EHRC Reference Guide
Understanding Regulation (EU) 2016/1012
“Animal Breeding Regulation” – Key Principles for Herd-Book Organizations

Table of Content

EU EHRC Reference Guide
Understanding Regulation (EU) 2016/1012
"Animal Breeding Regulation" – Key Principles for Herd-Book Organizations

---

1. Purpose and Scope

Regulation (EU) **2016/1012 of the European Parliament and the Council** — commonly known as the **Animal Breeding Regulation (ABR)** — establishes harmonized **zootechnical and genealogical rules** across the European Union for:

- **Purebred breeding animals** (bovine, porcine, ovine, caprine, and equine species);
- **Hybrid breeding pigs**; and
- Their **germinal products** (semen, oocytes, embryos).

Its purpose is to:

- Ensure **mutual recognition** of breeding organizations and certificates;
- Facilitate **free trade** of breeding animals and germinal products within the EU; and
- Guarantee **common technical standards** for herd-books, performance testing, and breeding value estimation.

For the **Holstein and Red Holstein breeds**, this Regulation defines the operational and legal framework under which European Herd-Book Organizations must function.

---

2. Recognition of Breed Societies and Breeding Operations

(Articles 4–6, 19–21)

A Herd-Book Organization (HBO) may operate officially only if it is **recognized** by the **competent authority** of an EU Member State.

Essential Criteria for Recognition

A recognized herd-book organization must:

1. Represent active **breeders participating** in its breeding programme.
2. Maintain or establish a **breeding book** (herd-book) for the breed.
3. Define **breed standards and objectives**, ensuring genetic and phenotypic consistency.
4. Guarantee **equal treatment** and open participation for breeders within the approved territory.
5. Provide **transparent internal rules**, including appeal procedures and non-discrimination clauses.
6. Be **subject to supervision** and periodic official control by the national competent authority.

Recognition is granted per **breed and programme**.
Multiple organizations may be recognized for the same breed, provided this does not endanger genetic diversity or the coherence of the breeding population.

---

3. Approval of Breeding Programmes

(Articles 7–10 and Annex III)

Each recognized herd-book organization must operate an **approved breeding programme**.
This document is the foundation of all technical and genetic activities.

The programme must define:

- **Breed definition and population scope** (e.g., Holstein or Red Holstein).
- **Breeding objectives** (production, fertility, health, conformation, efficiency, sustainability).
- **Performance recording and genetic evaluation methods**, including genomic selection procedures.
- **Rules for herd-book entry, data management, and pedigree verification.**
- **Quality assurance systems** and the delegation of technical tasks (if any).
- **Cross-border implementation** arrangements where applicable.

Substantial Modifications

Changes that significantly affect the programme — such as objectives, selection methods, geographical scope, or evaluation systems — must be **notified and re-approved** by the competent authority before implementation.

---

4. Structure and Function of Herd-Books

(Articles 25–29)

Every herd-book must consist of:

- A **Main Section**, where only **purebred animals** with verified ancestry are entered or registered;
- Optionally, **Supplementary Section(s)**, for animals of the same species showing breed characteristics but lacking full pedigree information.

Merit Classification

The Main Section may be subdivided into **classes** based on genetic merit or performance.
Such divisions must be objective and transparent.

Upgrading

Progeny of animals from the Supplementary Section may be **upgraded** to the Main Section after successive generations of mating with purebred animals of the breed.
Upgrading is generally through the **female line**, except for equine species or endangered breeds.

5. Rights and Obligations of Breeders

(Articles 22–24)

Breeders' Rights

- To participate in the breeding programme within its defined territory.
- To have qualifying animals **entered in the herd-book**.
- To receive **zootechnical certificates** for animals and germinal products.
- To appeal any decision affecting participation or registration.

Herd-Book Organization Obligations

- Equal access and non-discrimination among breeders.
- Transparent, documented procedures for entry, recording, and dispute resolution.
- Confidential and accurate data management.
- Cooperation with official controls and external audits.

---

6. Zootechnical Certificates

(Articles 30–34 and Annex V)

A **zootechnical certificate** is the official document (paper or electronic) that must accompany any:

- Purebred breeding animal, or
- Germinal product (semen, oocyte, embryo)
  when traded, transferred between Member States, or registered in another herd-book.

The certificate must include:

- Identification and species;
- Breed and herd-book section;
- Pedigree and parentage details;
- Performance or breeding values (if available);
- Issuing body and date.

Certificates issued by one recognized herd-book must be **mutually accepted** across the EU, ensuring free trade and recognition of genetic evaluations.

---

7. Performance Testing and Genetic Evaluation

(Articles 52–54, Annex III)

The Regulation requires scientifically valid, transparent, and harmonized methods for:

- **Performance testing**,
- **Genetic evaluation**, and
- **Publication of breeding values**.

Herd-Book Organizations may perform these activities directly or through authorized third parties (e.g., national evaluation centres or international reference bodies).

The **Interbull Centre**, recognized as the EU Reference Centre for bovine evaluations, plays a key role in ensuring comparability across Member States.

Evaluation results must be **reproducible and traceable**, and data must be subject to **quality control**.

---

8. Official Controls and Supervision

(Articles 60–68)

Member State authorities are responsible for **official controls** to verify compliance with:

- Recognition conditions;
- Approved breeding programme requirements; and
- Data integrity, herd-book operation, and certificate accuracy.

Authorities may:

- Inspect data systems, genetic evaluation procedures, and herd-book records;
- Verify identification and parentage control methods;
- **Suspend or withdraw** recognition or programme approval in cases of serious non-compliance.

The European Commission may also conduct **audits and on-site inspections** to ensure uniform application across the Union.

---

9. Cross-Border Implementation

(Articles 30–32)

Recognized herd-book organizations may **extend their approved programme** into one or more other Member States through a simplified **notification procedure**.
This ensures:

- **Freedom to operate** across the EU, and
- **Breeder mobility** without technical barriers.

Cross-border participation requires mutual exchange of genealogical and performance data and consistency in the breed definition and objectives.

---

10. International and Trade Aspects

(Articles 57–59)

Breeding animals and germinal products entering the EU from third countries must come from **breeding bodies listed by the European Commission** and provide equivalent guarantees for:

- Pedigree verification,
- Performance testing, and
- Genetic evaluation standards.

Trade in purebred animals and semen within the EU is **free of customs duty** when accompanied by the required zootechnical certificate.

---

11. Preservation of Genetic Diversity

(Recitals 10, 23, 27, 28)

The Regulation recognizes that competitiveness must not endanger **genetic diversity**.
Breed societies are encouraged to:

- Monitor population size and inbreeding,
- Maintain genetic variability, and
- Support conservation or recovery of local and endangered breeds.

For mainstream breeds like Holstein and Red Holstein, the principle is to **avoid fragmentation** and ensure coordinated international breeding programmes.

---

12. Practical Interpretations for European Herd-Books

Concept	Practical Interpretation
Recognition	Legal authorization to operate a herd-book for a breed; subject to national approval and EU-wide recognition.
Approved Breeding Programme	The governing technical document — objectives, traits, methods, population, and rules for data and certificates.
Substantial Change	A modification that could affect selection, comparability, or the genetic base; must be pre-approved.
Zootechnical Certificate	The EU passport for genetic material; ensures traceability and harmonized pedigree data.
Cross-Border Operation	Recognition of herd-books operating in multiple Member States under a unified programme.
Official Control	Periodic audit by the competent authority verifying legal and technical compliance.
Genetic Evaluation	Performance- or genomics-based estimation of breeding values following EU and Interbull standards.

---

13. Key Principles for EHRC Members

✅ Ensure that your organization holds a **valid national recognition** and **approved breeding programme** for the Holstein breed.

✅ Operate your herd-book transparently, with consistent **data integrity and open breeder participation**.

✅ Maintain compatibility with **Interbull standards** for performance recording and genomic evaluation.

✅ Issue and accept **EU-compliant zootechnical certificates** for all traded animals and germinal products.

✅ Cooperate fully with **official controls** and **cross-border data exchange**.

✅ Promote **genetic diversity**, animal health, and long-term sustainability as integral parts of breeding objectives.

This Regulation provides the legal backbone for international cooperation among European Herd-Book Organizations.
By adhering to its principles, EHRC members ensure the credibility, transparency, and global competitiveness of the European Holstein and Red Holstein populations.

EU Q&A – Herd-Book Governance, Data Ownership, and Splitting Scenarios

(Based on Regulation (EU) 2016/1012 and established EU practice)

❓ Q1. What happens if a group of breeders wants to create a new Herd-Book Organization (HBO) and split from an existing recognized HBO?

Answer:
Under **Article 4 and Article 21**, any group of breeders may *apply* for recognition as a new breed society if they meet all legal conditions — but recognition is not automatic.

The **competent authority** (usually the national ministry or delegated agency) must evaluate:

- Whether the new HBO's breeding programme complies with the Regulation;
- Whether its creation would **compromise the preservation of the breed**, fragment the breeding population, or reduce genetic diversity;
- Whether it would cause **inconsistencies** in breed definition, selection objectives, or data comparability.

If the split would risk **fragmentation, inbreeding, or loss of data coherence**, the authority may **refuse recognition** even if the new group meets technical requirements.
This is explicitly foreseen in **Recital (21)** of the Regulation.

In practice, competent authorities and the existing HBO are encouraged to seek **coordination or cooperative structures** (e.g., regional branches, joint programmes) before authorizing a new herd-book.

❓ Q2. If the new HBO is approved, what happens to the existing data (pedigree, performance, genomic results, etc.)?

Answer:
The Regulation requires that **genealogical and zootechnical continuity** be preserved.
Pedigree and performance data are **part of the official breeding record** of the population, not private property that can simply be withheld or erased.

Thus, the competent authority may:

- Require the **transfer or sharing** of relevant pedigree and performance data to ensure uninterrupted breeding evaluation;
- Ensure that data integrity and traceability are maintained across both herd-books;
- Designate which body is responsible for the **"book of origin"** to prevent duplication or loss of historical records.

In short, **data must follow the animals**, and both the former and new HBOs must coordinate to preserve the official genealogical chain.

❓ Q3. Who legally "owns" the data — the breeders, the HBO, or the national authority?

Answer:
The Regulation itself does **not assign "ownership"** of data in the commercial sense, but it establishes **custodianship and responsibility**.

Type of Data	Legal Custodian / Responsibility
Pedigree (herd-book data)	The recognized breed society maintaining the herd-book. It acts as *data controller* on behalf of breeders.
Performance testing & milk records	Normally the authorized testing organizations or national control bodies; HBOs may use these under data-sharing agreements.
Genetic evaluations (EBVs/GEBVs)	The body performing the evaluation (national evaluation centre, Interbull partner, or authorized data processor).
Breeder-specific information	Remains the property of the breeder but can be used by the HBO for legitimate breeding-related purposes under consent or regulation.

In essence, data are **co-owned in functional terms**:

- **Breeders** are the original source,
- **HBOs** are the record-keepers and processors,
- **Competent authorities** ensure compliance, and
- **EU reference centres (e.g., Interbull)** maintain cross-border comparability.

❓ Q4. Can the original HBO charge the new HBO for transferring data?

Answer:
The Regulation is silent on direct **financial compensation**, but several principles apply:

1. **No obstruction to trade or data exchange.**
   Article 18 and Article 39 require that recognized herd-books cooperate and avoid discriminatory or anti-competitive practices.
   Charging *excessive or punitive fees* that effectively block access could be interpreted as a **barrier to free movement** of breeding animals and genetic information.

2. **Cost-recovery is acceptable.**
   The original HBO may legitimately request **reasonable administrative compensation** for:

   - Data extraction and formatting,
   - Verification of pedigrees,
   - Secure data transfer operations.
     These fees must be **transparent, proportionate, and non-discriminatory.**

3. **Competent authority oversight.**
   Any dispute about data access, cost, or alleged discrimination can be brought before the national authority, which may impose data-sharing or mediation measures to ensure compliance with the Regulation.

❓ Q5. What about the publication and use of breeding values (EBVs/GEBVs)?

Answer:
Breeding values are considered **derived results** produced within an approved breeding programme. Therefore:

- The **methodology and publication** are governed by the programme approval (Article 7–8, Annex III).
- A newly formed HBO cannot simply "re-use" the old evaluations without agreement or validation by the competent authority.
- However, breeders retain the right to access **their own animals' results**, and those data must remain traceable.

If the new HBO develops its own evaluation system, it must undergo separate **technical approval and validation**, ensuring compatibility with Interbull or national reference standards.

❓ Q6. Can both herd-books operate for the same breed in the same country?

Answer:
Yes — but only under specific conditions.
Article 21 allows recognition of more than one breed society per breed **if**:

- Breed preservation and data integrity are not endangered;
- There is no contradiction in breed definition or selection objectives;
- Cooperation and data exchange are maintained.

If the competent authority determines that a second herd-book would lead to fragmentation, duplication of data, or reduced genetic progress, it may **refuse the application**.
The guiding principle is **breed unity and data continuity**.

❓ Q7. What safeguards ensure continuity of historical data and breeder confidence?

Answer:
The Regulation obliges both new and existing HBOs to:

- Maintain **permanent genealogical records**,
- Prevent loss of ancestral links,
- Preserve data integrity for future evaluations, and
- Ensure that breeders retain **recognition and traceability** of their animals across herd-books.

The competent authority can mediate and, if necessary, impose **technical data-sharing protocols** or designate one organization as the **“breed of origin” keeper**.

⚖️ Summary Table

Issue	Reg. Reference	Key Principle
Creation of new HBO	Art. 4, 21	Allowed if it does not endanger breed preservation or data coherence.
Data continuity	Art. 25–29, 60	Pedigree and performance data must remain traceable and consistent.
Data “ownership”	Implicit across Reg.	Shared custodianship: breeders (source), HBOs (record), authority (oversight).
Transfer costs	Art. 18, 39 (non-discrimination)	Cost recovery acceptable; obstruction or excessive fees prohibited.
Breeding values	Art. 52–54, Annex III	Must be derived under approved programmes; re-use requires validation.
Cross-border operation	Art. 30–32	Recognition of herd-books in multiple Member States through notification.

☑️ EHRC Recommendation

When breeder groups consider forming a new Herd-Book Organization:

1. **Engage early with the competent authority** to evaluate the regulatory feasibility.
2. **Document data-sharing protocols** and responsibilities for pedigree, performance, and genomic data.
3. **Ensure mutual respect and transparency** between existing and new bodies.
4. **Avoid duplication of herd-book data** and ensure continued participation in international evaluations (Interbull, ICAR).
5. **Agree on fair, cost-based data transfer arrangements** supervised by the authority if necessary

Regulation (EU) 2016/1012 treats internationally recognized breeds such as Holstein and Holstein-Friesian in a particular way.

Below is a clear, structured explanation designed for EHRC and other European Herd-Book Organizations managing these breeds.

EU Internationally Recognised Breeds – Legal and Practical Situation under Regulation (EU) 2016/1012

1. Background: "Internationally Recognised Breeds"

Breeds such as **Holstein** and **Holstein-Friesian** are **globally standardised populations** with:

- A **common breed identity** (defined by WHFF – World Holstein-Friesian Federation);
- **Shared genealogical roots**, and
- **Cross-border breeding programmes** involving many national herd-books.

Under EU law, they are treated as *one breed* with multiple recognized **breed societies** operating in different Member States.

---

2. Legal Framework

➤ **Article 21 (Recital 21) – Multiple Herd-Books for the Same Breed**

"The recognition of more than one breed society for the same breed is possible, but competent authorities may refuse a further breeding programme if it would compromise preservation of the breed or genetic diversity."

For Holstein, this means:

- Each country can have its **own recognized Herd-Book Organization (HBO)** (e.g., France, Germany, Netherlands, Italy, Hungary, etc.);
- All these herd-books operate on the **same international breed definition**;
- The Regulation expects them to **cooperate** and **exchange data** rather than compete destructively.

---

3. The "Book of Origin" and International Harmonisation

➤ **Concept: *Book of Origin***

For internationally recognised breeds, one or more herd-books are identified as the **Book(s) of Origin** – i.e. those which historically defined the breed and established its first herd-book.
For Holstein and Holstein-Friesian, these are typically:

- **Holstein Association USA**, and
- The founding European herd-books (Netherlands, Germany, UK, etc.).

EU herd-books maintaining Holstein or Holstein-Friesian cattle must:

- Follow the **same breed description** as the book(s) of origin;
- Accept pedigrees and certificates issued by other recognized herd-books of the same breed;
- Ensure **interoperability** of data and classification systems (WHFF type codes, genetic defect nomenclature, etc.).

This is explicitly encouraged in **Recitals 30–33** and **Article 32**, which promote *cross-border cooperation* and *data exchange*.

---

4. Recognition and Cooperation Between Member States

For internationally recognized breeds, the Regulation provides a simplified framework:

Topic	Key Rule
Cross-border activity	A herd-book recognized in one Member State may **extend its breeding programme** into another Member State by simple *notification*, not by full re-approval.
Mutual acceptance	Breeding certificates and herd-book entries must be **mutually accepted** between all recognized herd-books of the same breed (Art. 30–34).
Breed definition consistency	Breed standards must remain consistent with the international (WHFF) definition. National deviations are allowed only for local adaptation or data coding, not for redefining the breed.
Genetic evaluation	Results must be comparable across Member States; the Interbull Centre serves as the EU reference for harmonisation.

---

5. Fragmentation and Risk Management

The Regulation specifically warns against **fragmentation of international breeds**:

"…the competent authority may refuse approval of a further breeding programme for the same breed where differences in objectives or breed characteristics would result in a loss of efficiency or genetic progress."
(Recital 21)

In practice, this means:

- A new group of breeders cannot redefine "Holstein" or "Holstein-Friesian" differently within the EU;
- A split herd-book must use **the same breed definition** and coordinate with existing herd-books;
- Divergent selection objectives that threaten genetic unity (e.g. nationalised or closed sub-populations) could be rejected by authorities.

---

6. Data Exchange and International Continuity

Because Holstein is an international breed, herd-books are expected to:

- Participate in **international data networks** (ICAR, Interbull, WHFF);
- Exchange **pedigree, performance, and genomic data** in standard formats;
- Respect data protection but ensure **traceability of animals** across countries.

The Regulation's **Articles 60–63** on *administrative cooperation* reinforce this obligation by requiring Member States and breed societies to assist each other in ensuring data continuity.

---

7. Ownership and Use of Data in International Context

Although each national herd-book is the **legal custodian** of its own records, the following principles apply to international breeds:

- **Pedigree and genealogical data** are part of a common, transnational dataset — they must be interoperable and shared for legitimate breeding purposes.
- **Breeding values and genomic results** derived from joint evaluations (e.g. Interbull or EuroGenomics) are subject to the consortium's data-sharing rules; they cannot be claimed as exclusive property of a single HBO.
- **Zootechnical certificates** issued by one herd-book must be accepted by others for animals of the same breed, provided they comply with EU standards.

Thus, data stewardship is **shared and cooperative**, not competitive.

---

8. Role of International Organisations

- **WHFF (World Holstein-Friesian Federation)** sets global standards for breed identity, type codes, and nomenclature;
- **EHRC (European Holstein and Red Holstein Confederation)** provides regional coordination and policy dialogue;
- **Interbull** ensures harmonised genetic evaluation;
- **ICAR** sets performance recording and data-exchange standards.

The Animal Breeding Regulation explicitly allows and encourages alignment with such international standards to guarantee the **global competitiveness and traceability** of EU breeding.

---

9. Practical Implications for European Herd-Books

1. **Breed Definition Consistency**
   All national herd-books must adhere to the internationally accepted Holstein/Red Holstein definition.
2. **Mutual Acceptance of Certificates**
   Pedigrees and zootechnical certificates from any recognized EU Holstein herd-book are valid throughout the EU.
3. **Coordinated Breeding Objectives**
   Selection goals should remain harmonised to prevent genetic drift or fragmentation.
4. **Cross-Border Recognition**
   Herd-books can operate in multiple countries by notification, ensuring seamless breeder participation.
5. **Data Sharing Obligations**
   Pedigree and evaluation data must be exchanged transparently under fair and non-discriminatory terms.
6. **Preventing Breed Fragmentation**
   Competent authorities may reject any new herd-book proposal that would undermine the unity of the Holstein breed within Europe.

---

10. In Summary

Principle	Meaning for International Breeds (Holstein / Red Holstein)
Single Breed Definition	Must follow the international (WHFF) standard.
Multiple Herd-Books Allowed	Yes, across Member States, but cooperation and data consistency are mandatory.
Mutual Recognition	All zootechnical certificates valid EU-wide for the same breed.
Book of Origin	Historical herd-books define the breed; others must align.
Fragmentation Control	Authorities can deny approval if breed unity or data integrity are at risk.
International Cooperation	ICAR, Interbull, WHFF frameworks form the technical backbone for compliance.

Q&A — What defines a breed, and who decides it? (Holstein / Holstein-Friesian focus)

❓ Q1. What is a “breed” in EU law?

Answer: A *breed* is a **population of animals sufficiently uniform** and regarded as distinct by one or more groups of breeders who **agree to enter those animals in breeding books** (with known ascendants) to reproduce those characteristics within a **breeding programme**.

Practical takeaway: EU law ties “breed” to (i) uniformity and distinctness, (ii) breeder consensus expressed through a breeding book, and (iii) a formal breeding programme.

❓ Q2. Who decides what the breed definition is in practice?

Answer: The **breed society (Herd-Book Organization)** defines the breed characteristics **inside its approved breeding programme**; this is **recognised/approved by the competent authority**. The legal architecture: recognition of breed societies (Art. 4), approval of breeding programmes (Arts. 7–10 & Annex III), and rules for herd-books (Arts. 15–18 & Annex II).

Practical takeaway: Breed definition is not “free-floating”: it lives in an approved breeding programme operated by a recognised HBO.

❓ Q3. Can multiple herd-books exist for the same breed?

Answer: Yes, **more than one breed society** may be recognised for the same breed. However, a competent authority may **refuse an additional programme** if it would compromise **breed preservation, genetic diversity, data coherence, or selection efficiency** (key recital explaining this discretion).

Practical takeaway: Plurality is allowed, fragmentation is not.

❓ Q4. How are “Holstein” vs “Holstein-Friesian” treated?

Answer: For internationally recognised breeds, herd-books operate against a **shared, internationally standardised breed identity**. EU law requires **mutual acceptance** of entries and certificates for purebred animals **of the same breed**, and facilitates **cross-border operation** of programmes by notification (no re-approval). The legal hooks are the mutual-recognition and cross-border recitals and provisions: certificates (Art. 30), cross-border facilitation (Recitals 30–33).

Practical takeaway: Whether you use the name “Holstein” or “Holstein-Friesian”, the breed identity must **remain consistent** across EU herd-books; national naming conventions cannot redefine the breed.

One-page takeaway (for Holstein / Red Holstein):

- **Definition lives in the HBO's approved programme** and must align with the internationally recognised breed identity.
- **Multiple herd-books** can operate, but **no fragmentation** or inconsistent definitions.
- **Herd-book structure** (Main/Supplementary, upgrading) is harmonised at EU level.
- **Certificates + cross-border notification** keep Holstein one interoperable breed across the EU.

EHRC-style to refuse approval of an additional Herd-Book Organisation (HBO) for the same breed (e.g., Holstein / Red Holstein). It combines the **exact legal hooks** from Reg. (EU) 2016/1012 with a **quantitative impact test** (effective population size, inbreeding trend, connectedness, etc.) and a **decision memo template**.

When (and how) to refuse a second HBO for the same breed

1) Legal basis you will cite (verbatim anchors)

- **Recital (21)** – you **may refuse** a further breeding programme for the same breed **even if it meets all formal requirements** where approval would **compromise breed preservation** or **genetic diversity**, cause **fragmentation** (↑ inbreeding, ↑ genetic defects, ↓ selection potential, ↓ breeder access), or where there are **inconsistencies in breed characteristics or main objectives**.
- **Article 10 / Article 12(3)** – you may refuse (also for cross-border notifications) if a further programme **compromises essential traits, preservation, or genetic diversity** (incl. endangered/autochthonous cases). You must give a **reasoned explanation**.
- **Annex I, Part 1** – recognition/approval require a **sufficiently large population** and participation; your assessment explicitly includes **population size** covered by existing programmes.

  These are the precise hooks you quote in the decision.

---

2) The quantitative "fragmentation risk" test (make it standard in your file)

A. Effective population size (Ne) and inbreeding rate (ΔF)

1. **Compute baseline Ne** for the current (single) programme.
   A practical estimator for dairy cattle (AI-driven) is:

- If you track **effective numbers of sires and dams** used each year:

$$N_e \approx \frac{4N_m N_f}{N_m + N_f}$$

  where N_m = effective sires used; N_f = effective dams contributing replacements.

- If you track **realised inbreeding trend** from pedigrees/genomics:

$$\Delta F \text{ (per generation)} \approx \frac{1}{2N_e} \Rightarrow N_e \approx \frac{1}{2\Delta F}$$

2. **Project Ne after a split**. Do it with the **actual, proposed breeder lists** and semen distribution plans:

- Recalculate $N_{e,1}$ and $N_{e,2}$ from the **post-split sire/dam usage**.
- If gene flow between the two sub-populations will be limited (as is typical in separate herd-books), the **overall drift** increases. The intuitive effect is immediate: **halving the effective sire pool** or restricting exchange **lowers Ne** and **raises ΔF**.

  Worked example (simple, transparent):
  Today: 120 AI sires and 30 000 dams effectively contribute → $N_e \approx \frac{4 \cdot 120 \cdot 30{,}000}{120+30{,}000} \approx 480.$
  Proposed split: each side uses ~60 sires on ~15 000 dams → $N_{e,1} \approx 240$, $N_{e,2} \approx 240.$
  Even with modest exchange, **ΔF** will rise relative to the unified programme; **selection intensity** and **connectedness** decline on both sides.

  Record these numbers in an annex table.

  B. Inbreeding trend and coancestry

- Compare **five-year moving average** of **realised inbreeding (%)** and **genomic coancestry** under (i) status quo vs (ii) split.
- Flag if the split **raises ΔF** or **breaks genomic connectedness** between the two evaluation bases.

  C. Genetic connectedness and EBV stability

- Compute **genetic ties** between herds (shared sires, relationships) and the **connectedness diagnostics** (e.g., PEVD/PEV ratios across herds).
- Show how a split **weakens EBV comparability** (poorer link sires, fewer common contemporaries), risking **loss of efficiency in genetic progress**—explicitly referenced in Recital (21).

  D. Selection objective alignment

- Side-by-side the **selection indices** (trait lists, weights).
- **Material inconsistency** in “main objectives” or “essential traits” = stand-alone refusal ground.

  E. Breeder access / market functioning

- Document any **reduced access** to bulls/semen/embryos for breeders forced into a much smaller pool—**explicitly listed** in Recital (21) as a harm from fragmentation (reduced access to purebred animals or germinal products).

---

3) The documentary checklist you ask from the applicants (and evaluate)

1. **Population file** (all animals, by herd; active dams; AI sire usage last 3–5 yrs).
2. **Projected post-split participation** (named herds; semen sources; expected sire numbers).
3. **Data-sharing protocol** (genealogy, performance, genomics) with the incumbent HBO—**to avoid loss of continuity**.
4. **Evaluation plan** (who computes EBVs/GEBVs; Interbull participation; quality control; publication rules).
5. **Breed definition** and **index composition** (traits + weights) with **evidence of consistency** with the internationally recognised Holstein/Red Holstein standard.
6. **Breeder access plan** (no discrimination; availability of germinal products across the territory).
7. **Risk mitigation** for **genetic defects**, **ΔF**, and **Ne** (annual reporting and thresholds).

   Failure to satisfy #3, #4 or #5 is typically **fatal** in internationally recognised breeds.

---

4) The refusal memo (structure you can copy-paste)

Subject: Refusal to approve an additional breeding programme for *[Breed]* under Reg. (EU) 2016/1012

Legal grounds:

- **Recital (21)** – Approval would **compromise preservation/genetic diversity** via **fragmentation**, with foreseeable ↑ inbreeding, ↓ selection potential, and **reduced breeder access**; and/or there are **inconsistencies in main objectives/essential traits** between programmes.
- **Article 10(1)(a–c)** – Compromise of **essential traits/main objectives**; or **preservation/genetic diversity**; and for preservation breeds, **effective implementation** concerns.
- **Article 12(3)** (if cross-border notification) – Same refusal grounds apply; **reasoned explanation** provided within 90 days.
  Evidence (Annexed):

1. **Ne & ΔF analysis** (baseline vs split) demonstrating **significant Ne drop** and **ΔF increase** after split (Annex A).
2. **Connectedness diagnostics** showing **loss of links** and **reduced EBV comparability** (Annex B).
3. **Objective inconsistency** – material differences in trait sets/weights vs incumbent programme (Annex C).
4. **Breeder access assessment** – smaller germinal product pool for part of the population (Annex D).

Conclusion:
Approval is refused under the cited provisions. The applicants retain the right to **appeal** and may **resubmit** with (i) **single, unified objectives**, (ii) **binding data-sharing/continuity** with the existing herd-book, and (iii) **population-size safeguards** ensuring Ne and ΔF are **not worsened**.

---

5) Offer a constructive alternative (conditions to allow co-existence)

If politically desirable, you can **condition** approval on all of the below (turns a “no” into an actionable “if and only if”):

- **Single, harmonised breed definition & main objectives** (attach the common index spec). Ref.: breed-book structure & objectives must be consistent.
- **Formal, bilateral data-sharing MOU** (genealogy, performance, genomics), preserving **continuity of records** and **mutual certificate acceptance**. Ref.: certificates, cross-border/data cooperation.
- **Population safeguards:** annual **Ne ≥ baseline** and **ΔF ≤ baseline**, with public reporting; corrective measures if breached. (Use the Ne/ΔF formulas above.)
- **Connectedness floor:** minimum number of **shared link sires** per year across both programmes to keep EBVs **jointly interpretable** (Interbull standards).
- **Independent evaluation** (or common evaluation service) to avoid **divergent scales** and **loss of genetic progress**.

If the applicants **reject** any of the above, you have **documented refusal grounds** under Recital (21)/Art. 10.

---

6) One-page “numbers sheet” you attach to the decision

- **Baseline (current)**
  - Effective sires $N_m = \cdots$, effective dams $N_f = \cdots$
  - $N_e \approx \frac{4N_m N_f}{N_m + N_f} = \cdots$
  - Realised ΔF per generation (pedigree/genomic): … → $N_e \approx \frac{1}{2\Delta F} = \cdots$
- **Applicants’ projection (post-split)**
  - Side A: $N_{m,1} = \cdots$, $N_{f,1} = \cdots \rightarrow N_{e,1} = \cdots$
  - Side B: $N_{m,2} = \cdots$, $N_{f,2} = \cdots \rightarrow N_{e,2} = \cdots$
  - **Comparison:** Δ in Ne, projected ΔF ↑, link sires ↓, PEVD ↑
- **Decision trigger**
  - **Ne falls** and/or **ΔF rises** vs baseline;
  - **Connectedness falls** (documented), **objectives inconsistent**, **access reduced**.

Why this survives challenge

- You are squarely within the **explicit refusal grounds** in **Recital (21)** and **Articles 10 & 12(3)**.
- You provided a **reasoned explanation** and **quantitative evidence** (Ne/ΔF, connectedness, objectives, access).
- You offered a **proportionate path** to coexistence (conditions), showing refusal is **not protectionist** but **breed-preservation-driven**.

If you want, I can drop this into a **2-page decision template** (with placeholders for the Ne table and connectedness plots) you can reuse case-by-case.