

Swedish environmental classification of pharmaceuticals

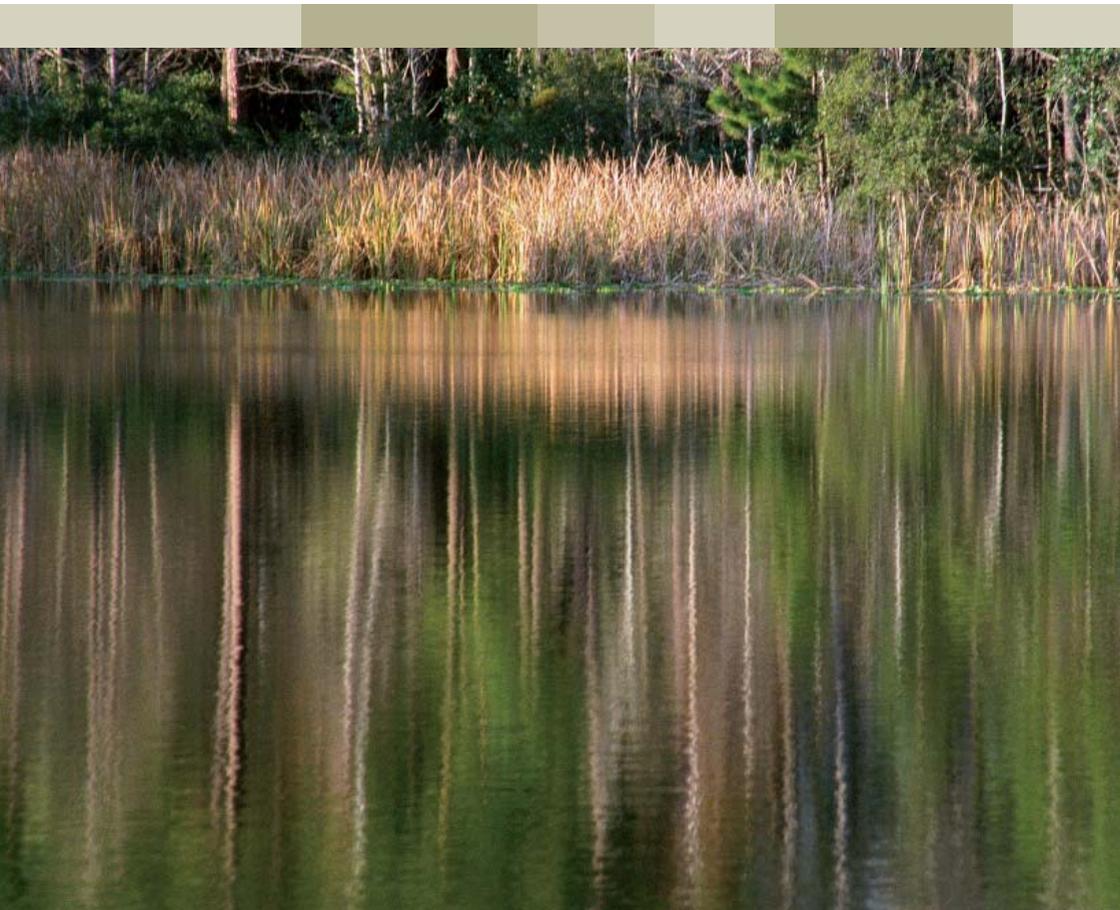


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Background

The issue of possible environmental influence by pharmaceuticals has come under increasing scrutiny in the last couple of years. Considerable research is now being conducted, including joint projects between government authorities, universities and pharmaceutical companies. The present state of knowledge is that the very low concentration of pharmaceuticals detected in the environment in Sweden has no immediate effects on animals and plants. The risk of long-term adverse effects is probably also low, but some studies indicate negative effects.

Growing public interest in the possible environmental effects of pharmaceuticals is one of the main reasons for the introduction of the Swedish voluntary environmental drug classification system on the website www.fass.se. There has also been significant pressure from the government for more information about this issue. In 2002, the Swedish government instructed the Swedish Medical Products Agency (MPA) to conduct a survey of the state of knowledge on the environmental effects of pharmaceuticals, cosmetics and hygiene products. On a European level, the EU has recently implemented new guidelines on how to conduct environmental risk assessments when registering new pharmaceuticals. The new EU chemical substances legislation, REACH, also focuses on the environmental impact of chemical products.

In its final report of 2004, the Swedish MPA concluded that EU rules applied and that it was not legally possible to implement a mandatory environmental classification and labelling system in Sweden. Nevertheless, the then Minister of the Environment, Lena Sommestad, made it very clear that she expected better information on environmental effects of pharmaceuticals. Thus LIF, the Swedish Association of the Pharmaceutical Industry, took the initiative to develop a voluntary environmental classification scheme, in partnership with other interested parties in the healthcare sector.

The model for presenting environmental data was developed by LIF, Stockholm County Council, the pharmacy monopoly chain Apoteket AB, the Swedish Association of Local Authorities and Regions (SKL), and the MPA. The goal was to develop a model which clearly showed environmental information, both to interested members of the public and healthcare professionals.

The environmental information draws on data from the pharmaceutical companies. An independent organisation, the Swedish Environmental Research Institute, IVL, acts as a reviewer of all data and assessments and classifications. The information and classification of the first groups of substances was published in October 2005. The operational plan is for all pharmaceutical product groups to have been processed by the end of 2010.

How do pharmaceuticals reach the environment?

There are several ways in which pharmaceuticals can reach the environment. One is through leaks in the manufacturing process. Another is when pharmaceuticals are flushed down the toilet or thrown in the rubbish. Left over pharmaceuticals should always be returned to a pharmacy, which will arrange proper disposal.

A third way for a pharmaceutical substance or its metabolites to reach the environment is through proper use. Once consumed, the substance or its metabolites are excreted in urine or faeces and reach the water supply through the sewage system. If the sewage passes through a treatment plant, the substance may sometimes be degraded or deposited in the sewage sludge. In other cases, the substance passes through treatment and ends up in the environment.

Environmental risk and environmental hazard

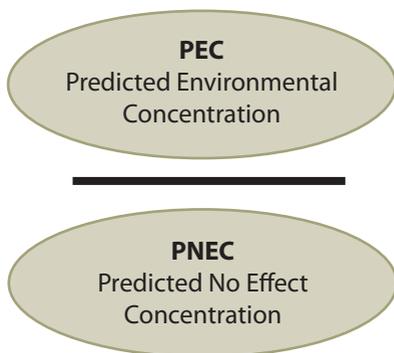
The inherent environmental hazard of a pharmaceutical substance is taken to mean its toxicity; its degradability and its potential for deposition in fat tissue in, for example, fish. A substance which is deemed environmentally hazardous and highly potent and toxic need not automatically be the one posing the greatest environmental risk. For example a cytotoxin, which is very poisonous but only given to very few patients, may result in a negligible environmental risk. Of course, it is crucial to use and handle such substances correctly and with the utmost care, but less potent and less poisonous substances used in greater quantities may result in a significantly higher environmental risk.

That is why it is important to distinguish between environmental risk and environmental hazard, and why the Swedish environmental classification of pharmaceuticals on Fass.se focuses on environmental risk.

How is environmental risk assessed and computed?

To assess whether a pharmaceutical substance poses an environmental risk or not, you first need to know the highest level of concentration of that specific substance which is anticipated NOT to cause negative effects in animals and plants. The tests for this are standardised and conducted in laboratories. Since the classification on Fass.se focuses on possible adverse aquatic environmental effects, the data is normally from algae, daphnia and fish.

The data is computed by comparing the no-effect concentration with the anticipated concentration in Swedish waters.



If the PEC/PNEC quota is higher than 1, i.e. there is a higher concentration in the aquatic environment than is expected to be safe for animals and plants in water, then the substance in question is considered to result in moderate or high environmental risk.

Based on the above quota, the following phrases are used to describe environmental risk in the Swedish classification system:

- Use of the substance has been considered to result in insignificant environmental risk
(The quota of PEC/PNEC is less than 0.1)
- Use of the substance has been considered to result in low environmental risk
(The quota of PEC/PNEC is between 0.1 and 1)
- Use of the substance has been considered to result in moderate environmental risk
(The quota of PEC/PNEC is between 1 and 10)
- Use of the substance has been considered to result in high environmental risk
(The quota of PEC/PNEC is higher than 10)



Pharmaceuticals may degrade in the environment through several different processes.

How is environmental hazard assessed?

On the Fass.se website, in addition to information on environmental risk, you may also obtain information on whether a certain pharmaceutical substance is persistent or biodegradable, and whether it can bioaccumulate in aquatic organisms.

Biodegradation of pharmaceuticals in the environment

There are several ways in which pharmaceuticals naturally degrade. Biological degradation takes place in soil or water by means of microorganisms. However, non-biological degradation is based on chemical reactions or reactions to UV rays in sunlight.

Pharmaceuticals are classified regarding biodegradation according to standardised laboratory tests. More information on the underlying principles and details of the tests for each medicinal product can be found on Fass.se.

The Swedish classification system uses the following phrases regarding degradability:

- The substance is *degraded* in the environment
- The substance is *slowly degraded* in the environment
- The substance is *potentially persistent*

Bioaccumulation of pharmaceuticals in the environment

Highly lipid-soluble pharmaceuticals may have the ability to bioaccumulate in the fat tissue of animals. Animals higher in the food chain are more susceptible to this. They eat animals which in turn have eaten other organisms which may have absorbed the substance.

Pharmaceuticals are classified in regard to bioaccumulation based on standardised laboratory tests.

The Swedish classification system uses the following phrases regarding bioaccumulation:

- *No significant bioaccumulation potential*
- *Potential* to bioaccumulate in aquatic organisms

Substances exempted from environmental classification

Certain pharmaceuticals are exempted from classification as for various reasons they are considered not to cause any environmental effect. This is in line with the EU's environmental risk assessment guidelines for pharmaceuticals.

The exception covers:

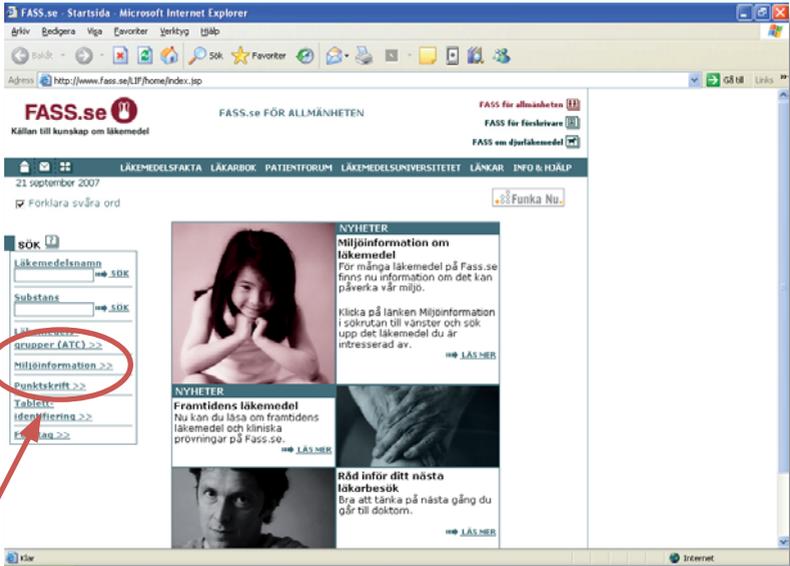
- vitamins
- electrolytes
- amino acids, peptides, proteins
- carbohydrates
- lipids
- vaccines
- herbal medicinal products

The Swedish environmental classification system uses the following phrase for pharmaceuticals which contain any of the above substances (XX):

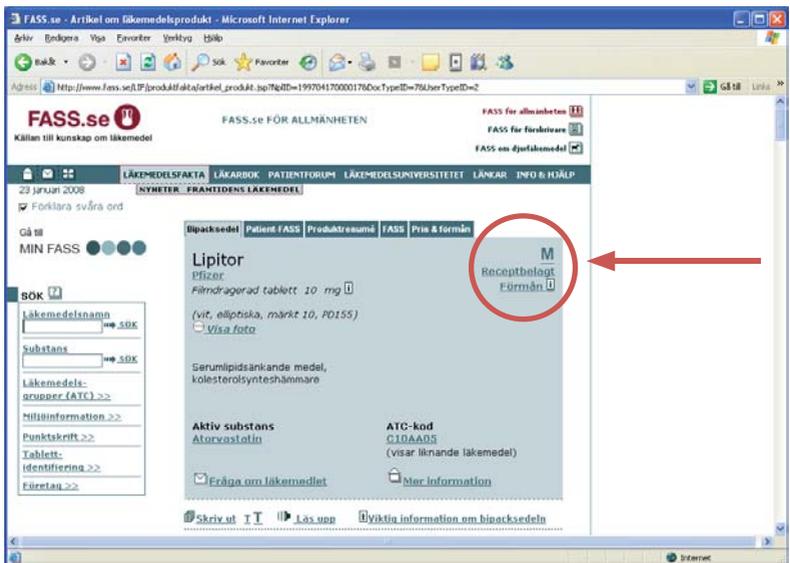
- Use of XX has been considered to result in insignificant environmental impact



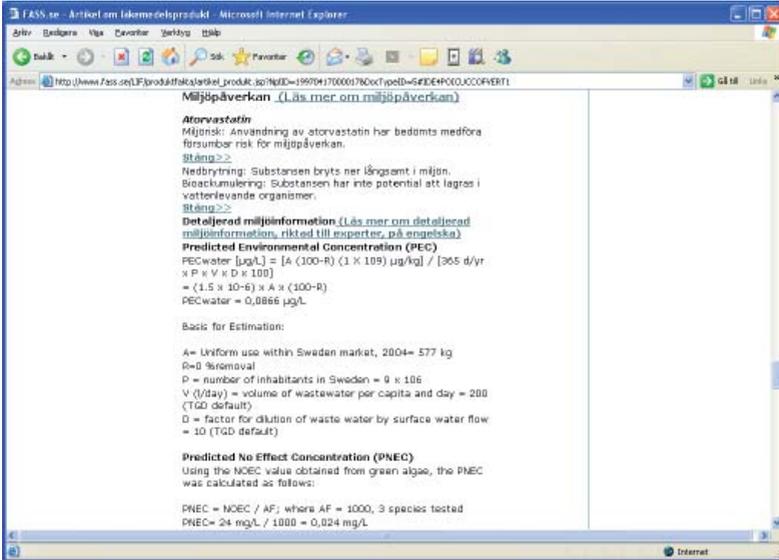
How to find the environmental classification on Fass.se



1. Go to www.fass.se
2. Under the link "Miljöinformation>>" ("Environmental information") you can find all pharmaceuticals which have been classified. You may sort them alphabetically by their (Swedish) product name, alphabetically by company name or by ATC code (therapeutic group).



3. Alternatively, you can find the page for a specific product, as with a normal Fass search. In the upper right-hand corner, there is an "M" meaning that the medicine has been classified. Click the "M" to be redirected to the environmental classification for the product in the section "Miljöpåverkan".



4. You can also scroll down to the section "Miljöpåverkan" (Environmental impact). The Swedish text covers environmental risk (Miljörisk), but also Biodegradation (Nedbrytning) and Bioaccumulation (Bioackumulering). The text also gives information on the detailed laboratory results, the total amount of sold active substance in Sweden, and the resulting computation of the PEC/PNEC quota. Quite often the background data is written in English.

Further information



You can read more about the Swedish environmental classification of pharmaceuticals on: www.fass.se/environment

1. www.fass.se/environment (in English)
2. “Environmental classification of pharmaceuticals in www.fass.se – guidance for pharmaceutical companies, 2007”. (English text, available through the link in 1).
3. “Miljöpåverkan från läkemedel samt kosmetiska och hygieniska produkter”. (“Environmental effects of pharmaceuticals as well as cosmetics and hygiene products”, report by the Swedish MPA, 2004, contains a summary in English, www.lakemedelsverket.se)
4. The Swedish Association of the Pharmaceutical Industry AB, (LIF) www.lif.se





In 2004 LIF, the Swedish Association of the Pharmaceutical Industry, took the initiative to develop a system of voluntary environmental classification of pharmaceuticals. The model was a collaboration between LIF, the Swedish Medical Products Agency (MPA), The Swedish Association of Local Authorities and Regions (SKL), the pharmacy monopoly chain Apoteket AB and the Stockholm County Council. In October 2005 the first environmental classifications were published on the well-known website www.fass.se which is the publicly available Swedish Medicinal Products List. The work continues, and according to the operation plan it is anticipated that all pharmaceuticals will have been classified by late 2010. The Swedish Environmental Research Institute (IVL), acts as an independent reviewer of all environmental data.

