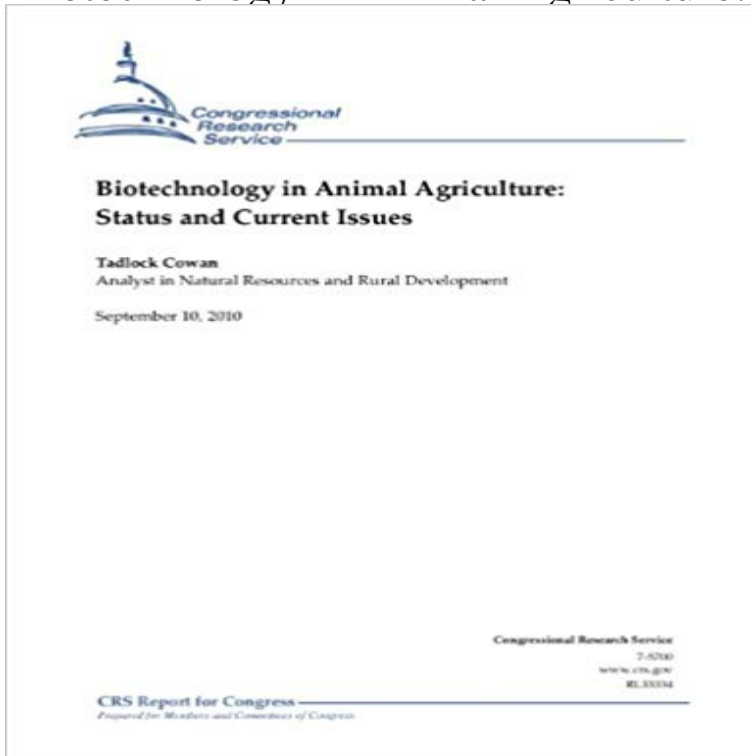


Biotechnology in Animal Agriculture: Status and Current Issues



Animal agriculture is being transformed by rapid advances in biotechnology a term that encompasses a variety of technologies, including genetic engineering (GE), genetic modification, transgenics, recombinant DNA techniques, and cloning, among others. Producers are interested in the application of biotechnology to improve productivity, consistency, and quality; to introduce new food, fiber, and medical products; and to protect the environment. Potential human health applications of transgenic animals include producing biopharmaceuticals and generating organs, tissues, and cells for xenotransplantation. Criticisms of such applications involve issues ranging from food safety and social resistance to potential negative impacts on animal welfare and on ecosystems. Questions also have arisen about the adequacy of the current regulatory structure to assess and manage any risks created by these technologies. On January 15, 2009, the U.S. Food and Drug Administration (FDA) released final guidance on how it is to regulate GE animals and products. FDA is to do so under its existing statutory authority and regulations. Generally, GE-derived foods, for example, are to be regulated like non-GE foods; if their composition does not differ from their conventional counterparts, they will not have to be labeled. Nonetheless, developers of GE animals and of GE-derived products must gain FDA pre-market approval. On February 6, 2009, the FDA announced the first approval of a drug from a GE animal. The drug is a human anti-clotting agent produced in the milk of transgenic goats. The FDA is currently considering approval of the first genetically modified animal for human consumption, having declared in August 2010 that a GE salmon is safe to eat and poses no threat to the environment. Although animal biotechnology involves many techniques

other than cloning, this latter technology has attracted widespread attention. A final risk assessment and industry guidance on the safety of meat and milk from cloned cattle, pigs, and goats and their offspring were released January 15, 2008, by FDA. The documents generally echoed the FDA's December 28, 2006, draft risk assessment, which found that such products are as safe to eat as those of conventionally bred animals. The FDA also concluded that cloning poses the same risks to animal health as those found in animals created through other assisted reproductive technologies although the frequency of such problems is higher in cloning. (Scientists stress that cloning is an assisted reproduction technique that does not involve any transfer or alteration of genes through GE.) The agency said it was no longer asking industry to refrain voluntarily from marketing the products of cloned animals and their offspring, although the U.S. Department of Agriculture (USDA) did ask that it be continued for products from clones (but not from the offspring of clones). Bills on animal cloning introduced in the 110th Congress would have required all food from cloned animals or their offspring to be labeled, and prohibited food from cloned animals from being labeled as organic. These and other bills on cloning or other regulation of animal biotechnology could be offered in the 111th Congress.

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