Policy Environment and Commercial Potential of Gene- edited Crop in China

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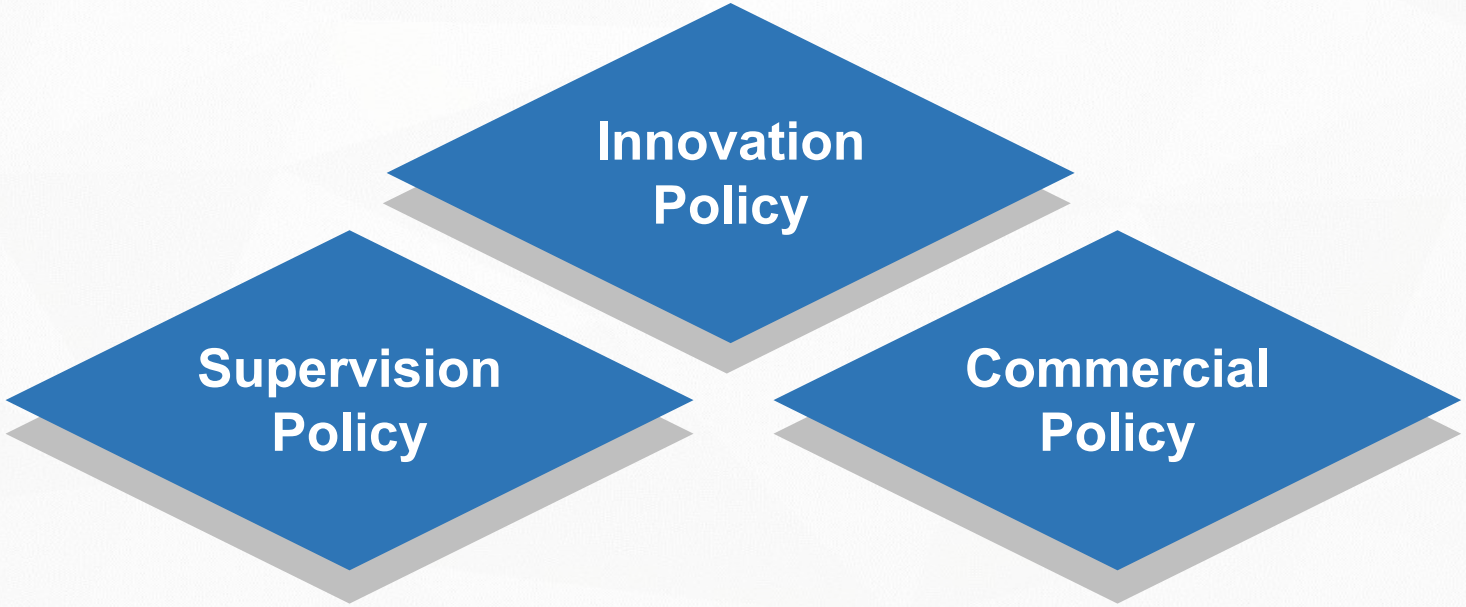
Current Policy System

In general, all crops and their products obtained through gene editing technology are treated as agricultural GMO

Agricultural GMO: animals, plants, microorganisms and their products that use genetic engineering technology to change the genome composition for agricultural production or agricultural product processing

Genetic Engineering Technology: the recombinant DNA technology with vector system and the technology of introducing recombinant DNA molecules into organisms by physical, chemical and biological methods

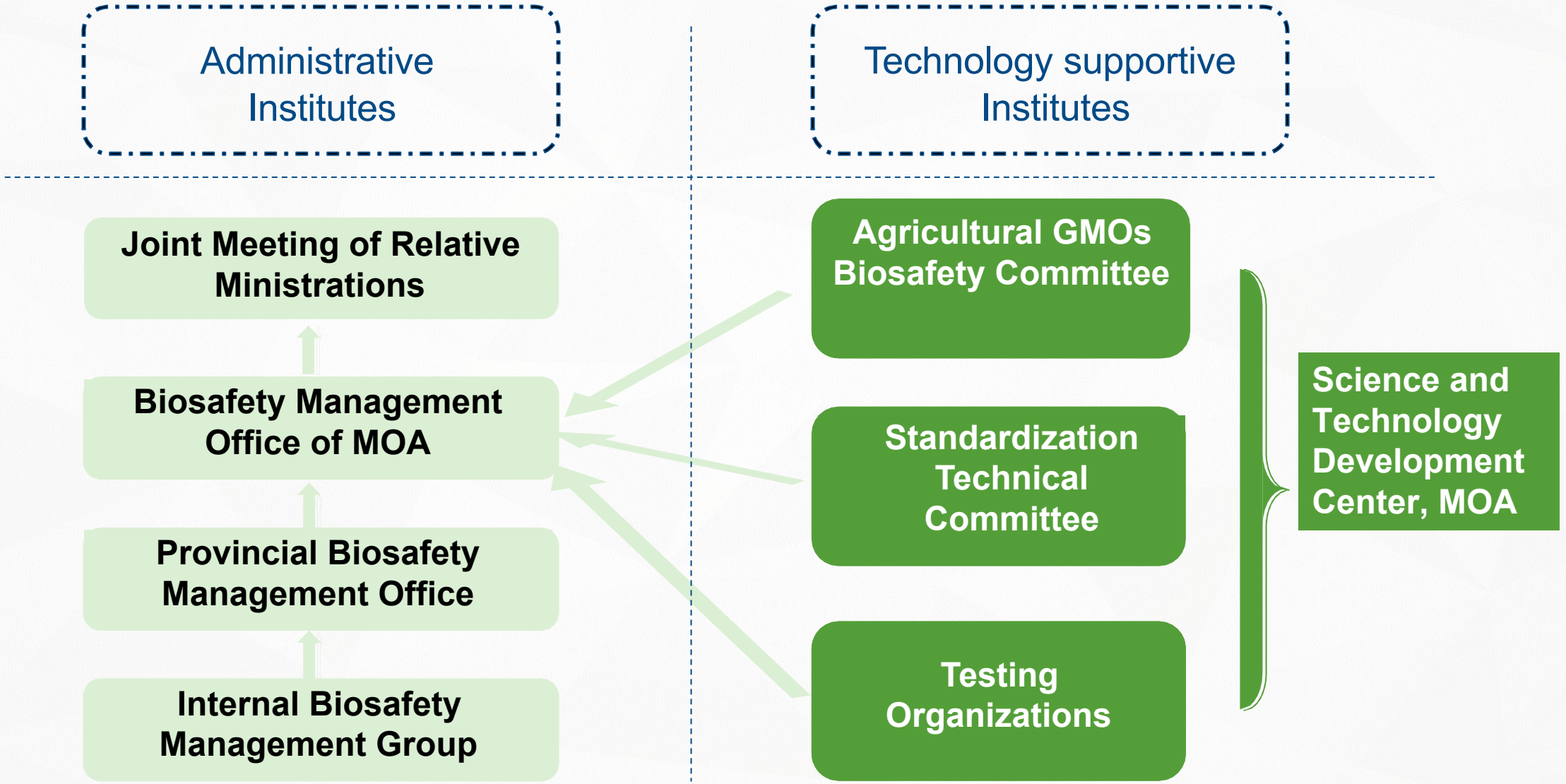


Supervision Policy--- Regulations

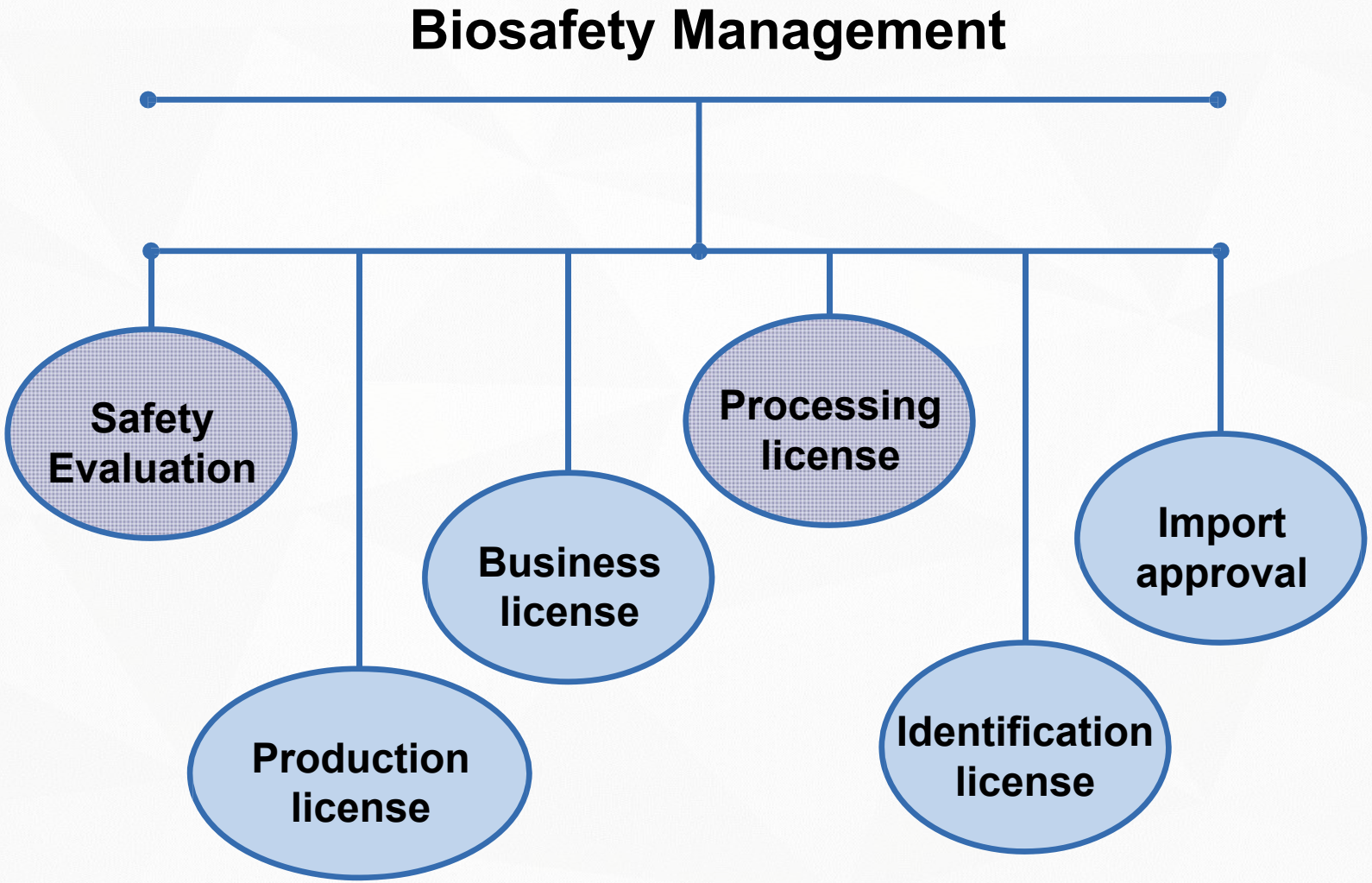
	Policy Title	Issued Institute	Issued Time	Revised Time
1	Regulations on the Safety Management of Agricultural GMOs	State Council	2001	2017
2	Administrative Measures for the Safety Evaluation of Agricultural GMOs	Ministry of Agriculture	2002	2004\2016\ 2017
3	Administrative Measures for the Import Safety of Agricultural GMOs	Ministry of Agriculture	2002	2004\2017
4	Administrative Measures for the Marks of Agricultural GMOs	Ministry of Agriculture	2006	2019

In recent years, safety evaluation guidelines and a series of testing standards have been formulated

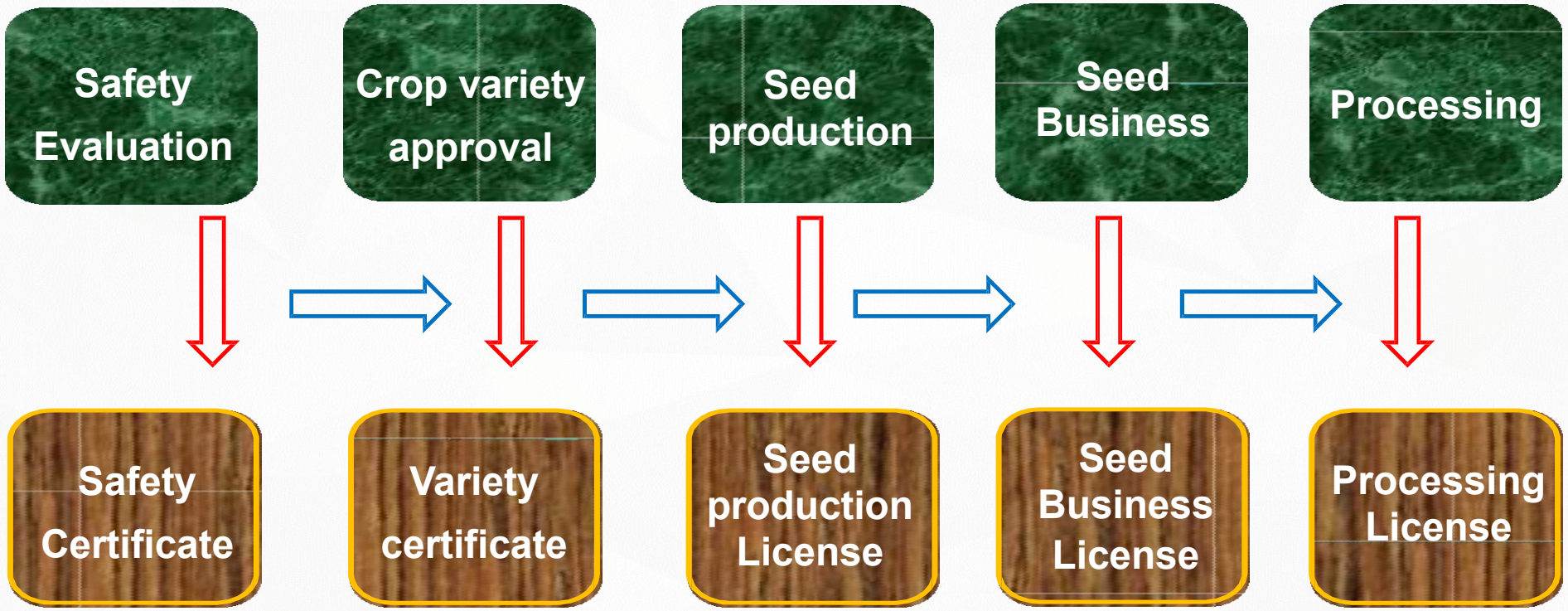
Supervision Policy--- Authorities



Supervision Policy--- Five Aspects



Supervision Policy--- From the Lab to the Customer



Whether it is safe or not is determined by scientific evaluation, whether it can be planted or not is handled according to laws and regulations, and whether to eat or not is chosen by the customers.

Supervision Policy--- Crop Variety Approval


中华人民共和国
农业转基因生物安全证书（生产应用）
农基安证字（2014）第029号
单位名称：华中农业大学
项目名称：转cryIAb/cry1Ac基因抗虫水稻华恢1号在湖北省生产应用的安全证书
转基因生物：华恢1号
外源基因：cryIAb/cry1Ac
安全等级：II
有效区域、规模：湖北省
安全措施及要求：见附件
有效期：2014年12月11日至2019年12月11日

- **There is no approved variety !**

  Article 44 of The Measures for the examination and approval of major crop varieties stipulates that "the measures for the examination and approval of genetically modified crop (excluding genetically modified cotton) varieties shall be formulated separately", but so far, the specific rules have not been issued

- **Safety certificate restarted after 10 years suspension**!

  2009: 2 kinds of insect resistant rice (Huazhong Agricultural University)and 1kind of Phytase forage Maize (Institute of biotechnology, Chinese Academy of Agricultural Sciences)

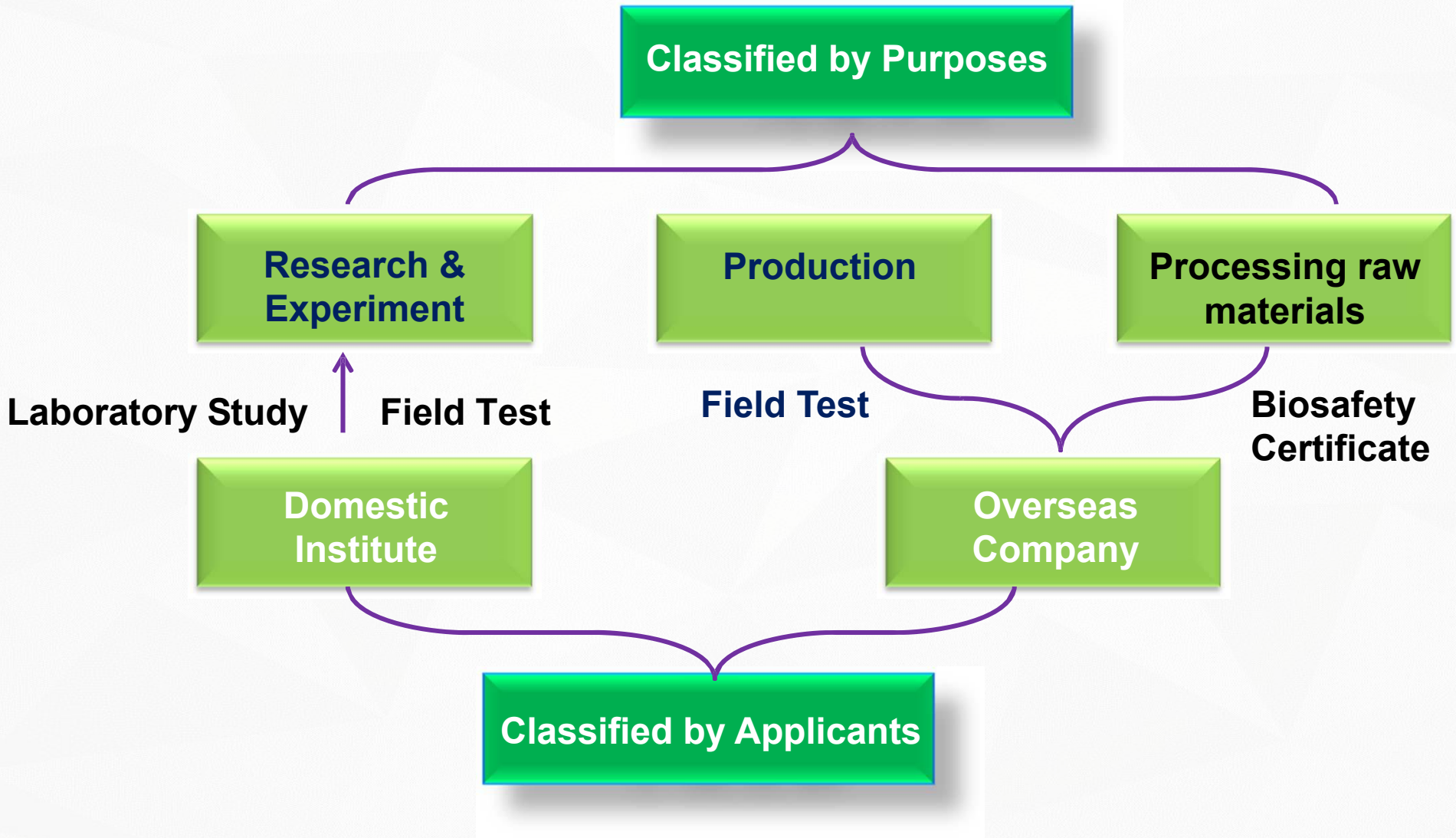
  2019: 2 kinds of transgenic maize (Beijing Dabei agricultural biotechnology Co., Ltd, Hangzhou Ruifeng Biotechnology Co., Ltd. and Zhejiang University) and 1 kind of transgenic soybean (Shanghai Jiaotong University)

  2020: 2 kinds of transgenic maize (Beijing Dabei agricultural biotechnology Co., Ltd) and 1 kind of transgenic soybean (Beijing Dabei agricultural biotechnology Co., Ltd)

Supervision Policy--- The Biosafety Evaluation Chain

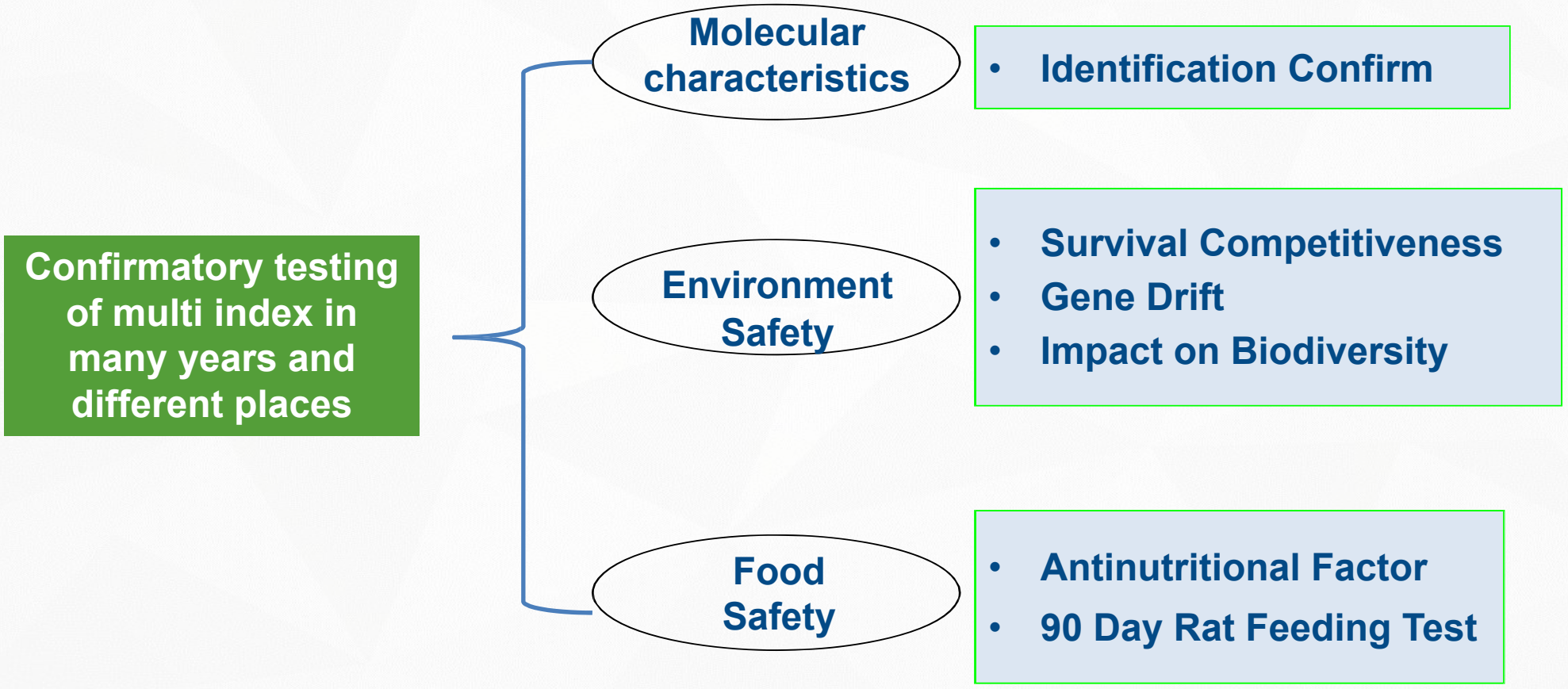
1. Laboratory study
2. Restricted field testing
3. Enlarged field testing
4. Productive field testing
5. Apply for biosafety certificate of GMO

Supervision Policy--- The Import Approval Chain

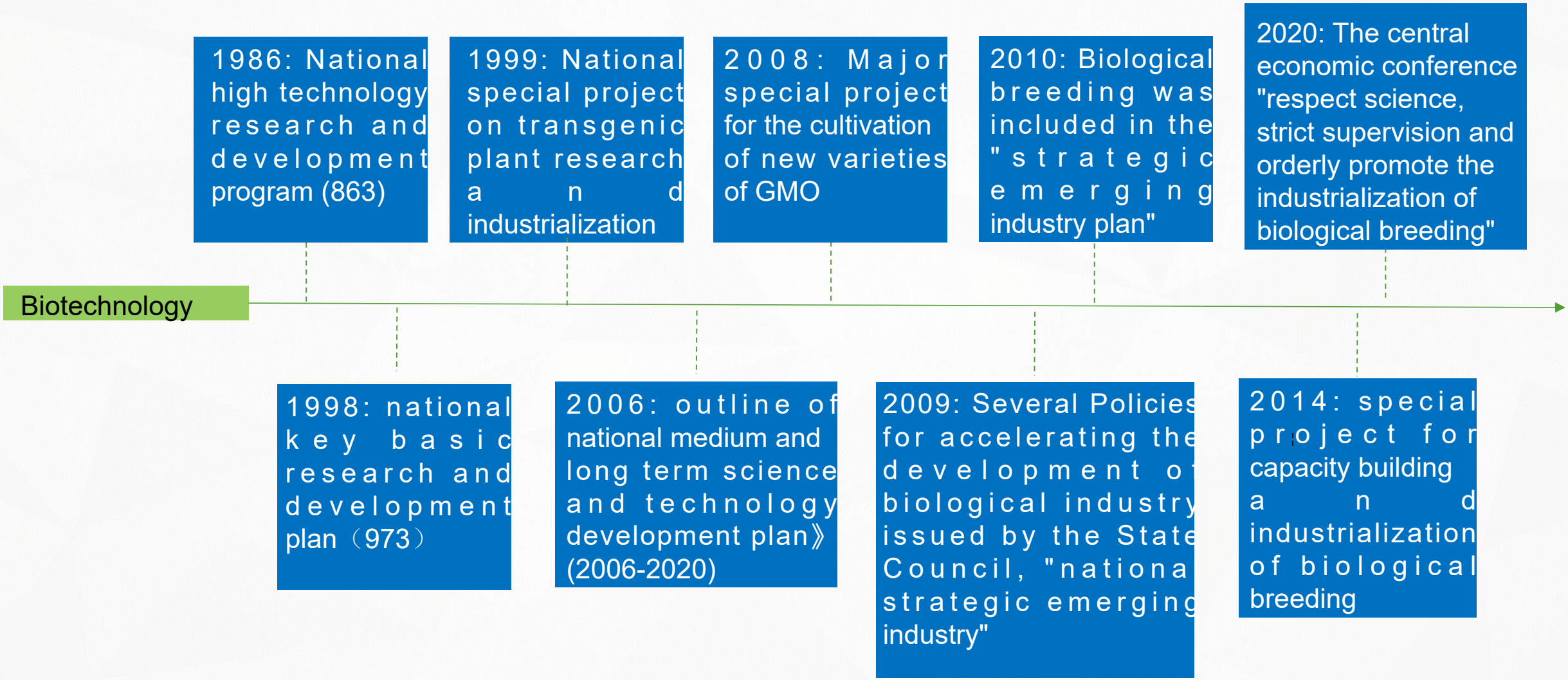


Supervision Policy--- The Detection Index

Import as Processing Raw Materials---Transgenic Herbicide Resistant Crops



Policy-R&D Investment



Main Innovative Achievements And the Commercialization Status

Overall progress of scientific research activities

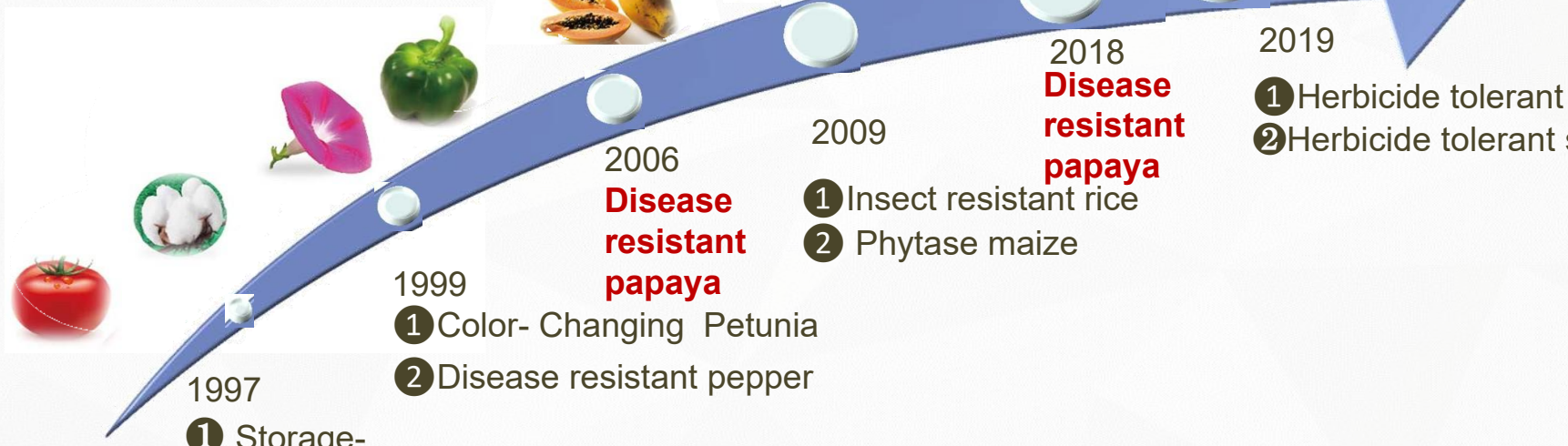
Research Papers of Main Countries

Country	Amount	Time	Highly cited papers	Percentage
US	6617	1974-2017	854	57%
China	1534	2005-2017	114	8%
Japan	1140	1992-2017	54	4%
German	1209	1979-2017	103	7%
UK	774	1999-2017	75	5%

Core Patent of Main Countries

Country	Amount	Percentage
US	933	74.5%
China	145	11.6%
France	45	3.6%
UK	16	1.3%
German	45	3.6%
Korea	12	1.0%
Japan	7	0.6%

Production Approval



1997
1. Storage-resistant tomato
2. **BT cotton**

1999
1. Color- Changing Petunia
2. Disease resistant pepper

2006
Disease resistant papaya

2009
1. Insect resistant rice
2. Phytase maize

2018
Disease resistant papaya

2019
1. Herbicide tolerant maize
2. Herbicide tolerant soybean

2020
1. Herbicide tolerant maize
2. Herbicide tolerant soybean

Only BT cotton and disease resistant papaya have been commercially produced.

Import Approval

Transformants approved for import as processing raw materials

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Maize 20
- ✓ IR
- ✓ HT
- ✓ Drought Tolerant
- ✓ Quality Improvement

Soybean 19
- ✓ IR
- ✓ HT
- ✓ Quality Improvement

Cotton 9
- ✓ IR
- ✓ HT

Canola 9
- ✓ HT

Sugarbeet 1
- ✓HT

Papaya 1
- ✓ Disease resistant

GM Foods in the China Market

- ✓ **Cottonseed oil (domestic or imported)**
- ✓ **Papaya (domestic or imported)**
- ✓ **Soybeans (imported)**
- ✓ **Corn (imported)**
- ✓ **Rapeseed oil (imported)**
- ✓ **Syrup (imported)**

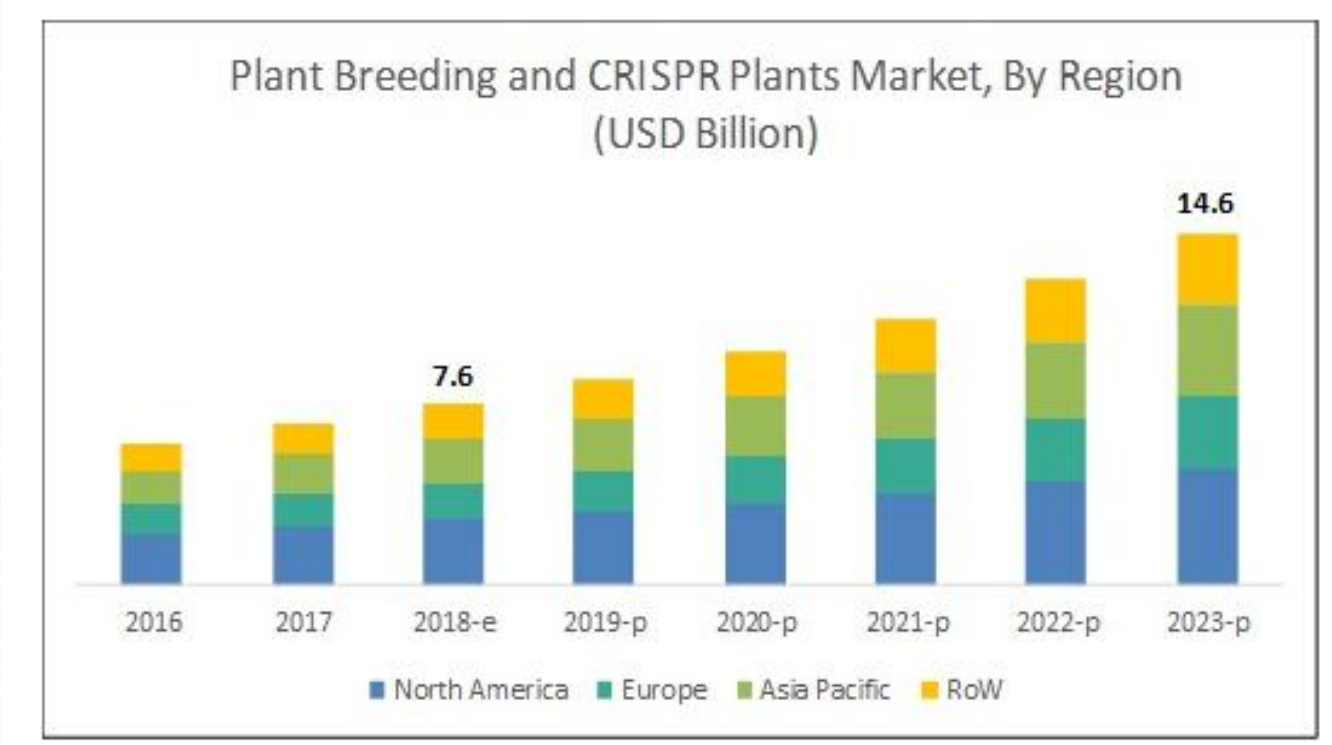
✓**Relevant foods added with genetically modified food additives (genetically modified enzyme preparation)**

Industrialization layout of the four agricultural companies

	Technology Corporation	Products
Syngenta	**In 2017, a global license agreement was reached with Broad Institute on crispr-cas9 gene editing technology.**	**It is applied to the research and development of corn, wheat, tomato, rice, sunflower and other crops**
DuPont Pioneer	In 2015, it obtained the technical license and authorization from Vilnius University and caribou company.	New maize and wheat lines edited by CRISPR Technology
Bayer	In 2014, it cooperated with Cellectis to develop rape.	Cotton lines with insect resistance and herbicide resistance
Dow AgroSciences	Develop EXZACT precise genome modification technology in cooperation with Sangamo.	Herbicide tolerant and phosphorus efficient maize edited by ZFN

The Near Future of Gene- edited Crop Market

- Genome editing technology has shown its advantages over traditional transgenic technology in **efficiency, accuracy and economy**.
- In the future, a large number of new varieties of genome editing crops will appear, and the market capacity will continue to increase



MarketsandMarkets Report：CRISPR plant breeding market is expected to reach US $14.6 billion by 2023, with a CAGR of 13.95% in the forecast period, and the Asia Pacific region is expected to have the highest increase.

Future Trends	Impact		Effects
By 2030, 10-15% of farms (60-100 million farms) will choose to use genetically edited seeds	Income Increase（billion $）	40-100	1-2% of gross value of agricultural output
	Yield increase（billion ton）	0.1-0.4	1-5% of gross value of agricultural output
	Food Loss reduction（million ton）	5-20	1-2% of food loss
	Micronutrient reduction（million）	20-100	1-5% of Total number of people in malnutrition

Report of the world economic forum: The Role of Technological Innovation in Accelerating the Transformation of the Food System

Management framework expectations

- The management method of gene editing products containing foreign genes should be consistent with that of traditional GMOs
- Gene editing products that do not contain foreign genes can be supervised according to the following procedures：

(1) In the laboratory and field experiment stage, the management should be strictly controlled to avoid escaping

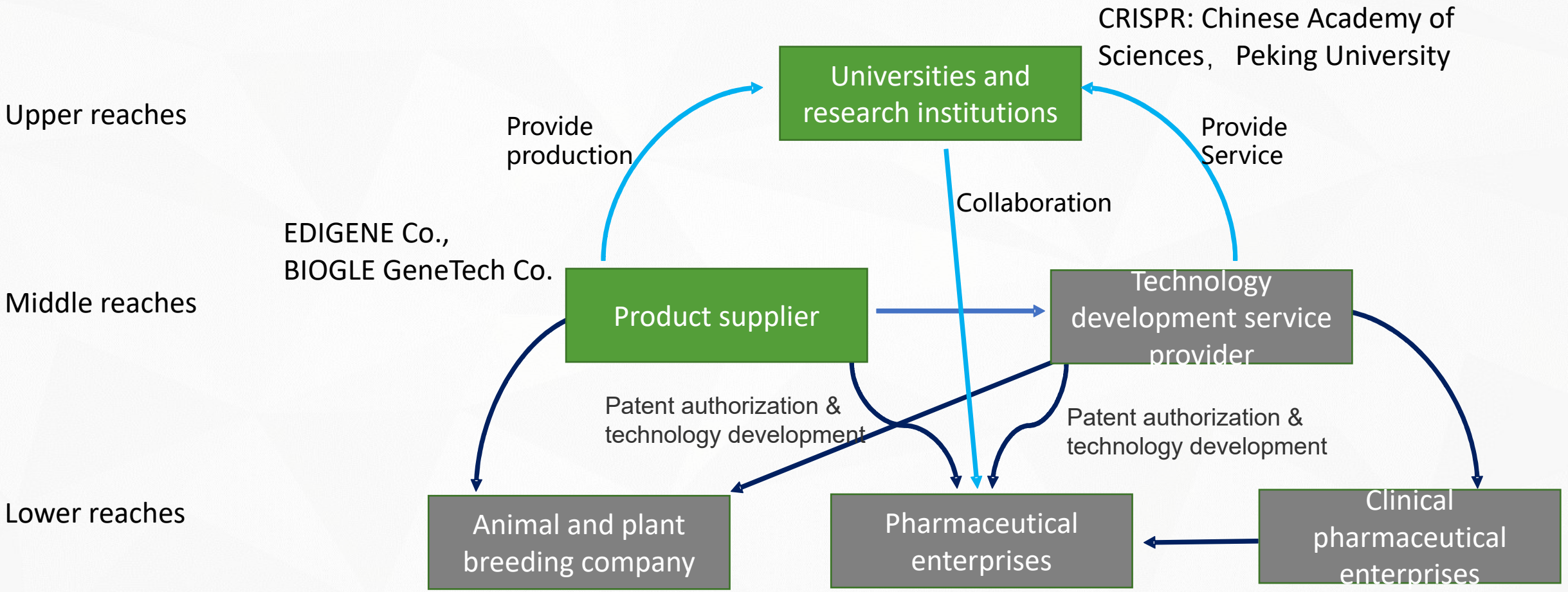
(2) If the elements of gene editing are introduced in the form of DNA vector in the development process, it must be completely removed

(3) Accurately report and record detailed DNA sequence changes at the target site.

(4) Ensure that the main targets in the product do not have unexpected secondary editing events.

(5) The above four points shall be described in detail in the registration data of new varieties. Only on the basis of meeting the above five conditions can genome editing crop products be subject to the same supervision as conventional breeding crops before entering the market

Industrial chain layout expectation



Thanks for your attention!