Essentially Derived Varieties in Europe and America: Legislation System, Practices and Case Studies

欧洲和美国的实质性派生品种：法律体系、实践和案例研究

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EDV: Answering Key Questions
实质性派生品种（EDV）：解答关键问题

- Why is the EDV concept needed?

  为何要引入EDV概念？
- Who decides if a variety is an EDV?

  谁来决定一个品种是否为EDV？
- How to decide if a variety is an EDV?

  如何确定一个品种是否为EDV？
- Case Studies-Practical Examples

  案例研究 – 实践示例
- Conclusions-Discussion

  结论-讨论
  - Intellectual Property and genetic gain

    知识产权和遗传增益

The Purpose of the EDV Concept
EDV概念的目的

- “To ensure sustainable plant breeding development by:
  “通过如下方式确保植物育种的可持续发展：
  - Providing effective protection for the classical breeder
    为传统育种者提供有效保护
  - Encouraging cooperation between classical breeders and developers of new technologies such as genetic modification” (UPOV)
    鼓励传统育种者和新技术（例如基因修饰）研发者之间的合作”（UPOV）

EDV and Genetic Transformation
EDV和遗传转化

Initial protected variety
初始受保护品种

Transformed variety with essential characteristics of initial variety
具有初始品种基本特征的转化品种

Without EDV concept, developer of transformed variety captures all the ownership rights of the Initial variety. Undermines future research incentives of first breeder.

如果没有EDV概念，转化品种的研发者会获得初始品种的全部所有权。逐渐削弱首位育种者进一步研究的积极性。

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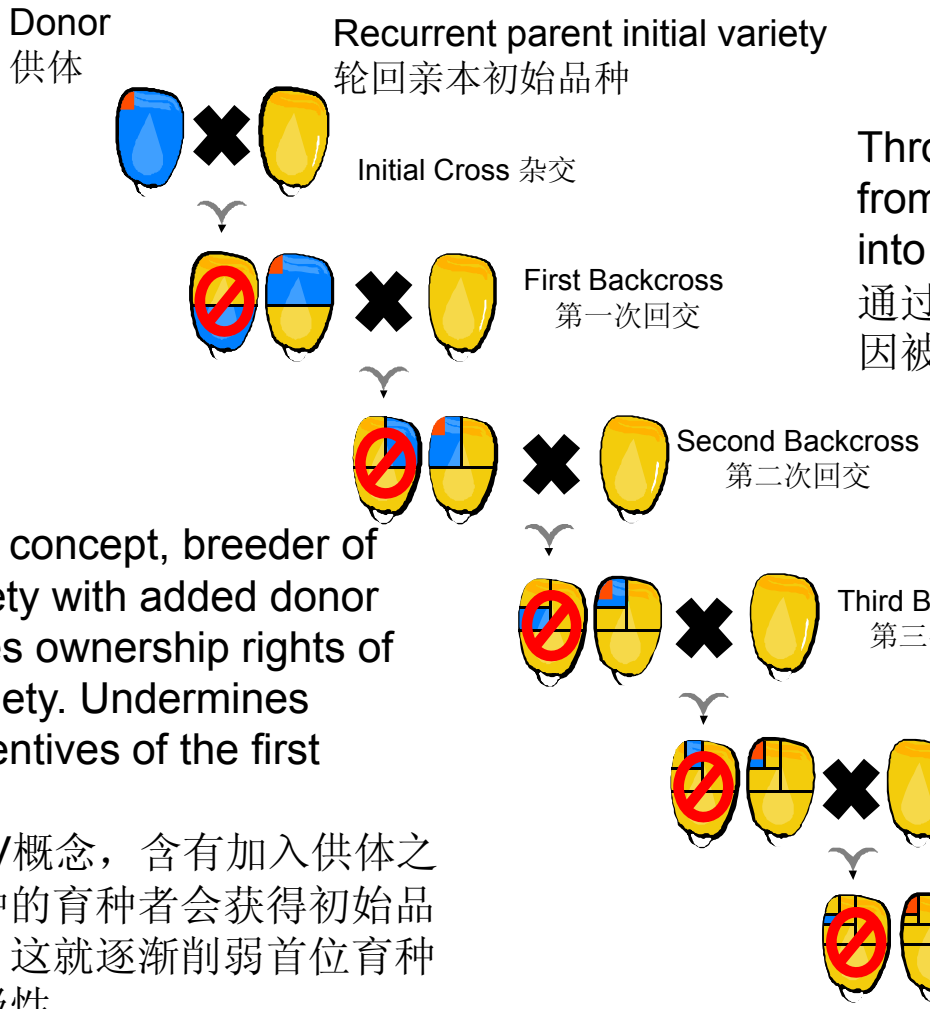
EDV and Backcrossing
EDV与回交



Through backcrossing, desired genes from a “donor” plant are integrated into elite Germplasm
通过回交，来自“供体”植物的所需基因被整合至良种种质

Without EDV concept, breeder of the new variety with added donor gene captures ownership rights of the initial variety. Undermines research incentives of the first breeder.
如果没有EDV概念，含有加入供体之基因的新品种的育种者会获得初始品种的所有权，这就逐渐削弱首位育种者的研究积极性。

New variety with donor gene
具有供体基因的新品种

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Essentially Derived Varieties

- predominantly derived from 'A'
- retains expression of essential chars. of 'A'
- clearly distinguishable from 'A'
-conforms to 'A' in essential chars.
(except for differences from act of derivation)

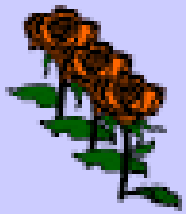
- 主要从“A”派生
- 保留A的基本特征表达
- 与A明显区分
- 在基本特征方面与“A”一致
（除了与派生行为不同之外）

Breeder 1 育种者1

Initial Variety 'A'
(Protected)
初始品种“A”
（受保护）

Predominantly derived
主要派生

Breeder 2
育种者2



Essentially Derived Variety 'B'
实质性派生品种“B”

授权品种B的商业化必要步骤

Authorization to commercialize variety B REQUIRED

Commercialization
商业化

Who decides if a Variety is an EDV?
谁来决定一个品种是否为EDV？

International Seed Federation 2005
国际种子联合会 2005

- "(EDV) mainly involves questions of scope of protection and enforcement of the rights of the breeder."

  "(EDV)主要涉及有关保护范围和育种者权利实施的问题。"

- It is the initiative of the breeder to enforce these rights.

  育种者应带头主张实施这些权利。

- "The determination of essential derivation is not part of the procedure of the granting of the Breeder's Right."

  "实质派生的确定并不是育种者权利授予程序的一部分。"

- Regulation for the Arbitration of Disputes concerning Essential Derivation (RED) 实质派生争议仲裁法规（RED）
  - (www.worldseed.org/cms/medias/file/Rules/EssentialDerivation/RED_Arbitration_EDV.pdf)
- Crop Specific guidelines 农作物特别指导原则 (www.worldseed.org)
  - Cotton 棉花 (*Gossypium hirsutum*) (ISF 2007), lettuce 莴苣 (*Lactuca sativa* (ISF 2004), maize 玉米 (ISF 2008), oilseed rape 油菜(*Brassica rapa*) (ISF 2007) and ryegrass 黑麦草(*Lolium perenne* L.) (ISF 2009).

European Union Community Plant Variety Office
欧盟植物品种办公室

- “There is no role for authorities charged with granting plant variety rights to determine whether a variety is an EDV” (Kiewiet 2006).

  确定一个品种是否为EDV并非负责授予植物品种权利的监管机构的职责”（Kiewiet 2006）。

Law Courts Can Decide
法庭可以确定

- Wheat (Triticum aestivum L.), succession of court hearings has now reached a High Court in Germany after 10 years (UPOV BMT 2011).
  小麦，经过10年，法院听证的终于到达了德国的最高法院（UPOV BMT 2011）。
- After 8 years in litigation the Court of Appeal in The Hague (Danziger Flower Farm vs. Astee Flowers) ruled that Blancanieves (Gypsophilia spp.) was not an EDV.
  8年诉讼之后，海牙上诉法院（Danziger Flower Farm 与 Astee Flowers) 裁定 Blancanieves（满天星属）并非EDV。
- The District Court of The Hague (Van Zanten Plants BV vs. Hofland B.V.) supported plaintiff in a Freesia spp. EDV case.
  海牙州地方法院（Van Zanten Plants BV 与 Hofland B.V）在小苍兰属EDV案例中支持了原告。

Despite Guidance from UPOV some PVP Offices have chosen to decide
尽管有UPOV指导原则，但某些PVP办公室已决定

- Australia PVP Act

  澳大利亚PVP法案

  - No EDVs declared to date

    迄今为止还没有宣布有EDV

- Indian PPV-FRA

  印度PPV-FRA

  - Can even apply for an EDV certificate

    甚至可以申请EDV证书

  - Not UPOV compliant

    不符合UPOV

How to Decide if a Variety is an EDV?
怎样确定一个品种是否为EDV?

- "The EDV provision is appropriate but the definition is unclear, and there are few established protocols for making EDV determinations.

  "EDV条款是合适的，但是定义尚不明确，并且制定EDV决议的公认协议少之又少。

- There is scope for improvement in this area."
  该领域尚有改善的空间。"

  - Advisory body to the EU Community PVP Office (GHK 2011)
    欧盟PVP办公室顾问机构（GHK 2011）

Providing Solutions: Involvement of Plant Breeders
提供解决方案：涉及植物育种者

- Breeders value an IP process that is simple, predictive, and that avoids diversion of resources or delays caused by protracted legal disputes.
  育种者重视简单、具有预测性的知识产权程序，该程序能避免资源转移或避免由受保护的法律争议引起的延迟。
- Advantageous for breeders and other technical experts to create guidelines on how to determine EDV status.
  有利于育种者和其他技术专家制定出如何确定EDV状态的指导原则。
- Feared the absence of guidelines would increase prospects for litigation. 担心缺少相关指导原则会提高产生诉讼的机率。
  - Legal examples seem to support this concern
    法律案例似乎正是印证了该忧虑

How to Decide if a Variety is an EDV?
怎样确定一个品种是不是EDV?

- Requirement 1-Conformity

  要求1 – 一致性

  - Conformity to the initial variety in the expression of the essential characteristics that result from the genotype or the combination of genotypes of the initial variety

    由基因型或初始品种的基因型组合产生的基本特征表达与初始品种一致

    - ISF View on IP (2009)
      ISF对IP的观点（2009）

How to Decide if a Variety is an EDV?
怎样确定一个品种是不是EDV?

- Requirement 2-Predominant Derivation

  要求2-主要的派生

  - Implies that the initial variety has been used in the breeding process. 意味着初始品种已经用于育种过程
  - To prove that use, various criteria or a combination thereof may be used: 为了证明该使用，可能使用多种标准或其组合：
    - Combining ability (heterosis) 结合能力（杂种优势）
    - Phenotypic characteristics 表型特征
    - Molecular characteristics 分子特征
  - Breeding records 育种记录
    - ISF View on IP (2009)

      ISF对IP的观点（2009）

Evidence to help determine an EDV?
有助于确定EDV的证据？

- Heterosis and phenotypic characteristics require replicated field testing. 杂种优势和表型特征需要重复的田间试验。
  - Very consuming of time and of other resources.
    非常消耗时间及其他资源。
- Proprietary parental inbred lines are not usually freely available to the owner of the initial variety.
  初始品种的所有者通常不能自由地得到专有的亲本自交系。
- Pedigree data of the suspected EDV may also not be readily available, or could be in error.
  可能也不容易得到待查的EDV的系谱数据，或者得到的数据可能是错误的。
- Molecular data are often the only initial source of evidential data available to the owner of the initial variety.
  分子数据通常是初始品种的所有者能够得到的可作证据数据的唯一初始来源

Evidence to help determine an EDV?
有助于确定EDV的证据？

- The owner of the initial variety will usually be disadvantaged in respect of being able to obtain the information required to determine EDV status.

  在能够获取确定EDV状态所需信息的方面，初始品种的所有者通常处于不利位置。

- Therefore, ISF insists on the necessity of clearly defining a starting point in determining dependence or conformity (ISF 2005).

  因此，ISF主张在确定依赖性或一致性时需要明确地定义起点（ISF 2005）

- "For *prima facie* proof, the following elements should be sufficient to cause a reversal of the burden of proof:

  "对于初步证据，下列元素应该足以引起举证责任的逆转：

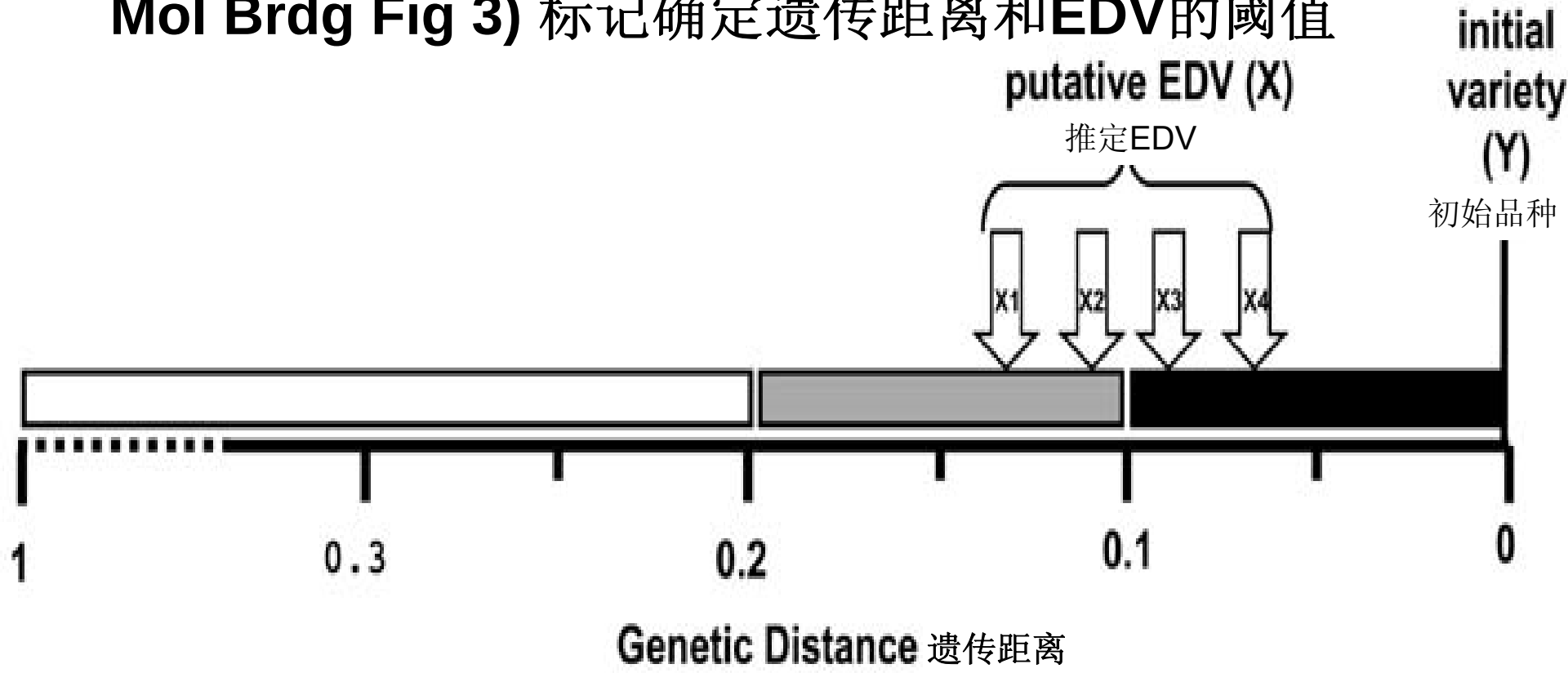
  - Strong phenotypic similarity 强有力的表型相似性
    - Only small differences in some simply inherited characteristics
      仅有某些简单遗传性状方面的较小差异
    - Strong genetic similarity
      强有力的遗传相似性

Evidence to help determine an EDV?
有助于确定EDV的证据？

- ISF (2006) states: “DNA markers may be used to define genetic similarity trigger points for starting a dispute resolution process in cases of alleged essential derivation.”

  ISF（2006）声称：“DNA标记可能用于定义遗传相似性触发点，以在提起的关于实质性派生的案例中启动争议解决程序。”

Marker determined thresholds of genetic distance (1-similarity) and EDV (Heckenberger et al., 2002 Mol Brdg Fig 3) 标记确定遗传距离和EDV的阈值



zone of non-distinctness or indisputable essential derivation 无区别或无可争辩的实质性派生区域

zone of uncertainty 不确定区域

zone of non-derivation (independence) 非派生区域（独立）

Case Studies: Guidelines Procedures adopted by Breeders
案例研究：指导原则育种者采用的程序

- Work on a crop specific basis 在特定农作物的基础上进行
- Select well-known varieties including pairs known to be very similar by pedigree and agronomic performance
  选择著名品种，包括已知的系谱和农学性能非常相似的配对
  - Including pairs that breeders could agree would be putative EDVs
    包括那些育种者同意是假定的EDV的配对
- Profile varieties using markers 使用标记综合分析品种的基本情况
- Compute genetic distances 计算遗传距离
- Determine protocols 确定研究方案
- Establish marker based thresholds 确定基于标记的阈值
  - To reverse burden of proof 举证责任的逆转
  - Also to provide contributing evidence 提供有用的证据

Case Studies: ISF EDV Protocols
案例研究：ISF EDV方案

- The ISF provides EDV guidelines for:
  ISF为以下品种提供EDV指导原则：
  - Cotton 棉花 (*Gossypium hirsutum*) (ISF 2007),
  - Lettuce 莴苣 (*Lactuca sativa* (ISF 2004),
  - Maize 玉米 (ISF 2008),
  - Oilseed rape 油菜 (*Brassica rapa*) (ISF 2007),
  - and 和
  - Ryegrass 黑麦草 (*Lolium perenne* L.) (ISF 2009).

Case Studies: Establishing Guidelines for Maize in the US and Europe
案例研究：在美国和欧洲制定玉米指导原则

- Under the auspices of the ISF the following RFLP-based thresholds agreed (UPOV BMT 2007):
  在ISF的支持下，下列基于RFLP的阈值已达成一致（UPOV BMT 2007）：
  - Red zone: above 90% of similarity 红色区域：高于90%相似性
  - Orange zone: between 90 and 85% 橙色区域：90~85%之间
  - Green zone: below 85% 绿色区域：低于85%
- New analyses (2010) using SSRs completed by ASTA and SEPROMA -> New thresholds:
  由ASTA和SEPROMA完成的使用SSR的新分析（2010）->新的阈值：
- Red zone: above 90% of similarity 红色区域：高于90%相似性
  - Orange zone: between 90 and 82% 橙色区域：90~82%之间
  - Green zone: below 82% 绿色区域：低于82%

Case Studies: Establishing Guidelines for Maize
案例研究：确立玉米指导原则

- 2011-2012
  - ASTA+UFS SNP study near completion
    ASTA+UFS SNP研究几近完成
  - 50K Infinium SNP chip (publicly available SNPs)
    50K Infinium SNP芯片（公开可得的SNPs）
  - Profile maize inbreds of known pedigree
    综合分析已知系谱的玉米近亲交配
  - 26,874 SNPs fit for purpose
    26,874 SNPs 适用于该目的
  - Compare with SSR data to translate to SNP thresholds
    与SSR数据比较以转换为SNP阈值
- Other countries – regions could adopt same approach using their representative germplasm to determine EDV thresholds.
  其他国家 – 各地区可以使用其各自的种质、采用相同的方法来确定EDV阈值
- Sequence based markers should be mostly platform independent and so protocols should not need revising on a regular basis!
  以序列为基础的标记应该是一个独立的平台，因此无需定期修改协议

Conclusions and Discussion
结论及讨论

Significance of Plant Variety Protection System

植物品种保护系统的重要性

investment

Breeders

Further breeding

Collection of fund

PVP system

Breeding of New Variety

Registration

Exclusive property

Positive cycle

Plant varieties can be easily propagated

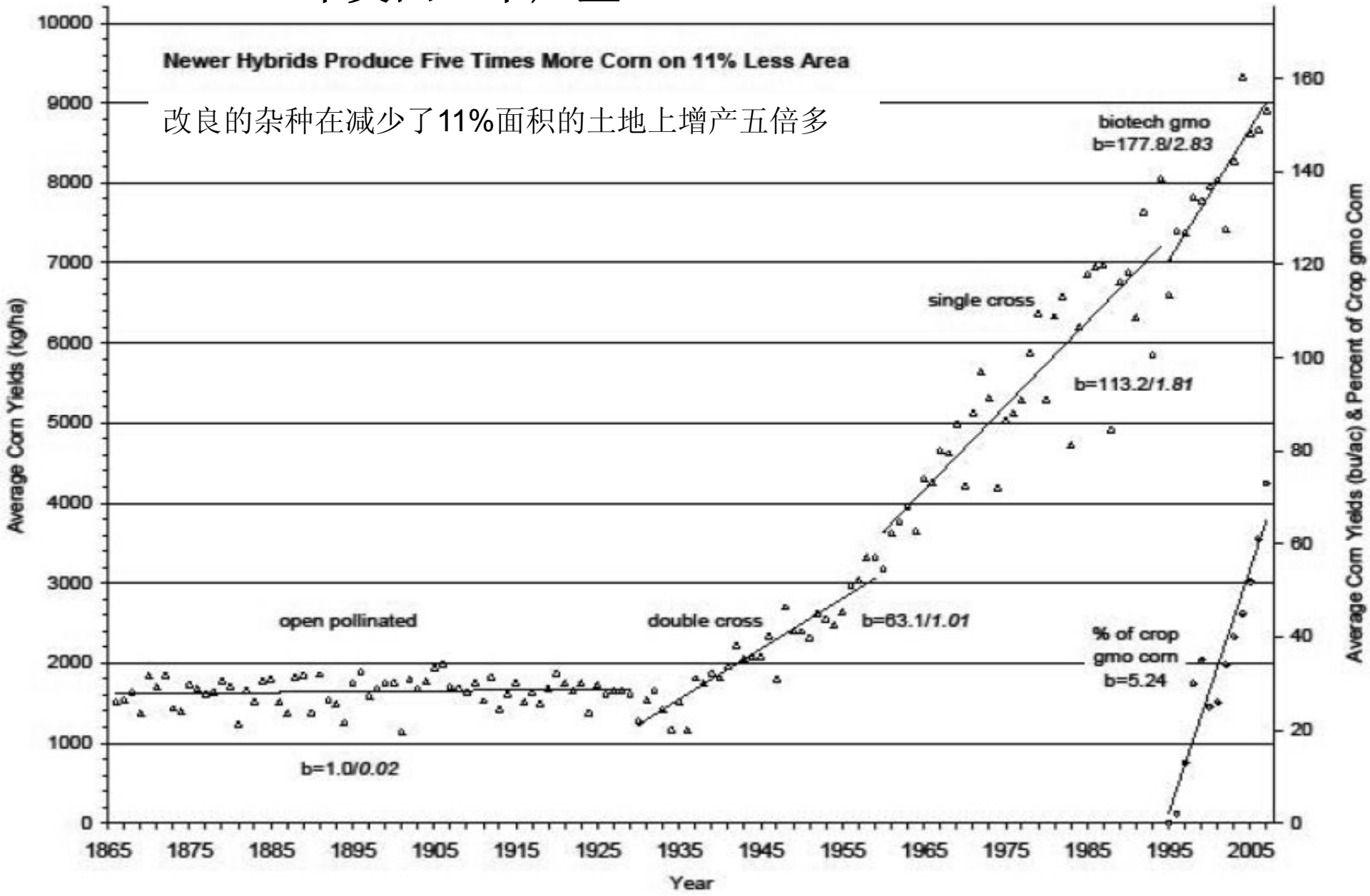
Development of breeding

Promotion of breeding of new variety

Developing of Agricultural industry based on new varieties

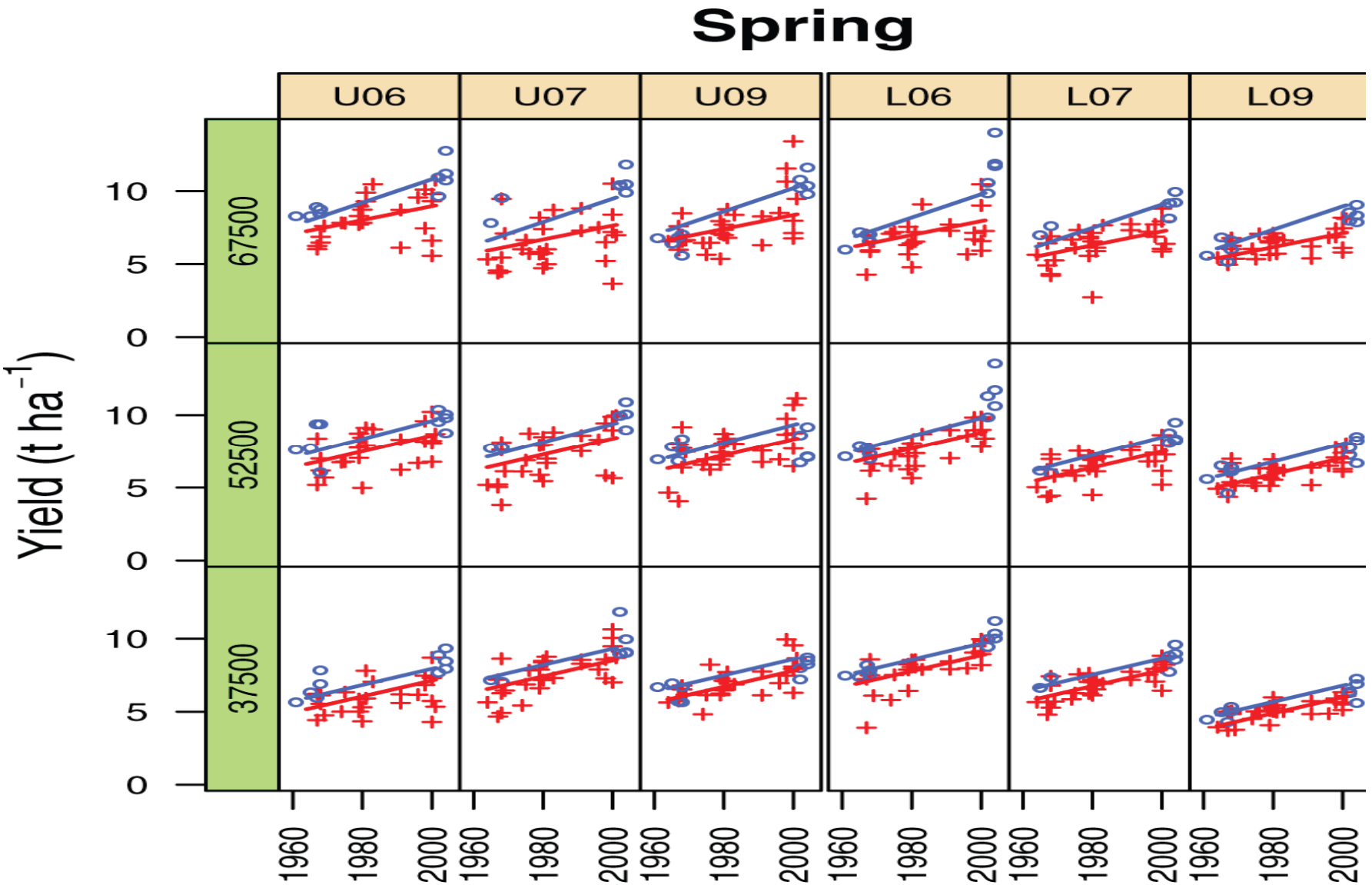
Maize Yields US 1865-2005
1865-2005年美国玉米产量

Troyer, Crop Science
46: 528-543 (2006)



China Maize Yields Increase at Higher Planting Density: Breeding many genetic differences

更高种植密度使中国玉米产量增加：培育多种遗传差异



With an effective EDV system
拥有有效的EDV系统

- Balance of incentives among breeders of IV and later improvers
  平衡初始育种者和后续改良者的积极性
  - Develop new initial varieties and improvement of existing varieties
    开发新的初始品种以及改良现有品种
  - More comprehensive use and supply of germplasm
    更广泛使用和供应种质资源
    - Use by breeders 由育种者使用
    - Supply to meet farmers needs 提供以满足农民需要的品种
  - Increased abilities to prevent cosmetic, plagiaristic, or “me-too” breeding
    提高了预防装饰性、剽窃或“仿制”育种的能力
    - Help ensure high quality varieties and seed
      帮助确保高质量的品种和种子

Without an effective EDV system
没有有效的EDV系统

- Later developer captures ALL of the commercial benefits of the IV
  后续改良者获得初始育种者的所有商业利益
- Undermines incentives:
  逐渐削弱以下工作的积极性：
  - To continue breeding new Ivs
    持续培育新的初始品种
  - For higher risk more substantive genetic change breeding
    对于更高风险的更实质性的遗传改变育种
    - Less use of total germplasm pool 更少使用总种质池
    - Limits productivity gains on farms by breeding 育种限制农场生产力的提高
    - Genetic diversity in agriculture may narrow 农业遗传差异性缩小
    - Greater likelihood of “me-too” breeding and misappropriation-poorer seed quality 仿制育种和盗用的可能性更大：种子质量更差

Concluding Comments
总结评述

- The EDV concept was introduced to encourage both the creation of new improved (initial) varieties that are developed as a result of relatively significant changes in the genome and the making of relatively small genetic changes provided they also contributed significant agronomic improvements

  引入EDV概念，既是为了鼓励新改良（初始）品种（该品种是由基因组的相对显著性的改变开发的）的开发，亦是为了鼓励相对较小的遗传改变（只要它们可促成了显著的农艺改良）

- With transgenic technology in a PVP environment effective use of the EDV concept is ESSENTIAL to protect the IP of the breeder of the initial variety.

  在PVP环境中的转基因技术，有效使用EDV概念对于保护初始品种的育种者的知识产权至关重要。

- In the EU “Most respondents emphasized that the EDV provision discourages ‘plagiarism’ of varieties and facilitates research and investment in breeding activity.” (GHK 2011 stakeholder consultation survey).

  在欧盟，“大部分受访者强调，EDV条款有助杜绝品种的‘剽窃’并促进了育种活动的研究和投资。”（GHK 2011利益相关者咨询调查）。