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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the enforcement and effectiveness of plant health measures relating to imports into the Union territory

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ABBREVIATIONS

BCP: Border Control Post

BTSF: Better Training for Safer Food

CA: Competent Authority

CP: Control Point

DG SANTE: Directorate General for Health and Food Safety

EFSA: European Food Safety Authority

EU: European Union

EUROPHYT: European Union Notification System for Plant Health Interceptions

HRP: High Risk Plants, plant products and other objects

IPPC: International Plant Protection Convention

NPPO: National Plant Protection Organisation

OCR: Official Controls Regulation (EU) 2017/625

PC: Phytosanitary Certificate

PRM: Plant Reproductive Material

RNQP: Regulated Non-Quarantine Pest

TRACES-NT: Trade Control and Expert System

1 INTRODUCTION

Import measures for plant health aim to protect the European Union (EU) from the introduction of pests. The EU legislative framework for those measure was based on Council Directive 2000/29/EC[1], until 2019. It established a risk-based and World Trade Organisation (WTO)-Sanitary and Phytosanitary (SPS) compliant system, in general open to imports, with some restrictions such as the need for a phytosanitary certificate (PC), specific import requirements, and certain prohibitions. It also established the system for official controls on plant health organised and carried out by EU Member States.

Following the evaluation report of the plant health regime in 2010, the need to replace the previous legislation was identified. Regulation (EU) 2016/2031 ('Regulation') was adopted in 2016 and started applying from 14 December 2019. This Regulation maintained the risk-based approach and compliance with the WTO-SPS agreement, but in light of experience, measures were introduced to reinforce the protection of the Union territory, and enhance pro-active preparedness for crisis management.

In light of the significant changes to the EU plant health import regime, the co-legislators introduced in Article 50 of the Regulation the obligation for the Commission to present by 14 December 2021, a report to the European Parliament and the Council with the objective to assess the enforcement and effectiveness of measures relating to imports into the EU, including a cost-benefit analysis, and, where appropriate, to also present a legislative proposal to address any need for amendments.

The scope of this report includes the main changes brought forward by the Regulation, i.e. main changes in the import measures and the organisation of the official controls for those measures.

The report assesses (i) the impact of the inclusion in the Regulation of Regulated Non Quarantine Pests (RNQPs) previously covered by the legislation on the production and marketing of plant reproductive material[2]('PRM legislation'), on import measures and control systems; (ii) the enforcement and effectiveness of the measures to deal with newly identified risks, for which different measures could be envisaged ranging from post import quarantine to temporary prohibition; (iii) the enforcement and effectiveness of the extension of the obligation of a PC for plants and plant products presented at import to new commodities (with a minimum 1% of controls at the borders) and to plants brought in with passengers' luggage; (iv) the current procedures for granting derogations from import prohibitions as well as the provisions for a temporary prohibition of certain plants, plant products and other objects identified as high risk, the import of which is allowed after a commodity risk assessment has been carried out by the European Food Safety Authority (EFSA) on a technical dossier submitted by the interested country of origin, followed by an EU legal act with the import conditions for the commodity; (v) the changes introduced with regard to the import conditions for material for official testing, scientific and other related purposes as well as the changes introduced for the use of quarantine stations and confinement facilities; (vi) the impact on the enforcement and effectiveness of the import controls as a result of the significant changes brought forward by the Regulation, with the inclusion of the plant health

[1]OJ L 169, 10.07.2000, p. 1.

[2] https://ec.europa.eu/food/plants/plant-reproductive-material/legislation/specific-legislation_en

controls under Regulation (EU) 2017/625[3], the Regulation on Official Controls (OCR), which took effect the same time as the Regulation.

Methodology

In order to answer the requirements of the report, the Commission set up a methodology that included the evaluation of all available evidence. The Commission undertook a stakeholder[4] consultation using questionnaires on four main areas where the legislation introduced changes: (i) phytosanitary import procedures, (ii) the use of the PC, (iii) import prohibitions and (iv) plant health provisions of OCR. The questionnaires, which were developed in consultation with EU NPPOs and relevant EU-level associations, aimed to get feedback on policy aspects of enforcement and implementation as well as on costs, benefits and impacts, to carry out the cost-benefit analysis. Invitations to respond to the questionnaires were sent to the 27 Member State-EU NPPOs, Certification competent authorities ('CAs'), and customs authorities, to 2 EU institutions, to 48 relevant EU-level associations and to 178 non-EU NPPOs. Member-State-level associations, operators, laboratories, research institutions and the general public could access the questionnaires via the DG SANTE website. In the latter case, the Commission and EU NPPOs helped advertise the questionnaires via social media and other channels. A total of 386 replies were received. The level of participation varied amongst the different categories of stakeholders and the different questionnaires, with the questionnaire on OCR having the lowest participation of the EU plant authorities (15 out of the 27 EU NPPOs) and an overall low participation of EU and Member State level associations, non-EU NPPOs, operators and general public.

In addition, publicly available data, for which a statistical analysis was carried out, was used from two sources: (i) data on interceptions of plants and plant products imported into or traded within the EU were obtained from EUROPHYT and TRACES-NT for the period 2019-2020 and (ii) trade data were analysed for the period 2013-2020. Since the commodities in the Regulation do not correspond to individual trade nomenclatures, comparison on interception and trade dynamics was made for groups of commodities, affected by the legislative change.

To support this report, the Commission produced four technical reports[5] with information about the feedback received and an extensive analysis of that feedback.

Finally, for the assessment of the measures related to OCR, the results of the first 5 audits on import controls in Member States were also considered. The reports of all relevant audits are publicly available[6].

The Commission analysis is hampered by three factors: first, the partial contribution of EU and non-EU NPPOs and associations in certain cases, which affected the representativeness

[3] OJ L 95, 7.4.2017, p.1.

[4] European Union (EU)- and non-EU National Plant Protection Organisations (NPPOs), Authorities responsible for Marketing Directives (Certification Competent Authorities), Associations at EU and Member State level (EU and MS associations), operators and general public

[5] https://publications.jrc.ec.europa.eu/repository/handle/JRC126792
https://publications.jrc.ec.europa.eu/repository/handle/JRC126791
https://publications.jrc.ec.europa.eu/repository/handle/JRC126695
https://publications.jrc.ec.europa.eu/repository/handle/JRC126790

[6] https://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

of the responses, and the very limited contribution from general public and operators which did not allow for a triangulation of the findings; second, the very short time between the entry into application of the different provisions and the request for feedback which affected the sample size for the analysis; and last, the impact of the COVID-19 pandemic on trade and relevant activities despite the existence of Regulation (EU) 2020/466[7] on temporary measures to contain risks during certain serious disruption of the Member States' control systems due to COVID-19.

Because of the abovementioned limitations, conclusions on the enforcement and effectiveness of the import measures could not be drawn in certain cases. The assessment of the costs and benefits was carried out to the extent possible because of the scattered feedback on the quantitative data requested, or surveyed through economic literature. An in-depth qualitative analysis of the costs and benefits was undertaken instead. Finally, for these reasons, the Commission has restricted itself to identifying topics that merit further discussions.

2 IMPORT PROCEDURES

Since the inclusion in the Regulation of rules on RNQPs, NPPOs have taken over the responsibility for official controls on RNQPs from Certification CAs. While the implementation of the RNQP rules at import could be considered as effective in terms of achieving their goal of ensuring the compliance with the RNQP requirements, 25% of NPPOs, 41% of operators and 5 out of 6 Certification CAs gave a negative rating because of the lack of coherence between the plant health and the PRM legislation. Views were divided as to whether compliance with the measures on RNQPs should also be included under the heading 'Additional Declaration' of the PC, a provision not covered by Article 71(2) of the Regulation.

A clear benefit of the Regulation is the increase in efficiency of official controls, as indicated by the responses. Almost two thirds of NPPOs and Certification CAs started carrying out simultaneous controls for RNQPs and quarantine pests since the implementation of the Regulation, whereas only 30% were already doing so in the past. The impact of the Regulation on financial resources of carrying out those controls seems to be minimal, as the majority of CAs declared that costs had not increased. This situation is also confirmed by private operators.

There seems to be a lack of clarity regarding the actions in case of RNQP-related non-compliances. Over half of respondents reject non-compliant consignments and inform the non-EU country concerned. Very few consult the operator about special treatments. Some respondents would welcome the development of relevant guidelines. Almost 75% of respondents would be in favour of notifying RNQP-related non-compliances to TRACES-NT for the purpose of transparency. However, the Regulation does not cover such notification.

An assessment on the usefulness of Article 49 for measures on newly identified pest risks could not be carried out because of the poor feedback.

[7] OJ L 98, 31.03.2020, p.98.

3 PHYTOSANITARY CERTIFICATES

The extension of the obligation for a PC to the commodities of Part B of Annex XI of Regulation (EU) 2019/2072 (hereafter 'new commodities'), introduced with Article 73 of the Regulation (hereafter 'PC extension') could be considered beneficial for the protection of the EU against pests. Clear benefits have been recorded: increased traceability, enhanced protection against pests, and increased accountability of non-EU NPPOs. Moreover, about 33% of non-EU NPPOs declared an improvement in their capacity to detect pests in pre-export inspections.

In addition, operators mostly declared that the PC extension had not affected the level playing field, or that there have been positive changes because of increased awareness, equal rules and increased number of controls.

Based on the survey, 22% of respondents considered that the overall situation of the PC system had improved and 35% considered that the situation had remained the same, while 15%, mainly operators, declared it had worsened due to the lack of proportionality of the new obligation with the associated risks. It was not possible to assess if the transition to the new requirement was smooth, as 42% of respondents considered it smooth while 38% considered it problematic (different requirements between commodities of Part A and Part B of Annex XI which are difficult to explain to operators, e.g. only Part A commodities have to be prenotified at Border Control Posts (BCP); distinguishing between Parts A and B; detecting seeds sold by distance sales). Non-EU NPPOs consider that it is now more complex to identify the new commodities, especially the intended use which determines the need for a PC. However, the criteria to distinguish those commodities in the past when they did not require a PC have remained the same.

The PC extension could also be considered beneficial for the overall functioning of trade. Private stakeholders experience a decrease in fraudulent practice, an increase of the level of trust among actors in the supply chain, an improved capacity to monitor contracts and an overall reduction of risk.

Furthermore, the PC extension seems to have increased awareness regarding plant health issues amongst operators, citizens and CAs.

On the negative side, PC extension seems to have increased the administrative burden and associated costs. EU-wide associations rated increased workload as equally important. Three Member States adapted their IT systems with a limited cost, and one improved its facilities to undertake inspections. Four Member States increased the level of sampling and testing for the detection of potential newly identified pest risks, but below 5%.

The PC extension generated some costs for non-EU NPPOs as well, mainly because they increased the number of staff and upgraded facilities and laboratories.

While it seems that the time and costs to complete the controls at the EU points of entry for the additional commodities have increased (as declared by the majority of the private sector - 44%), the capacity to make long-term investments or strategic decisions has not been majorly impacted, as 17% of the respondents considers that that capacity is affected.

Very few rejections of consignments, mainly seeds, fruits and cut flowers, were reported due to lack of or incomplete PC for the new commodities. All EU stakeholders consulted declared that they had not detected any major change in volumes of imports to the EU, EU production or prices for the new commodities. The responses of non-EU NPPOs, although limited, could confirm that there were neither changes to volumes of exports to the EU nor increased costs for exporters. The responses provided by stakeholders are in line with the conclusion reported in Soto el al. (2021), that the change in legislation has had a negligible effect on overall trade of plants. Checking the compulsory 1 % of the new commodities at import was by many respondents not experienced as complex, while almost as many respondents experienced difficulties to distinguish the 'new' from the 'old' regulated commodities, as well as a lack of uniform procedures across Member States.

With regard to the provision of Article 71(2) of the Regulation to include in the PC the full wording of the specific requirement that is fulfilled, whenever the respective implementing act allows for different options, over half of the respondents find it rather clear, while 32% find it rather unclear. Both the EU and non-EU NPPOs consider the requirement clear, but private stakeholders consider the opposite. Despite the endorsement by all 27 Member States of the clarifications provided by the Commission , operators and their representatives mentioned in their responses that the implementation of the requirement was not homogenous across the EU and those different approaches were difficult to follow. However, that was the case only for the beginning of the implementation of that requirement.

The extension of the PC requirement for plants brought by passengers is also considered beneficial, as, according to over 80% of the stakeholders, it has led to increased protection of the EU against pests. Responses obtained from the general public (17) were too few to make any assessment.

4 PROHIBITIONS

Introduction into Union territory of certain commodities is prohibited according to the provisions of Article 40 of the Regulation. The current procedure for granting derogations from import prohibitions, i.e. allowing imports of otherwise prohibited commodities, based on information submitted by the interested countries, has been working relatively well. Nevertheless, further standardisation of that procedure could be envisaged. The current procedure for granting derogations from import prohibitions, was considered satisfactory by 47% of the respondents and unsatisfactory by another 30%. Dissatisfaction prevails among EU- and Member State- level associations due to lengthy processes, lack of transparency, limited scientific basis, and increased administrative and financial efforts.

Article 42 of the Regulation on high risk plants, plant products and other objects (HRP), can be considered as an effective provision in terms of enhancing the protection of the EU against pests, as confirmed by 61% of respondents who also find the HRP list included in the Annex to Regulation (EU) 2018/2019[8] and the procedures included in Regulation (EU) 2018/2018[9] clear. This is also confirmed by the evaluation of the impact of the HRP list on the probability of outbreaks, with only one association considering it has increased. Respondents overall also

[8] OJ L 323, 19.12.2018, p. 10–15.
[9] OJ L 323, 19.12.2018, p. 7–9.

agreed that the stringency of the ban is adequate. Seven associations and 4 NPPOs declared the opposite. Finally, there was a call for more transparency on the procedure used to develop the HRP list.

Besides the increased protection of the EU against pests and the increased preparedness against potential newly identified pest risks, cited by most respondents (69%) (the latter was attributed to the commodity risk assessments carried out), the increased awareness of the need to protect the EU against pests, was an additional benefit, cited by more than 50% of respondents.

The negative impact most cited, was the increase in the administrative burden. In fact, 29 of the 77 stakeholders consider that the administrative burden had increased due to the complexity of controls at border, inspections and surveillance measures. At the same time the additional resources allocated, have increased the capacity to trace the commodities included in the HRP list and to identify the already delisted HRP.

Besides the targeted training on plant health topics organised by the Commission under BTSF, other stakeholders, mainly NPPOs, undertook additional training activities to facilitate the implementation of the import ban on HRP. DG SANTE, EFSA and 13 of the 21 EU NPPOs, declared to have significantly increased their dissemination activities. Private stakeholders overall rated positively those dissemination efforts, especially those by EFSA and NPPOs.

The ban on imports of HRP did not have a significant impact on the domestic market in terms of domestic production, prices and sales or on operators' capacity to export HRP or to undertake long-term investments or on the actual number of operators in the sector. However, operators, Member State- and EU- level associations, consider that HRP trade is more complex mainly due to the need for suppliers of new plants. Nevertheless, they have managed to replace the prohibited HRP species with others. Results of the trade analysis presented in Soto et al. (2021) confirms the feedback obtained from stakeholders.

The four non-EU NPPOs that declared they had submitted a dossier to lift the import ban of HRP from their country consider the process complex, with too specific information requested and no detailed guidelines available. They also consider that inspections and their capacity to certify delisted HRPs were complex, but increased training helped address that complexity. Data on quantification of costs were too limited to perform any assessment.

The provisions of Articles 8 and 48 of the Regulation on material for official testing, scientific and other related purposes, seem to have been simplified compared to the past, as confirmed by the majority of respondents, but 11 out of the 31 respondents, of which 3 out of the 4 laboratories which are the main users, consider the opposite. The experience with the Letter of Authority was rated unsatisfactory by the majority of respondents (32%), due to problems with the endorsement of the letter by non-EU NPPOs, administrative burden, lack of clarity of the provision, lack of harmonisation amongst Member States, and the repeated request for such a letter to the same consignor.

The provisions of Articles 60-64 of the Regulation regarding the use of quarantine stations and confinement facilities, can be considered satisfactory, as confirmed by the vast majority

of respondents. The procedure for release of material from quarantine conditions seems to be clear and effective for all respondents.

5 OFFICIAL CONTROLS

The plant health sector has been included within the scope of the OCR, and import controls are now carried out along the same procedures as for other sectors of the food chain, with few exceptions.

Related to the limitations outlined in the introduction, it is worth noting that the questionnaire for the OCR had lower participation rate.

Conclusions could not be drawn on the level of effectiveness and harmonisation of import controls: 35 out of the 65 responding stakeholders considered the implementation of the new regime for import controls as effective and harmonised, while initial feedback from the first 5 out of a series of 15-20 Commission audits on the implementation of the OCR, revealed shortcomings, with Member States not ensuring that the minimum requirements for BCPs and CPs are met. Audit and verification procedures, documented procedures, monitoring and sampling plans to ensure consistency of physical checks, all are at different stages of development. TRACES-NT is operational, but shortcomings still exist in Member States with the implementation of the requirements for personal consignments and wood packaging material.

The use of TRACES-NT can be considered an important improvement brought by the OCR. In fact, the functionality offered to notify non-compliances at import was declared as effective by 80% of the respondents. The NPPOs also rated positively the interconnection with other systems, the user-friendliness and the availability of information.

The OCR introduced new rules for controls at control points (CP) and for risk-based controls on commodities in transit. Despite being in place for a short period of time, those controls could be considered efficient, as declared by 47 out of 52 and 31 out of 36 respondents respectively.

The establishment of harmonised rules for the sampling for physical checks performed by visual inspection (Annex III to Regulation (EU) 2019/2130[10]) has been an important improvement of the system of official controls. In fact, previous audit series had identified significant variation in the sampling for physical checks and this has been seen as a weakness by the Commission and Member States. According to the responses, the sample size is now decided more uniformly, because of clearer requirements. However, some stakeholders reported that the sample size of consignments with small lots of different commodities is disproportionally high in order to reach the minimum accepted confidence level established in the legislation, and 33% of them ask for more harmonization, with regard to the minimum quantities to be exempted from controls. Regulation (EU) 2019/2130 also introduced new provisions regarding sampling and testing for latent infections. According to the feedback of the questionnaire, these new provisions did not affect the costs but allowed for those tests to be routinely implemented.

[10] OJ L 321, 12.12.2019, p. 128-138.

Most NPPOs did not increase their staff or the workload to implement the changes resulting from the OCR. The Commission's BTSF programme included a dedicated section on the new OCR for plant health inspectors. In addition, nearly half of the respondents undertook training and awareness raising activities for the OCR.

Moreover, the changes in legislation led to very limited changes in the number of BCPs and CPs, compared to the past. Four NPPOs closed points of entry and three closed approved places of destination mainly because of lower import volumes, cost-effectiveness and financial reorganization.

According to 25% of the responses provided by operators and their associations, the benefits from the changes resulting from the OCR have come at a cost as the capacity to import plants and plant products has been reduced. The decline of the import capacity is mainly because currently goods are cleared based on the PC, while before clearance was based on the transport document, which covered different PCs. Moreover, nearly 1 out of 3 respondents from the private sector declared that costs of controls had increased, although by less than 10%. For a similar number of respondents costs remained the same.

Over half of NPPOs agreed that the cost of consumables to undertake controls was not affected. However, 67% of NPPOs indicated that the time needed to undertake controls either remained the same as before or it increased by less than 10%. No additional cost was reported by NPPOs and the same was declared both for costs of controls at BCPs and for total costs as reported by operators and associations.

The cost for putting in place a monitoring plan for wood packaging material and updating the inspection protocols is considered to have increased by 2 NPPOs, and the additional cost is less than 10%.

In order to implement the requirements of the OCR for controls on passenger luggage, the majority of NPPOs kept using the risk–based approach they were using before the implementation of the OCR. However, the majority of NPPOs delegated the documentary checks of the PCs to custom authorities and few had to upgrade their facilities to perform those checks.

The requirement for post-import controls for plants for planting entering the EU in dormant stage had been in place for just over half a year when the questionnaires were launched. This may explain why 61.1% of respondents had no opinion. However, 22.3% of respondents rated the measure as effective. Half of the respondent NPPOs highlighted the complexity for tracing imports of commodities via other Member States. Regarding the organisation of the post-import checks, most NPPOs considered the procedure simple but an important share rated it as not easy at all. Too few data were obtained on the number and costs of post-import inspections carried out for plants for planting imported in dormant stage to draw conclusions.

When asked about the controls of the commodities sold through e-commerce, most respondents agree that the controls for distance sale should be implemented the same way as those for the traditional supply-chain, to ensure a level playing field in maintaining the level of protection against plant health risks.

6 CONCLUSIONS

Based on the assessed data, it could be considered that the Regulation and the inclusion of the plant health controls within the scope of the OCR have contributed towards achieving the objectives to enhance phytosanitary protection of the EU and to increase proactive action against pests while being in compliance with IPPC, through risk-based and transparent approaches. NPPOs' views were positive on provisions that provided clarity in plant health controls and on provisions that further enhanced protection of the EU against pests. Provisions, the introduction of which was perceived to have caused difficulties in already established trade were perceived negatively by EU- and Member State- level associations.

Furthermore, the analysis of the feedback gathered from stakeholders on changes to PC requirements, changes due to the OCR and the introduction of the temporary import ban for HRPs, together with the analysis of the available trade data (Soto et al. 2021) point towards a situation where benefits outweigh costs. A major aspect that might have led to this positive assessment is the training and dissemination activities. The situation is less clear-cut for changes in procedures upon import and in particular for RNQPs. EU and non-EU authorities highlight more the benefits of the legislative changes than private operators. The latter tend to identify a higher number of minor shortcomings in the implementation of the legislative changes and signal areas where more fine-tuning is needed.

To enhance the effectiveness and practical implementation of the Regulation and OCR rules and to achieve better usefulness, some areas might be considered for further discussion. This applies to (1) the improvement of the coherence of the provisions for RNQPs and their controls, (2) the procedures for granting derogations from import prohibitions under Article 40 of the Regulation, (3) reinforcing transparency on the procedures for high risk plants under Article 42, and (4) targeted official controls on plants and plant products imported through distance sales. Any putative amendment however should be limited in scope, as it would mainly relate to adjustments to an already functioning system.