



Appendix 4 to the Framework Agreement for Gene and Cell Therapy – Contract Requirements for Ethical Trade

Contract performance clauses for safeguarding basic human rights in the supply chain.

The Supplier shall, for the duration of the contract period, comply with clauses 1–4 of this document.

The contractual performance clauses are based on the United Nations Guiding Principles on Business and Human Rights (UNGP) and the OECD Guidelines for Responsible Business Conduct with due diligence as method. These frameworks both recommend due diligence as the preferred method for identifying, preventing, mitigating, and accounting for how business address their actual potential adverse labour and human rights impacts in their own operations and the supply chain.

The requirement in this contract is applicable to Supplier and all its subcontractors. The supplier has an obligation to communicate the requirements to all its subcontractors, and to contribute to compliance with, the requirements in the supply chain.

1. Compliance with international conventions and labour legislation in countries of production

The goods and services delivered under this contract shall be produced under conditions that are consistent with the requirements specified below. The requirements apply in the Suppliers own operations and in the supply chain. The requirements include:

- The ILO Core conventions on forced labour, child labour, discrimination, freedom of association and the right to collective bargaining: No. 29, 87, 98, 100, 105, 111, 138, and 182¹. Where convention 87 and Convention 98 are restricted by national law, the employer shall facilitate, and not hinder, the development of alternative forms of independent and free workers' representations and negotiations.
- The UN Convention on the Rights of the Child², article 32.
- National legislation labour rights in countries of production³. Particularly relevant matters are 1) wages and working hours; 2) occupational health and safety; 3) regular employment conditions, including contracts of employment; 4) statutory insurance and social schemes.

Where international conventions and national law differentiate, the highest standard shall apply.

¹ <https://www.ilo.org/global/standards/introduction-to-international-labour-standards/conventions-and-recommendations/lang--en/index.htm>

² <https://www.ohchr.org/EN/ProfessionalInterest/Pages/CRC.aspx>

³ This includes all countries in the supply chain where extraction and production of raw materials and/or components/semi-finished products and/or finished goods, including their distribution and transport, takes place.



2. Policies and routines for Human Rights Due Diligence

To fulfil the requirements in contract clause 1, as well as to prevent and manage any deviations from the requirements, the Supplier shall upon contract commencement, have adopted policies and routines for due diligence.

This means that the Supplier shall, in cooperation with its stakeholders, identify, prevent, mitigate and accounting for how it addresses the actual and potential adverse impacts on human and labour rights as set out in clause 1 in its own operations and in the supply chain. In line with the OECD due diligence guidance stakeholders, and especially affected rights holders, must be involved. Most salient risk, regardless of where it is occurs in the supply chain, should be prioritised first. The due diligence shall, as a minimum, consist of:

- 2.1. One or more publicly available policies adopted by the Board of Directors. The content of these policies shall, as a minimum, include commitment to comply with the contract requirements in clause 1, in the Supplier's own operation and in the supply chain. One or more employees at the management level shall be responsible for compliance and continuously report the due diligence progress to the Board of Directors. The Supplier shall have routines to embed and follow up the policy for responsible business conduct in its own operations and the operations of subcontractors in the supply chain.
- 2.2. Due diligence routines for undertaking regular risk analysis in own business and in the supply chain. This involves mapping and assessing the risk of breach of the requirements in clause 1.
- 2.3. The due diligence routines shall describe the measures implemented by the Supplier to cease, prevent and mitigate, with regards to adverse impacts on human and labour rights as set out in clause 1, in their own operations and in the supply chain, are addressed.
- 2.4. The Supplier shall describe the routines to control and ensure that the measurements are carried out with efficient results.
- 2.5. The Supplier shall publicly disclose available information on the due diligence routines in their own operations and in the supply chain. This includes how the risk of breaches of the contract clause 1, and how the potential adverse impacts in its own operations and in the supply chain, are addressed.
- 2.6. If the Supplier has caused adverse impacts, the Supplier shall address such impacts by providing for, or cooperation to provide for, remediations and compensation to the victims.

3. Contract follow-up

The Supplier shall ensure compliance with the requirements in clause 1 and 2 in its own operations and in the supply chain. If the Supplier is made aware of conditions in the supply chain that are in breach of clauses 1 and 2, the Supplier shall inform the Contracting Authority without undue delay. The Contracting Authority may require that compliance is documented by one or more of the following means:

- 3.1. Adopted policies and routines, cf. clause 2.
- 3.2. An overview of production units in the supply chain for selected risk products, and/or components, and/or raw materials, determined by the Contracting Authority.



- 3.3. A completed Self-assessment questionnaire, sent by the Contracting Authority, within six weeks, unless the Contracting Authority has set a different deadline.
- 3.4. A risk assessment, and a report on how adverse impacts is accounted for and managed.
- 3.5. Participation in follow-up meetings with the Contracting Authority, and with any other relevant stakeholders.
- 3.6. Provision of report(s) relevant to the requirements in clause 1 and 2.
- 3.7. An assessment and/or audit of the requirements in clause 1 and 2 at the Supplier.
- 3.8. An assessment and/or audit of the requirements in clause 1 and 2 in the supply chain.

The contract follow-up is managed by the Contracting Authority or by other public organisations with whom the Contracting Authority collaborates.

The Contracting Authority reserves the right to share the audit reports and other contract follow-up information with other public organisations, under duty of confidentiality.

4. Sanctions

In case of any contract breaches of clauses 1–3, or incomplete documentation, the sanction provisions in the main contract apply with the following additions and clarifications.

The Contracting Authority can:

- 4.1. Require rectification: The Supplier shall provide a Corrective Action Plan (CAP) for when and how the contract breaches are to be rectified. The rectifications shall be reasonable in relation to the nature extent of the breaches. The CAP shall be presented within four weeks. For serious breaches a shorter deadline may be required. The Contracting Authority shall approve the CAP and authorise the documented rectifications.
- 4.2. Implement a temporary suspension in all or part of the delivery when the supplier does not meet the requirement to submit a CAP or the CAP is not complied with. During temporary suspension, replacement purchases made from another supplier will not be considered a breach of contract. Under temporary suspension, any purchase from an alternative supplier will not be considered as a breach of the contract.
- 4.3. Require the Supplier change sub-supplier(s): Upon serious breach of the contract, reoccurring serious breaches, or if the CAP is not adhered to. This shall be done at no cost to the Client.
- 4.4. Termination of the contract: Upon serious breach of the contract, reoccurring serious breaches, or if the CAP is not adhered to.