#### SE – SWEDEN

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# 1. Requirements for Deposit

If an invention refers to a biological material which is neither generally available nor can be described in the application in such a manner that a person skilled in the art using the teachings of the document could exercise the invention; or if the invention includes the use of such a material, the biological material shall be deposited on the day the application is made, at the latest. Thereafter the biological material shall be made continuously available at the depositary institution so that those who are entitled by this law to obtain a sample of the material can have their sample delivered to them within Sweden. The government prescribes where the deposits may be made. If a deposited biological material ceases to be viable or if for any other reason a sample cannot be supplied from the material, it may be replaced by a new deposit of the same biological material within the time and in the manner prescribed by the government. Once this is done, the new deposit is considered to have been made when the earlier deposit was made. Law (2004:159).

(Patents Act, Section 8(a))

### 2. Time of Deposit

The biological material shall be deposited on the day the application is made, at the latest.

(Patents Act, Section 8(a))

Such a deposit as referred to in Section 8(a) first paragraph of the Patent Act is made in an institution which is an international deposit authority in accordance with the agreement decided upon in Budapest the 28 April 1977 regarding the international recognition of the deposit of micro-organisms in connection with patent cases (The Budapest Treaty).

The deposit is made according to the Budapest Treaty.

The patent office establishes a list of those institutions which are international deposit authorities according to the Budapest Treaty.

(Patent Decrees, Section 17(a))

### 3. Duration of Storage

The deposit is made according to the Budapest Treaty.

(Patent Decrees, Section 17(a))

If a biological material has been deposited in accordance with Section 8, everyone, with the limitations described in this and the following paragraphs, has the right to obtain samples from the material once the case has been made available to the general public in accordance with the first, second or third paragraph. This is the case regardless of if the patent has been terminated or declared invalid. Samples may not be given to a person who according to the law or another constitution may not be in possession of the deposited material. Neither is it permitted to give a sample to a person whose possession of the sample could be considered as an obvious risk with regard to the material's destructive properties.

Until a patent has been communicated/granted or a patent application has been processed without leading to a patent, a sample from a deposit may only be given to an expert in the field, if the applicant permits it. If the patent application is rejected or withdrawn, the equivalent applies during a period of 20 years starting from the day the application was submitted. The government prescribes the time scale within which a request for confinement may be made and who of those persons who wish to obtain the sample shall be appointed as the expert. A person who wishes to obtain a sample shall submit both a written request to the patent office and a statement, the contents of which are prescribed by the government in order to prevent misuse of the sample. If the sample may be given to only one particular expert, the statement is instead submitted by that expert. Law (2004:159).

(Patents Act, Section 22)

## 4. Conditions for the Furnishing of Samples

### (i) <u>Time of Availability of Samples</u>

A sample of a microorganism becomes available as from the date on which the patent application is made available to the public.

If a culture of a microorganism has been deposited according to Section 8(a), any person has the right to obtain a sample from the culture after the documents have become available to anyone in accordance with the following rules.

When 18 months have passed from the day when the patent application was filed or, if priority is claimed, from the day from which priority is claimed, the documents shall be available to anyone, even if the application has not been laid open to public inspection. However, if a decision has been made to dismiss or reject an application, the documents shall be made available only if the applicant requests that the application be resumed, lodges appeal, or makes a petition pursuant to Section 72 or 73 of the Patents Act.

At the applicant's request, the documents shall be made available earlier than set out in the first and second paragraphs.

When the documents become available pursuant to either of the two aforementioned circumstances, this fact shall be announced.

If a document contains business secrets and if it does not concern the invention for which a patent is sought, the Patent Authority, upon request and if there are special reasons for this, may order that the document shall not be made available. If such a request has been made, the document shall not be made available until the request has been refused by a decision which has taken legal effect.

(Patents Act, Section 22)

# (ii) Restrictions Concerning the Furnishing of Samples

The patentee may request that a sample of the deposited microorganism be available only to an expert in the art until the patent application has been laid open to public inspection or has been finally decided upon without having been laid open to public inspection. An expert is a person whose name is included in a list published in the Patent Office for the purpose of handling samples of deposited microorganisms.

This does not mean, however, that samples are issued to anyone who in consequence of provisions in a law or other ordinance may not handle the deposited microorganism. Nor does this mean that samples are issued to anyone whose handling of the sample can be assumed to involve an evident risk in view of the harmful properties of the organism.

(Patents Act, Section 22; Patents Decree, Section 25(b))

According to Section 22 paragraph seven of the Patent Act, a request that a sample may only be given to a particular expert shall be made on the day that the technical preparations to make the patent application available to the public are considered to have been completed, at the latest.

The patent office establishes a list of suitable persons who have stated they are willing to undertake the position of expert. The decision concerning which persons are included in the list of experts shall be announced in the manner described in Section 49. If a sample may only be given to one particular expert, it shall be stated in the description of the sample who shall be appointed as the expert. A written statement shall be attached to the description from the designated expert to the patent applicant corresponding to the statement prescribed in Section 25(a) first-third paragraphs. If the

description refers to samples which shall be given out according to Section 22 paragraph seven, second sentence, the Patent Act, the legally binding statement shall be valid for 20 years from the day the patent application was submitted. Those persons who are named in the list may be appointed as experts or in special cases a person accepted by the patent applicant. Regulation (2004:162).