Atlantic Salmon Federation * Michael Black * The Campaign to Label Genetically Engineered Foods * Center for Food Safety * Center for Science in the Public Interest * Colorado Genetic Engineering Action Network * Consumer Federation of America * Consumer Policy Institute/Consumers Union * The Edmonds Institute * Environmental Defense * Friends of Blue Hill Bay * Friends of Miller Peninsula State Park * GRACE Public Fund * Greenpeace Genetic Engineering Campaign * Greenpeace USA * The Humane Society of the United States * Institute for Agriculture and Trade Policy * Institute for Fisheries Resources * Kooskooskie fish * Mangrove Action Project * Marine Environmental Consortium * National Environmental Trust * Natural Resources Defense Council * Pacific Coast Federation of Fishermen's Associations * Pesticide Action Network North America * Public Citizen * Sierra Club, national Marine Wildlife and Habitat Committee * Sierra Club, Upper Columbia River Group * Sustainfish * Tools for Change Institute * U.S. PIRG * Union of Concerned Scientists * The Washington Biotechnology Action Council

April 4, 2003

Dear Senator:

We, undersigned consumer, environmental, and other public-interest organizations, are writing to urge you not to co-sponsor nor support the *Minor Use and Minor Species Animal Health Act* ("MUMS") (S.741) introduced recently by Senator Sessions. That bill is controversial because it will provide transgenic animals, including the fast-growing salmon, with streamlined, abbreviated review procedures before marketing. While we do not oppose the bill's goal of making available animal drugs for minor species and minor uses, the legislation as currently written will have the inadvertent effect of compromising and weakening current regulation of transgenic animals.

As you probably know, many universities and companies are applying sophisticated molecular techniques to genetically engineer a wide range of "transgenic" animals for diverse purposes. Transgenic animals being developed include fish engineered to produce new hormones that make them grow faster and cows and goats engineered to produce human pharmaceuticals in their milk. What you may not know is that the Food and Drug Administration (FDA) intends to regulate transgenic animals under the Food Drug and Cosmetic Act's animal drug provisions (Section 512). The Agency is already entertaining at least one application under this law for a transgenic animal, a fast-growing salmon, and may be considering applications for other animals as well.

The MUMS bill provides an alternative to Section 512's approval process for two categories of animals drugs: those that are intended for minor uses in major species (cattle, horses, swine, chickens, turkeys, dogs, and cats) or those intended for any uses in minor species (animals other than major species). Thus, to the extent that FDA regulates transgenic animals under Section 512, transgenic animals that are minor species or are intended for minor uses would be eligible for the weak, streamlined procedures established by the MUMS bill. At a minimum, this means that applications of genetic engineering to fish, such as the current application for a faster growing salmon, would not need full FDA approval before proceeding to market.

It is, at best, premature to weaken regulation of transgenic animals. The application of genetic engineering in plant agriculture has already proven controversial. For the very reason that animals are involved, the commercialization of transgenic animals will almost certainly draw even more

public concern than transgenic plants such as soybeans. Weak or abbreviated FDA reviews of transgenic animals will do little to allay these concerns. Moreover, there are potentially significant food safety and environmental concerns about transgenic animals. A recent report from the National Academy of Sciences Animal Biotechnology: Science Based Concerns (2002) argues that transgenic fish, in particular, may easily escape fish farms and pose ecological hazards.

For these reasons, we ask that you not cosponsor S. 741 as it is now written, and work to amend the legislation to exclude the products of genetic modification in animals, and the animals themselves. (We suggest that the exclusion apply to all animals, rather than simply to transgenic animals, since FDA has not yet defined the scope of its applicable regulatory policy.) Thank you for considering our request.

Yours truly,

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