ANIMAL JUSTICE
Leading the legal fight for animal protection

**Bill S-5, *Strengthening Environmental Protection for a Healthier Canada Act***

**Backgrounder on Toxicity Testing Amendments**

## What is Bill S-5?

Bill S-5 was introduced in February, 2022 and overhauls the *Canadian Environmental Protection Act, 1999* ("**CEPA**")—one of Canada's most important environmental laws. CEPA establishes Canada's legal framework to protect the environment and human health from the use of toxic substances. It also governs the import, manufacture, and use of genetically modified animals.

## What is toxicity testing?

Toxicity testing is done to determine whether chemicals are toxic to the environment or human health. CEPA lacks any requirement for non-animal methods to be developed, validated and used for toxicity testing. This is problematic for several reasons. First, according to the Canadian Council on Animal Care ("**CCAC**"), toxicity testing is the most harmful type of animal use in Canadian science. Many experiments fall under Category E—the highest category of invasiveness—causing severe pain to unanesthetized conscious animals. Tests can involve forced ingestion followed by vomiting, forced inhalation causing throat and lung irritation and burning to animals restrained in inhalation chambers, and skin or eye irritation causing painful and itchy sores and rashes. Once a given experiment is done, the animals involved are generally killed.

Second, although many non-animal methods for toxicity testing exist, Canada has no federal legislation limiting the use of animals in testing or setting out the conditions under which animals may be used for testing. Amendments to Acts like CEPA are the only mechanisms that exist to ensure that there is a legal requirement to develop, validate, and use non-animal methods.

For these reasons, the Liberal Party of Canada's 2021 election platform included a commitment to phase out toxicity testing on animals by 2035.

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**How many animals are used in toxicity testing in Canada?**

It is difficult to overstate the need for action to protect animals from harmful toxicity testing. Data from the CCAC shows that 3.5-5 million animals are used in Canadian science each year. The number of animals used in toxicity testing each year also varies, but is generally around 150,000. In some years, more than 90,000 animals have been used in Category E toxicity tests alone—the most severe category of harm that animals can experience according to the CCAC.

Because Canada's system of oversight for animals in research is non-governmental and voluntary, it is impossible to know how many animals are being used at laboratories that choose not to opt-in to the CCAC system.

**How will Bill S-5 phase out toxicity testing on animals?**

Bill S-5 makes several key amendments to CEPA to eliminate unnecessary toxicity testing on animals. These include:

- Amending the preamble of the Act to recognize the need to reduce, replace, and refine the use of vertebrate animals in testing and assessment under the Act.
- Adding to the Government's duties in administering the Act the need to encourage the development and timely incorporation of scientifically justified alternatives to animal testing (section 2).
- Giving the Governor in Council authority to pass regulations detailing procedures and practices for replacing, reducing, or refining the use of animals in toxicity testing (section 67).
- Requiring the Ministers of Health and the Environment to use scientifically justified alternative methods and strategies to replace testing on animals to the extent practicable (section 68.1). Where the use of animals is "refined" only, and not reduced or replaced, the Bill is clear that refinement must actually minimize pain and distress caused to animals.
- Requiring that the Ministers publish a plan within two years specifying activities or initiatives to promote the development and implementation of non-animal methods (section 73). The Ministers will be required to report annually to Parliament on progress made under the plan.

**What are other jurisdictions doing to end toxicity testing on animals?**

There is strong international precedent for the adoption of non-animal methods for toxicity testing, and for corresponding laws and regulations requiring the development, validation and use of non-animal alternatives. For instance, when the EU and US updated their toxics laws to provide better protection for people and the environment, both jurisdictions also established legal requirements to prevent unnecessary toxicity testing on animals. The US Environmental Protection Agency has committed to reducing toxicity testing on mammals by 30% by 2025 and eliminating it altogether by 2035.

The EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (EC 1907/2006) regulation requires companies to share data in order to avoid unnecessary animal testing. Those wishing to perform animal tests must first get approval from the European Chemicals Agency. Under REACH, animal testing is to be avoided in favour of alternative methods, and registrants can only carry out tests involving the use of animals as a last resort.

In fact, Members of the European Parliament recently demanded an EU-wide action plan to reduce and replace the use of animals in all EU laboratories.

**What non-animal alternatives are available?**

Non-animal testing methods – including cell and tissue tests, computer models, and other sophisticated methods – are becoming increasingly available. They are often more reliable than tests using animals, as well as more time- and cost-effective. Since many of these non-animal methods use human cells and tissues (that can be collected non-invasively and with consent), they are much better than animal studies at predicting human responses to exposure to harmful substances.

To phase out toxicity testing on animals by 2035, Canada will need to invest in the development and validation of these methods, including through funding for Canada's recently-established and only national centre dedicated to non-animal alternatives, the Canadian Centre for Alternatives to Animal Methods (CCAAM) at the University of Windsor. Jurisdictions like the US and EU countries fund similar centres, but to date CCAAM has not received federal or provincial funding to carry out its mission.

**Does Bill S-5 improve protections for new genetically modified animals?**

Bill S-5 makes few amendments to Part 6 of CEPA, which governs the manufacture, use, and import of new GM organisms, though there appears to be widespread agreement that Part 6 of the Act is in need of a significant overhaul.

Although there have been relatively few GM animals developed or manufactured in Canada to-date—with the AquAdvantage Salmon being the most notable and contentious example—an increasing number of GM animals will likely be developed for varying uses in the coming years, particularly in the agricultural context. Deliberate attempts to influence the genetic makeup of animals can pose very real animal health and welfare risks. This includes the direct manipulation of genetic information in an organism using gene editing technology such as CRISPR. The increased ease of manipulating animal genomes makes it all the more important that CEPA include strong statutory and/or regulatory mechanisms to ensure that in any instance where such options are being considered, thorough ecological, welfare, and other ethical considerations are given due regard.

Animal Justice is pleased that Bill S-5 creates a new opportunity for public consultation when new GM vertebrate animals are proposed for manufacture and use in Canada. We will continue working to advocate for improvements to Part 6 of CEPA to protect the health and well-being of GM animals.

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