Analysis of Dutch position on Biotech Act Part I

The BNC fiche reflects a Netherlands that is broadly positive about the objectives of the Biotech Act, but substantively cautious, risk-averse, and focused primarily on feasibility. Whereas the Netherlands positioned itself as a driver of "bold moves" in biotech in earlier non-paper and strategies, the sense of leadership is missing here. The government raises valid questions about financing, governance, and industry involvement—but offers no solutions, nor any willingness to co-invest. The appreciation is neutral on the what and hesitant on the how, with extensive attention to burdens, risks, and procedural details, and very little attention to impact, strategic strength or the ambitions the Netherlands itself claims to support. In short: we see concerns about implementation where ambition is needed. The Biotech Act is acknowledged as an opportunity for competitiveness and enabling conditions, but the government does not take a strong position on whether the concrete proposals truly advance these goals.

Positive points: What does the Netherlands say that we appreciate?

- ➜ Positive about the overarching objectives: The Netherlands values that the Biotech Act contributes to competitiveness, market creation, a level playing field, and stronger production conditions in Europe. The recognition is welcome, though phrased in very general terms.
- ➜ Supportive of acceleration and harmonisation:
  - ⟶ The Netherlands recognises that biotech is a cross-border sector and that alignment between Member States is essential.
  - ⟶ Appreciates flexible, future-proof legislation and the ability to respond quickly to innovation and technological change.
  - ⟶ Welcomes the avoidance of overlap with other legislation.
  - ⟶ Values that the EU framework contributes to greater consistency, accessibility, and predictability.
- ➜ Highlights its own successes: The Netherlands proudly points to national examples such as the Code of Practice for cultivated meat tastings and innovative fermentation. It also references NAMs as impactful innovations.
- ➜ Requests clarification and analysis of impact and regulatory burden:
  - ⟶ Because the Commission did not conduct an impact assessment, the government commits to carrying out its own analysis with stakeholders before taking a final position.
  - ⟶ Sensibly asks for clarification on key frameworks (governance, financing, definitions).
  - ⟶ Correctly identifies potential regulatory burden stemming from biosecurity measures and new structures.

Negative points: Where is the Netherlands too cautious, too technical, or simply not ambitious enough?

- ➜ Adopts an overly cautious stance:
  - ⟶ Focuses heavily on "workability" and barely on "level of ambition". The Netherlands sees many obstacles: funding, capacity, governance, obligations. High risk-reflex, low ambition.
  - ⟶ The government focuses almost exclusively on governance risks (overlap, capacity). It ignores how governance could increase effectiveness.
  - ⟶ The strong tone from the Dutch non-paper, its own national biotech vision and BNC-fiches on the Bioeconomy Strategy and feed & food omnibus is absent. The approach feels obligatory rather than opportunity-driven.
  - ⟶ The Netherlands poses sharp questions ("how, exactly?") but offers no solutions. There is no indication of willingness to co-invest or to enable the ambitions it claims to support. It gives the impression that the Netherlands wants to benefit from EU measures without contributing itself.
- ➜ Does not assess whether the Act's goals are actually achieved:

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- ⟶ Little is said about whether the Act truly contributes to strategic autonomy, financial strength, an attractive investment climate, competitiveness, or clinical research attractiveness. The Netherlands repeats that the broadly formulated goals could contribute but does not assess whether the concrete proposals do so.
- ⟶ For example, the government does not state whether it agrees with advantages such as accelerated principles or prioritisation (neither yes nor no). This leaves influence on the table.
- ⟶ The lack of an impact assessment is rightfully criticised—but also used as a reason not to take a position.

- ➔ Wants broad innovation but simultaneously pushes for unmet medical needs such as women's health.
- ➔ Is cautious on privacy and ethics:
- ⟶ Opposes delegated powers on personal data rules in biotech data projects—wants to retain national control.
- ⟶ Wants to maintain national control over fast-track and combined trials → caution outweighs innovation acceleration.

In summary: We question the government's ambition, while they question implementation.

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