidance in developing an RSL and examples of RSLs see 6
Corporate	Does your	25%	No	0	N/A	
Chemicals Management Policies, Procedures, and Practices	company have a corporate chemicals policy posted on website that commits the organisation to avoiding chemicals of high concern to human health or the environment?		Yes	20	Documentation on company's website that includes its corporate chemicals policy.	A corporate chemicals policy commits a company to addressing chemicals beyond the regulatory requirements of the nation(s) it operates in. A comprehensive policy covers: intent, scope, suppliers, safer alternatives, transparency to customers, and public goals. For a template of a comprehensive corporate chemicals policy and examples of corporate policies see ⁷
Corporate ChemicalsDoes your company participate in the ChemicalPolicies, Procedures, and PracticesFootprint Project annual Survey (or equivalent	es your 25%	No	0	N/A		
	participate in the Chemical Footprint Project annual Survey (or		Yes	20	Statement that company participated in the Chemical Footprint Project Survey or an equivalent survey.	For all information related to the Chemical Footprint Project Survey see ⁸ For the list of Chemical Footprint Project Survey questions and guidance for participating in the Survey see ⁹

equivalent survey)?

 ⁶ <u>https://www.bizngo.org/safer-chemicals/RSL</u>
 ⁷ <u>https://www.bizngo.org/safer-chemicals/corporate-chemicals-policy</u>

 ⁸ <u>https://www.chemicalfootprint.org</u>
 ⁹ <u>https://www.chemicalfootprint.org/assess</u>

¹⁰ https://www.chemicalfootprint.org/results

Chemicals – Level 2 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Corporate	Has your	40%	No	0	N/A	
Chemicals Management Policies, Procedures, and Practices	company implemented its RSL (developed under Level 1) for all substances restricted by the European Union in all relevant products? "Implemented" means that all products sold by your company meet the RSL requirements.		Yes	20	Documentation that includes the list of chemicals on the RSL and that the RSL is fully implemented for all relevant products.	The difference between Level 1 and Level 2 is that at Level 1 a company develops an RSL, and at Level 2 the RSL is implemented for all products sold by the company for the product category. Therefore, cosmetic products will meet the requirements of the Cosmetics Directive, medical devices will meet the requirement of Medical Devices Directive, electrical and electronic equipment will meet the requirements of the RoHS Directive, and all relevant products will meet the requirements of REACH. See the Directives to understand exceptions and exemptions to specific product categories.
Corporate	Does your	20%	No	0	N/A	
Chemicals Management Policies, Procedures	company have a corporate chemicals policy posted on website that meets Level 1 requirements and commits the company to preferring safer alternatives to	rporate emicals policy sted on website at meets Level 1 quirements and mmits the mpany to eferring safer	Yes	20	Documentation that includes the corporate chemicals policy.	In Level 1, a company's corporate chemicals policy commits it to addressing chemicals beyond the regulatory requirements of the nation(s) it operates in.
Procedures, and Practices						In Level 2, a company's corporate chemicals policy commits it to identifying safer alternatives to chemicals of high concern to human health and the environment, in addition to committing it to addressing chemicals beyond regulatory requirements. A comprehensive policy covers: intent, scope, suppliers, safer alternatives, transparency to customers, and public goals.

¹¹ <u>https://www.bizngo.org/safer-chemicals/RSL</u>.

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Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
	chemicals of high concern?					For a template of a comprehensive corporate chemicals policy and examples of corporate policies see ¹²
Corporate	Does your	20%	No	0	N/A	
Chemicals Management Policies, Procedures, and Practices	company have a goal or goals to reduce chemicals of high concern to human health or the environment (beyond substances listed in EU regulations) and posted on website?		Yes	20	Documentation that includes the company's goal to reduce hazardous chemicals and how it measures progress to reduce those chemicals.	Companies are setting goals to reduce chemicals of high concern that go beyond regulatory compliance. These goals include timelines, percent of products covered, and specific chemicals and materials to be eliminated. For example, the medical products company, Becton Dickinson and Co., has set goals for the elimination of polyvinyl chloride (PVC) plastic and certain phthalates in medical devices, brominated flame retardants and heavy metals in instruments, and PVC and expanded polystyrene in packaging (see ¹³). For examples of company goals to reduce hazardous chemicals in products beyond regulatory compliance see ¹⁴ .
Corporate	Has your	20%	No	0	N/A	
Chemicals Management Policies, Procedures, and Practices	company participated in the Chemical Footprint Project annual Survey and publicly disclosed score (or equivalent survey)?		Yes	20	Company's Chemical Footprint Project Survey score is published on https://www.chemicalfootprint.o rg/.	For results from past Chemical Footprint Project Surveys see ¹⁵ . For a list of past responders to the Chemical Footprint Project Survey, including their scores and answers see ¹⁶ . For all information related to the Chemical Footprint Project Survey see ¹² . For the list of Chemical Footprint Project Survey questions and guidance for participating in the Survey see ¹⁸ .

¹² <u>https://www.bizngo.org/safer-chemicals/corporate-chemicals-policy</u>.

¹³ https://www.bd.com/en-us/company/trading-partners/bd-suppliers/sustainable-procurement-and-expectations-for-suppliers

¹⁴ https://www.chemicalfootprint.org/results/chemial-footprint-goals

¹⁵ https://www.chemicalfootprint.org/results

¹⁶ <u>https://www.chemicalfootprint.org/results/companies</u>

¹⁷ https://www.chemicalfootprint.org

¹⁸ https://www.chemicalfootprint.org/assess

Chemicals – Level 3 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Corporate	Does your	50%	No	0	N/A	
Chemicals Management Policies, Procedures, and Practices	company have an RSL for products or a manufacturing RSL (MRSL) that includes groups/classes of chemicals of high concern, including at least one of the following three chemical groups: per- and polyfluoroalkyl substances (PFAS), ortho- phthalates, or Bisphenol A (BPA) and structural analogues?		Yes	20	Documentation that its RSL or MRSL includes at least one of the following chemical groups and uses the definition and chemicals specified in Appendix A2.2: Chemicals, organisation, level 3: Restricted Substances Lists (RSLs) and Manufacturing RSLs (MRSLs) for the Chemical Groups of: Bisphenol A (BPA) and structural analogs, Ortho- Phthalates, and Per- and Polyfluoroalkyl Substances (PFAS).	The chemical groups are specified in Appendix A2.2 Chemicals, organisation, level 3: Restricted Substances Lists (RSLs) and Manufacturing RSLs (MRSLs) for the Chemical Groups of: Bisphenol A (BPA) and structural analogs, Ortho-Phthalates, and Per- and Polyfluoroalkyl Substances (PFAS). The "RSL" covers chemicals in products. The "Manufacturing RSL" covers chemicals used to make a product but are not incorporated into the final product. Note: the chemical group must be relevant to your products or manufacturing processes. In other words, these chemical groups are used by other companies in similar products or manufacturing processes.
Corporate	Does your	25%	No	0	N/A	
Chemicals Management Policies, Procedures, and Practices	company publicly disclose at least 95% of the chemical substances intentionally		Yes	20	List of 95% of the chemical substances intentionally added to the product by weight. See Guidance for details on disclosure requirements.	Disclose at least 95% of the chemical substances intentionally added to the product by weight. Disclosure comprises at a minimum for each chemical substance in a product its: a) name; b) CAS Registry Number (CASRN) or European Inventory of Existing Chemical Substances number (EINECS); and c) presence of the

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
	added to the product by weight?					 chemical on any of the following lists: i) EU Cosmetics Directive list of carcinogens, mutagens, and reproductive toxicants (CMRs)¹⁹; EU substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR 1A/1B) or endocrine-disrupting substances (EDS) in amounts over 0.1% in Medical Devices Directive²⁰ ; jiii) REACH list of restricted substances²¹; and iv) RoHS Directive list of restricted substances in electrical and electronic equipment²². Additional information may include function and other chemical hazard characteristics of the ingredient. For examples of disclosure requirements see: Health Product Declarations²³ Principles for Chemical Ingredient Disclosure²⁴
Corporate	Does your	25%	No	0	N/A	
Chemicals Management Policies, Procedures, and Practices	company publicly disclose its progress towards its goal(s) of reducing chemicals of high concern?		Yes	20	Documentation that includes the company's goal to reduce hazardous chemicals, how it measures progress to reduce those chemicals, and annual status report of progress towards meeting the goal.	For examples of company goals to reduce hazardous chemicals in products beyond regulatory compliance and reporting progress to those goals see ²⁵

¹⁹ https://ec.europa.eu/growth/sectors/cosmetics/products/cmr-

substances en#:~:text=EU%20cosmetics%20legislation%20contains%20provisions,apart%20from%20in%20exceptional%20cases

²⁰ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02017R0745-20170505

²¹ https://echa.europa.eu/substances-restricted-under-reach

²² https://www.rohsguide.com/

 ²³ <u>https://www.hpd-collaborative.org/</u>
 ²⁴ <u>https://www.bizngo.org/public-policies/principles-for-chemical-ingredient-disclosure</u>

²⁵ https://www.chemicalfootprint.org/results/chemial-footprint-goals.

Chemicals – Level 1 – Product

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Restricted Substances List (RSL): All Products	ces your product any substance on L): the following United Nations (UN) or World Health	20	Company must attest on website or in writing that chemicals listed under the Minamata Convention, Montreal Protocol, Rotterdam Convention, Stockholm Convention, and WHO 10 Chemicals of Major Public Health Concern are not intentionally added into its product(s) above 1 part per million (ppm).	The specified lists are: - Minamata Convention on Mercury ²⁶ - Montreal Protocol on Substances that Deplete the Ozone Layer ²⁷ - Rotterdam Convention, Annex III list of pesticides and industrial chemicals ²⁸ - Stockholm Convention on Persistent Organic Pollutants ²⁹ - WHO 10 Chemicals of Major Public Health Concern ³⁰		
		Yes	0	N/A		
	- WHO 10 Chemicals of Major Public Health Concern					

 ²⁶ <u>https://www.mercuryconvention.org/</u>
 ²⁷ <u>https://ozone.unep.org/treaties/montreal-protocol</u>
 ²⁸ <u>http://www.pic.int/TheConvention/Chemicals/AnnexIIIChemicals</u>
 ²⁹ <u>http://chm.pops.int/TheConvention/ThePOPs/ListingofPOPs/tabid/2509/Default.aspx</u>
 ³⁰ <u>https://www.who.int/ipcs/assessment/public_health/chemicals_phc/en/</u>

Chemicals – Level 2 – Product

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Restricted Substances List (RSL) for	Is your product in compliance with one of the RSLs listed below? - Carpets: Health Care Without Harm Healthy	50%	No	0	N/A	
specific product categories: carpets, cleaning chemicals, flooring, furniture and furnishings, gloves, hand hygiene products, medical products, and sterilants and disinfectants.	Carpet Criteria - Cleaning chemicals: Health Care Without Harm Cleaning Chemicals criteria - Flooring: Health Care Without Harm Healthy Flooring Criteria - Furniture and furnishings: Health Care Without Harm / Practice Greenhealth: Guidance for Manufacturers to Achieve the Healthy Interiors - Gloves: Health Care Without Harm Gloves criteria - Hand hygiene products: Health Care Without Harm Hand hygiene products criteria		Yes, in compliance with one of the specified lists	20	Product must be listed by the entity that created the RSL as meeting its requirements.	For further information on the certifications go to: - Carpets: Health Care Without Harm Healthy Carpet Criteria ³¹ - Cleaning chemicals: Health Care Without Harm Cleaning Chemicals criteria ³² - Flooring: Health Care Without Harm Healthy Flooring Criteria ³³ - Furniture and furnishings: Health Care Without Harm / Practice Greenhealth: Guidance for Manufacturers to Achieve the Healthy Interiors ³⁴ - Gloves: Health Care Without Harm Gloves criteria ³⁵ - Hand hygiene products: Health Care Without Harm Hand hygiene products criteria ³⁶

 ³¹ <u>https://noharm-uscanada.org/documents/healthy-carpet-criteria</u>
 ³² <u>https://practicegreenhealth.org/sites/default/files/2019-02/finalhhgreencleaningguidance-version2.0december2016.pdf</u>

 ³³ <u>https://pohrm-uscanada.org/healthyflooring</u>
 ³⁴ <u>https://practicegreenhealth.org/topics/safer-chemicals/healthy-interiors</u>

³⁵ <u>https://noharm-global.org/sites/default/files/documents-</u> files/6751/Protection%20without%20Pollution%20-%20Guidance%20for%20sustainable%20glove%20purchasing.pdf

³⁶ https://practicegreenhealth.org/sites/default/files/upload-files/safer hand hygiene - get started guide.pdf

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Certified products	Is your product in compliance with one of the following product certifications? - Blue Angel - Cradle to Cradle Certified® Product Standard	50%	No	0	N/A	
	Version 4: silver or higher - EU Ecolabel - EU Green Public Procurement (GPP) - Greenhealth Approved - LEVEL® by BIFMA: must be LEVEL certified and meet the criteria in Section 7.4.4 Targeted Chemical Elimination of ANSI/BIFMA e3-2019 Furniture Sustainability Standard: the targeted chemicals are flame retardants; per- and poly- fluorinated chemicals; chemical antimicrobials; polyvinyl chloride (PVC); and formaldehyde and other volatile organic compounds (VOCs) - GreenScreen Certified - Nordic Swan Ecolabel - Swedish National Agency for Public Procurement Sustainability Criteria		Yes, meets the requirements of one of the listed product certifications	20	Product must be listed on one of the product certifications' website.	For further information on the certifications go to: - Blue Angel ³⁷ - Cradle to Cradle Certified® Product Standard Version 4 (silver or higher) ^{38 39} - EU Ecolabel ⁴⁰ - EU GPP ⁴¹ - Greenhealth Approved ⁴² - GreenScreen Certified ⁴³ - LEVEL® by BIFMA ⁴⁴ and ANSI/BIFMA e3-2019 Furniture Sustainability Standard, Section 7.4.4 ⁴⁵ - Nordic Swan Ecolabel ⁴⁶ - Swedish National Agency for Public Procurement Sustainability Criteria ⁴⁷
	- Or equivalent product certification					

³⁷ https://www.blauer-engel.de/en

³⁸ <u>https://www.c2ccertified.org/get-certified/product-certification</u>

- ³⁹ https://www.levelcertified.org/
- ⁴⁰ https://ec.europa.eu/environment/ecolabel/
- ⁴¹ <u>https://ec.europa.eu/environment/gpp/eu_gpp_criteria_en.htm</u>
- ⁴² https://greenhealthapproved.org/
- ⁴³ https://www.greenscreenchemicals.org/certified
- ⁴⁴ https://www.levelcertified.org/
- ⁴⁵ <u>https://www.bifma.org/page/e3standard</u>
 ⁴⁶ <u>https://www.nordic-ecolabel.org/</u>

⁴⁷ https://old.upphandlingsmyndigheten.se/

4.4 Gender, human and labour rights (GHLR)

The GHLR section of the SPIH contains five modules, as set out in the table below. These modules aim to establish the supplier's capacity to understand, manage and improve GHLR in its own operations and within its supply chain.

The social impacts of procurement can be significant, both positive and negative. There is a focus on employment, contract management, gender, and LGBTQI+ and broader human rights issues. Certain supply chains have high risks in relation to these areas, as can be seen on almost a daily basis through media and academic exposés. However, there is also a long established and evolving set of audit standards, certifications and collaborations which seek to identify and resolve issues.

To support action on GHLR, the themes covered in the SPIH GHLR modules include:

- Labour standards
- Auditing
- Gender impact and privacy
- Capacity / management systems in place with suppliers
- Supply chain information for the supplier organisation
- Gender and diversity

The structure of the modules for the GHLR theme is as follows:

Theme	Level	Scope	Relevance	Questions	Max score	Pass score
Gender, human and labour rights	1	Product	All products	2	12.00	6.00
Gender, human and labour rights	2	Product	All products	3	30.00	15.00
Gender, human and labour rights	1	Organisation	All organisations	3	25.00	12.50
Gender, human and labour rights	2	Organisation	All organisations	4	22.50	11.25
Gender, human and labour rights	3	Organisation	All organisations	6	20.00	10.00

The full details of the modules follow in this section.

GHLR – Level 1 – Organisation

Maximum Score	25
Pass threshold	12.5

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Policy	Is there a labour /	50%	No	0	N/A	
	human rights policy in place for the company, in addition to plus contractors, subcontractors etc.?	in place for mpany, in on to plus	No, but currently developing one	10	Information demonstrating timeframe to develop the policy	Some evidence should be presented to prove that this is in development. This may be from an internal memo or email, news article, company report or similar.
			Yes, in place and	20	Copy of policy – that clearly covers all the issues pertinent	IFC Performance Standard 2 sets out useful information on developing a policy on labour, see $^{\rm 48}$
			communicat ed		to the organisation, including basic labour standards	Other standards such as the ETI base code are useful to understand basic supply chain labour standards $^{\rm 49}$
Capacity / managem ent system	managem management ent function in place	anagement action in place direct apployees and currently developing one Market Market Currently developing one	currently developing	0	N/A	
			20	Job functions, numbers and role	In some companies and countries, the HR function is very limited to basic transactional tasks like ensuring workers have the right paperwork and are paid on time, with the right records.	
			Yes, with strategic inputs	30	Job function, numbers and role	Where HR is better integrated, it should have a role in deciding strategy on how people are employed and how this fits into the company's overall strategy.

⁴⁸ <u>https://www.ifc.org/wps/wcm/connect/topics_ext_content/ifc_external_corporate_site/sustainability-at-ifc/policies-standards/performance-standards/ps2</u>
⁴⁹ <u>https://www.ethicaltrade.org/eti-base-code</u>

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
						 HR should also have sight of any business plans and changes to provide input and support. Strategic HR also involves a function which can assess ways to understand and deal with challenges and is able to engage on gender related issues, including how to promote and encourage better women's participation in the workplace.
Capacity / managem ent system	managem department/functi ent on(s) in your	25%	No, but currently developing one	0	N/A	
	responsible for supply chain labour standards?		Yes, but only with very basic functions in checking contracts include provision on labour and human rights	20	Contract terms requiring labour and human rights provisions.	The entry level approach to supply chain management relies exclusively on implementation of contractual standards into the contract provisions with suppliers.
			Yes, with strategic inputs	30	Description of that function's remit/responsibility for supply chain issues	 The Swedish national procurement agency requirements for medicinal products provides that there should be An appointed manager at the highest management level, responsible for compliance with the Terms, Adopted routines to regularly carry out risk analyses, i.e. to identify and prioritise current and potential risks of deviation from the Terms, as well as mapping the supply chain with special regard to high-risk operations, Adopted routines for regular follow-up of the Terms compliance, and Adopted routines to immediate action to prevent and limit deviations from the Terms, and to make amendments to identified deviations.

GHLR - Level 2 - Organisation

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Policy	Is there a labour	25%	No	0	N/A	
	standards policy, aligned with national / international standards, in place for your company and is it communicated widely?		Yes	20	Copy of Policy	IFC have published a useful guide to labour standards which includes developing a policy for both businesses and their supply chains, see ⁵⁰
Supply chain	Are social /		No	0	N/A	
	labour audit reports available?		Yes	20	Copy of audit	Depending on the nature of the supply chain and audit programme, audits may be available on a sharing platform such as Sedex.
Supply chain	Is the supply	25%	No	0	N/A	
information	chain mapped to Tier 1 (i.e. those with which you		Some elements present	10	Evidence of mapping	Sedex provide guidance on the benefits and approaches for supply chain mapping, see ⁵¹
hav	have direct contracts)?		Yes, as part of a broader risk assessment process	15	Plan and outcomes	They suggest four steps:

⁵⁰ <u>https://www.ifc.org/wps/wcm/connect/e0e8e968-132a-4dbf-af0b-4b971e4a4b9b/SAI_IFC_LaborHandbook.pdf?MOD=AJPERES&CVID=jkD0.wG</u>
⁵¹ <u>https://www.sedex.com/mapping-your-supply-chain-how-to-get-started/</u>

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
			Yes, a specific labour standards approach	20	Labour standards plan	 Learn where suppliers and their suppliers are located by working with procurement and using existing supplier lists. Integrate information on your suppliers from different sources using a spreadsheet or data platform. Supply chains can change rapidly; a system for managing supplier data will help you to keep information current and in one place. Conduct an initial risk assessment to help you prioritise where to focus next.
						 Use several tools to research your suppliers. Collect information about what is happening at supplier worksites, and research the inherent risks associated with the countries and sectors they operate within.
Policy	Do you have a policy on supply chain labour rights and direct HR practices?	25%	No, but currently developing one	0 10	N/A Draft of policy or internal documents demonstrating that the policy is in development, in addition to the date for publication.	Some evidence should be presented to prove that this is in development. This may be from an internal memo or email, news article, company report or similar.
		Ye bro or		20	Copy of section from policy	IFC have published a useful guide to labour standards which includes developing a policy for both businesses and their supply chains, see ⁵²
			Yes, a specific policy or plan	30	Copy of policy or plan	

⁵² <u>https://www.ifc.org/wps/wcm/connect/e0e8e968-132a-4dbf-af0b-4b971e4a4b9b/SAI_IFC_LaborHandbook.pdf?MOD=AJPERES&CVID=jkD0.wG</u>

GHLR – Level 3 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Policy	Do you have an anti-	15%	No	0	N/A	
corruption policy in place for your company plus contractors, subcontractors etc.?		No, but currently developing one10Draft of policy or internal documents demonstrating that the policy is in development, in addition to the date for publication		internal documents demonstrating that the policy is in development, in addition to the date	Transparency International have produced a significant report looking at bribery and corruption in the pharmaceutical sector, with recommendations for action, see ⁵³ This may be a useful reference. There are many examples of anti-corruption and bribery policies available for review and comparison. There are many resources also available to assist in drafting and reviewing a policy, including this ⁵⁴	
			Yes, in place and communic ated	20	Copy of policy or plan	There are many examples of anti-corruption and bribery policies available for review and comparison. There are many resources also available to assist in drafting and reviewing a policy, including this ⁵⁴
Supply	Are supply chains	nd Tier 1 ding olier uses	No	0	N/A	
chain informatio n	(e. understanding ho your supplier uses		20	Overview of mapping
Supply	Are certification	15%	No	0	N/A	
informatio sourcing of relev	schemes used for sourcing of relevant high-risk materials?			20	Examples of certification	There are various established certification schemes in place that deal with labour, human rights and gender issues, depending on the products. There are a wide number of sustainability and other certifications which cover labour standards, including FSC,

⁵³ <u>https://www.transparency.org.uk/sites/default/files/pdf/publications/29-06-2016-Corruption_In_The_Pharmaceutical_Sector_Web-2.pdf</u>
 <u>https://info.unitedlanguagegroup.com/hubfs/-%20ULG%20-%20Aug%202019/Services/Translation/ULG_Ebook_CorpComplianceLS.pdf</u>

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
						Better Cotton, Rainforest Alliance, etc. Many are members of the ISEAL alliance. See more information here $^{\rm 55}$
Supply	Is your company	20%	No	0	N/A	
chain involved in informatio collaborative social n initiatives in relation to the supply chain?		Yes	20	Summary / case study of collaboration	There are a wide number of collaborative initiatives which cover labour and human rights standards, including FSC, Better Cotton, Rainforest Alliance, etc. Many are members of the ISEAL alliance. See more information here. ⁵⁵ In addition, collaborations like ETI, BSCI and the Pharmaceutical Supply Chain Initiative deal with specific labour and human rights issues in supply chains by setting standards and also promoting collaboration.	
Gender	Does your company	20%	No	0	N/A	
	demonstrate women ownership or leadership?		Yes	20	Statistics demonstrating gender proportions in leadership or supplier ownership	IFC Women's Employment Program has a range of programmes and guides on women's leadership, including case studies and guidance on women's leadership in healthcare, see ⁵⁶
Gender	Does your company	15%	No	0	N/A	
and diversity	incorporate measurable diversity and inclusivity processes and goals into recruitment, training, remuneration, performance evaluation, and other structures (women, disability, migrants etc).?		Yes	20	Evidence of the goals and processes that have been implemented. Statistics showing outcomes, where possible.	 There are many resources and guidance documents available on diversity and inclusion, some include the following: McKinsey overview of challenges and performance⁵⁷ This NHS guidance and programmes in the UK⁵⁸

 ⁵⁵ <u>https://www.isealalliance.org</u>
 ⁵⁶ <u>https://www.ifc.org/wps/wcm/connect/a062e443-5503-4e87-af07-</u>

⁵⁹³db1bed033/IFC+Women+Leaders+Healthcare FinalWeb4.pdf?MOD=AJPERES&CVID=mCRI3Yb ⁵⁷ https://www.mckinsey.com/featured-insights/diversity-and-inclusion/diversity-wins-how-inclusion-matters#

⁵⁸ https://www.leadershipacademy.nhs.uk/resources/inclusion-equality-and-diversity/

GHLR – Level 1 – Product

Maximum Score	12
Pass threshold	6

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Labour	Has the country	40%	No	0	N/A	Ratification by convention and country can be found here ⁵⁹
standar of production ds ratified all ILO core labour standards?		Yes	20	Demonstration that the country is in the ILO records.	Ratification by convention and country can be found here ⁵⁹	
Labour	Is the country	60%	No	20	N/A	List of goods are found here ⁶⁰
standar ds	and product on the US Department of Labor – List of Goods - Forced or child labour?		Yes, but evidence that this supplier is meeting required standards	20	Clear audit findings demonstrating no forced or child labour	List of goods are found here ⁶⁰ If product and country are on the list, there would need to be a specific audit finding dealing with these issues for the product to score 20.
			Yes	0	N/A	

⁵⁹ <u>https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:10011:0::NO::P10011_DISPLAY_BY,P10011_CONVENTION_TYPE_CODE:1,F</u> ⁶⁰ <u>https://www.dol.gov/agencies/ilab/reports/child-labor/list-of-goods</u>

GHLR – Level 2 – Product

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Auditing	Has your production	20%	No	0	N/A	
	been subjected to a labour audit in the last 2 years?		No, audit is planned in next 2 months	10	Evidence of request for audit in past 2 months	Audit should be diarised with a reputable audit company.
			Yes, partial audit	20	A copy of the audit report.	Accepted audits include: Pharmaceutical Supply Chain Initiative, Eti base code, Smeta, SA 8000, or equivalent. A copy of the audit or summary outcome should be provided. If an alternative audit is provided it should be mapped against the requirements of one of the accepted audits.
			Yes, full audit	30	A copy of the audit report.	Accepted audits include: Pharmaceutical Supply Chain Initiative, Eti base code, Smeta, SA 8000, or equivalent. A copy of the audit or summary outcome should be provided. If an alternative audit is provided it should be mapped against the requirements of one of the accepted audits.
	What was the outcome of the	40%	Substantial non- compliances	0	N/A	
auc	audit?		Minor non- compliances	10	A copy of the audit report.	A copy of the audit or a summary outcome should be provided. Accepted audits include: Pharmaceutical Supply Chain Initiative, Eti base code, Smeta, SA 8000, or equivalent. If an alternative audit is provided it should be mapped against the requirements of one of the accepted audits.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
			No non-compliances	30	A copy of the audit report	A copy of the audit or a summary outcome should be provided. Accepted audits include: Pharmaceutical Supply Chain Initiative, Eti base code, Smeta, SA 8000, or equivalent. If an alternative audit is provided it should be mapped against the requirements of one of the accepted audits.
	What is your	40%	No action plan	0	N/A	
	response to the audit?		Developing action plan	10	A draft of the action plan, or internal documents detailing its development are provided.	
			Published action plan, not yet implemented	15	Action plan available for review	The action plan should clearly identify the findings of the audit that need to be addressed and a timebound action plan which addresses each of the findings.
			Partially/fully implemented action plan or no action plan needed		Action plan available for review, including progress against several metrics	The action plan should clearly identify the findings of the audit that need to be addressed and a timebound action plan which addresses each of the findings. It should also include the date by which each action plan was completed.

4.5 Summary

The box below summarises the information presented in this section.

Summary of SPIH for General Products

- GHG:
 - The GHG section of the SPIH contains five modules which cover six themes.
 - The themes covered in the SPIH GHG modules include: reporting of GHG emissions, including scope of emissions considered and disclosure; supplier policy on GHG reduction; governance; targets for GHG reduction; consideration of all emissions associated with the manufacture of the product; and any certifications achieved.
- Resources:
 - The resource section of the SPIH contains five modules which cover three themes.
 - The themes covered in the SPIH resource depletion modules include: supplier policy on resource efficiency governance; third party / supplier review; consideration of all resource use associated with the manufacture of the product
- Chemicals:
 - The Chemicals section of the SPIH contains five modules which cover four themes.
 - The themes covered in the SPIH Chemicals modules include: corporate chemicals management policies, procedures, and practices; restricted substances lists (RSLs) and manufacturing RSLs (MRSLs); certifications achieved; progress to green chemistry for the pharmaceutical industry
- GHLR:
 - The GHLR section of the SPIH contains five modules which cover six themes.
 - The themes covered in the SPIH GHLR modules include: labour standards; auditing; gender impact and privacy; capacity / management systems in place with suppliers; supply chain information for the supplier organisation; gender and diversity

Box 7 Section 4 summary

5 Technical chapters for each theme – Pharmaceutical version

5.1 Greenhouse gases (GHGs)

The GHG section of the SPIH contains five modules, as set out in the table below. These modules aim to establish the supplier's capacity to understand, manage and reduce GHG emissions in its own operations and within its supply chain.

As established in Health Care Without Harm's report "Health Care's Climate Footprint", healthcare represents 4.4% of global emissions, with 71% of these emissions associated with emissions in the healthcare supply chain, from delivery of services, and manufacture and use of healthcare products. Therefore, measuring and managing GHG emissions is a key priority action area for the healthcare sector, and it should strive to reduce its impacts in line with the Paris Agreement.

To support climate action, the themes covered in the SPIH GHG modules include:

- Reporting of GHG emissions, including scope of emissions considered and disclosure
- Supplier policy on GHG reduction
- Governance
- Targets for GHG reduction
- Consideration of all emissions associated with the manufacture of the product
- Any certifications achieved

The structure of the modules for the GHG theme is as follows:

Theme	Level	Scope	Relevance	Questions	Max score	Pass score
GHG emissions	1	Organisation	All organisations	2	20.00	10.00
GHG emissions	2	Organisation	All organisations	4	30.00	15.00
GHG emissions	3	Organisation	All organisations	4	30.00	15.00
GHG emissions	2	Product	All products	3	20.00	10.00
GHG emissions	3	Product	All products	3	20.00	10.00

The full details of the modules follow in this section.

GHG – Level 1 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance	
Scope	Do you measure	50%	No	0			
	your Scope 1 & 2 GHG footprint?		Yes, following a recognised methodology [from list in Appendix A2]	10	Link / documenting that the company reports in accordance with the relevant standard	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated. Scope 1 and 2 emissions should be clearly stated.	
			Yes, following another methodology	10	Link / document evidencing that company reports to a different standard that meets minimum criteria (including Scope 1 and 2 and using recent data)	Your footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated and include details on the which company activities are included, emission factors used. Scope 1 and 2 emissions should be clearly stated.	
Reporting	Do you report your	50%	No	0	N/A		
	GHG footprint?		The results are published internally	10	Published results	Screenshot evidence of how they are reported should be provided, and this should clearly show Scope 1 and 2 emissions and be less than three years old.	
				They are provided on request	10	Published results	A report/data should be provided which details Scope 1 and 2 emissions clearly and be less than three years old.
			Yes, published on our website	30	Link to published report	The weblink should be accessible. The reporting should clearly state Scope 1 and 2 emissions and be less than three years old.	

GHG – Level 2 – Organisation

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Laws and	Are there any	0%	No	0	N/A	
regulations	national laws or regulations which you have to follow related to GHGs?		Yes, there are legally binding GHG targets which have implications for the organisation	0	N/A	This question is for information only and can help identify whether there is a regulatory framework which may promote GHG reduction in the healthcare sector.
			Yes, there are legally binding net zero GHG targets which have implications for the organisation	0	N/A	This question is for information only and can help identify whether there is a regulatory framework which may promote GHG reduction in the healthcare sector.
Policy	Does your company	25%	No	0	N/A	
	have a policy or plan which addresses GHG emissions reduction?		No, but currently developing one	10	Policy document	Some evidence should be presented to prove that this is in development. This may be from an internal memo or email, news article, company report or similar.
			Yes, as part of a broader policy or plan	20	Policy document	A copy of the policy or plan should be provided. Actions and intent for GHG emissions reduction should be clearly stated.
			Yes, a specific policy or plan	30	Policy document	A copy of the policy or plan should be provided.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Governance	Do you have a	25%	No	0	N/A	
	person responsible for GHG-related matters?		Yes, at the operational level	15	Name and job title of the person(s) responsible.	Name and job title of the person should be provided.
			Yes, at the operational level and the senior/board level	30	Name and job title of the person(s) responsible.	Name and job titles of the persons should be provided.
Targets	Do you have a	25%	No	0	N/A	
	carbon reduction plan in place for your Scope 1 and 2 emissions?		Yes, applicable for the next 5 years or less	15	Carbon reduction plan for at least Scope 1 and 2 for next ≤5 years	The plan should document specific actions that the organisation has put in place, and may include aspects such as energy efficiency, renewable energy, reducing process emissions or training and skills development, applicable for the next five years. It may also quantify the potential benefits and set targets.
			Yes, applicable beyond the next 5 years	30	Carbon reduction plan for at least Scope 1 and 2 for next >5 years	As above but should include actions that go beyond the next five years.
Targets		25%	No	0	N/A	
	your targets and reduction plan?		Only internally	10	Internal memo, email, news article, report or similar, to demonstrate that this is the case.	Some evidence should be presented to prove that this is the case. This may be from an internal memo or email, news article, company report or similar.
			Yes, they are published on our website	30	Link to published targets and reduction plan	The weblink should be accessible.

GHG – Level 3 – Organisation

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Scope 3	Does your company	25%	No	0	N/A	
	measure and report on Scope 3 emissions?		Yes, but only business travel	10	Scope 3 emissions report	These should be included as part of the GHG emissions report and clearly identified and be less than three years old. This should be consistent with the GHG Protocol's definition of Scope 3, Category 6 (business travel).
			Yes, including business travel and upstream emissions	20	Scope 3 emissions report	In addition to the above, upstream emissions should include those associated with the extraction of raw materials and services (i.e. the supplier's supply chain) consistent with GHG Protocol's definition of Scope 3, Categories 1 and 2 (purchased goods and services, capital goods).
			Yes, including business travel, upstream emissions and downstream emissions (including logistics)	30	Scope 3 emissions report	In addition to the above, downstream emissions should include those associated with logistics and use of sold products, consistent with GHG Protocol's definition of Scope 3, Categories 9 (downstream transportation and distribution) and, where relevant 11 and 12 (use of sold products and end of life treatment).
Disclosure	Do you report to a	25%	No	0	N/A	
	voluntary GHG reporting mechanism?		Yes	30	List [from list in Appendix A2]	Evidence of participation should be provided. This may be a weblink or email confirming participation. The most recent reporting should be more than three years old.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Targets	Do you have a	25%	No	0	N/A	
	carbon reduction target in place for your Scope 3?	arget in place for		15	Evidence of target, and explanation of which parts of scope 3 it applies to	This may be documented as part of a carbon reduction plan or policy. The target should identify which aspects of scope 3 are included.
			All of scope 3	30	Evidence of target	This may be documented as part of a carbon reduction plan or policy. Note that not all categories of Scope 3 may apply to a specific company. Those categories which have scoped out should be documented with an appropriate explanation.
Targets	ets Have you adopted science-based targets (in line with the Paris Agreement) for your organisation?			0	N/A	
			Yes, covering scope 1 and 2 emissions	15	Evidence of SBT target	If the targets have been verified by a third party (e.g., Science Based Targets Initiative) then a relevant weblink or documentation should be provided. If not, then evidence should be provided which should clearly set out the method used, and which climate scenarios have been used to establish the SBT. This should at least be in line with the 'well below 2 degrees' scenario.
			Yes, covering scope 1, 2 and 3 emissions	30	Evidence of SBT target	As above, but applicable to all relevant emission Scopes.

GHG – Level 2 – Product

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Scope 3	Do you measure the	30%	No	0	N/A	
	emissions from business travel, including logistics?	ss travel,	Yes, following a recognised methodology [from list in Appendix A2]	20	List	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated. Scope 3 business travel and logistics emissions should be clearly stated.
			Yes, following another methodology	10	Evidence of calculations for Scope 3 emissions	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated and include details on the which company activities are included, emission factors used. Scope 3 business travel and logistics emissions should be clearly stated.
	Do you measure the	nissions from your oduct supply ain?	No	0	N/A	
	emissions from your product supply chain?		Yes, following a recognised methodology [from list in Appendix A2]	20	List	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated. Scope 3 purchased goods and services emissions should be clearly stated.
			Yes, following another methodology	10	Evidence of calculations for Scope 3 emissions	The footprint should include that associated with the relevant product you are supplying and be less than three years old. The methodology should be stated and include details on the which company activities are included, emission factors used. Scope 3 purchased goods and services emissions should be clearly stated.
e p	Do you manage the emissions from your product supply chain?	nissions from your oduct supply	Yes, we require our Tier 1 suppliers to: have a policy and have a carbon target	20	Evidence of targets	Documentation should be available from the supplier which demonstrates that it requires this of its own supply chain, for example a pre-qualification questionnaire or sustainable procurement policy document.
			No	0	N/A	

GHG – Level 3 – Product

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Product	Do you have a	33.33%	No	0	N/A	
certification	detailed understanding of your product's carbon footprint?		Yes, undertaken an LCA of product	20	LCA assessment report or claim	An LCA report should be provided. This should represent the specific product being sourced or the family of products to which is belongs. The LCA should clearly represent (and justify) the relevant aspects of the product lifecycle that have been included in the assessment. Impacts on greenhouse gas emissions should be included. The methodology used should be clearly stated. The LCA study should be less than 5 years old.
Product		oduct-level	No	0	N/A	
certification	product-level certification?		Yes, produced an EPD or similar third- party reviewed product declaration	20	Evidence of EPD / Declaration	A certificate, approval or formal letter of certification should be provided. This should clearly refer to the product being sourced or the family of products to which it belongs. The relevant methodology should be stated and/or the Product Category Rules which have been used. The certification should be less than 5 years old.
		Yes, achieved a recognised standard for product [from a selected list relevant to GHG]	30	Evidence of achieving standard	A certificate, approval or formal letter of certification should be provided. This should clearly refer to the product being sourced or the family of products to which it belongs. The relevant methodology should be stated. The certification should be less than 5 years old.	
Product	Do you collect data	e supply chain ssions that you nform decision	No	0	N/A	
certification	certification from the supply chain on emissions that you use to inform decision making?		Yes	10	Description of data collected	The evidence might include an explanation of what has been done as part of a GHG report, or a typical data collection form. It should include which data is requested from the supplier's supplier, for example Scope 1 and 2 emissions or product-level LCA or similar.

5.2 **Resource depletion**

The resource section of the SPIH contains five modules, as set out in the table below. These modules aim to establish the supplier's capacity to understand, manage and reduce resource use (energy, water, materials) in its own operations and within its supply chain.

The depletion of resources is recognised as harming the health of human beings and the planet directly and indirectly. Therefore, reducing resource use is a key priority action area for the healthcare sector and it should strive to reduce the use of resources.

To support action on reducing resource use, the themes covered in the SPIH resource depletion modules include:

- Supplier policy on resource efficiency
- Governance
- Third party / supplier review
- Consideration of all resource use associated with the manufacture of the product

Theme	Level	Scope	Relevance	Questions	Max score	Pass score
Resource depletion	1	Organisation	All organisations	2	30.00	15.00
Resource depletion	2	Organisation	All organisations	3	20.00	10.00
Resource depletion	3	Organisation	All organisations	3	20.00	10.00
Resource depletion	2	Manufacturing	All products	13	20.00	10.00
Resource depletion	1	Organisation	All products	3	20.00	10.00

The structure of the modules for the resource depletion theme is as follows:

The full details of the modules follow in this section.

Resource depletion – Level 1 – Organisation

Maximum Score	30
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Laws and	Are there any	0%	No	0	N/A	
regulations	national laws or regulations which you have to follow related to resource		Yes, there are legally binding resource efficiency targets which have implications for the organisation	0	N/A	This question is for information only and can help identify whether there is a regulatory framework which may promote resource efficiency in the healthcare sector.
efficiency?	efficiency?		Yes, there are ambitious legally binding resource efficiency targets which have implications for the organisation	0	N/A	This question is for information only and can help identify whether there is a regulatory framework which may promote resource efficiency in the healthcare sector.
Policy	Do you have	ronmental cies or plans in e which address resource iency aspects vant to your	No	0	N/A	
	environmental policies or plans in place which address key resource		No, but currently developing one	10	Environmental Policies / Plans	Some evidence should be presented to prove that this is in development. This may be from an internal memo or email, news article, company report or similar.
	efficiency aspects relevant to your business?		Yes, as part of a broader policy or plan	20	Environmental Policies / Plans	A copy of the policy or plan should be provided. Actions and intent for resource efficiency should be clearly stated.
			Yes, a specific policy or plan	30	Environmental Policies / Plans	A copy of the policy or plan should be provided.
Governance	Do you have a	r responsible r resource on aspects nt to your	No	0	N/A	
	person responsible for key resource depletion aspects relevant to your		Yes, at the operational level	10		Name and job title of the person should be provided.
	business?		Yes, at the operational level and the senior/board level	30		Name and job titles of the persons should be provided.

Resource depletion - Level 2 - Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Governance	Do you have an environmental management system in place?	33.33%	No	0	N/A	
			Yes, in compliance with ISO14001	20	Certificate of compliance	A copy of the certificate should be provided. It should be less than three years old.
			Yes, following another standard	20	Certificate of compliance or copy of the EMS	A copy of the certificate should be provided. It should clearly state the approach taken to environmental management and/or the scheme/system that it is compliant to. The evidence should be less than three years old.
Monitoring	Do you monitor resource	33.33%	No	0	N/A	
use at an organisational level (water, energy, etc)?		Yes	20	Evidence of monitoring	A monitoring report for key environmental impacts should be produced, and/or a copy of a monitoring protocol. This should cover environmental issues relevant to the product being supplied, typically including water, waste and energy. The monitoring information should be less than three years old.	
Strategy	Do you have a plan which addresses the key relevant aspects of environmental impacts/resource efficiency relevant to your business and tracks progress against its actions?	33.33%	No	0	N/A	
			Yes, tracking progress using key criteria from ISO14001 and GRI	20	Plan document	A copy of the plan should be provided.
			Yes, tracking progress using other criteria	20	Link / document evidencing that company reports to a different	A copy of the plan or link to the plan should be provided. If a weblink is provided, it should be accessible.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
					standard that meets minimum criteria (including Scope 1 and 2 and using recent data)	
Innovation	What improvements have you made in your environmental performance or resource consumption in the last two years?	0%	Free text	0	N/A	Narrative description of positive outcomes should be provided to give context on steps the organisation is taking to promote resource efficiency.

Resource depletion – Level 3 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Third party review	Has your environmental management system been independently reviewed?	50%	No	0	N/A	
			Yes, our environmental management system is independently reviewed	20	Third party verification certificate	A certificate, approval or formal letter of certification should be provided. This should clearly refer to company supplying the product or service. The relevant standard should be stated. The certification should be less than three years old.
Supplier	Do you monitor the	25%	No	0	N/A	
review	environmental performance of your suppliers?		Yes, we actively monitor the environmental performance of our suppliers (% of suppliers with their own Environmental Policy)	20	Evidence of monitoring suppliers' performance	Information on what monitoring is undertaken should be provided, and any data on performance. This might include information on whether their suppliers have their own policy, their energy, water or waste performance or any other relevant aspects. A copy of the monitoring form or information request might alternatively be provided.
Reporting	Do you report to a voluntary scheme to disclose your environmental performance?	luntary scheme to sclose your wironmental	No	0	N/A	
			Yes, we report to a recognised voluntary scheme	20	Link to CDP Water security score / report	A copy of or link to the CDP Water Security report should be provided.
			Yes, we report to another voluntary scheme	10	Link to GRI Reporting standards score / report	A copy of or link to the GRI Reporting standards score or the report should be provided.

Resource depletion - Level 2 - Manufacturing

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Recycled content of product	Have you calculated the recycled content of the product?	7.69%	No	0	N/A	
			Yes, each product has <50% post- consumer recycled content	10	Evidence of the levels of recycled content	Evidence should be provided to support the claim of recycled content of the product. This might include information on the composition of the product, evidence on the origin of the materials and any specific label/labelling scheme that is relevant for the product.
			Yes, each product has ≥50 and ≤100% post-consumer recycled content	20	Evidence of the levels of recycled content	Evidence should be provided to support the claim of recycled content of the product. This might include information on the composition of the product, evidence on the origin of the materials and any specific label/labelling scheme that is relevant for the product.
Recycled	Are major	7.69%	No	0	N/A	
content of product	components of the product recyclable?		Yes	20	Evidence that supports that the main components can be recycled	Evidence should be provided supporting the claim that the product can potentially be recycled (or refurbished). This should apply to at least 80% of the mass of the product.
	Does the	7.69%	No	0	N/A	
circular economy	manufacturer operate a take-back programme?		Yes	20	Details of programme and agreement	Details of the take back programme should be provided, which describe how the programme works and how it can be accessed.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Water use in	Do you undertake	7.69%	No	0	N/A	
manufacturing	wastewater management and monitoring?		Yes, we assess water quality monitoring data (e.g. PNECs)	20	Evidence of monitoring	A monitoring plan should be provided which documents how and when wastewater quality is measured, the instrumentation used and how it is reported. This might be a specific plan or part of a broader environmental management system. Further evidence of monitoring data would provide increased confidence.
			Yes, we assess other data	10	Evidence of monitoring	A monitoring plan should be provided which documents how and when wastewater quality is measured, the instrumentation used and how it is reported. This might be a specific plan or part of a broader environmental management system. Further evidence of monitoring data would provide increased confidence.
Energy use in	Have you calculated	7.69%	No	0	N/A	
manufacturing	the % use of renewable energy in final manufacturing stage?		Yes, each product has <50% renewable energy used in final manufacturing stage	10	Evidence of renewable energy purchasing and use in manufacturing process	Evidence might include information of on-site renewable energy generation amounts showing the proportion contributed to the total, as well as utility bills/documentation showing the use of a renewable energy electricity tariff is similar. Note this information might also be presented as part of the GHG emissions report. Confidence is increased when the evidence is directly representative of the place of manufacturer, as opposed to a whole-company average. The evidence should be less than three years old.
			Yes, each product has ≥50 and ≤100% renewable energy used in final manufacturing stage	20	Evidence of renewable energy purchasing and use in manufacturing process	Evidence might include information of on-site renewable energy generation amounts showing the proportion contributed to the total, as well as utility bills/documentation showing the use of a renewable energy electricity tariff is similar. Note this information might also be presented as part of the GHG emissions report. Confidence is increased when the evidence is directly representative of the place of manufacturer, as opposed to a whole-company average. The evidence should be less than three years old.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Energy use in	Are your procedures	7.69%	No	0	N/A	
manufacturing	in line with ISO50001 or similar energy management approach?		Yes, in line with ISO5001	20	Evidence of ISO5001 certification	A copy of the certificate should be provided. It should clearly state the facility(s) included, which should include the main place of manufacture of the product or location from which services are provided. The evidence should be less than three years old.
			Yes, in line with another energy management approach	10	Evidence of alternative EMS	A copy of the management plan should be provided. It should clearly state the facility(s) included, which should include the main place of manufacture of the product or location from which services are provided. It should set out how energy use is monitored and improvement activities that are being put in place to minimise energy use. The evidence should be less than three years old.
Water use in	Have you quantified		No	0	N/A	
manufacturing	water use at final manufacturing stage?		Yes	20	Evidence of calculation	A report/data should be provided setting out calculations of water use at final manufacturing stage and be less than three years old.
Water use in		7.69%	No	0	N/A	
manufacturing	water conservation technologies?		Yes	20	Evidence of technologies/measures	Evidence should be provided to support the claim that water conservation technologies are used. This could be in the form of photographs.
Packaging	Have you calculated	7.69%	No	0	N/A	
	the recycled content of the product packaging?	he product kaging? Yes, eac has <50° packagin Yes, eac has ≥50	Yes, each product has <50% recycled packaging content	10	Evidence of the recycled packaging content	Evidence should be provided to support the claim of recycled content of the packaging. This might include information on the composition of the packaging, evidence on the origin of the materials and any specific label/labelling scheme that is relevant for the packaging.
			Yes, each product has ≥50 and ≤100% recycled packaging content	20	Evidence of the recycled packaging content	Evidence should be provided to support the claim of recycled content of the packaging. This might include information on the composition of the packaging, evidence on the origin of the materials and any specific label/labelling scheme that is relevant for the packaging.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance	
Packaging	Is the product	7.69%	No	0	N/A		
	packaged without PVC and polystyrene?		Yes	20	Evidence of materials contained within packaging.		
Transport	Do you have a	7.69%	No	0	N/A		
	mitigation strategy in place to minimise the impact of product distribution?		Yes	20	Link to strategy	A copy of the strategy should be provided.	
Land use	and use Have you assessed the risks associated with sourcing the main raw materials in your products from potentially vulnerable ecosystems?		7.69%	No	0	N/A	
			Yes	20	Link to risk review	A copy of the risk assessment should be provided.	
Air pollution	Do you quantify the	7.69%	No	0	N/A		
	release of harmful pollutants such as		Yes	20	Evidence of monitoring	Evidence of compliance in relation to relevant permits.	
	sulphur dioxide (SO2), nitrogen oxides (NOx), particulate matter (PM), ammonia (NH3) carbon monoxide (CO) and volatile organic compounds (VOCs)?		N/A	20	Please confirm that this issue is not relevant to you	Evidence of auditing in the past 3 years demonstrating that this is not relevant.	

UNDP

5.3 Chemicals

The Chemicals section of the SPIH contains modules for all products used in health care (excluding pharmaceutical products), as set out in the table below. These modules aim to establish the capacity of suppliers to understand, manage and reduce the use of toxic chemicals in products, operations, and supply chains.

Toxic chemicals impair the health of people and planet by causing adverse health outcomes, polluting drinking, ground, and surface waters, and polluting the air. As such toxic chemicals in products and supply chains are impediments to achieving many UN SDGs, including #3 Good Health and Well-Being, #6 Clean Water and Sanitation, and #12 Responsible Consumption and Production. Therefore, measuring and managing toxic chemicals is a key priority action area for the healthcare sector and it should strive to reduce its impacts of these chemicals.

To support action in substituting toxic chemicals in products and manufacturing operations with safer alternatives, the themes covered in the SPIH Chemicals modules include:

- Corporate chemicals management policies, procedures, and practices
- Restricted substances lists (RSLs) and manufacturing RSLs (MRSLs)
- Certifications achieved
- Progress to green chemistry for the pharmaceutical industry, including solvents, reagents, and process mass intensity

Theme	Level	Scope	Relevance	Questions	Max score	Pass score
Chemicals and toxic impact	1	Organisation	Pharmaceuticals	1	30.00	15.00
Chemicals and toxic impact	2	Organisation	Pharmaceuticals	3	30.00	15.00
Chemicals and toxic impact	3	Organisation	Pharmaceuticals	4	20.00	10.00
Chemicals and toxic impact	1	Product	Pharmaceuticals	1	20.00	10.00
Chemicals and toxic impact	2	Product	Pharmaceuticals	1	10.00	5.00

The structure of the modules for the chemicals theme is as follows:

The full details of the modules follow in this section.

Pharmaceuticals Chemicals – Level 1 – Organisation

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Solvents used in manufacturing active pharmaceutical ingredients (APIs)	Do you use any of the following hazardous or highly hazardous solvents in the production process of any APIs: 1,2-dichloroethane (DCE); 1,4-dioxane; benzene; carbon tetrachloride (CCl4); chloroform; diethyl ether; diisopropyl ether; dimethylacetamide (DMAc); dimethyl ether (DME); dimethylformamide (DMF); hexane; methoxyethanol; n-methyl-2-	100%	Νο	30	Link to statement on company website, or other policy document, that the 16 highly hazardous solvents referenced in the question are not used in the manufacture of its APIs	Use the following CAS numbers to be certain of compliance with the list of highly hazardous solvents: 1) 1,2-dichloroethane (DCE) - 107-06-2 2) 1,4-dioxane - 123-91-1 3) benzene - 71-43-2 4) carbon tetrachloride (CCl4) - 56-23-5 5) chloroform - 67-66-3 6) diethyl ether - 60-29-7 7) diisopropyl ether - 108-20-3 8) dimethylacetamide (DMAc) - 127-19-5 9) dimethyl ether (DME) - 115-10-6 10) dimethylformamide (DMF) - 68-12-2 11) hexane - 110-54-3 12) methoxy-ethanol - 109-86-4 13) n-methyl-2-pyrrolidone (NMP) - 872-50-4 14) nitromethane - 75-52-5 15) pentane - 109-66-0 16) triethylamine (TEA) - 121-44-8
	pyrrolidone (NMP); nitromethane; pentane; or triethylamine (TEA)?		Yes, for <25% of solvents used in the manufacture of APIs by mass	20	Link / document / policy evidencing that products do not contain listed hazardous substances	Company statement that includes: a) goal of elimination of the 16 highly hazardous solvents; and b) progress to that goal as measured by: total mass of solvents used in the manufacturer of all APIs divided by mass of the 16 highly hazardous solvents used in the manufacture of all APIs to equal percent of the 16 highly hazardous solvents used in the manufacture of all APIs by mass

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
			Yes, for ≥25% and <50% of solvents used in the manufacture of APIs by mass	10	Link / document / policy evidencing that products do not contain listed hazardous substances	Company statement that includes: a) goal of elimination of the 16 highly hazardous solvents; and b) progress to that goal as measured by: total mass of solvents used in the manufacturer of all APIs divided by mass of the 16 highly hazardous solvents used in the manufacture of all APIs to equal percent of the 16 highly hazardous solvents used in the manufacture of all APIs by mass
			Yes, for ≥50% of solvents used in the manufacture of APIs by mass	0	N/A	Use the following metric: total mass of solvents used in the manufacturer of all APIs divided by mass of the 16 highly hazardous solvents used in the manufacture of APIs to equal percent of the 16 highly hazardous solvents used in the manufacture of all APIs by mass

Pharmaceuticals Chemicals – Level 2 – Organisation

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Solvents & Reagents used in manufacturing	Reagents used APIs that use only "Recommended"		No	0	N/A	
manufacturing active pharmaceutical ingredients (APIs) solvent Selection Tool (or equivalent green chemistry solvent selection guide)?		Yes	10	Link / document / policy evidencing use of the Solvent Selection Tool (https://www.acsgcipr.org/tools- for-innovation-in- chemistry/solvent-tool/)	The American Chemical Society (ACS) Green Chemistry Institute (GCI) Pharmaceutical Roundtable ⁶¹ is an excellent resource on green chemistry and engineering in the global pharmaceutical industry, including its Solvent Selection Tool ⁶² . Company demonstrates its commitment to green chemistry in manufacturing by using the Solvent Selection Tool (or equivalent) to evaluate and select safer solvents in the manufacture of APIs.	
Solvents & Reagents used	Do you use the Reagent Guides (or	33%	No	0	N/A	
in manufacturing active pharmaceutical ingredients (APIs)	equivalent green chemistry reagent selection guide) to inform your selection of reagents in the		Yes	10	Link / document / policy evidencing use of the Reagent Guides (https://reagents.acsgcipr.org/)	The American Chemical Society (ACS) Green Chemistry Institute (GCI) Pharmaceutical Roundtable ⁶³ is an excellent resource on green chemistry and engineering in the global pharmaceutical industry, including its Reagent Guides. ⁶⁴ Company demonstrates its commitment to green chemistry in manufacturing by

⁶¹ <u>https://www.acsgcipr.org/</u>
 ⁶² <u>https://www.acsgcipr.org/tools-for-innovation-in-chemistry/solvent-tool/</u>
 ⁶³ <u>https://www.acsgcipr.org/</u>
 ⁶⁴ <u>https://reagents.acsgcipr.org/</u>).

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
	manufacture of APIs?					using the Reagent Guides (or equivalent) to evaluate and select safer reagents in the manufacture of APIs.
Solvents & Reagents used	Do you measure Process Mass		No	0	N/A	
in manufacturing active pharmaceutical ingredients (APIs)	Intensity (PMI) for APIs produced?		Yes	10	Link / document / policy evidencing PMI measurements ⁶⁵	The American Chemical Society (ACS) Green Chemistry Institute (GCI) Pharmaceutical Roundtable ⁶⁶ is an excellent resource on green chemistry and engineering in the global pharmaceutical industry, including resources on measuring PMI ⁶⁷ . PMI is a means of benchmarking green chemistry and engineering performance. Companies use PMI to develop better and more cost effective and sustainable manufacturing processes.

 ⁶⁵ <u>https://www.acsgcipr.org/tools-for-innovation-in-chemistry/</u>
 <u>https://www.acsgcipr.org/</u>
 ⁶⁷ <u>https://pubs.acs.org/doi/10.1021/op200097d</u>

Pharmaceuticals Chemicals – Level 3 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Solvents & Reagents used in	Do you set goals to reduce Process Mass Intensity (PMI)2	duce Process ass Intensity	No	0	N/A	
manufacturing (PMI)? active pharmaceutical ingredients (APIs)		Yes	10	Documentation on company's website, or written statement, that includes PMI reduction goal for the manufacture of APIs.	The American Chemical Society (ACS) Green Chemistry Institute (GCI) Pharmaceutical Roundtable ⁶⁸ is an excellent resource on green chemistry and engineering in the global pharmaceutical industry, including resources for measuring PMI ⁶⁹ .	
Solvents & Reagents used in	Do you set goals to reduce hazardous and/or highly	educe hazardous nd/or highly	No	0	N/A	
in and/or highly manufacturing active bharmaceutical ingredients (APIs) and/or highly hazardous solvents used to produce APIs?		Yes	10	Documentation on company's website, or written statement, that includes goal(s) to reduce highly hazardous and/or hazardous solvents used in the manufacture of APIs.	The American Chemical Society (ACS) Green Chemistry Institute (GCI) Pharmaceutical Roundtable ⁷⁰ is an excellent resource on green chemistry and engineering in the global pharmaceutical industry, including its Solvent Section Tool ⁷¹ .	

⁷¹ <u>https://www.acsgcipr.org/tools-for-innovation-in-chemistry/solvent-tool/</u>

UNDP

 ⁶⁸ <u>https://www.acsgcipr.org/</u>
 ⁶⁹ <u>https://pubs.acs.org/doi/10.1021/op200097d</u>
 ⁷⁰ <u>https://www.acsgcipr.org/</u>

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Solvents & Reagents used	Do you measure progress to the	25%	No	0	N/A	
in goals? goals? goals? pharmaceutical ingredients (APIs)	goals?		Yes	10	Documentation on company's website, or written statement, that includes how the company measures progress to its goal(s) of reducing: a) highly hazardous and/or hazardous solvents used in the manufacture of APIs; and/or b) PMI.	The American Chemical Society (ACS) Green Chemistry Institute (GCI) Pharmaceutical Roundtable ⁷² is an excellent resource on green chemistry and engineering in the global pharmaceutical industry, including its Tools for Innovation in Chemistry. ⁷³
Solvents &	Do you publicly	25%	No	0	N/A	
Reagents used in manufacturing active pharmaceutical ingredients (APIs)	agents used disclose goals, progress to goals, PMI, annual solvent use, and solvents armaceutical restricted from use in manufacturing?		Yes	10	Documentation on company's website or other public disclosure that includes goals and progress towards achieving goals for the reduction solvents, reagents, and PMI.	The American Chemical Society (ACS) Green Chemistry Institute (GCI) Pharmaceutical Roundtable ⁷⁴ is an excellent resource on green chemistry and engineering in the global pharmaceutical industry, including its Tools for Innovation in Chemistry. ⁷⁵

 ⁷² <u>https://www.acsgcipr.org/</u>
 ⁷³ <u>https://www.acsgcipr.org/tools-for-innovation-in-chemistry/</u>.
 ⁷⁴ <u>https://www.acsgcipr.org/</u>
 ⁷⁵ <u>https://www.acsgcipr.org/tools-for-innovation-in-chemistry/</u>

Pharmaceuticals Chemicals – Level 1 – Product

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Persistent,	Have you have	100%	No	0	N/A	
Bioaccumulative, and Toxic (PBT) substances	evaluated your product for its environmental attributes, including persistence, bioaccumulation, toxicity, and environmental risk?		Yes	20	Documentation on website, or written statement, that demonstrates how the company evaluated its product for persistence, bioaccumulation, toxicity, and environmental risk in accordance with the criteria of the Swedish National Agency for Public Procurement's requirements for environmental information for medicinal products (see https://old.upphandlingsmyndigheten.se/en/s ustainable-public-procurement/sustainable- procurement-criteria/nursing-and- care/medicinal-products/medicinal- products/available-environmental- information-for-medicinal- products/#avancerat)	Swedish National Agency for Public Procurement's requirements for environmental information for medicinal products ⁷⁶ : "The winning supplier must, no later than the start of the agreement, make environmental information available for the medicinal products that are included in the agreement and that are covered by the European Medicines Agency's (EMA's) guidelines ^{77,78} for environmental risk assessments. At the request of the contracting authority, or in accordance with an implementation plan for the agreement or similar, the supplier must be able to refer to where environmental information for contracted medicinal products is available to the public. Publicly available environmental information refers to information that is available on a free website without any requirement for membership, payment etc. The environmental information must at least include details regarding persistence, bioaccumulation, toxicity and environmental risk. It must be compiled in accordance with the EMA's latest guidelines ^{77,78} , the most recently published

⁷⁶ <u>https://old.upphandlingsmyndigheten.se/en/sustainable-public-procurement/sustainable-procurement-criteria/nursing-and-care/medicinal-products/medicinal-products/available-environmental-information-for-medicinal-products/#avancerat</u>

⁷⁷ See article 8.g of directive 2001/83/EC and chapter 3, section 1 of the Swedish Medical Products Agency's regulations LVFS 2006:11, which entered into force on 30 June 2006.

⁷⁸ European Medicines Agency, 2006. Committee for medicinal products for human use (CHMP). Guideline on the environmental risk assessment of medicinal products for human use. Ref EMEA/CHMP/SWP/4447/00 corr 2, <u>http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500003978.pdf</u>.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
						FASS guidelines regarding environmental information for medicinal products, ⁷⁸ or another equivalent publicly available model for environmental information.
						The special contract term does not cover medicinal products that are exempted from environmental information requirements according to the EMA's guidelines. ^{77,78} The winning supplier must ensure that environmental information is kept available for the entire term of the contract for these medicinal products.
						If the supplier deems that access to the information requested according to the special contract term is missing, the supplier must make reasonable efforts to compile or obtain access to the information. The supplier must be able to explain the efforts that have been made in this regard."

Pharmaceuticals Chemicals – Level 2 – Product

Maximum Score	10
Pass threshold	5

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Persistent, Bioaccumulative, and Toxic (PBT) substances	Do you provide environmental information on the product, including its persistence, bioaccumulation, toxicity, and environmental risk and make it publicly available?	Weighting 100%	No Yes	0 20	No Documentation available publicly e.g. on company website of the product's persistence, bioaccumulation, toxicity, and environmental risk in accordance with the criteria of the Swedish National Agency for Public Procurement's requirements for environmental information for medicinal products (see https://old.upphandlingsmyndigheten.se/en/susta inable-public-procurement/sustainable- procurement-criteria/nursing-and-care/medicinal- products/medicinal-products/available- environmental-information-for-medicinal-	Swedish National Agency for Public Procurement's requirements for environmental information for medicinal products ⁷⁹ : "The winning supplier must, no later than the start of the agreement, make environmental information available for the medicinal products that are included in the agreement and that are covered by the European Medicines Agency's (EMA's) guidelines, ^{80,81} for environmental risk assessments. At the request of the contracting authority, or in accordance with an implementation plan for the
					products/#avancerat)	agreement or similar, the supplier must be able to refer to where environmental information for contracted medicinal products is available to the public. Publicly available environmental information refers to information that is available on a free website without any requirement for membership, payment etc.

⁷⁹ <u>https://old.upphandlingsmyndigheten.se/en/sustainable-public-procurement/sustainable-procurement-criteria/nursing-and-care/medicinal-products/medicinal-products/available-environmental-information-for-medicinal-products/#avancerat</u>

⁸⁰ See article 8.g of directive 2001/83/EC and chapter 3, section 1 of the Swedish Medical Products Agency's regulations LVFS 2006:11, which entered into force on 30 June 2006.

⁸¹ European Medicines Agency, 2006. Committee for medicinal products for human use (CHMP). Guideline on the environmental risk assessment of medicinal products for human use. Ref EMEA/CHMP/SWP/4447/00 corr 2, <u>http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/10/WC500003978.pdf</u>.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
						The environmental information must at least include details regarding persistence, bioaccumulation, toxicity and environmental risk. It must be compiled in accordance with the EMA's latest guidelines, ^{80,81} the most recently published FASS guidelines regarding environmental information for medicinal products, ⁸¹ or another equivalent publicly available model for environmental information. The special contract term does not cover medicinal products that are exempted from environmental information is kept available for the entire term of the contract for these medicinal products. If the supplier deems that access to the information requested according to the special contract term is missing, the supplier must make reasonable efforts to compile or obtain access to the information. The supplier must be able to explain the efforts that have been made in this regard."

5.4 Gender, human and labour rights (GHLR)

The GHLR section of the SPIH contains five modules, as set out in the table below. These modules aim to establish the supplier's capacity to understand, manage and improve GHLR in its own operations and within its supply chain.

The social impacts of procurement can be significant, both positive and negative. There is a focus on employment, contract management, gender, and LGBTQI+ and broader human rights issues. Certain supply chains have high risks in relation to these areas, as can be seen on almost a daily basis through media and academic exposés. However, there is also a long established and evolving set of audit standards, certifications and collaborations which seek to identify and resolve issues.

To support action on GHLR, the themes covered in the SPIH GHLR modules include:

- Labour standards
- Auditing
- Gender impact and privacy
- Capacity / management systems in place with suppliers
- Supply chain information for the supplier organisation
- Gender and diversity

The structure of the modules for the GHLR theme is as follows:

Theme	Level	Scope	Relevance	Questions	Max score	Pass score
Gender, human and labour rights	1	Product	All products	2	12.00	6.00
Gender, human and labour rights	2	Product	All products	3	30.00	15.00
Gender, human and labour rights	3	Product	Pharmaceuticals	2	30.00	15.00
Gender, human and labour rights	1	Organisation	All organisations	3	25.00	12.50
Gender, human and labour rights	2	Organisation	All organisations	4	22.50	11.25
Gender, human and labour rights	3	Organisation	All organisations	6	20.00	10.00

The full details of the modules follow in this section.

GHLR – Level 1 – Organisation

Maximum Score	25
Pass threshold	12.5

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Policy	Is there a labour /	50%	No	0	N/A	
	human rights policy in place for the company, in addition to plus		No, but currently developing one	10	Information demonstrating timeframe to develop the policy	Some evidence should be presented to prove that this is in development. This may be from an internal memo or email, news article, company report or similar.
contractors, subcontractors etc.?		Yes, in place and communicated	20	Copy of policy – that clearly covers all the issues pertinent to the organisation, including basic labour standards	IFC Performance Standard 2 sets out useful information on developing a policy on labour, see ⁸² Other standards such as the ETI base code are useful to understand basic supply chain labour standards ⁸³	
Capacity / managem			No, but currently developing one	0	N/A	
		Yes, but only functional for payroll and documentation issues	20	Job functions, numbers and role	In some companies and countries, the HR function is very limited to basic transactional tasks like ensuring workers have the right paperwork and are paid on time, with the right records.	
				30	Job function, numbers and role	Where HR is better integrated, it should have a role in deciding strategy on how people are employed and how this fits into the company's overall strategy. HR should also have sight of any business plans and changes to provide input and support.
						Strategic HR also involves a function which can assess ways to understand and deal with challenges and is able to engage on gender

⁸² <u>https://www.ifc.org/wps/wcm/connect/topics_ext_content/ifc_external_corporate_site/sustainability-at-ifc/policies-standards/performance-standards/ps2</u>
 ⁸³ <u>https://www.ethicaltrade.org/eti-base-code</u>

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
						related issues, including how to promote and encourage better women's participation in the workplace.
Capacity / managem		25%	No, but currently developing one	0	N/A	
ent system	on(s) in your business that is responsible for supply chain labour standards?		Yes, but only with very basic functions in checking contracts include provision on labour and human rights	20	Contract terms requiring labour and human rights provisions.	The entry level approach to supply chain management relies exclusively on implementation of contractual standards into the contract provisions with suppliers.
			Yes, with strategic inputs	30	Description of that function's remit/responsibility for supply chain issues	 The Swedish national procurement agency requirements for medicinal products provides that there should be An appointed manager at the highest management level, responsible for compliance with the Terms, Adopted routines to regularly carry out risk analyses, i.e. to identify and prioritise current and potential risks of deviation from the Terms, as well as mapping the supply chain with special regard to high-risk operations, Adopted routines for regular follow-up of the Terms compliance, and Adopted routines to immediate action to prevent and limit deviations from the Terms, and to make amendments to identified deviations.

GHLR - Level 2 - Organisation

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Policy	Is there a labour	25%	No	0	N/A	
	standards policy, aligned with national / international standards, in place for your company and is it communicated widely?		Yes	20	Copy of Policy	IFC have published a useful guide to labour standards which includes developing a policy for both businesses and their supply chains, see ⁸⁴
Supply chain	Are social /	it	No	0	N/A	
information	labour audit reports available?		Yes	20	Copy of audit	Depending on the nature of the supply chain and audit programme, audits may be available on a sharing platform such as Sedex.
Supply chain	Is the supply			0	N/A	
information chain mapped to Tier 1 (i.e. those with which you have direct contracts)?	Tier 1 (i.e. those	1 (i.e. those which you e direct	Some elements present	10	Evidence of mapping	Sedex provide guidance on the benefits and approaches for supply chain mapping, see ⁸⁵
			Yes, as part of a broader risk assessment process	15	Plan and outcomes	They suggest four steps:

⁸⁴ <u>https://www.ifc.org/wps/wcm/connect/e0e8e968-132a-4dbf-af0b-4b971e4a4b9b/SAI_IFC_LaborHandbook.pdf?MOD=AJPERES&CVID=jkD0.wG</u>
⁸⁵ <u>https://www.sedex.com/mapping-your-supply-chain-how-to-get-started/</u>

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
			Yes, a specific labour standards approach	20	Labour standards plan	 Learn where suppliers and their suppliers are located by working with procurement and using existing supplier lists. Integrate information on your suppliers from different sources using a spreadsheet or data platform. Supply chains can change rapidly; a system for managing supplier data will help you to keep information current and in one place. Conduct an initial risk assessment to help you prioritise where to focus next. Use several tools to research your suppliers. Collect information about what is happening at supplier worksites, and research the inherent risks
Policy	Do you have a	25%	No	0	N/A	associated with the countries and sectors they operate within.
	policy on supply chain labour rights and direct HR practices?		No, but currently developing one	10	Draft of policy or internal documents demonstrating that the policy is in development, in addition to the date for publication.	Some evidence should be presented to prove that this is in development. This may be from an internal memo or email, news article, company report or similar.
			Yes, as part of a broader policy or plan	20	Copy of section from policy	IFC have published a useful guide to labour standards which includes developing a policy for both businesses and their supply chains, see ⁸⁶
			Yes, a specific policy or plan	30	Copy of policy or plan	

⁸⁶ <u>https://www.ifc.org/wps/wcm/connect/e0e8e968-132a-4dbf-af0b-4b971e4a4b9b/SAI_IFC_LaborHandbook.pdf?MOD=AJPERES&CVID=jkD0.wG</u>

GHLR – Level 3 – Organisation

Maximum Score	20
Pass threshold	10

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Policy	Do you have an anti-	15%	No	0	N/A	
	corruption policy in place for your company plus contractors,		No, but currently developing	10	Draft of policy or internal documents demonstrating that the	Transparency International have produced a significant report looking at bribery and corruption in the pharmaceutical sector, with recommendations for action, see ⁸⁷ This may be a useful reference.
	subcontractors etc.?		one		policy is in development, in	There are many examples of anti-corruption and bribery policies available for review and comparison.
					addition to the date for publication	There are many resources also available to assist in drafting and reviewing a policy, including this ⁸⁸
			Yes, in 20 place and communic ated	20	Copy of policy or plan	There are many examples of anti-corruption and bribery policies available for review and comparison.
						There are many resources also available to assist in drafting and reviewing a policy, including this ⁵⁴
Supply	Are supply chains	15%	No	0	N/A	
information 1 (i.e who uses	mapped beyond Tier 1 (i.e. understanding who your supplier uses in their supply chain)?	anding blier	Yes	20	Overview of mapping	Mapping of a supply chain should clearly identify where goods come from, what degree of subcontracting might be taking place, and how direct the line of sight is between suppliers and contractors.
Supply	Are certification	d for elevant	No	0	N/A	
chain information	schemes used for sourcing of relevant high-risk materials?		Yes	20	Examples of certification	There are various established certification schemes in place that deal with labour, human rights and gender issues, depending on the products. There are a wide number of sustainability and other certifications which cover labour standards,

⁸⁷ <u>https://www.transparency.org.uk/sites/default/files/pdf/publications/29-06-2016-Corruption_In_The_Pharmaceutical_Sector_Web-2.pdf</u>
 <u>https://info.unitedlanguagegroup.com/hubfs/-%20ULG%20-%20Aug%202019/Services/Translation/ULG_Ebook_CorpComplianceLS.pdf</u>

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
						including FSC, Better Cotton, Rainforest Alliance, etc. Many are members of the ISEAL alliance. See more information here ⁸⁹
Supply	Is your company	20%	No	0	N/A	
chain information	involved in collaborative social initiatives in relation to the supply chain?		Yes	20	Summary / case study of collaboration	There are a wide number of collaborative initiatives which cover labour and human rights standards, including FSC, Better Cotton, Rainforest Alliance, etc. Many are members of the ISEAL alliance. See more information here. ⁵⁵ In addition, collaborations like ETI, BSCI and the Pharmaceutical Supply Chain Initiative deal with specific labour and human rights issues in supply chains by setting standards and also promoting collaboration.
Gender	Does your company	onstrate women ership or	No	0	N/A	
	demonstrate women ownership or leadership?		Yes	20	Statistics demonstrating gender proportions in leadership or supplier ownership	IFC Women's Employment Program has a range of programmes and guides on women's leadership, including case studies and guidance on women's leadership in healthcare, see ⁹⁰
Gender and	Does your company	15%	No	0	N/A	
diversity	incorporate measurable diversity and inclusivity processes and goals into recruitment, training, remuneration, performance evaluation, and other structures (women, disability, migrants etc).?		Yes	20	Evidence of the goals and processes that have been implemented. Statistics showing outcomes, where possible.	 There are many resources and guidance documents available on diversity and inclusion, some include the following: McKinsey overview of challenges and performance⁹¹ This NHS guidance and programmes in the UK⁹²

https://www.isealalliance.org
 https://www.ifc.org/wps/wcm/connect/a062e443-5503-4e87-af07-

⁵⁹³db1bed033/IFC+Women+Leaders+Healthcare FinalWeb4.pdf?MOD=AJPERES&CVID=mCRI3Yb
⁹¹ https://www.mckinsey.com/featured-insights/diversity-and-inclusion/diversity-wins-how-inclusion-matters#

⁹² https://www.leadershipacademy.nhs.uk/resources/inclusion-equality-and-diversity/

GHLR – Level 1 – Product

Maximum Score	12
Pass threshold	6

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Labour	Has the country of	40%	No	0	N/A	Ratification by convention and country can be found here ⁹³
standar ds	production ratified all ILO core labour standards?		Yes	20	Demonstrati on that the country is in the ILO records.	Ratification by convention and country can be found here ⁵⁹
Labour	Is the country and	60%	No	20	N/A	List of goods are found here ⁹⁴
standar ds	standar product on the US ds Department of Labor – List of Goods - Forced or child labour?		Yes, but evidence that this supplier is meeting required standards	20	Clear audit findings demonstrati ng no forced or child labour	List of goods are found here ⁶⁰ If product and country are on the list, there would need to be a specific audit finding dealing with these issues for the product to score 20.
			Yes	0	N/A	

⁹³ <u>https://www.ilo.org/dyn/normlex/en/f?p=NORMLEXPUB:10011:0::NO::P10011_DISPLAY_BY,P10011_CONVENTION_TYPE_CODE:1,F</u>
⁹⁴ <u>https://www.dol.gov/agencies/ilab/reports/child-labor/list-of-goods</u>

GHLR – Level 2 – Product

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance
Auditing	Has your production	20%	No	0	N/A	
	been subjected to a labour audit in the last 2 years?		No, audit is planned in next 2 months	10	Evidence of request for audit in past 2 months	Audit should be diarised with a reputable audit company.
			Yes, partial audit	20	A copy of the audit report.	Accepted audits include: Pharmaceutical Supply Chain Initiative, Eti base code, Smeta, SA 8000, or equivalent. A copy of the audit or summary outcome should be provided. If an alternative audit is provided it should be mapped against the requirements of one of the accepted audits.
			Yes, full audit	30	A copy of the audit report.	Accepted audits include: Pharmaceutical Supply Chain Initiative, Eti base code, Smeta, SA 8000, or equivalent. A copy of the audit or summary outcome should be provided. If an alternative audit is provided it should be mapped against the requirements of one of the accepted audits.
	What was the outcome of the	40%	Substantial non- compliances	0	N/A	
	audit?		Minor non- compliances	10	A copy of the audit report.	A copy of the audit or a summary outcome should be provided. Accepted audits include: Pharmaceutical Supply Chain Initiative, Eti base code, Smeta, SA 8000, or equivalent. If an alternative audit is provided it should be mapped against the requirements of one of the accepted audits.

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance	
			No non-compliances	30	A copy of the audit report	A copy of the audit or a summary outcome should be provided. Accepted audits include: Pharmaceutical Supply Chain Initiative, Eti base code, Smeta, SA 8000, or equivalent. If an alternative audit is provided it should be mapped against the requirements of one of the accepted audits.	
	What is your	40%	No action plan	0	N/A		
	response to the audit?		Developing action plan	10	A draft of the action plan, or internal documents detailing its development are provided.		
					Published action plan, not yet implemented	15	Action plan available for review
			Partially/fully implemented action plan or no action plan needed	30	Action plan available for review, including progress against several metrics	The action plan should clearly identify the findings of the audit that need to be addressed and a timebound action plan which addresses each of the findings. It should also include the date by which each action plan was completed.	

GHLR – Level 3 – Product

Maximum Score	30
Pass threshold	15

Sub Theme	Question	Question Weighting	Response	Response Score	Evidence	Guidance											
Gender impact	Have you carried	50%	No	0	N/A												
	out a gender impact analysis in relation to the product use?		No, but currently carrying out analysis	10	Date for assessment and methodology/tool used for analysis	Evidence of starting to complete analysis. E.g. draft report/research.											
			Yes, as part of a broader approach or plan	20	Gender impact section for review	There are a number of documents which include reviews of gender impact analysis, which may be useful references. For example, UN											
			Yes, a specific analysis or gender plan	30	Gender impact analysis report	Women has developed a provisional tool, the UN Women Private Sector Accountability Framework (UNW-PSAF). Its objective is to encourage and aid private sector partners to: benchmark their own performance over time; locate and systematically monitor their progress in implementing gender equality considerations into their business; and highlight their strengths and potential areas for improvement. ⁹⁵											
Privacy	Have you carried	50%	No action plan	0	No												
	out a privacy assessment in relation to patient or testing data in		No, but currently carrying out an assessment Yes, but only for s countries											carrying out an	10	Date for assessment	Although different jurisdictions have different rules, the guidance from the UK Information Commissioner is a good overview of the principles of data protection impact assessments, see ⁹⁶
	relation to the product?			Yes, but only for specific countries	20	Example of report	Guidance from the European Union on data processing and clinical trials sets out what is global best practice in this area, see ⁹⁷										
			Yes, global	30	Assessment report												

⁹⁵ <u>https://www.unwomen.org/en/digital-library/publications/2015/9/un-women-private-sector-accountability-framework</u>

⁹⁶ https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/data-protection-impactassessments/

⁹⁷ <u>https://ec.europa.eu/health/sites/default/files/files/documents/qa_clinicaltrials_gdpr_en.pdf</u>

5.5 Summary

The box below summarises the information presented in this section.

Summary of SPIH for Pharmaceutical Products

- GHG:
 - The GHG section of the SPIH contains five modules which cover six themes.
 - The themes covered in the SPIH GHG modules include: reporting of GHG emissions, including scope of emissions considered and disclosure; supplier policy on GHG reduction; governance; targets for GHG reduction; consideration of all emissions associated with the manufacture of the product; and any certifications achieved.
- Resources:
 - The resource section of the SPIH contains five modules which cover three themes.
 - The themes covered in the SPIH resource depletion modules include: supplier policy on resource efficiency governance; third party / supplier review; consideration of all resource use associated with the manufacture of the product
- Chemicals:
 - The Chemicals section of the SPIH contains five modules which cover four themes.
 - The themes covered in the SPIH Chemicals modules include: corporate chemicals management policies, procedures, and practices; restricted substances lists (RSLs) and manufacturing RSLs (MRSLs); certifications achieved; progress to green chemistry for the pharmaceutical industry
- GHLR:
 - The GHLR section of the SPIH contains five modules which cover six themes.
 - The themes covered in the SPIH GHLR modules include: labour standards; auditing; gender impact and privacy; capacity / management systems in place with suppliers; supply chain information for the supplier organisation; gender and diversity

Box 8 Section 5 summary

6 The SPIH Tool

This section sets out information and guidance in relation to the Excel-based tool that has been developed, which sets out the criteria in an easy-to-use form. This should be completed and reviewed by suppliers and buyers, respectively.

As stated in Section 2.3, two forms of the tool have been produced. The General SPIH Tool targets general healthcare commodities, whilst the Pharmaceutical SPIH Tool targets pharmaceutical products only. The Pharmaceutical SPIH tool contains tailored criteria.

The tool has six worksheets:

- A cover page;
- An overview of the scoring within the SPIH;
- Four thematic worksheets (GHG emissions; resource depletion; chemicals and toxic impact; gender, human and labour rights) which contain modules and criteria, to be completed by the user.

The cover page introduces the SPIH and provides instructions for suppliers on how to complete the tool.

The SPIH scoring worksheet contains an overview of the SPIH scoring. It presents the overall level that has been achieved, and the results for each individual module within the four themes. No input from the user is required within this worksheet (*Figure 7*).

There is a worksheet for each of the sustainability themes.

- **GHG emissions**: this worksheet contains the modules within the GHG emissions theme. For this thematic area, the modules relate to organisation and product;
- **Resource depletion**: this worksheet contains the modules within the resource depletion theme. For this thematic area, the modules relate to organisation and product, in addition to one module that is related to manufacturing;
- Chemicals and toxic impact: this worksheet contains the modules within the chemicals and toxic impact theme. For this thematic area, the modules relate to organisation, product, and manufacturing; and
- **Gender, human and labour rights**: this worksheet contains the modules within the gender, human and labour rights theme. For this thematic area, the modules relate to organisation, product, and manufacturing.









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Figure 7 The SPIH scoring worksheet within the Excel-based tool, showing the level achieved and module results.

Within each of the above thematic worksheets, a series of tables are presented which represent the modules within the theme (*Figure 8*). These modules relate to organisation, product, or manufacturing. Questions are presented within each module that need to be answered by the supplier. The weighting for each question and the points associated with different answers are also presented.

When completing the worksheet, the supplier should complete the cells that are shaded green. The first green column of cells contains drop down menus from which the supplier can select a high-level response to the question. Once selected, the required evidence will be presented in the adjacent cell. Any information relating to this evidence can be entered into the worksheet in the next column of green cells. Where the required evidence is a copy of a report or document, please name the document within the Excel-based tool and share it separately with the buyer.

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egulations	follow related to resource	0%	targets which have implications the organisation	IOF IN/A	
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	address key resource efficiency aspects relevant to your business?		plan	Policies/Plans	
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Figure 8 The resource depletion worksheet, demonstrating the tables which represent the modules for each theme and the questions within them. The weighting for each question and required evidence are presented. The supplier response is required in the green cells.

6.1 Summary

The box below summarises the information presented in this section.

- An Excel-based tool has been developed, which sets out the criteria in an easy-to-use form. This should be completed and reviewed by suppliers and buyers respectively.
- Two forms of the tool have been produced the General SPIH Tool targets general healthcare commodities, such as medical gloves whilst the Pharmaceutical SPIH Tool targets pharmaceutical products only, such as malaria medication.
- The tool has six worksheets: a cover page; an overview of the scoring within the SPIH; and four thematic worksheets.

• When completing the worksheet, the supplier should complete the cells that are shaded green.

Box 9 Section 6 summary

A1 Appendix 1 – Definitions

A1.1 GHG emissions

- Scope 1 emissions GHG emissions that arise directly from operations that are owned or controlled by the reporting company.
- Scope 2 emissions indirect GHG emissions from the generation of purchased energy.
- Scope 3 emissions all indirect emissions that are not included within scope 2 that occur in the value chain of the reporting company. This includes both upstream and downstream emissions.⁹⁸
- GHG reporting mechanism a framework incorporating measurement and monitoring requirements for GHG emissions.
- Science-based target a target that is in line with what the latest climate science deems necessary to achieve the Paris Agreement, specifically limiting global warming to well-below 2°C above pre-industrial levels and pursuing efforts to limit warming to 1.5°C.⁹⁹

A1.2 Resource depletion

- Resource efficiency using the Earth's resources in a sustainable manner whilst minimising the environmental impacts.¹⁰⁰
- Environmental management system a set of processes and practices than enable an organisation to reduce its environmental impacts and increase its operational efficiency.¹⁰¹
- ISO50001 a company-level certification related to energy management. It is designed to support organisations across all sectors in improving energy use through the development of an energy management system (EnMS).¹⁰²

A1.3 Chemicals

• Hazardous / highly hazardous solvents – "**Hazardous**: the constraints on scale-up are very strong. The substitution of these solvents during process development is a priority. **Highly hazardous**: solvents to be avoided, even

https://ec.europa.eu/environment/resource_efficiency/. Accessed 09/08/2021. ¹⁰¹ EPA (2021) 'Learn about Environmental Management Systems' (online). Available at: https://www.epa.gov/ems/learn-about-environmental-management-systems. Accessed 09/08/2021.

⁹⁸ Anthesis (n/d) 'Understanding Scope 1, 2 and 3 emissions' (online). Available at: <u>https://www.anthesisgroup.com/scope-1-2-3-emissions/</u>. Accessed 09/08/2021.

⁹⁹ Science based targets (n/d) 'FAQs' (online). Available at:

https://sciencebasedtargets.org/faqs#what-are-science-based-targets. Accessed 09/08/2021. ¹⁰⁰ European Commission (n/d) 'Resource efficiency' (online). Available at:

¹⁰² ISO (n/d) 'ISO 50001: Energy Management' (online). Available at: <u>https://www.iso.org/iso-50001-energy-management.html/</u>. Accessed 09/08/2021.

in the laboratory." On how to identify hazardous and highly hazardous solvents see Prat et al. $^{103}\,$

- Active pharmaceutical ingredients (APIs) "A substance used in a finished pharmaceutical product (FPP), intended to furnish pharmacological activity or to otherwise have direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease, or to have direct effect in restoring, correcting or modifying physiological functions in human beings."¹⁰⁴
- Process mass intensity (PMI) "is the total mass of materials used to produce a specified mass of product. Materials include reactants, reagents, solvents used for reaction and purification, and catalysts."¹⁰⁵
- Persistent, Bioaccumulative, and Toxic (PBT) substances A PBT substance must meet the criteria for P + B + T described below.¹⁰⁶
- Persistence A substance fulfils the persistence criterion (P) in any of the following situations:
 - the degradation half-life in marine water is higher than 60 days;
 - the degradation half-life in fresh or estuarine water is higher than 40 days;
 - the degradation half-life in marine sediment is higher than 180 days;
 - the degradation half-life in fresh or estuarine water sediment is higher than 120 days; or
 - the degradation half-life in soil is higher than 120 days.
- Bioaccumulation A substance fulfils the bioaccumulation criterion (B) when the bioconcentration factor [BCF] in aquatic species is higher than 2000
- Toxicity A substance fulfils the toxicity criterion (T) in any of the following situations:
 - the long-term no-observed effect concentration (NOEC) or EC10 for marine or freshwater organisms is less than 0,01 mg/l;
 - the substance meets the criteria for classification as carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or

¹⁰³ Prat et al. (2015) 'CHEM21 selection guide of classical- and less classical-solvents' (online). Available at:

https://www.researchgate.net/publication/280944149 CHEM21 selection guide of classical - and less classical - solvents. Accessed 23/08/2021.

¹⁰⁴ WHO (2011) 'Definition of active pharmaceutical ingredient' (online). Available at: <u>https://www.who.int/medicines/areas/quality_safety/quality_assurance/DefinitionAPI-QAS11-</u> <u>426Rev1-08082011.pdf</u>. Accessed 23/08/2021.

¹⁰⁵ Jimenez-Gonzalez et al. (2011) 'Using the Right Green Yardstick: why Process Mass Intensity is used in the pharmaceutical industry to drive more sustainable processes' (online). Available at: <u>https://pubs.acs.org/doi/full/10.1021/op200097d</u>. Accessed 23/08/2021.

¹⁰⁶ REACH Online (n/d) 'Annex XIII: Criteria for the Identification of Persistent, Bioaccumulative and Toxic Substances, and Very Persistent and Very Bioaccumulative Substances' (online). Available at: <u>https://reachonline.eu/reach/en/annex-xiii.html</u>. Accessed 23/08/2021.

toxic for reproduction (category 1A, 1B, or 2) according to Regulation EC No 1272/2008; or

• there is other evidence of chronic toxicity, as identified by the substance meeting the criteria for classification: specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008.

A1.4 Gender, Human and Labour Rights

- ILO core labour standards the four standards included in the ILO's Declaration on Fundamental Rights Freedom of Association and Collective Bargaining; no Child Labour; no Forced Labour; and non-discrimination and equal opportunities.
- Social / labour auditing a process whereby suppliers are assessed against defined labour standards by professional social auditors. The process should include interviews with workers and their representatives, as well as management interviews and review of workplace records and documents
- Gender impact analysis analysis of the impact that the business has on gender, including both employment, business partnerships, procurement and patients.
- Privacy assessment assessment of the way in which the service or business affects the data and privacy rights on workers, patients, trial participants and customers.
- HR management function professionally experienced or qualified individuals with experience of managing labour relations, employee engagement, talent development, grievance and discipline, etc
- Supply chain labour standards standards which set out what is expected on working conditions and outcomes for workers in the supply chain. Standards which are appropriate here include: ETI Base Code, SA8000, PSCI, BCI, FSC
- Anti-corruption policy a policy setting out the standards and expectations of gifts, influence, bribery and other related matters.
- Tier 1 suppliers the level of supplier which has direct contractual relationship with the buyer of the product.
- Collaborative social initiatives sector or global partnerships to identify and collaboratively respond to defined problems related to gender, human and labour rights. This can be sector or geographic in coverage and can be restricted to companies, or include civil society, governments and international organisations.
- Partial audit an audit which has considered a specific area of production or is limited in the subject areas it covers.

A2 Appendix 2 – Reference Lists

A2.1 GHG standards

Relevant modules:

- GHG emissions, Level 1, Organisation, All organisations
- GHG emissions, Level 3, Organisation, All organisations
- GHG emissions, Level 2, Product, All organisations

Recognised GHG methodologies

- Resource efficiency using the Earth's resources in a sustainable manner whilst minimising the environmental impacts.¹⁰⁷
- ABI Energia Linee Guida
- Act on the Rational Use of Energy
- Australia National Greenhouse and Energy Reporting Act
- Bilan Carbone
- Brazil GHG Protocol Programme
- Canadian Association of Petroleum Producers, Calculating Greenhouse Gas Emissions, 2003
- China Corporate Energy Conservation and GHG Management Programme
- Defra Voluntary Environmental Reporting Guidelines: Including streamlined energy and carbon reporting guidance, 2019
- ENCORD: Construction CO2e Measurement Protocol
- Energy Information Administration 1605(b)
- Environment Canada, Aluminum Production, Guidance Manual for Estimating Greenhouse Gas Emissions
- Environment Canada, Base Metals Smelting/Refining, Guidance Manual for Estimating Greenhouse Gas Emissions
- Environment Canada, Cement Production, Guidance Manual for Estimating Greenhouse Gas Emissions
- Environment Canada, Primary Iron and Steel Production, Guidance Manual for Estimating Greenhouse Gas Emissions
- Environment Canada, Lime Production, Guidance Manual for Estimating Greenhouse Gas Emissions

¹⁰⁷ European Commission (n/d) 'Resource efficiency' (online). Available at: <u>https://ec.europa.eu/environment/resource_efficiency/</u>. Accessed 09/08/2021.

- Environment Canada, Primary Magnesium Production and Casting, Guidance Manual for Estimating Greenhouse Gas Emissions
- Environment Canada, Metal Mining, Guidance Manual for Estimating Greenhouse Gas Emissions
- EPRA (European Public Real Estate Association) guidelines, 2011
- EPRA (European Public Real Estate Association) Sustainability Best Practice Recommendations Guidelines, 2017
- French methodology for greenhouse gas emissions assessments by companies V4 (ADEME 2016)
- Hong Kong Environmental Protection Department, Guidelines to Account for and Report on Greenhouse Gas Emissions and Removals for Buildings, 2010
- India GHG Inventory Programme
- IPCC Guidelines for National Greenhouse Gas Inventories, 2006
- ISO 14064-1
- Japan Ministry of the Environment, Law Concerning the Promotion of the Measures to Cope with Global Warming, Superseded by Revision of the Act on Promotion of Global Warming Countermeasures (2005 Amendment)
- Korea GHG and Energy Target Management System Operating Guidelines
- New Zealand Guidance for Voluntary, Corporate Greenhouse Gas Reporting
- Philippine Greenhouse Gas Accounting and Reporting Programme (PhilGARP)
- Programa GEI Mexico
- Recommendations for reporting significant indirect emissions under Article 173-IV (ADEME 2018)
- Smart Freight Centre: GLEC Framework for Logistics Emissions Methodologies
- Taiwan GHG Reduction Act
- Thailand Greenhouse Gas Management Organization: The National Guideline Carbon Footprint for organization
- The Climate Registry: General Reporting Protocol
- The Cool Farm Tool
- The GHG Indicator: UNEP Guidelines for Calculating Greenhouse Gas Emissions for Businesses and Non-Commercial Organizations
- The Greenhouse Gas Protocol: A Corporate Accounting and Reporting Standard (Revised Edition)
- The Greenhouse Gas Protocol: Scope 2 Guidance
- The Tokyo Cap-and Trade Program

- Toitū carbon reduce programme
- Toitū carbon zero programme
- US EPA Mandatory Greenhouse Gas Reporting Rule
- VfU (Verein fur Umweltmanagement) Indicators Standard

A2.2 Chemical regulations/standards

Relevant modules:

• Chemicals, Level 3, Organization, All organisation

Restricted Substances Lists (RSLs) and Manufacturing RSLs (MRSLs) for the Chemical Groups of: Bisphenol A (BPA) and structural analogues, Ortho-Phthalates, and Per- and Polyfluoroalkyl Substances (PFAS)

• Bisphenol A (BPA) and Structural Analogues – at a minimum, the RSL/MRSL shall specify that the following chemicals are avoided:

Chemical Name	CASRN
Bisphenol G	127-54-8
Bisphenol TMC	129188-99-4
Bisphenol M	13595-25-0
Bisphenol AF	1478-61-1
Bisphenol C2	14868-03-2
Bisphenol AP	1571-75-1
Bisphenol E (BPE)	2081-08-5
Bisphenol P	2167-51-3
Bisphenol PH	24038-68-4
4-cumylphenol (HPP)	599-64-4
Bisphenol F (BPF)	620-92-8
Bisphenol B (BPB)	77-40-7
Bisphenol A (BPA)	80-05-7
Bisphenol C	79-97-0
Bisphenol S (BPS)	80-09-1
Bisphenol Z	843-55-0

Table 1: Chemicals specified in the RSL/MRSL to be avoided

In addition to the above list of BPA and structural analogues, companies shall specify that suppliers avoid BPA analogues that meet the following criteria:

- 1. All compounds with a Tanimoto Coefficient of 0.9-1.0 (compared to Bisphenol-A CASRN 80-05-7) are restricted. Note: Tanimoto Coefficient as calculated using the United States Environmental Protection Agency's CompTox Dashboard (https://www.epa.gov/chemical-research/comptoxchemicals-dashboard).
- 2. Any compound with a Tanimoto Coefficient of 0.8-0.9 is restricted until there are publicly available, valid in vitro or in vivo hazard data that enable evaluation of oestrogen and androgen receptor agonism and

antagonism. If a compound does not have significant endocrine disrupting potential, it would not be included.

- 3. Chemicals with a Tanimoto Coefficient <0.8 would be considered restricted if the compound:
 - a) Has demonstrated endocrine disrupting potential (oestrogen and/or androgen receptor agonism and/or antagonism) and is used as a functional substitute for BPA; or
 - b) Is detected in environmental media or human biomonitoring studies and it is used as a functional substitute for BPA and publicly available hazard data to evaluate endocrine disrupting potential (oestrogen and/or androgen receptor agonism and/or antagonism) are lacking.

Note: If the compound is detected in environmental media or human biomonitoring studies and it is used as a functional substitute for BPA but has sufficient publicly available hazard data to demonstrate that it does not have endocrine disrupting potential (oestrogen and/or androgen receptor agonism and/or antagonism), it is not restricted.

Sources:

- a. HCWH resources
 - a. Cleaning chemicals: Health Care Without Harm Cleaning Chemicals criteria¹⁰⁸
 - b. Gloves: Health Care Without Harm Gloves criteria Guidance for sustainable glove purchasing fact sheet¹⁰⁹
 - c. Hand hygiene products: Health Care Without Harm Hand hygiene products criteria Safer Hand Hygiene Getting triclosan and triclocarban out of hand soaps, sanitizers, and lotions¹¹⁰

b. GreenScreen Certified, Standard for Furniture & Fabrics, Version 1.0, September 2020.¹¹¹

• Ortho-Phthalates

UNDP

¹⁰⁸ Practice Greenhealth (2016) 'Guidance to Achieve Safer Chemicals Challenge for Green Cleaning' (online). Available at: <u>https://practicegreenhealth.org/sites/default/files/2019-02/finalhhgreencleaningguidance-version2.0december2016.pdf</u> Accessed 23/08/2021.

¹⁰⁹ Practice Greenhealth (no date) 'Protection without Pollution: Guidance for sustainable glove purchasing' (online) Available at: <u>https://noharm-global.org/documents/guidance-sustainable-glove-purchasing</u> Accessed 23/08/2021.

¹¹⁰ Practice Greenhealth (no date) 'Safer Hand Hygiene Getting triclosan and triclocarban out of hand soaps, sanitizers, and lotions' (online) Available at:

https://practicegreenhealth.org/sites/default/files/upload-files/safer hand hygiene - _____get_started_guide.pdf Accessed 23/08/2021.

¹¹¹ GreenScreen Certified (2020) 'Standard for Furniture and Fabrics' (online). Available at: <u>https://www.greenscreenchemicals.org/images/ee_images/uploads/resources/GreenScreen_Certifie_d_Furniture_Fabric_v1_20201001.pdf</u>. Accessed 23/08/2021.

Definition: Dialkyl ortho-phthalates (or phthalate esters) are defined by the chemical structure below, and contain alkyl side groups, meaning the side groups contain only carbon and hydrogen.

• RSL/MRSL List – The RSL/MRSL shall specify the avoidance of chemicals that meet the above definition for ortho-phthalates and the following list of ortho-phthalate chemicals:

Chemical Name	CASRN
Di(2-ethylhexyl)phthalate (DEHP)	117-81-7
Di-n-pentyl phthalate (DNPP)	131-18-0
Diisodecyl phthalate (DIDP)	26761-40-0
Diisononyl phthalate (DINP-2 or DINP-3, mixture of isomers as manufactured)	28553-12-0
Diisononyl phthalate (DINP)	68515-48-0 or 28553-12-0
Di-isodecyl phthalate (DIDP)	68515-49-1 or 26761-40-0
Di-cyclohexyl phthalate (DCHP)	84-61-7
Di-isobutyl phthalate (DIBP)	84-69-5
Dibutylphthalate (DBP)	84-74-2
Di-n-hexyl phthalate (DnHP)	84-75-3
Benzylbutylphthalate (BBP)	85-68-7

Table 2: Chemicals specified in the RSL/MRSL to be avoided.

 Per- and Polyfluoroalkyl Substances (PFAS) – The Organisation for Economic Cooperation and Development's (OECD) Portal on Per and Poly Fluorinated Chemicals is one of the most up-to-date resources on PFAS. The OECD Portal includes both a definition of PFAS as well as a list of chemicals that meet the definition at <u>https://www.oecd.org/chemicalsafety/portalperfluorinated-chemicals/</u>. The RSL/MRSL shall specify the avoidance of chemicals that meet the OECD's definition for PFAS and the PFAS listed in the OECD PFAS Portal.

A3 Appendix 3 – Acknowledgements

Project team

- Anna Tuddenham, Consultant, Arup
- Terry Ellis, Associate, Arup
- Mark Rossi, Clean Production Action
- Steve Gibbons, Ergon Associates
- Kristian Steele, Associate, Arup
- Callum Newman, Associate Director, Arup

UN-SPHS Secretariat

- Dr. Rosemary Kumwenda, UN-SPHS Coordinator and Regional HIV/Health Team leader, UNDP
- Ian Milimo, Sustainable Health in Public Procurement (SHiPP) Project Manager, UNDP
- John Macauley, Regional HIV, Health and Development Programme Specialist, UNDP
- Mirjana Milic, Associate UN-SPHS Coordinator, UNDP
- Nevra Gomdeniz, Communications Specialist, UNDP

Contributions

UN-SPHS Members

- UNDP
- Unitaid
- UNOPS
- Global Fund

UNDP SHiPP Project Countries that participated in the SPIH piloting

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- Mr Pankaj Bector, National Centre for Disease Control, Ministry of Health & Family Welfare, Government of India
- Mr Sohail Nath, Hindustan Syringes & Medical Device Ltd
- Ms. P.R. Sigappi, Aravind Eye Hospital
- Mr C Azarrudheen, Aurolab Manufacturing Unit
- Paolo Beneduce Padron & Jonas Age Saide Schwartzman, SPDM -Associação Paulista para o Desenvolvimento da Medicina
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