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REGULATORY SCRUTINY BOARD OPINION

Revision of the plant and forest reproductive material legislation

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Brussels,
RSB

Opinion

Title: Impact assessment / Revision of the plant and forest reproductive material legislation

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

Twelve Directives regulate the marketing of seeds and other Plant Reproductive Material (PRM). They cover PRM for various crop groups such as cereals, fodder plants, beet, oil and fibre plants, vegetables, fruit plants, vine, seed potatoes, ornamental plants, and Forest Reproductive Material (FRM). Eleven Directives are specific to each type of crop and one Directive establishes the common catalogues of varieties of agricultural species.

This initiative aims to revise the plant and forest reproductive material legislation to align it with the political objectives of: (i) the Green Deal and its Farm to Fork, (ii) Biodiversity, (iii) EU Climate Adaptation, (iv) European Digital and (v) the new EU Forest Strategies. The objective of the revision is to update the legal framework to support innovation, the sustainability of agricultural and food production and to strengthen its contribution to the conservation of agro-biodiversity and plant genetic resources, while continuing to guarantee seed quality and food security and support the competitiveness of the sector.

(B) Summary of findings

The Board notes the additional information provided and commitments to make changes to the report.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

- (1) The report does not present a comprehensive analysis of costs and benefits. The analysis of impact on competitiveness of EU operators, including on SMEs, is not sufficiently developed.**
- (2) The comparison of the options in terms efficiency, is flawed.**

(C) What to improve

(1) The report should explain how the concerns raised by the European Parliament in rejecting the Commission's '2013 PRM proposal' have been addressed by this initiative. It

This opinion concerns a draft impact assessment which may differ from the final version.

should explain how the evaluative studies carried out in 2020 and 2021 fed into the impact assessment and in particular the problem definition. It should also explain why previous amendments to the PRM legislation were not sufficient to address the identified issues. The report should further elaborate on the consequences of the problem and the magnitude of the problem. The description of the dynamic baseline should be supplemented with quantitative assessment where feasible. The report should explain, if the baseline takes into consideration the move from south to north of agronomic and forestry practices and the varieties plants and trees used to compensate for climate change.

(2) The intervention logic should be more clearly presented. The report should better link the specific objectives with the identified problems. It should introduce a diagram illustrating the link between the problems, the general objectives, the specific objectives, and the options. The specific objectives should be expressed in more SMART terms to better understand the expected contribution and ensure that progress and success can be effectively measured.

(3) Based on a clearer intervention logic, the report should explain in more detail how the policy options were designed. It should explain what criteria were used, and clearly indicate how the available policy choices were identified and to what extent alternative combinations of measures that stakeholders may have suggested were considered. The report should further explain how stakeholders' views were considered when designing the policy options and what the views of stakeholders are on the range of options presented. It should further clarify the differences between Option 1 and the dynamic baseline. The main report should present greater detail on the content of each option by integrating the overview table currently presented in the annex. It should also indicate how and to what extent each option will address the identified problems.

(4) The report should assess the impact on the EU operators, seed producers, foresters, and farmers, including on their international competitiveness. The report should clarify if an SME test was performed, and if mitigating actions were considered. It should set out the trade-offs between harmonisation and flexibility, including as regards sustainability objectives, such as genetic diversity conservation and locally adapted varieties. The report should elaborate on Member States' and other stakeholder's groups views on the expected impact of the options under consideration.

(5) The report should present a clear and comprehensive overview of the costs and benefits of each of the three options. It should present the impact of each measure, including in quantitative terms. It should present the net benefit of each option, as well as the Benefit Cost Ratio. It should clearly explain the key assumptions and related uncertainties for the calculations of the main impacts.

(6) Throughout the report and in all comparison tables the scores of the baseline should be set at zero. The comparison of options overview table should be revised to avoid double-counting, so that the relevant impact scores inform the effectiveness section, and the efficiency assessment contains the related cost estimates or alternatively presents Benefit Cost Ratios to measure efficiency. This should also help to better justify the choice of the preferred option.

(7) The report should systematically refer to the views of different stakeholder categories, including diverging views, throughout the report.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion

The DG must revise the report in accordance with the Board’s findings before launching the interservice consultation.

If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Revision of the plant and forest reproductive material legislation
Reference number	PLAN/2020/7576
Submitted to RSB on	18 January 2023
Date of RSB meeting	15 February 2023

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
<i>Description</i>	<i>Amount</i>	<i>Comments</i>
<i>Direct and indirect benefits</i>		
All certification tasks are permitted under official supervision except the issuing of the official label.	<ul style="list-style-type: none"> • EUR 1.1 million per year in reduced certification costs¹ (direct benefit) • Efficiency gains and flexibility, not monetised (indirect benefits) 	<ul style="list-style-type: none"> • Operators
VCU examination is permitted under official supervision	<ul style="list-style-type: none"> • 7% saving in variety registration costs² (direct benefit) 	<ul style="list-style-type: none"> • Operators
Strengthened sustainability requirements	<ul style="list-style-type: none"> • Avoided loss in crop output ranging from EUR 221 to 2 086 million annually (indirect benefit) • Reduced losses in forestry (indirect benefit, not monetised) 	<ul style="list-style-type: none"> • Farmers • Foresters
Harmonisation of official controls subject to OCR	<ul style="list-style-type: none"> • Efficiency gains (direct benefit, not monetised) 	<ul style="list-style-type: none"> • NCAs
<i>Administrative cost savings related to the 'one in, one out' approach</i>		
Decisions for addition of new species in (or removal of species from) the scope of the PRM legislation and on the equivalence to EU rules for third countries will be taken by means of tertiary legislation.	Shorter time to reach such decisions but the benefits are rather limited as only a small number of decisions every year (0-4) are concerned. Not monetised.	<ul style="list-style-type: none"> • Commission • NCAs • Operators
The transfer/notification of new varieties from national to Common Catalogues will be managed by the MS without the need for a Commission Decision.	The period between acceptance in a national catalogue and access to the common market will be shortened by 1 to 4 months for about 4 000 new varieties every year. Not monetised.	<ul style="list-style-type: none"> • Commission: need for adoption of 24 Decisions every year is removed • NCAs: need to notify new varieties to the Commission is removed • Operators: avoidance of unnecessary waiting time
Introduction of a dynamic reference to DUS protocols of CPVO and UPOV for the purposes of variety registration.	Avoidance of discrepancies between the applicable DUS protocols for the purposes of variety registration and for the purposes of granting plant variety rights. Not monetised.	<ul style="list-style-type: none"> • Commission: need for adoption every year of an implementing act referring to the new DUS protocols is removed • NCAs: need to transpose the abovementioned Directive is removed; avoidance of having to adhere to different

¹ The certification costs are considered as *testing costs* and not as *administrative costs*.

² The variety registration costs are considered as *testing costs* and not as *administrative costs*.

		<p>DUS protocols</p> <ul style="list-style-type: none"> Operators: avoidance of having to adhere to different DUS protocols
Allow MS to decide themselves on permitting temporarily the marketing of seed that does not satisfy the requirements in respect of minimum germination, if germination is not lower than 15 % than the required germination rate.	In average 30 notifications annually (for a total of 50 000 tonnes of seed, or about 0.01% of the quantities of seed certified annually) become redundant. Not monetised.	<ul style="list-style-type: none"> Commission and NCAs: avoiding the handling of on average 30 notifications per year Operators: Reduced waiting time by at least 15 days for each notification avoided.
Lighter rules for seed conservation networks, marketing to amateur gardeners and exchange in kind of PRM, simplification of current rules for conservation varieties and extension of those rules to cover new locally adapted varieties and broadened scope for heterogeneous material.	Operators would benefit from lighter procedures for access to market. Number of operators and quantities of PRM concerned are unknown. Though number of operators could be in the range of several thousands, the quantities are considered to be very limited.	<ul style="list-style-type: none"> Operators: Several hundred or few thousand varieties or heterogeneous material to be brought in the market over the next ten years. For each of them, applications and costs for variety registration and PRM certification are avoided. Global savings are not quantifiable.

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Strengthened sustainability requirements	Direct adjustment costs	N/A	N/A				
	Direct administrative costs	N/A	N/A				
	Direct regulatory fees and charges	N/A	N/A		Increased registration costs: <ul style="list-style-type: none"> EUR 6.4 million annually (PRM) EUR 0.16 million annually (FRM)³ 		
	Direct enforcement costs	N/A	N/A				EUR 43 to 98 million annually
	Indirect costs	N/A	EUR 400 million annually in increased PRM costs for farmers, corresponding to 3% increase in cost of PRM or 0.15% increase in cost of global inputs		Up to 200 varieties less (or 5% less) registered every year (PRM)		
Harmonisation of OCs subject to OCR	Direct adjustment costs	N/A	N/A			Reallocation of resources, depending on current organisation (not monetised)	
	Direct administrative costs	N/A	N/A		Modified rate of OCs (increase or decrease)		<ul style="list-style-type: none"> Multi-

³ The fees for variety registration are considered as *testing costs* and not as *administrative costs*.

					depending on current situation per MS. Not quantifiable.		annual national control plan • Annual report on OCs
	Direct regulatory fees and charges	N/A	N/A				
	Direct enforcement costs	N/A	N/A				Depending on current implementation (not quantifiable)
	Indirect costs	N/A	N/A				
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	N/A	N/A	N/A	N/A		
	Indirect adjustment costs	N/A	N/A	N/A	N/A		
	Administrative costs (for offsetting)	N/A	N/A	N/A	N/A		