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Intentional Genomic Alteration

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Why in News

Recently, the **US Food and Drug Administration (FDA)** approved a **first-of-its-kind Intentional Genomic Alteration (IGA)** in a line of domestic pigs referred to as **GalSafe pigs**.

This will be the **first time** that the regulator has approved an **animal biotechnology product for both food and biomedical purposes**.

Key Points

- **Intentional Genomic Alteration (IGA):**

- IGA in animals means **making specific changes to the genome of the organism using modern molecular technologies** that are popularly referred to as **“genome editing” or “genetic engineering”**.

- **Genome editing** is a group of technologies that give scientists the ability to change an organism's **Deoxyribonucleic Acid (DNA)**.

DNA is the chemical name for the molecule that **carries genetic instructions in all living things**.

- The DNA molecule consists of two strands that wind around one another to form a shape known as a **double helix**.
- Each strand has a backbone made of **alternating sugar (deoxyribose) and phosphate groups**.
- These technologies allow genetic material to be **added, removed, or altered at particular locations** in the genome.
 - One such technology is **Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR)**, which replicates natural defence mechanisms in bacteria to fight virus attacks, using a **special protein called Cas9**.
 - **Emmanuelle Charpentier** of France and **Jennifer A Doudna** of the USA have been awarded the **2020 Nobel Prize in Chemistry** for developing CRISPR/Cas9 genetic scissors.
- A **Genetically Modified Organism (GMO)** is an animal, plant, or microbe whose DNA has been altered using genetic engineering techniques.

- An IGA is inserted into an animal to **change or alter its structure and function**.
- The difference between an animal with an IGA and one that does not have an IGA is that the IGA **gives them a new trait or characteristic, such as faster growth or resistance to certain diseases**.

- **Use of IGA:**

Changes in the **DNA** sequence of an animal may be carried out **for research purposes, to produce healthier meat** for human consumption and **to study disease resistance** in animals, among other reasons.

One example is of using IGAs to make an **animal more susceptible to certain diseases such as cancer**, which helps researchers **get a better understanding of the disease and develop new therapies** to treat it.

- **FDA's Approval:**

- The FDA allowed IGA in GalSafe pigs to **eliminate a type of sugar found in mammals called alpha-gal.**
- GalSafe pigs may potentially be used to produce human medical products, IGA will help eventually free these products from detectable alpha-gal sugar, thereby **protecting their human consumers from potential allergies.**
Sugar is present on the surface of GalSafe pigs' cells and when they are **used for products such as medicines or food** (the sugar is found in red meats such as beef, pork and lamb), the **sugar makes some people with Alpha-gal Syndrome (AGS) more susceptible to developing mild to severe allergic reactions.**

Legislation in India Related to Genetically Modified Organisms

- In India, Genetically Modified Organisms (GMOs) and the products thereof are regulated under the **Rules for the manufacture, use, import, export & storage of hazardous microorganisms, genetically engineered organisms or cells, 1989** (referred to as Rules, 1989) notified under the **Environment (Protection) Act, 1986.**
- The **Rules, 1989** are supported by a series of guidelines on contained research, biologics, confined field trials, food safety assessment, environmental risk assessment etc.
- These rules are very broad in scope essentially **covering the entire spectrum of activities involving GMOs and products thereof.**
 - They also **apply to any substances, products, and food stuffs, etc.**
 - **New gene technologies apart from genetic engineering** have also been included.
- Rules, 1989 are implemented by the **Ministry of Environment, Forest and Climate Change (MoEFCC)** jointly with the **Department of Biotechnology (DBT)**, Ministry of Science & Technology and **state governments.**
- Six Competent Authorities and their composition have been notified under these Rules that include:
 - rDNA Advisory Committee (RDAC)
 - Institutional Biosafety Committee (IBSC)
 - Review Committee on Genetic Manipulation (RCGM)
 - Genetic Engineering Appraisal Committee (GEAC)
 - State Biotechnology Coordination committee (SBCC)
 - District Level Committee (DLC)

While the RDAC is advisory in function, the IBSC, RCGM, and GEAC are responsible for regulating function. SBCC and DLC are for monitoring purposes.

- **Indian Initiatives Related to GMOs:**

- **Indian GMO Research Information System** : It is a database on activities involving the use of GMOs and products thereof in India.

The primary purpose of this website is to make available objective and realistic scientific information relating to GMOs and products thereof under research and commercial use to all stakeholders including scientists, regulators, industry and the public in general. It is also expected to promote collaborations and avoid duplication of work.

- **Bt cotton** is the only **Genetically Modified (GM) crop** that is allowed in India. It has alien genes from the soil bacterium *Bacillus thuringiensis* (Bt) that allows the crop to develop a protein toxic to the common pest pink bollworm.
- India is also a signatory of **Cartagena Protocol on Biosafety** which seeks to **protect biological diversity** from the potential risks posed by **Living Modified Organisms** resulting from modern biotechnology.

Source:IE