

# Gene Editing: Regulation at EPA

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Gene Editing Discussion – U.S. Environmental Protection Agency

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In September 2016, EPA indicated in the National Strategy for Modernizing the Regulatory System for Biotechnology Products (put forward by the United States EPA, USDA, and FDA) that it intends to clarify its approach to pesticidal products derived from genome editing.

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EPA has exempted plant-incorporated protectants (PIPs) from sexually compatible plants that are moved through conventional plant breeding (40 CFR 174.25) from the United States Federal Insecticide, Fungicide, and Rodenticide (FIFRA) requirements, e.g. for product registration/licensing and field testing.

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EPA has also exempted residues of plant-incorporated protectants (PIPs) from sexually compatible plants that are moved through conventional plant breeding (40 CFR 174.508) from the United States Federal Food, Drug and Cosmetic Act (FFDCA) tolerance requirements, e.g. for pesticide residues in food or feed, provided the residues are not present in food at levels that are injurious or deleterious to human health.

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It has been argued that PIPs created using CRISPR/ Cas9 and similar techniques also fall within the 40 CFR 174.25 and 174.508 exemptions. However, when these exemption were written in 2001, CRISPR/ Cas9 (SDNs) did not exist as a gene editing technique.

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The United States' EPA is evaluating the extent to which the current exemptions cover gene-edited PIPs and considering approaches to clarify the regulatory status of these materials.