

INFORMATION

Natural Health Products Regulations – What is an Act? What are Regulations?

What Is an Act?

An Act is a means by which laws are made. Generally, Acts begin in draft form (“bills”) and can originate either in the House of Commons or in the Senate. For a bill to become law, it must be approved by both the House of Commons and the Senate and by the Governor General of Canada. Certain procedures must also be followed in the law-making process. Bills are discussed by members of both Houses during what is formally known as First Reading, Second Reading and Third Reading. As well, bills are submitted to a Parliamentary Committee for review. The Committee usually seeks out the views of interested parties, including the public. Finally, a bill becomes law (an Act) through a formal process known as proclamation. Proclamation is done by the Governor in Council (Cabinet, i.e., the Prime Minister and his or her Federal Ministers).

What Are Regulations?

Like an Act, regulations (often referred to as *delegated legislation* or *subordinate legislation*) are a means of making laws and should reflect policy objectives. Regulations are not made by Parliament but rather by someone to whom Parliament has delegated the authority to make them. For example, an Act (known as the *enabling legislation*) would state that a minister, an administrative agency or, as in the case of the *Food and Drugs Act*, the Governor in Council (Cabinet) is given the power to make regulations. All regulations must be consistent with the authority under which they are made. They can not go beyond what the Act provides. Regulations may be viewed as the operational part of a law, commonly dealing with matters such as what is meant by certain terms used in an Act, procedures and processes that must be followed or standards that must be met, etc. in order to comply with an Act.

Further information on the regulatory process can be found at the Privy Council Office Web site

<http://www.pco-bcp.gc.ca/raoics-srdc/default.asp?Language=E&page=aboutregs> or by contacting the Privy Council Office at: Privy Council Office, General Enquiries, Room 1000, 85 Sparks Street, Ottawa, Ontario, Canada, K1A 0A3, Telephone : (613) 957-5153, TTY : (613) 957-5741, Fax : (613) 957-5043.

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What Is the *Canada Gazette*?

The *Canada Gazette* is the official newspaper of the Government of Canada and is published under the authority of the *Statutory Instruments Act*. It consists of three parts, Part I, Part II and Part III.

Part I contains all formal public notices, official appointments, miscellaneous notices and *proposed* (draft) regulations from the government and private sectors that are required to be published by an Act or by a regulation. When proposed regulations are published in Part I, a period of time usually between 30 and 90 days is provided for comments to be submitted to the sponsor of the regulations, for example, a Federal Department.

Part II of the *Canada Gazette* contains regulations (as adopted by the appropriate authority) and certain other classes of statutory instruments.

Regulations, whether in draft or adopted form, are published in the *Canada Gazette* along with a document known as a *Regulatory Impact Analysis Statement* (RIAS). The RIAS is an important policy document. It is a clear language explanation of the regulations for Canadians, spelling out the need for the regulations, their cost and benefit to industry players, government and the public and the way they will be applied and enforced.

Part III of the *Gazette* contains the most recent Acts of Parliament and their enactment proclamations.

Further information on the *Canada Gazette* can be found at the *Canada Gazette* Web site, <http://canadagazette.gc.ca/index-e.html>, or by contacting the Communications Coordination Services Branch of Public Works and Government Services Canada at: 1-(613)-991-1215, direct written inquiries to Constitution Square Building, 4th floor, 350 Albert St., Ottawa, Ontario, K1A 0S5.

What Are Guidance Documents?

Guidance documents (sometimes called guidelines or directives) are important administrative documents which support laws and regulations. Unlike laws and regulations, guidance documents do not have the force of law. However, they are important documents which set out how a department, regulatory authority or other body applies laws and regulations under their jurisdiction. They provide transparency in decision-making and fill in details sometimes missing from the strict nature of legal language in laws or regulations. Examples of guidance documents would be Standards of Evidence, or Good Manufacturing Practices.