



Do you manufacture or import a “new substance” used in biofuel production?

FIND OUT ABOUT THE NEW SUBSTANCES NOTIFICATION REGULATIONS (ORGANISMS)

If you manufacture or import (produce, grow, develop) a new substance that is used in biofuel production (ethanol, biodiesel, etc.), you must ensure that these new substances have been assessed for the potential risk to the environment or human health as required by the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

CEPA 1999 is the key authority for the government to ensure that all new substances are assessed for their potential to harm the environment or human health before they are imported or manufactured in Canada. However, The *New Substances Notification Regulations (Organisms)* [NSNR (Organisms)] do not apply to a substance that is manufactured or imported for a use that is regulated under any other Act of Parliament that provides for notice to be given before the manufacture, import or sale of the substance and for an assessment of whether it is toxic or capable of becoming toxic. These Acts are listed on Schedule 4 of CEPA 1999. New substances intended for uses other than those covered under these Acts are subject to notification under the NSNR (Organisms) of CEPA 1999.

Micro-organisms and organisms other than microorganisms used in biofuel production may be subject to the NSNR (Organisms):

- Yeast used to ferment sugars to produce ethanol
- Genetically modified catalysts and fermentation agents (e.g. enzyme production, yeasts)
- Biomass/feedstock (e.g. algae, jatropha)
- Genetically modified crops used as biomass/feedstock
- Fermentation with genetically engineered strains of bacteria
- Genetically modified microorganisms developed to produce enzymes or biofuels
- Genetically modified microorganisms used to solubilize hemicellulose

WE ALL BENEFIT WHEN YOU COMPLY WITH THE LAW

See reverse for details on the NSNR (Organisms) and some of its definitions



NEW SUBSTANCES NOTIFICATION REGULATIONS (Organisms)

WHY SUCH REGULATIONS?

The **New Substances Notification Regulations (organisms)** [NSNR (Organisms)] of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) are an integral part of the federal government's "cradle to grave" management approach to toxic substances.

CEPA 1999's approach to the control of new substances is both proactive and preventative, employing a **pre-manufacture and pre-import notification and assessment process**. When this process identifies that a new substance may pose a risk to the environment or human health, CEPA 1999 empowers the Ministers of the Environment and Health to intervene prior to or during the earliest stages of its introduction into Canada. This ability to act early makes the new substances program a unique and essential component of the federal management of toxic substances.

WHAT IS A SUBSTANCE?

A substance is described as means any distinguishable kind of organic or inorganic matter, whether animate or inanimate. Animate matter or "living organisms" consist of micro-organisms (*i.e.*, bacteria, fungi, yeasts, protozoa, algae, viruses, eukaryotic cell culture and any culture which is not pure) or other organisms (*i.e.*, animals and some plants, such as those that are not indigenous to Canada or are genetically modified). Inanimate matter that is produced by microorganisms consists of biochemicals and biopolymers.

WHAT IS A NEW SUBSTANCE?

A new substance is any substance that does not appear on the Domestic Substances List (DSL) of CEPA 1999.

WHAT IS THE DOMESTIC SUBSTANCES LIST?

The DSL is a compilation of all known substances that were in Canadian commerce between 1984 and 1986 or that were added to the DSL in accordance with CEPA 1999. In certain circumstances, the Minister of the Environment may amend the DSL by adding or deleting substances according to CEPA 1999.

WHERE CAN I GET A COPY OF THE DSL?

The DSL can be searched on the New Substances Website at the following address: <http://www.ec.gc.ca/substances/>

Any substance that does not appear on the DSL is subject to the **NSNR (Organisms)**

ARE THERE NEW SUBSTANCES THAT ARE NOT SUBJECT TO THE NSNR (Organisms)?

Yes. Substances regulated under any other Federal Act that requires a notice prior to manufacture or import and an assessment of toxicity are not subject to the NSNR (Organisms). These Acts are listed on Schedule 4 of CEPA 1999.

I WANT TO MANUFACTURE OR IMPORT A NEW ANIMATE OR INANIMATE MATTER. WHAT SHOULD I DO?

Please consult us in advance of initiating the manufacture or importation process of a new substance. You will need information on the composition and use of the new substance to determine how to fulfill your obligation under CEPA 1999 and the NSNR (Organisms).

You must fulfill the requirements of the NSNR (organisms) before manufacturing or importing a new substance. Enforcement of the NSNR (Organisms) will be conducted in accordance with the Compliance and Enforcement Policy for CEPA 1999. (<http://www.ec.gc.ca/CEPARRegistry/documents/policies/candepolicy/toc.cfm>)

ARE THERE FEES FOR SUBMITTING A NEW ANIMATE OR INANIMATE MATTER?

No, at this time, the *New Substances Fees Regulations* do not apply to substances subject the NSNR (Organism).

WHERE CAN I GET MORE INFORMATION?

To find out more on the NSNR (Organisms) provisions, to consult the DSL, or to obtain instructions on how to complete the notification, visit the New Substances Web site at the following address: <http://www.ec.gc.ca/substances/>

WHO DO I CONTACT?

National Office (Gatineau, Hull Sector):
Telephone: 1-800-567-1999 (within Canada)
(819) 953-7156 (outside Canada)
Facsimile: (819) 953-7155
E-mail: NSN-Infoline@ec.gc.ca

The information presented here is not exhaustive. The intent is to highlight relevant points in the NSNR (Organisms) established by CEPA 1999. In case of a discrepancy between this bulletin, CEPA 1999 and the NSNR (Organisms), the legislation and the Regulations will prevail. Please refer to the Regulations for complete details on the requirements.