Al-Farabi Kazakh National University (KazNU)

Faculty of Biology and Biotechnology

Department of Molecular Biology and Genetics

Discipline: «Modern Problems of Plant Genetics»

Lecture 8

Risks of Modern Biotechnologies and Legal Aspects in Agriculture

Global biotech crop trajectory, agritech economics, ecological & IP risks, food security vs safety, international treaties, and Kazakhstan legal governance

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Aim and Structure of the Lecture

Aim: critically examine biological, socio-economic, and legal dimensions governing agricultural biotechnology worldwide and in Kazakhstan

KEY FOCUS

Lecture Plan & Modules

Key sections:
1. Global Adoption & Economics
2. Ecological & Agronomic Risks
3. Food Security vs Food Safety
4. IP, Patents & Farmers' Rights
5. Global Regulatory Divergence
6. Kazakhstan & EAEU Law

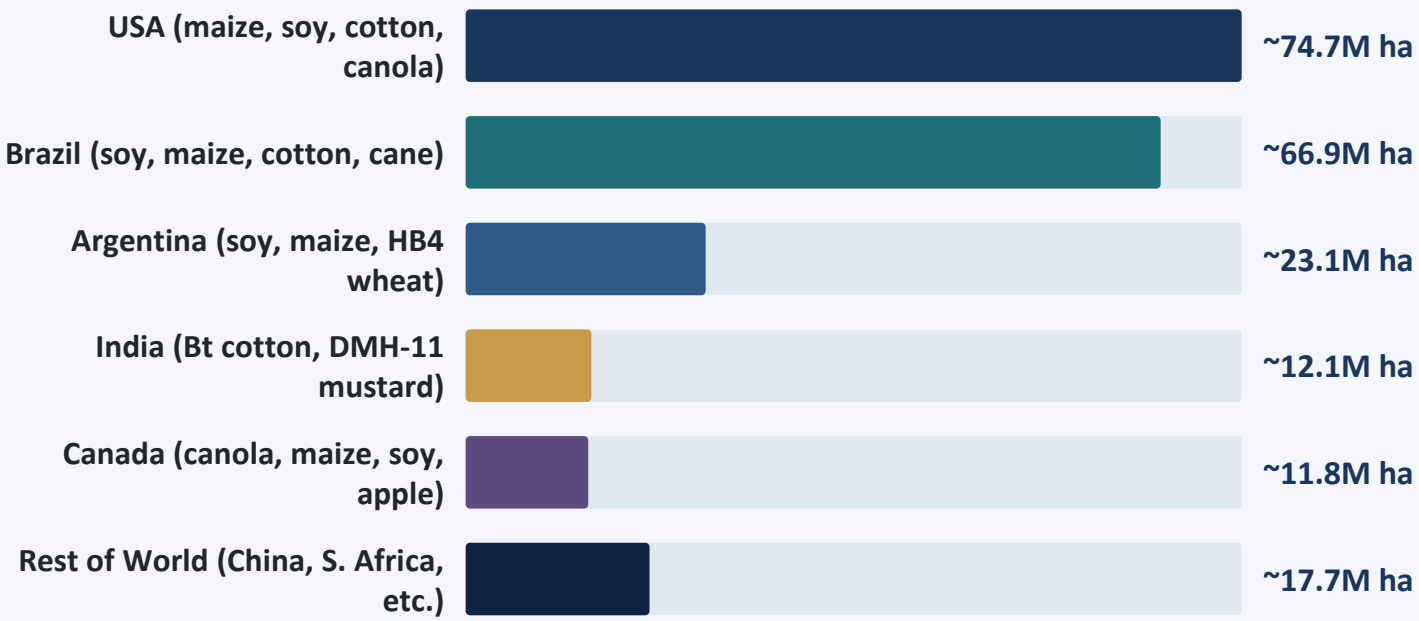
- **Global Adoption & Economics:** Three-decade expansion (>206M ha biotech crops globally) and Agritech market trajectory to 2034
- **Ecological & Agronomic Risks:** Weed resistance, gene flow, agrobiodiversity concentration, and mitigation via multi-trait stewardship
- **Food Security vs Food Safety:** Distinguishing FAO's four food security pillars from toxicological/microbiological food safety standards
- **IP, Patents & Farmers' Rights:** Balancing biotech patent incentives, UPOV Plant Breeders' Rights, and Nagoya Protocol benefit-sharing
- **Global Regulatory Divergence:** WTO SPS/TBT, Cartagena Protocol, Codex Alimentarius, and contrasting US/EU/Asia governance
- **Kazakhstan & EAEU Law:** Kazakhstani Law on Genetic Engineering, EAEU Technical Regulations (TR TS 021/022), and public trust

Global Biotech Crop Adoption and Agritech Market Scale

Consistent expansion over 28+ commercial seasons paired with precision-breeding and digital agriculture growth (2024–2026)

>206M ha	27+	$106.6B	$242.2B
Global Biotech Area	Planting Countries	Agritech Market 2024	Forecast 2034 (8.5% CAGR)

Top Biotech Crop Adopting Countries (Million Hectares)



Crop Share & Emerging Shift

- Soybean (~50%), maize (~33%), cotton (~11%), and canola (~5%) account for ~99% of planted area
- Stacked HT + IR traits now cover >45% of global biotech hectares, boosting management flexibility
- Drought-tolerant wheat (HB4), Bt cowpea, and CRISPR crops expand developing-world share

Sources: AgbioInvestor GM Monitor (2023/2024 global area 206.3M ha across 27 planting + 45 importing countries); Global Market Insights Agritech forecast.

Four Decades of Agricultural Biotech and Biosafety Law

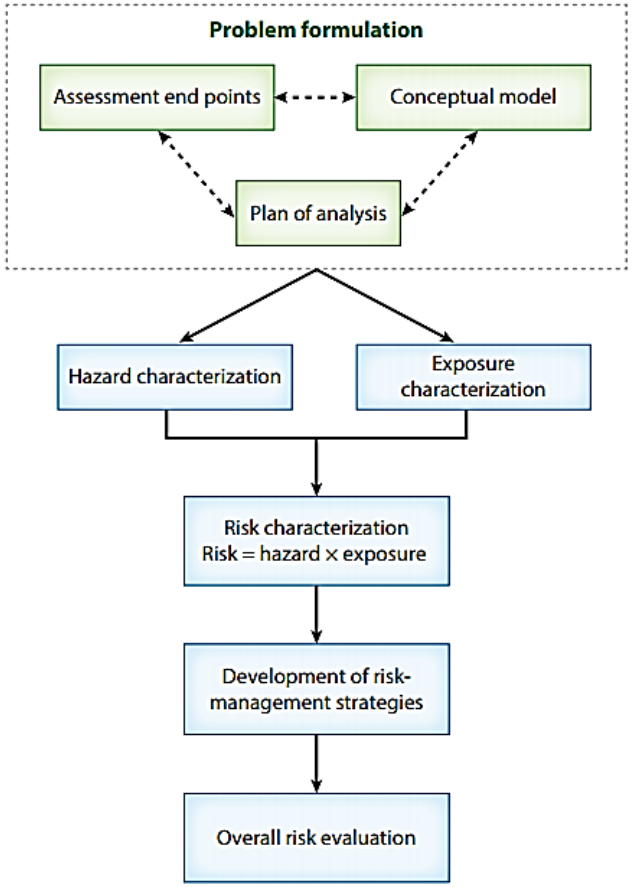
Co-evolution of genetic engineering capabilities and international legal governance

1986–1994	1996–2005	2006–2015	2016–2026
Foundational Rules	**Global Take-Off**	**Stacked Traits & IP**	**Genome-Editing Era**
▸ US Coordinated Framework (1986) splits EPA/FDA/USDA duties ▸ **Flavr Savr tomato (1994):** first commercial transgenic food	▸ Commercial launch of Bt maize/cotton & RR soybean ▸ Cartagena Protocol enters force (2003); EU Reg 1829/2003	▸ Multigene trait stacks & RNAi rootworm defense emerge ▸ Nagoya Protocol (ABS, 2014) curbs biopiracy risks	▸ Argentina, USA, Japan, UK & India exempt SDN-1 edits ▸ GABA tomato & HB4 drought-tolerant wheat commercialized

Multidimensional Risk Landscape in Agricultural Biotechnology

Technical biosafety risks operate alongside economic concentration and societal governance challenges

- **Agronomic Weed & Pest Shifts:** Over-reliance on single herbicide modes (glyphosate) selected >50 resistant weed species globally; Secondary non-target pests can rise when broad-spectrum sprays decline
- **Ecological & Gene-Flow Risks:** Outcrossing of fitness-enhancing transgenes into sexually compatible wild landraces (e.g., weedy rice); Requires mapping regional centers of crop origin prior to field release
- **Socio-Economic & Seed Consolidation:** High regulatory compliance costs ($50M–$150M per GM event) favor large multinational corporations; Restricts smallholders and public universities from commercializing local orphan crops
- **Consumer Trust & Trade Friction:** Zero-tolerance thresholds for unapproved events trigger port rejections and cargo losses; Polarized risk perceptions necessitate transparent science communication



Multidimensional environmental risk landscape in agri-biotechnology

Food Security vs Food Safety: Complementary Policy Pillars

Distinguishing macro-level nutritional access from biological and chemical product wholesomeness

Food Security (FAO Four Pillars)

- **Availability:** reliable domestic production, yield stability, reserves, and resilient supply chains
- **Access:** physical infrastructure and economic purchasing power for nutritious diets
- **Utilization:** dietary diversity, micronutrient adequacy, clean water, and sanitation
- **Stability:** resilience against droughts, pandemics, fertilizer price spikes, and geopolitical shocks

Food Safety (Codex & Sanitary Standards)

- **Microbiological control:** preventing Salmonella, Listeria, E. coli, and mycotoxin contamination
- **Chemical & residue compliance:** heavy metals, pesticide MRLs, veterinary drugs, processing toxins
- Biotech allergenicity & toxicology verification prior to market authorization
- Traceability systems (ISO 22000, HACCP) enabling rapid recall and supply-chain accountability

Biotechnology Risk Scenarios and Evidence-Based Mitigations

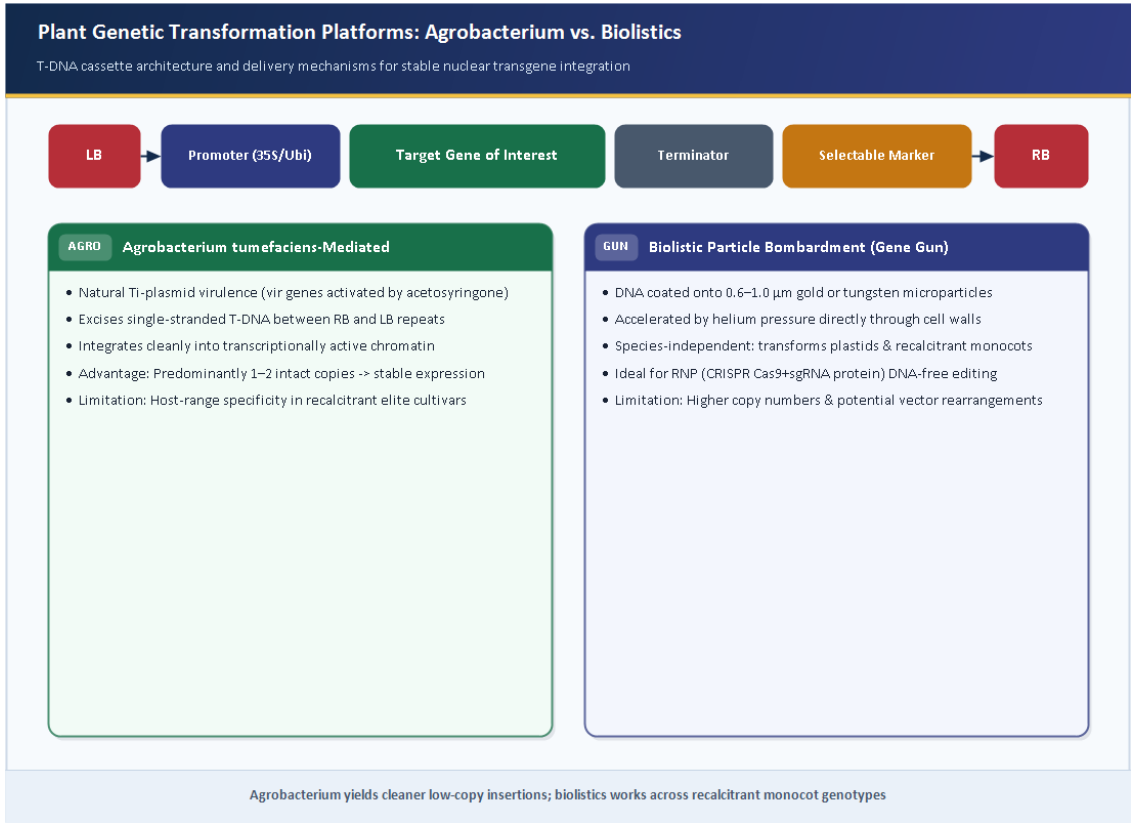
Scientific stewardship converts theoretical hazards into manageable operational protocols

Risk Domain	Causal Mechanism	Documented Example	Scientific & Legal Mitigation
Herbicide-Tolerant Weeds	Continuous mono-cropping & single-herbicide spraying	Glyphosate-resistant Amaranthus palmeri in Americas	Rotate modes of action (dicamba/2,4-D/HPPD), cover crops, integrated tillage
Target Insect Resistance	Sub-lethal toxin dose + lack of susceptible mates	Pink bollworm Cry1Ac field resistance in India	Pyramided Cry+Vip+RNAi stacks paired with mandatory 5–20% non-Bt refuges
Cross-Pollination / LLP	Pollen drift or shared grain handling equipment	Triffid flax & StarLink maize supply disruptions	Biological isolation (plastid/sterility), spatial buffers, validated PCR tests
Genetic Erosion	Widespread adoption of few elite uniform cultivars	Decline in regional landrace cultivation	Seed banks (Svalbard, national NGB), participatory public breeding, ABS sharing
Biosafety Cost Barrier	Prohibitive deregulation expenses for minor crops	Delayed Vitamin-A crops & orphan legumes	Harmonized SDN-1 exemptions for edits mimicking natural mutations

Intellectual Property, Seed Patents, and Farmers' Rights

Legal instruments balance corporate R&D returns against biodiversity sovereignty and public access

- **Innovation Incentives:** Patents vs UPOV PBR: Utility Patents: grant ~20-year exclusivity over recombinant constructs, promoters, and trait technologies; prohibit seed saving
- **UPOV Plant Breeders' Rights (1991 Act):** protects distinct, uniform, stable (DUS) varieties while keeping Breeder's Exemption
- Research Exemption enables universities to use commercial germplasm for further breeding
- Gene-editing licenses increasingly separate commercial royalty tiers from humanitarian royalty-free waivers
- **Genetic Sovereignty & Farmers' Privilege:** Nagoya Protocol (ABS): requires Prior Informed Consent (PIC) & Mutually Agreed Terms when accessing national germplasm
- **ITPGRFA (FAO Plant Treaty):** Multilateral System pools 64 food/forage crops for fair global breeding exchange



Transgene cassette design, event traceability & IP protection

International Legal Architecture Governing Biotech Trade

Tension frequently arises between CBD precautionary trade restrictions and WTO science-based market access

KEY FOCUS

Key Classification

Focus on the biological mechanisms and practical significance of this topic.

- **WTO SPS & TBT Agreements:** Binding on 160+ WTO members — Scientific risk assessment & international standards — Prohibits disguised trade barriers lacking empirical safety evidence
- **Codex Alimentarius:** FAO/WHO reference benchmark — Substantial equivalence & clinical safety review — Presumed SPS-compliant benchmark in WTO trade disputes
- **Cartagena Protocol (CBD):** Binding on 173 Parties (excl. USA) — Precautionary Approach & AIA notice — Requires import authorization for living modified seeds/organisms
- **UPOV Convention:** Intergovernmental IP framework — DUS variety testing + Breeder Exemption — Harmonizes plant variety protection across 79 members
- **Nagoya Protocol (CBD):** Binding ABS mechanism (2014) — Benefit-sharing from genetic resources & DSI — Governs Digital Sequence Information (DSI) equity funds (COP16)

Global Divergence in National Crop Biotech Regulations

Jurisdictions diverge sharply on whether transgene-free gene-edited plants require full GMO dossiers

Jurisdiction	Lead Agencies	GM Transgenic Rule	Genome-Edited (SDN-1 / No Foreign DNA)
United States	USDA-APHIS, FDA, EPA	Plant-pest & food consultation + PIP review	Exempt under SECURE Rule if achievable via conventional breeding
European Union	EFSA & European Commission	Strict Directive 2001/18 & Reg 1829/2003	Currently regulated as GMO; Category-1 NGT reform advancing
Canada	CFIA & Health Canada	Plants with Novel Traits (product-triggered)	Exempt from PNT pre-market notice if no foreign DNA & safe history
Japan	MHLW & MAFF	Cartagena domestic safety + labeling	Fast prior notification; no GMO labeling (GABA tomato sold since 2021)
Argentina / Brazil	CONABIA / CTNBio	Event-by-event ERA & commercial clearance	Case-by-case exemption before planting if final genome lacks rDNA

★ Key Takeaway

- Jurisdictions diverge sharply on whether transgene-free gene-edited plants require full GMO dossiers
- **Comparison scope (5):** United States; European Union; Canada; Japan; Argentina / Brazil
- **Priority synthesis:** Argentina / Brazil — Case-by-case exemption before planting if final genome lacks rDNA

Asynchronous Approvals and Global Grain Trade Disruptions

When an exporting country cultivates a biotech variety before importing nations complete regulatory review

Drivers of Regulatory Asynchrony

- Approval timelines vary from 1.5–2 years (USA, Argentina) to 5–8+ years (EU multi-committee voting)
- **Differing tolerance for trace Low-Level Presence (LLP):** 0% zero-tolerance for unapproved events vs practical margins
- Political vetoes by member states in spite of positive EFSA scientific safety opinions
- Unilateral bans often cause grain shipment rerouting without improving measurable consumer safety

Economic Impacts & Harmonization Paths

- Costs include vessel demurrage, costly identity-preserved segregation, and lost feed imports
- **Example:** MIR162 maize asynchronous approval cost billions in stalled cross-Pacific grain shipments
- Global Low-Level Presence Initiative (GLI) promotes joint safety dossiers and quantitative risk thresholds
- Convergence on SDN-1 exemptions reduces trade friction for transgene-free CRISPR varieties

Legal Pathway for Biotech R&D and Release in Kazakhstan

National governance integrates ecological expertise, sanitary safety, and Eurasian Economic Union customs rules

1 Contained R&D

- Accredited KazNU / NCB labs follow BSL containment
- Biosafety inventory of recombinant constructs

2 Ecological Review

- State Ecological Expertise evaluates ERA dossier
- Assesses steppe flora outcrossing & soil impacts

Stage 3 Variety & Food Test

- State Variety Testing Commission agronomic trials
- Sanitary–epidemiological compliance (TR TS 021)

Stage 4 Registry & Labeling

- Inclusion in State Register + event PCR checks
- Mandatory EAEU >0.9% GMO consumer labeling

Regulatory updates aim to align Kazakhstan's legislation with Cartagena Protocol obligations and modern precision breeding standards.

Republic of Kazakhstan and EAEU Regulatory Instruments

Domestic statutes work in tandem with supranational Eurasian Economic Union technical regulations

KEY FOCUS

Core Analytical Focus

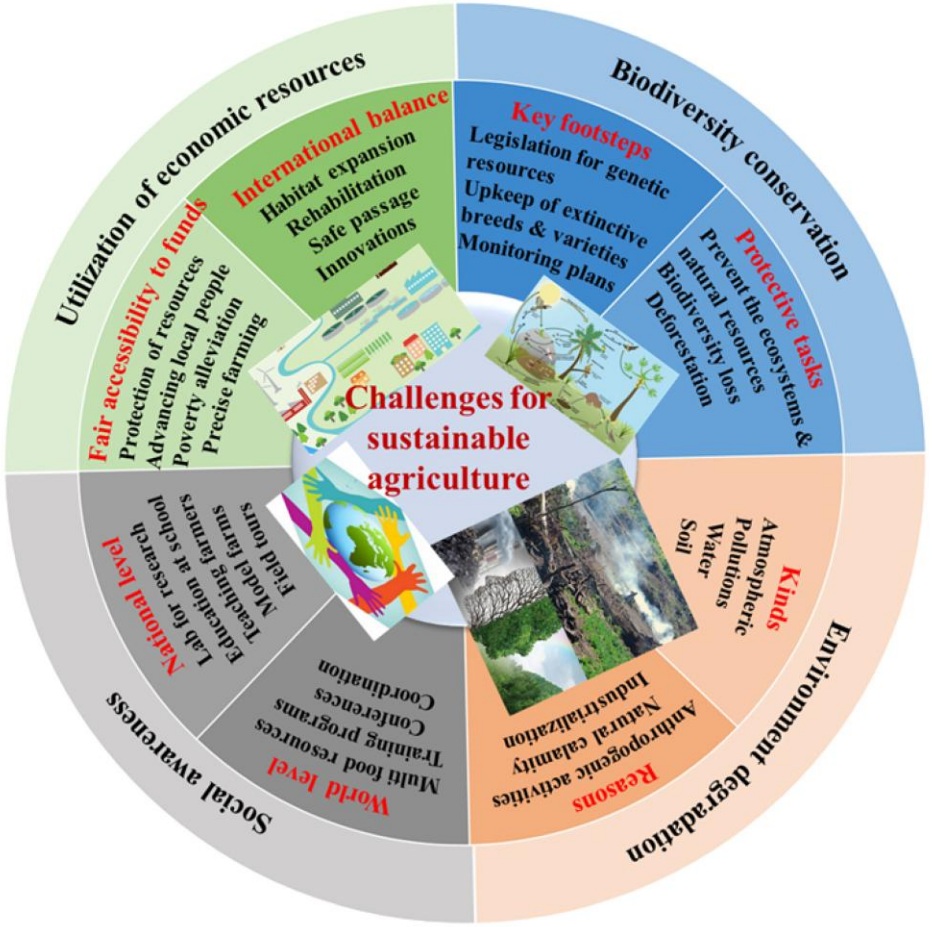
Key sections:
1. RK Genetic Engineering Law
2. EAEU TR TS 021/2011 & 022/2011
3. RK Environmental Code & CBD
4. Laws on Seeds & Science Policy

- **RK Genetic Engineering Law:** Law «On State Regulation of Genetic Engineering Activity» governs containment, safety monitoring, and risk assessment; Clarifies licensing, public registry access, and liability for unauthorized environmental release
- **EAEU TR TS 021/2011 & 022/2011:** Technical Regulations on Food Safety & Food Labeling mandate pre-market registration of GMO food/feed lines; Sets 0.9% accidental threshold requiring prominent «Contains GMO» package labeling above limit
- **RK Environmental Code & CBD:** Kazakhstan is a Party to the Convention on Biological Diversity and implements national biosafety impact assessments; Safeguards native wild apple (Malus sieversii) and cereal genetic reserves in Alatau & steppe ecosystems
- **Laws on Seeds & Science Policy:** RK Law «On Seed Production» & IP statutes protect registered varieties and national breeding institutes; Supports modern marker-assisted and CRISPR R&D at KazNU, National Center for Biotechnology (NCB), and KazNIIZ

Public Perception, Bioethics, and Science Communication

Why scientific consensus (~90% AAAS/NAS) does not automatically translate into public acceptance

- **Roots of Public Skepticism:** Heuristic biases: unfamiliarity, «naturalness» bias, and conflation of genetic traits with agrochemical monopolies
- Lack of visible consumer benefits in first-generation herbicide/insect traits (farmer-oriented, not nutritional)
- Sensationalized media coverage of retracted or poorly controlled animal studies
- Distrust when regulatory processes appear opaque or overly corporate-driven
- **Building Evidence-Based Trust:** Transparent public-sector research on consumer-valued traits (nutritional quality, zero pesticides, climate rescue)
- Full open access to toxicology, allergenicity, and ERA raw data via EFSA/FDA portals



Balancing public perception, bioethics and sustainable food security

Control Questions and Key Takeaways

Connecting biological risk governance with international and national law

? Control & Review Questions

- 1. How large is global biotech crop adoption today, and which four crops and five countries lead production?
- 2. Compare the risks of herbicide-resistant weeds and gene flow to wild relatives, and explain how each is mitigated.
- 3. Distinguish the four FAO pillars of Food Security from Food Safety regulatory standards.
- 4. Contrast the legal mandates of WTO SPS/TBT vs the Cartagena and Nagoya Protocols.
- 5. Summarize how EAEU Technical Regulations (TR TS 021/022) and Kazakhstan laws regulate GM products and labeling.

✓ Key Takeaways

- Biotech crops cover >206M ha globally, while Agritech expands at 8.5% CAGR toward $242.2B by 2034.
- Agronomic and ecological risks (resistant weeds, gene flow, LLP) are manageable through stewardship & containment.
- Global regulatory divergence over SDN-1 gene editing creates asynchronous trade barriers awaiting harmonization.
- Kazakhstan enforces biosafety via state ecological/sanitary reviews and EAEU >0.9% GMO labeling standards.

Recommended Literature and Legal Resources

Authoritative global reports, treaties, and national statutory frameworks

1 Main Literature

- 1. AgbioInvestor / ISAAA. Global Status of Commercialized Biotech/GM Crops (annual adoption & country profiles).
- **2. FAO (2023). Gene Editing and Agrifood Systems:** Opportunities, Risks and Regulatory Governance. Rome: FAO.
- 3. Secretariat of the Convention on Biological Diversity (2000/2010). Text of the Cartagena Protocol on Biosafety & Nagoya–Kuala Lumpur Protocol.
- 4. EAEU Technical Regulations TR TS 021/2011 («On Food Safety») and TR TS 022/2011 («Food Products in Terms of Labeling»).

2 Additional Literature & Databases

- 1. Turnbull, C., Lillemo, M., Hvoslef-Eide, T.A.K. (2021). Global Regulation of Genetically Modified Crops Amid the Gene Edited Crop Boom. Frontiers in Plant Science.
- 2. Smyth, S.J., Phillips, P.W.B., Castle, D. (Eds.). Handbook on Agriculture, Biotechnology and Development. Edward Elgar.
- **3. Republic of Kazakhstan Statutory Portal (adilet.zan.kz) —** Laws on State Regulation of Genetic Engineering Activity & Seed Production.
- 4. Global Market Insights / FAO SOFI (2024–2025). Global Agritech Market Trajectory and Food Security Outlook.

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