

# New Substances nouvelles



## Do you manufacture or import a “new substance”?

### FIND OUT ABOUT THE NEW SUBSTANCES NOTIFICATION REGULATIONS (CHEMICALS AND POLYMERS)

If you manufacture or import new substances, you must ensure that these new substances have been assessed for their 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 into or manufactured in Canada. However, substances imported or manufactured for uses regulated by other Acts and Regulations that meet certain pre-market notification and assessment criteria are not subject to the New Substances Notification Regulations (Chemicals and Polymers) [NSNR (Chemicals and Polymers)]. Acts and Regulations that meet these criteria are listed in Schedule 2 of CEPA 1999. New substances intended for uses other than those covered under these Acts and Regulations are subject to notification under the NSNR (Chemicals and Polymers) of CEPA 1999. Please note that the Food & Drugs Act is not listed in Schedule 2.

If you manufacture or import a new substance for use in any of the following applications, whether for commercial purposes or for research and development, you may be subject to the NSNR (Chemicals and Polymers) of CEPA 1999. Please note that this list is not exhaustive:

- Pharmaceutical active ingredients
- Natural Health Products
- Novel Foods
- Cosmetics
- Pharmaceutical excipients
- Biologics
- Food Additives
- Personal Care Products
- Veterinary Drug active ingredients
- Veterinary Drug excipients
- Medical Devices
- Food Packaging
- Enzymes

### WE ALL BENEFIT WHEN YOU COMPLY WITH THE LAW

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



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## **NEW SUBSTANCES NOTIFICATION REGULATIONS (Chemicals and Polymers)**

### **WHY SUCH REGULATIONS?**

The **New Substances Notification Regulations (chemicals and Polymers)** [NSNR (Chemicals and Polymers)] 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 any distinguishable kind of organic or inorganic matter, whether animate or inanimate. Inanimate matter is addressed under the NSNR (Chemicals and Polymers) and includes organic and inorganic chemicals, biochemicals, polymers 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 program's 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 (Chemicals and Polymers)**

### **ARE THERE NEW SUBSTANCES THAT ARE NOT SUBJECT TO THE NSNR (CHEMICALS AND POLYMERS)?**

Yes. Substances regulated under other Federal Acts and Regulations that meet certain pre-market notification and assessment criteria are not subject to the NSNR (Chemicals and Polymers). Acts and Regulations that meet these criteria are listed in Schedule 2 of CEPA 1999. Please note that the Food & Drugs Act is not listed in Schedule 2.

### **I WANT TO MANUFACTURE OR IMPORT A NEW SUBSTANCE. 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 (Chemicals and Polymers).

You must fulfill the requirements of the NSNR (Chemicals and Polymers) before manufacturing or importing a new substance. Enforcement of the NSNR (Chemicals and Polymers) 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 SUBSTANCE NOTIFICATION?**

No. New Substances Notifications (NSNs) for substances intended solely for use in products regulated under the Food & Drugs Act are not subject to the *New Substances Fees Regulations*. However, fees are required for most other notifications.

### **WHERE CAN I GET MORE INFORMATION?**

To find out more about the NSNR (Chemicals and Polymers) provisions, to consult the DSL or to obtain instructions on how to prepare and submit a notification, visit the New Substances program 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](mailto:NSN-Infoline@ec.gc.ca)

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

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