

# China drafts rules on biotech after gene-editing scandal

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In this Oct. 9, 2018, file photo, Zhou Xiaoqin installs a fine glass pipette into a sperm injection microscope in preparation for injecting embryos with Cas9 protein and PCSK9 sgRNA at a lab in Shenzhen in southern China's Guangdong province. China has unveiled draft regulations on gene-editing and other new biomedical technologies it considers to be "high-risk." The measures follow claims in November 2018 by Chinese scientist He Jiankui that he helped make the world's first genetically-edited babies. That roiled the global science community and elicited widespread outcry over the procedure's ethical implications. (AP Photo/Mark Schiefelbein, File)

China has unveiled draft regulations on gene editing and other potentially risky biomedical technologies after a Chinese scientist's claim of helping to create gene-edited babies roiled the global science community.

Under the proposed measures released Tuesday, technology involving gene editing, gene transfer and gene regulation would be categorized as "high-risk" and managed by the health department of the State Council, China's Cabinet.

The measures follow assertions in November from scientist He Jiankui that he altered the DNA of twin girls born that month using a powerful new tool. The technology, called CRISPR-cas9, makes it possible to operate on DNA to supply a needed gene or disable one that's causing problems.

The revelation that it may have been used to conceive children elicited widespread outcry over the procedure's ethical implications. Researchers said He's actions exposed the twins to unknown health risks, possibly including a higher susceptibility to viral illnesses.

Gene editing for reproductive purposes is effectively banned in the U.S. and most of Europe. In China, ministerial guidelines prohibit research on embryos that "violates ethical or moral principles." Ethical guidelines published in 2003 say that gene editing is permitted for research, but that the experimental embryo cannot be nurtured for more than 14 days.

He Jiankui said he edited the babies' genes at conception in hopes of making them resistant to the AIDS virus, as their father is HIV positive. His lab was in Shenzhen, China's southern tech hub, and he recruited study participants through an AIDS advocacy group. He said his goal was to rewrite DNA before birth to make some children immune to HIV during their lifetime.

China immediately halted He's experiments after his announcement.

He also pursued international experts at Stanford and Rice universities, where he had done graduate studies work, and elsewhere, seeking advice before and during the experiment.



In this Oct. 9, 2018, file photo, Qin Jinzhou, an embryologist who was part of the team working with scientist He Jiankui, adjusts a microplate containing embryos that have been injected with Cas9 protein and PCSK9 sgRNA at a lab in Shenzhen in southern China's Guangdong province. China has unveiled draft regulations on gene-editing and other new biomedical technologies it considers to be "high-risk." The measures follow claims in November 2018 by Chinese scientist He Jiankui that he helped make the world's first genetically-edited babies. That roiled the global science community and elicited widespread outcry over the procedure's ethical implications. (AP Photo/Mark Schiefelbein, File)

In an interview with The Associated Press the month before his project was publicized, the 34-year-old scientist said he believed gene editing of human embryos resulting in live births was legal in China because the country has no law specifically forbidding it.

China's official Xinhua News Agency reported last month that He had breached national guidelines and would be punished for any legal violations. Xinhua didn't say which laws He might have violated, but noted that he had fabricated an ethical review.

Along with the birth of the twins, another embryo yet to be born reportedly resulted from He's experiment. All three will remain under medical observation with regular visits supervised by government health departments, Xinhua said.

Late last year, China's education ministry sent notices to universities requiring self-checks on research related to gene editing. In an email, the ministry told the AP that it called on educational institutions to strengthen management of scientific research ethics and inspect research involving gene-editing technology.

Kehkooi Kee, a Tsinghua University researcher who conducts gene editing on stem cells, said the volume of paperwork he must now fill out has increased as a result of being subject to more checks.

"He (Jiankui) is an irresponsible scientist," Kee said in late December after the Education Ministry issued its notification. "I don't even want to call him a scientist—he is an irresponsible man."

While He's work was widely condemned by his fellow scientists in China, it has had repercussions for others studying gene editing. It has also become more difficult to get gene-editing research approved, Kee said.

"The industry will develop at a slower pace," Kee said. "The government will be more cautious with research funds, and private organizations, such as charities and startups, will be less likely to invest."

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