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COVER NOTE

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COMMISSION STAFF WORKING DOCUMENT

EU's efforts to simplify legislation in 2021 - Annual burden survey

EU's efforts to simplify legislation in 2021

Annual burden survey

1. Introduction

In her political guidelines, President von der Leyen has stressed the Commission's commitment to take evidence-based political decisions without creating unnecessary burdens for citizens and business. In the Mission letters to the Commissioners, the President underlined that the institution 'must send a clear signal to citizens that our policies and proposals deliver and make life easier for people and for businesses'. In 2021, the Commission presented a new generation of better regulation guidelines that is now being put into practice. This came at a time when businesses and citizens were suffering greatly from the Covid-19 pandemic, and the prospect of any burden reduction was welcomed as a relief.

The Commission's better regulation system has been recognised as one of the most advanced regulatory approaches in the world¹ and is the result of continuous improvement. It ensures that the economic, social, and environmental impacts of policy action are systematically assessed resulting in high-quality legislation. The Commission has further improved this system by implementing the changes announced in its Communication on 'Better regulation: Joining forces to make better laws'² (adopted in April 2021) and by providing new guidelines and a new toolbox in November 2021 to support the process.³

As part of better regulation, the regulatory fitness and performance programme (REFIT)⁴ identifies and reduces unnecessary regulatory burdens and the complexity of legislation. Under REFIT, the Commission systematically seeks to simplify, reduce the burden of and modernise existing EU legislation, while ensuring policy objectives are achieved and high economic, social, and environmental standards met. Legislation should deliver these objectives at the lowest cost for citizens and business, in particular for small and medium-sized enterprises (SMEs). Compared to their bigger competitors, SMEs are often affected disproportionately by the costs of regulation because of their smaller size and more limited resources. The new better regulation toolbox strengthens its guidance on, among others, how to apply the SME test⁵. This work is further supported by the SME envoys network⁶ that uses an SME filter to signal to the Commission initiatives that merit closer attention from the perspective of SMEs.

To further minimise the burden associated with achieving EU policy objectives, the Commission has introduced a 'one in, one out' approach. This ensures that, when introducing new requirements, the Commission systematically and proactively reduces other requirements imposed by existing legislation. This approach complements the REFIT

¹ OECD (2018), [OECD Regulatory Policy Outlook 2018](#) (OECD Publishing, Paris).

² COM (2021) 219 final, https://ec.europa.eu/info/files/better-regulation-joining-forces-make-better-laws_en

³ https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en

⁴ COM(2012)746 of 12 December 2012, https://ec.europa.eu/info/files/commission-communication-eu-regulatory-fitness-2012_en

⁵ https://ec.europa.eu/info/files/chapter-3-identifying-impacts-evaluations-fitness-checks-and-impact-assessments_en

⁶ [SME envoys network | Internal Market, Industry, Entrepreneurship and SMEs \(europa.eu\)](#)

programme and required significant implementation and methodological adjustments. In 2021 the Commission tested it in a pilot project involving 10 initiatives, while running training and awareness activities throughout its different policy departments.

The work to simplify, and to ensure that legislation is efficient and modern, is supported by the Fit for Future Platform, a high-level expert group composed of representatives from Member States, the Committee of the Regions, the Economic and Social Committee and various stakeholders including business, trade unions and civil society. The Platform adopted 15 opinions, which the Commission has pledged to follow up

This annual burden survey presents an overview of the work carried out by the Commission in 2021 in its efforts to reduce burdens and simplify EU legislation, including the first results of the ‘one in, one out’ pilot. It provides concrete examples of this work, in line with the Commission’s commitment in the Interinstitutional Agreement on Better Law-Making⁷.

2. REFIT - the Commission’s regulatory fitness and performance programme

For two decades, burden reduction and simplification efforts have been part of the Commission’s work. The REFIT programme was established in 2012 and seeks opportunities for burden reduction, simplification, and modernisation, while safeguarding policy objectives and high standards, in the interest of both, the general public and business alike.

Over time, the REFIT programme has evolved. Since 2017, it requires that:

- all evaluations should consider how legislation can be simplified and made less burdensome;
- all impact assessments of legislative revisions should analyse the potential for burden reduction and simplification.

Simplification also means identifying potential for modernisation, in particular through digitalisation. Helping people and businesses adopt digital solutions by creating an enabling EU legal environment can help reduce the complexity of the single market legislation and increase its resilience.

The Commission monitors the REFIT programme through the online REFIT scoreboard⁸. This includes an overview of significant REFIT initiatives since 2015. It follows up on these initiatives throughout their life cycle.

The emphasis in the scoreboard is on the findings of the Commission’s evaluations and impact assessments, related to costs savings and simplification opportunities. The scoreboard also includes information on the outcome of the legislative process, in particular when amendments introduced by the European Parliament and the Council substantially impact the REFIT objectives and measures proposed by the Commission.

⁷ Interinstitutional Agreement on Better Law-Making between the European Parliament, the Council of the European Union and the European Commission on Better Law-Making: [https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016Q0512\(01\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016Q0512(01))

⁸ REFIT Scoreboard, <https://op.europa.eu/webpub/com/refit-scoreboard/en/index.html>

REFIT – An integrated approach

The REFIT programme is closely integrated into the Commission's better regulation system and policymaking. Achieving policy objectives at minimum cost requires the European Parliament and the Council to carefully consider the substantive amendments they propose, to preserve the REFIT gains of the Commission proposals. Similarly, Member States should consider this dimension when implementing EU legislation on the ground and should provide necessary data to inform the Commission's evaluations and impact assessments.

The high-level conference in December 2021 on joining forces for the next generation of better regulation⁹ focused particularly on the role of burden reduction and simplification to achieve a smooth recovery. Discussions in the conference strongly pointed to the need to preserve a balance between the costs and benefits of legislation, building foresight into all law-making and making better law-making a joint effort.

REFIT in the policy life cycle of an initiative

The REFIT dimension is considered from the outset, together with the political validation of an initiative. This is then carefully followed up in evaluations and impact assessments. It is also one of the aspects considered when consulting stakeholders and the public for specific initiatives. All evaluations and fitness checks assess the costs and benefits resulting from an initiative, and draw lessons related to the potential regulatory burden, complexity or inefficiencies of legislation. The findings inform subsequent impact assessments.

When the Commission prepares a proposal to revise legislation, the impact assessments identify the potential for burden reduction and simplification, and quantify it to the extent possible. The preferred option will consider whether the need to simplify and increase efficiency does not affect the overall goals of the legislation. The Commission's Regulatory Scrutiny Board provides independent internal quality control and checks whether the reports sufficiently explore the potential for simplification and burden reduction for citizens and business.¹⁰

The explanatory memorandum accompanying Commission proposals includes a REFIT section, explaining the proposed improvements to the original legislation in terms of complexity and regulatory burden. Where feasible, quantified information is provided. If there is no scope to simplify or reduce regulatory costs, the explanatory memoranda explain why.

REFIT in the Commission work programme and the strategic planning and programming cycle

The most important initiatives through which the Commission plans to give practical effect to its political priorities each year are part of the Commission work programme.¹¹ This includes

⁹ Speech by Vice-President Šefčovič at the high-level conference on 'Joining forces for the next generation of Better Regulation', Brussels, 2 December 2021

https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_6530

¹⁰ Since 2021, the Board introduced two new indicators to monitor this task. The indicators monitor if a simplification objective is included in impact assessments for revisions and if there is sufficient analysis of simplification potential in both evaluations and impact assessments.

¹¹ Commission work programme, https://ec.europa.eu/info/publications/commission-work-programme_en

the REFIT measures that are listed in Annex II. They aim to keep EU law fit for purpose, and are particularly relevant for identifying cost savings, implementing the ‘one in, one out’ approach. The 2021 work programme included 41 initiatives (revisions and evaluations), aimed at streamlining procedures, simplifying requirements for producing data, improving legislative consistency and allowing digital transformation.

Since 2020, REFIT is also integrated in the Commission’s strategic planning and programming cycle. The Commission incorporated in its 2020–24 strategic plans an indicator showing the proportion of legislative revisions that include burden reduction measures. This mandatory indicator is reported by all relevant Commission departments in their annual activity reports¹². These reports also list initiatives with significant potential for burden reduction and simplification.

Simplification – codification and recast

The Commission systematically considers the quality of EU legislation. Good quality also implies that legislation is clear and easy to comply with. The Commission seeks to remove obsolete provisions and to bring together subsequent amendments into a single act. This materialises in codifications¹³ and recasts¹⁴ of existing legislation, which make legislation more accessible and comprehensible.

In 2021, two Commission codification proposals were adopted by the Parliament and the Council¹⁵, while two others tabled by the Commission in previous years were still in the legislative procedure¹⁶. In 2021, the Commission also tabled three new codification proposals¹⁷ and 11 recast proposals¹⁸ for the European Parliament and Council to adopt.

Key REFIT achievements

Overall, the REFIT scoreboard monitors the programme’s progress since 2015. To date, the scoreboard includes in total:

- 222 legislative initiatives with a simplification and burden reduction objective **adopted**;
- 203 evaluations and fitness checks **finalised**.

In 2021, the following initiatives are adopted, finalised or ongoing under the REFIT programme:

- 35 legislative initiatives with a simplification and burden reduction objective **adopted**;
- 29 evaluations and fitness checks **finalised**;
- 62 legislative initiatives **pending adoption**;

¹² Annual activity reports, https://ec.europa.eu/info/strategy/reporting/annual-activity-reports_en

¹³ *Codification* is the process of bringing the rules in an existing act together with all the amendments to that act, in the form of a new legal act. This replaces and repeals the earlier act.

¹⁴ *Recast* is a tool that can help the simplification of EU legislation by taking the opportunity of an amendment to existing legislation to bring together all previous amendments into a single document. The result is the adoption of a new legal act which incorporates in one single text both the amendments and the unchanged provisions.

¹⁵ COM (2020) 323 and COM (2020) 48

¹⁶ COM (2020) 739; COM (2020) 49

¹⁷ COM (2021) 769 ; COM (2021) 483 ; COM (2021) 34

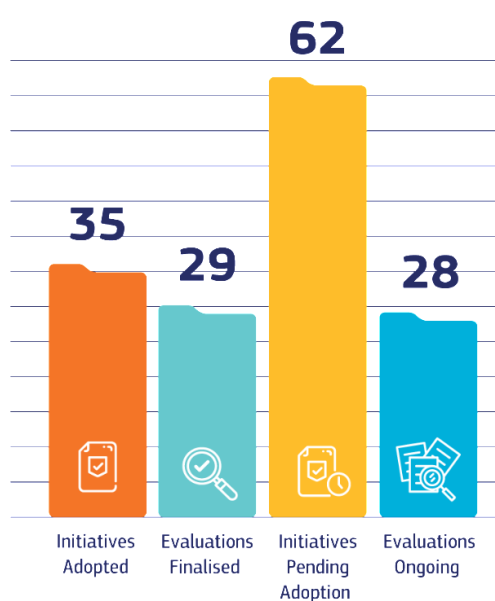
¹⁸ COM(2021)85, COM(2021)422, COM(2021)434, COM(2021)558, COM(2021)563, COM(2021)732, COM(2021)733, COM(2021)734, COM(2021)802, COM(2021)803 and COM(2021)804

- 28 evaluations **ongoing**.

These initiatives and evaluations cover an extensive number of areas such as the multiannual financial framework, agriculture and rural development, communications network and technology, competition, financial services, health, transport and the single market.

The Commission sought to quantify costs and benefits to the extent possible. When not feasible (due to limited data availability), qualitative assessments were used to explain the intended simplification and burden reduction instead.

Overview of 2021 REFIT measures



Examples of initiatives to simplify, reduce burden and modernise EU legislation in 2021



Multiannual financial framework

In 2021, the European Parliament and Council adopted the Commission proposals for programmes and funds for the 2021-2027 multiannual financial framework. The **measures to simplify the multiannual financial framework and procedures** proposed by the Commission are now expected to facilitate participation for beneficiaries, ease implementation across Member States and improve its impact on the ground.

The **Common Provisions Regulation**¹⁹, which entered into force in July 2021, provides for a simplified and more flexible framework for implementing grants, loans, guarantee and equity financial instruments under shared management. There is greater scope to combine grants in a single operation to maximise the impact of investments. This will facilitate synergies, for example, between cohesion policy and the asylum and migration funds to develop local integration strategies for migrants. The Simplification Handbook²⁰ provides a detailed view of the proposed simplification measures in the cohesion policy.



Agriculture and rural development

In 2021, the Commission finalised its evaluation²¹ of **geographical indications and traditional specialities guaranteed** in the EU. Building on the evaluation, the Commission started its preparatory work to revise the rules and improve the response of EU agriculture to social demands on the sustainability of agricultural production.

The Commission proposal will consider the objective of streamlining and clarifying the legal framework to simplify and align the procedures for registration of new names and amendments to product specifications. Streamlined procedures will result in faster processing of the applications and save resources both for producers and public authorities.

¹⁹ [Regulation \(EU\) 2021/1060](#) of the European Parliament and of the Council of 24 June 2021 laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, the Just Transition Fund and the European Maritime, Fisheries and Aquaculture Fund and financial rules for those and for the Asylum, Migration and Integration Fund, the Internal Security Fund and the Instrument for Financial Support for Border Management and Visa Policy

²⁰ [Simplification Handbook - 80 simplification measures in cohesion policy 2021-2027 - Regional Policy - European Commission \(europa.eu\)](#)

²¹ SWD(2021)427 of 20 December 2021



Communications networks, content and technology

The **European electronic identification and trust services** Regulation²² (eIDAS Regulation) provides the basis for cross-border recognition of electronic identification means and established a legal framework for trust services²³ within the EU. In 2021, the Commission adopted a proposal²⁴ to revise the regulation. While the main aim of the proposal is to provide access to trusted and secure digital identity solutions and trust services that can be used across borders, the proposal also aims to reduce administrative costs for public administrations and operational costs and expenditure related to security for online service providers. At the same time, the proposal opens the possibility for increased revenue for service providers with the introduction of new trust services. Citizens will benefit from reduced administrative burden, relying on digital means to securely exchange digital identity attributes with the same legal value across borders. Electronic identity providers will also benefit from savings in compliance costs. The estimated cost savings according to the impact assessment are in the range of EUR 3.5 to 7.1 billion.

In 2021, the Commission also adopted a proposal²⁵ to revise the **roaming** regulation²⁶. The Commission proposed to extend the rules regulating the EU-wide roaming market beyond 2022. The proposal amends the maximum wholesale charges and brings in new measures to ensure the quality of services for users, awareness of access to emergency services, and increased transparency, while repealing other measures that are no longer necessary.

Several amendments aim to simplify and reduce burden, for example, by aligning provisions on how to set maximum charges in currencies other than the euro for operators outside the eurozone and streamlining reporting obligations. This would also reduce the monitoring burden for authorities.



Competition

The Commission carried out a fitness check of the **state aid rules**²⁷ that identified some areas for improvement while concluding that, overall, the rules are broadly fit for purpose. In its 2021 work programme, the Commission consequently put forward eight initiatives to revise the state aid rules. They cover a wide range of sectors and aspects from energy and environment, regional aid, risk finance, research and development, major projects of common European interest, to agriculture and forestry as well as fishery and aquaculture.

²² [Regulation \(EU\) 910/2014](#) of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market

²³ Trust services comprise electronic signatures, electronic seals, electronic time stamps, electronic documents, electronic registered delivery services and certificate services for website authentication.

²⁴ COM(2021)281 of 3 June 2021

²⁵ COM(2021)85 of 24 February 2021

²⁶ [Regulation \(EU\) 2015/2120](#) of the European Parliament and of the Council of 25 November 2015 laying down measures concerning open internet access

²⁷ SWD(2020)257 of 30 October 2020

These revisions seek to streamline and simplify rules and adjust to recent legislative developments, current priorities, changes in markets and technology developments. For example, the revised risk finance guidelines²⁸ now only require a funding gap analysis for the largest risk finance aid measures (those allowing for investment amounts above EUR 15 million per individual beneficiary).

The revision introduces simplified requirements for assessing schemes that target exclusively start-ups and SMEs, which have not yet made their first commercial sale. The revised guidelines clarify and simplify the rules under which Member States can support and facilitate access to finance for European start-ups, small and medium-sized enterprises and companies with a medium capitalisation, while ensuring a level playing field in the single market.



Health and food safety

The Commission adopted a proposal²⁹ for a Regulation on a **European health data space**, which will tackle issues related to data protection, interoperability and security, both in the use and reuse of health data for the provision of healthcare, research, innovation, policy-making, regulatory activities, as well as further uses.

The initiative aims to empower citizens through increased access and control over their personal electronic health data and to support free movement of people by ensuring that health data follows them and are available throughout the EU. This initiative also aims to ensure a consistent and efficient framework for reusing health data in the EU, to provide improved access procedures and secure infrastructure, to provide common rules for electronic health record systems and wellness applications, and to establish common governance mechanisms.

The more intensive use of health data in the provision of healthcare services and the uptake of telemedicine are expected to save time, minimise errors and reduce duplications in healthcare, reducing overall administrative costs for patients by EUR 162 million per year.



Mobility and transport

The Commission carried out an evaluation³⁰ of the Directive setting common measures for the deployment of **alternative fuels infrastructure**³¹. Based on this evaluation, it adopted a proposal for a regulation³² in 2021, which increases the overall policy ambition and includes common rules for charge point operators and mobility service providers in the emerging e-mobility market.

²⁸ C/2020/4355 of 8 July 2020

²⁹ COM(2022)197 of 3 May 2022

³⁰ SWD(2021)637 of 14 July 2021

³¹ [Directive 2014/94/EU](#) of the European Parliament and of the Council of 22 October 2014 on the deployment of alternative fuels infrastructure

³² COM(2021)559 of 12 July 2021

The proposed regulation sets clear common minimum requirements that will simplify business operations and the use of the infrastructure by private and corporate consumers who currently face great fragmentation across Member States.

Markets and user groups will benefit from lower information costs, and market operators will also benefit from lower legal compliance costs (due to uniform arrangements) in the medium term. Public authorities will also benefit from a coherent EU-wide framework that will simplify coordination with public and private market operators. Lastly, the provision of standardised data formats, digitised data transfer and a common system of reporting to national access points of Member States is expected to considerably simplify reporting overall.



Single market

Building on the findings of an evaluation³³, the Commission has adopted a proposal³⁴ to revise the **machinery** Directive³⁵, which is the core European legislation regulating products from the mechanical engineering industries.

The proposal includes burden reduction and simplification opportunities for manufacturers dealing with product safety acts applying to their products. The impact assessment estimated, for example, that allowing digital instructions generates considerable economic benefits (e.g. through printing and paper cost savings) that greatly outweigh the costs generated for its introduction (e.g. by purchasing, setting up and maintaining a server). It is estimated that up to EUR 16.6 billion (or EUR 201 000 per company on average) in printing costs will be saved by using digital instructions and conformity declarations. Moreover, thanks to reduced vibration peaks in handheld machines, the initiative will result in costs savings estimated at EUR 15 million per year in social costs for sick leave and fewer occupational injuries.

³³ SWD(2018)160 of 7 May 2018

³⁴ COM(2021)202 of 21 April 2021

³⁵ [Directive 2006/42/EC](#) of the European Parliament and of the Council of 17 May 2006 on machinery

3. ‘One in, one out’ approach – results of the pilot project

What is ‘one in, one out’?

In her political guidelines, President von der Leyen outlined the goal of introducing a ‘one in, one out’ approach in the European Commission. ‘One in, one out’ means offsetting new burdens for businesses and citizens (resulting from the Commission’s legislative proposals) by reducing existing burdens in the same policy area. This mechanism requires to compare the costs stemming from Commission proposals for citizens and businesses with the costs removed by proposals in the same policy area. Several countries have applied this type of simplification and burden reduction policy over the years, including some Member States³⁶.

The 2021 better regulation communication³⁷ sets out the main principles of the approach. These are further developed in the Commission’s revised better regulation toolbox³⁸, which provides practical guidance on how to estimate costs and report them. The Commission has also developed a dedicated online calculator to facilitate the calculation and registration of cost estimates – see Annex II for further detail.

The Commission’s ‘one in, one out’ approach covers compliance costs for citizens and businesses. Administrative costs³⁹ are to be offset. Adjustment costs⁴⁰ are to be transparently presented in impact assessments together with benefits and are subject to review by the Regulatory Scrutiny Board. To the greatest extent possible, other measures are taken with a view to compensating adjustment costs too.

³⁶ See for instance: OECD: One-In, X-Out: regulatory offsetting in selected OECD countries (OECD regulatory policy working paper).

³⁷ COM(2021)219 final, https://ec.europa.eu/info/files/better-regulation-joining-forces-make-better-laws_en

³⁸ Tools #59 and #60, https://ec.europa.eu/info/sites/default/files/br_toolbox_-_nov_2021_-_chapter_8.pdf

³⁹ For definitions, see Tools #56 (*Typology of costs and benefits*) in the better regulation toolbox.

⁴⁰ These costs encompass those investments and expenses that citizens or business have to bear to adjust their activity to requirements contained in a legal rule.

One in, one out

covering compliance costs for citizens and businesses

Adjustment costs

(e.g. costs related to upgrading production lines, reducing damage to the environment, improving public health)

+

Administrative costs

(e.g. costs related to notification, submitting reports, information labelling, authorising, permits, certificates)

- **Recurring administrative costs**
- **One-off administrative costs**

Compensated to the greatest possible extent

(through specific instruments, e.g. financial programmes, technical assistance to SMEs)

Offset for citizens and businesses

Why a pilot project?

The Commission carried out a pilot project for applying the ‘one in, one out’ approach to test its draft guidance, methods and calculations. This pilot project ran during the second half of 2021.

The main purpose was to test the framework, the definition and coverage of costs. More precisely, the project was designed to test both, the specification of cost types covered and concrete calculations of cost estimates for specific proposals.

10 legislative proposals were selected for the pilot project in 2021, covering a broad range of policy instruments. These 10 projects represent diverse types of costs and impacts on different sectors and stakeholders.

Pilot projects

1. Solvency II⁴¹
2. Ozone layer protection - Revision of EU rules⁴²
3. Review of EU rules on fluorinated greenhouse gases⁴³
4. Revision of the industrial emissions Directive and the European pollutant release and transfer register Regulation⁴⁴
5. Revision of the energy performance of buildings Directive⁴⁵

⁴¹ COM(2021)582 of 22 September 2021

⁴² COM(2022)151 of 5 April 2022

⁴³ COM(2022)150 of 5 April 2022

⁴⁴ COM(2022)157 of 5 April 2022

6. Revision of the EU legislation on blood, tissues and cells⁴⁶
7. Digitalisation of visa procedures⁴⁷
8. Revision of Regulation on EU guidelines for the development of the trans-European transport network (TEN-T)⁴⁸
9. Revision of the design protection Directive and the design protection Regulation⁴⁹
10. Review of the marketing standards framework for fishery and aquaculture products⁵⁰

The description of all pilot proposals selected for ‘one in, one out’ is provided in Annex I.

Cost estimates

When analysing the cost estimates generated for the purpose of ‘one in, one out’, the following need to be considered:

- Cost estimates relating to Commission proposals indicate **expected costs** of an upcoming proposal and not actual costs. The purpose of estimates is to provide policymakers (and the public) with a reasonable indication of the magnitude of costs implied by a proposal.
- The estimates rely on **data provided by Member States and beneficiaries**, which are often difficult to obtain.
- Cost estimates are simply **assigned to the year in which the proposal is adopted** by the Commission (the base year), regardless of the fact that any real-world costs (if at all materialising) are likely to appear only several years later.
- Cost estimates **relate only to the Commission proposal**, not to the final EU regulation adopted. The Council and Parliament may decide to change a proposal significantly, relative to what the Commission proposed.

Main findings of the ‘one in, one out’ pilot project

While the pilot project did not explicitly require any offsetting for the cases involved, there are lessons to be learned for the upcoming offsetting process, based on the following **initial findings**:

- The Commission significantly strengthened its working methods by changing practices towards increased quantification and improvement of cost estimates;
- Designing the ‘one in, one out’ calculator was done in a consistent and flexible manner to cater for different situations faced;
- Working on a positive interplay between the ‘one in, one out’ approach and the

⁴⁵ COM(2021)802 of 15 December 2021

⁴⁶ COM(2022)338 of 14 July

⁴⁷ COM(2022)658 of 27 April 2022

⁴⁸ COM/2021/812 of 14 December 2021

⁴⁹ Planned adoption date: 2022 4Q

⁵⁰ Planned adoption date: 2022 4Q

REFIT programme allowed to comprehensively cover costs and beneficiaries in the overall reporting of the annual burden survey;

- Ensuring to the greatest possible extent compensation of adjustment costs and a quantification of wider benefits to avoid unbalanced discussions;
- Including one-off administrative costs that are to be offset together with recurrent administrative costs; and
- Ensuring the costs and cost savings relevant for ‘one in, one out’ were clearly presented in impact assessments required adaptation of the impact assessment template.

Adjusting working methods

The Commission has had systems in place for assessing and estimating administrative costs for years, using the basic estimation method of the EU standard cost model⁵¹. The ‘one in, one out’ approach builds on these existing practices and methodology, which are used internationally.

However, the new ‘one in, one out’ approach introduces further requirements and applies specific EU-level definitions. It requires more investment in basic data collection and skills for estimation purposes. Introducing ‘one in, one out’ in the Commission has led to significant strengthening of working methods concerning cost estimates and requirements facing policymakers. In short, the paradigm change brought by the new generation of better regulation has triggered a significant change of practice in implementation, accompanied with the necessary training of staff.

New support through a ‘one in, one out’ calculator

To support this process, the ‘one in, one out’ calculator (see illustration in Annex II) has been designed, to allow comparable aggregation of costs across the Commission. The calculator is an internal Commission tool for calculating and recording new and removed administrative burden for each policy proposal covered by the simplification/burden reduction exercise. It uses the above-mentioned EU standard cost model, based on the time necessary to perform an administrative obligation, multiplied by the average labour cost per hour (tariff).

Alternative estimation methods are allowed if it can be demonstrated that data availability is limited or depending on the character of the initiative. For example, when detailed information is not available for the basic components of the standard cost model formula (i.e. time and tariff), an estimation of the cost of an information obligation per company/person can be provided instead.

Similarly, the tool allows burden to be calculated on a per-unit basis (e.g. clinical trial, journey, etc.). In addition, it permits one-off administrative costs to be recorded.

Moreover, initiatives do not only add costs or remove them. Many do both: they add some costs while at the same time also introduce cost savings. The proposal on ozone-depleting substances, presented in Annex I, is an example of this. This proposal removes certain information requirements, such as “per shipment” licences, annual quotas and obligations to

⁵¹ [br_toolbox-nov_2021_en_0.pdf\(europa.eu\)](#), Tool #58

register. At the same time, new reporting requirements are introduced, such as on production emissions and sales and purchases of ozone-depleting substances.

The calculator caters for these situations. The flexibility to encode costs – depending on the character of the initiative, data availability and typology of costs – is a significant aspect that is strengthened as a result of the pilot.

‘One in, one out’ is complementary to the REFIT programme, and this allows costs and benefits to be covered comprehensively for all stakeholders

While the aim has been to implement the approach in a simple and uniform manner, it is clear from the pilot project that many different situations arise in legislative proposals which must be accounted for.

The approach covers both costs for citizens and businesses but does not concern costs and costs savings for national, local and regional authorities. Some proposals, however, include costs that concern these authorities or non-EU nationals.

For example, the impact analysis of the visa procedures initiative does not include any costs or costs savings for citizens and business, but shows tangible benefits in terms of cost saving and simplification for Member State administrations and for non-EU nationals applying for visa. The proposal is also likely to lead to an increase in visa applicants, which would particularly benefit the tourism industry and possibly other business sectors.

The REFIT programme covers all cost reduction and simplification measures. The ‘one in, one out’ approach therefore complements the comprehensive approach under REFIT to facilitate the identification of costs savings for all cost categories and beneficiaries and a consistent reporting in the annual burden survey.

Ensuring compensation of adjustment costs to the greatest possible extent and quantification of benefits for a balanced presentation

The ‘one in, one out’ approach accounts for adjustment costs and administrative costs, as explained above. Concerning *adjustment costs*, the Commission committed to compensate them to the greatest possible extent. These costs (e.g. upgrading production lines, reducing damage to the environment, improving public health or raising the level of consumer or worker protection) might not profit businesses directly. However, they often help them to profit from new business opportunities, to gain a competitive advantage, or to have indirect benefits, such as a level playing field in the single market.

The EU and/or Member States offer specific instruments to accompany the necessary adaptations. For example, with the revision of the EU legislation on blood, tissues and cells, some of these costs will be compensated by technical assistance through the EU4Health funds (EUR 13 million per year).

Moreover, while ‘one in, one out’ focuses on *costs* that can in most cases be estimated, quantifying *benefits* has generally been harder. This risks giving an unbalanced representation of the overall cost and benefits, stressing the cost component over the benefits resulting from legislation.

Including one-off administrative costs in the offsetting together with recurrent administrative costs

Administrative costs stem from administrative requirements specified in Commission proposals.⁵² When these costs are imposed on businesses or individuals, they are offset.

Other jurisdictions applying the ‘one in, one out’ approach in general only account for recurrent costs and not for costs that occur only once, at the start of the implementation. However, the Commission has decided to not only include recurrent administrative costs but also these one-off administrative costs.

The reason for this was that these costs, although only a one-off, can still be significant for citizens and businesses. For example, the impact assessment of the industrial emissions Directive shows that there are also significant administrative one-off costs when permits for industrial installations are revised to account for technological development⁵³.

The test phase shows that the reporting of one-off costs must be made in formats that are comparable with recurrent costs. Initiatives should thus include them in the ‘one in, one out’ calculator and provide *two administrative cost estimates*: recurrent costs per year and one-off costs.

Reporting clearly on all compliance costs required an adjustment of the impact assessment template

The ‘one in, one out’ approach includes all *compliance costs*⁵⁴, i.e. adjustment costs and administrative costs. These must be properly calculated and reported in impact assessments to ensure clarity and consistency.

As a rule, all costs related to the preferred option identified in the analysis were reported in the impact assessment report, together with the methodology used for the analysis. However, this presentation, while complete, was not sufficient to capture consistently the ‘one in, one out’ approach.

The presented cost categories in draft impact assessments often did not fully correspond to the ‘one in, one out’ cost classification. As explained above, not all costs (e.g. those for public authorities) are relevant for ‘one in, one out’ and thus could create confusion with the final figures used for offsetting.

For this reason, the Commission’s impact assessment template has been changed to more clearly reflect the cost categories and cost savings relevant for ‘one in, one out’. The template now also uses section headings that point directly to the relevant parts of the revised better regulation toolbox that should be consulted by Commission staff when preparing their impact assessments.

⁵² These concern costs resulting from notification, submitting reports, information labelling, information from third parties, authorisation, building permits, registration or certification. The following are not included: inspections on behalf of public authorities, cooperation with audits & inspections by public authorities, maintenance of records and applications for subsidies or grants.

⁵³ Limits for pollutants are set in permits based on ‘best available techniques’ identified together with stakeholders.

⁵⁴ This does not include fees and charges, which are enforcement costs.

Further follow-up through training and awareness-raising

In addition, the Secretariat-General provided a series of training and information sessions for the different Commission departments to raise awareness of the important changes that need to be considered following the publication of the revised guidelines and toolbox. Moreover, the implementation of ‘the one in, one out’ approach continues to be closely monitored.

Looking ahead

The next annual burden survey will offer a first comprehensive picture and report on the full implementation of ‘one in, one out’ in 2022, using figures presented and explained in the impact assessments for the proposals in question, as well as analyse the offsetting efforts made.

The Regulatory Scrutiny Board checks the quality of cost estimates presented in the impact assessments. The Board has already paid more attention to cost estimates in its scrutiny and also reported on its experience in its annual report.⁵⁵ It stated that it often asked for clearer distinctions between different cost categories and for further quantification of the administrative costs and savings.

It also observed an early positive and relevant trend by highlighting that the quantification of benefits and costs continued to increase further during the ‘one in, one out’ pilot phase. For instance, the percentage of impact assessments that provide at least a partial quantification of costs and benefits increased from 80% to 90%, while assessments that fully quantified have increased from 30% to 50%.

4. Fit for Future Platform

Mandate and work

The Commission set up a high-level expert group, the Fit for Future Platform⁵⁶, in May 2020 to play a key role in identifying opportunities for simplifying and modernising existing EU laws and removing unnecessary burden at EU, national, regional and local level stemming from EU legislation. The Platform, chaired by the European Commission’s Vice-President responsible for Interinstitutional Relations and Administration, Maroš Šefčovič, complements the Commission’s evidence base with the views and experience of its members, including the stakeholders that apply and comply with EU laws.

The Platform extends the REFIT programme’s outreach by bringing together the expertise of national administrations, regions, employers, trade unions, small and large businesses as well as consumer, health and environmental and other non-governmental organisations, the Committee of the Regions and the European Economic and Social Committee. It is this mixed composition, representing various interests, that gives the Platform its added value.

⁵⁵ Regulatory Scrutiny Board, Annual Report 2021, [Regulatory Scrutiny Board – Annual Report 2021 | European Commission \(europa.eu\)](#)

⁵⁶ C(2020)2977 of 11 May 2020

During its five-year mandate, the Fit for Future Platform is tasked with supporting the Commission's efforts to:

- reduce unnecessary burdens and costs;
- simplify existing EU laws;
- ensure that EU policies are forward looking and relevant in light of new developments and technological progress. This includes exploiting the potential of digitalisation for burden reduction and simplification.

The Platform further collaborates with the SME envoys network⁵⁷, which provides advice and input, in particular on burdens and complexity of legislation that affect small and medium-sized enterprises. Its work also benefits from the contribution of the Committee of the Regions' RegHub network⁵⁸ that brings together regional and local authorities that collect experiences on EU policy implementation by consulting stakeholders locally.

Individuals and organisations can also contribute to the work of the Platform by providing input on the *Have your say: Simplify!* portal⁵⁹. Through this portal, stakeholders can share their views and experience on any item of the Fit for Future Platform's annual programme or suggest other subjects for the Platform to consider.

The topics of the Fit for Future Platform's annual work programme relate to existing EU legislation that has potential for burden reduction, simplification or modernisation, in the Platform's view. The Platform can also work on general topics relevant to its mandate.

Simplify existing EU laws

Get involved in making EU laws more efficient and fit for future! The [Fit for Future Platform](#) will consider your suggestions when making its recommendations to the European Commission.

Share your suggestions at [Have your say: Simplify! >](#)

In 2021, 32,910 individuals and organisations visited the portal.

2021 annual work programme

The Fit for Future Platform adopted its first annual work programme in spring 2021⁶⁰. The annual programme was drawn up by the Platform members, based on a proposal from and in agreement with the Commission's Secretariat-General. It included mainly major evaluations and legislative revisions carried out by the Commission and took into account input provided by Member States, the SME envoys network, the Committee of the Regions and RegHub, as well as the European Economic and Social Committee.

⁵⁷ [SME envoys network | Internal Market, Industry, Entrepreneurship and SMEs \(europa.eu\)](#)

⁵⁸ [RegHub \(europa.eu\)](#)

⁵⁹ [Have your say: Simplify! \(europa.eu\)](#); [Make a suggestion: \(europa.eu\)](#). The Have your say: Simplify! portal replaced the 'Lighten the load' portal used by the REFIT Platform, the predecessor of the Fit for Future Platform.

⁶⁰ [Annual work programme | European Commission \(europa.eu\)](#)

The 2021 annual work programme focused on four **key areas**: digitalisation, efficient labelling, authorisation and reporting obligations and simplifying EU legislation. It comprised the following 15 topics:

Platform's 2021 work programme

1. New legislative framework for products⁶¹
2. Industrial emissions⁶²
3. Computer reservation systems⁶³
4. Ambient air quality legislation⁶⁴
5. Public e-procurement legislation⁶⁵
6. Combating late payment in commercial transactions⁶⁶
7. European fishery statistics⁶⁷
8. Single permit for non-EU nationals⁶⁸
9. Infrastructure for Spatial Information in the European Community (INSPIRE)⁶⁹
10. Eco-design⁷⁰
11. Completing the Banking Union⁷¹
12. Guidelines on state aid to the agricultural and forestry sectors and in rural areas and agricultural block exemption Regulation (ABER)⁷²
13. Union Customs Code⁷³
14. Application on patient rights in cross-border healthcare⁷⁴
15. Package travel and linked travel arrangements⁷⁵

The Platform gathered evidence throughout the year and formulated its suggestions in various consultation rounds. The opinions' strength comes from the concrete solutions that the Platform's members – representing different interests and positions – propose and jointly agree.

⁶¹ [Decision No 768/2008/EC](#) and [Regulation \(EC\) No 765/2008](#)

⁶² [Directive 2010/75/EU](#)

⁶³ [Regulation \(EC\) No 80/2009](#)

⁶⁴ [Directive 2008/50/EC](#) and [Directive 2004/107/EC](#)

⁶⁵ [Directive 2014/24/EU](#)

⁶⁶ [Directive 2011/7/EU](#)

⁶⁷ [Regulation 1921/2006](#); [Regulation \(EC\) No 762/2008](#); [Regulation \(EC\) No 216/2009](#); [Regulation \(EC\) No 217/2009](#); [Regulation \(EC\) No 218/2009](#)

⁶⁸ [Directive 2011/98/EU](#)

⁶⁹ [Directive 2007/2/EC](#)

⁷⁰ [Directive 2009/125/EC](#)

⁷¹ [Directive 2014/59/EU](#), [Regulation \(EU\) No 806/2014](#), [Directive 2014/49/EU](#)

⁷² [Commission Regulation \(EU\) No 702/2014](#) and [European Union Guidelines for State aid in the agricultural and forestry sectors and in rural areas 2014 to 2020](#)

⁷³ [Regulation \(EU\) No 952/2013](#)

⁷⁴ [Directive 2011/24/EU](#)

⁷⁵ [Directive \(EU\) 2015/2302](#)

Opinions

Notwithstanding the difficult circumstances (working remotely), the Platform adopted and completed all its 15 opinions from the 2021 work programme.⁷⁶ Across the opinions, members submitted over 150 contributions, which led to the formulation of 90 specific suggestions. These concern the potential for simplifying EU laws in areas such as competition, finance, health, environment, statistics, transport, customs and single market.

The Platform's suggestions have the potential to benefit citizens and businesses alike, at European, national and local and regional level. One of the key aspects highlighted by the Platform is the need to streamline the regulatory framework, ensuring EU laws are consistent and clear, and improve enforcement, compliance and implementation.

The Platform's opinions also point to the potential to strengthen the forward-looking perspective when revising EU laws. They include solutions to increase digitalisation and the use of digital information, improve interoperability and support dynamic approaches to overcome technical and border barriers.

Key priorities

Digitalisation

The Platform's opinions include different suggestions covering aspects of simplification, digitalisation, removing overlapping and streamlining procedures. Many of the Platform's opinions include suggestions pointing to burden reduction potential for businesses taking up digital solutions and accelerating the modernisation of the public sector. Examples from the Platform's 2021 opinions include:

European fisheries statistics	▶ improving the collection and digitalisation of data
Single permit for third-country nationals	▶ streamlining and digitising the single permit application and visa applications
New legislative framework for products	▶ exploring whether product information and documentation can be provided digitally by default
Combating late payments in commercial transactions	▶ e-invoicing (B2B transactions)
E-procurement	▶ ensuring the interoperability of platforms and their compatibility with various national databases, digitising the whole procurement procedure
INSPIRE	▶ clarifying pan-European needs and prioritising metadata

⁷⁶ [Adopted opinions](#) | [European Commission \(europa.eu\)](#)

Simplification

The Platform also focused on the simplification of EU legislation, to remove overlaps or inconsistencies between different European laws that are detrimental to businesses, in particular SMEs. Examples from the Platform's 2021 opinions include:

Eco-design	▶ making the legislation clearer and simpler, by avoiding duplication of regulations or inconsistencies, and keeping the eco-design legislative framework focused
Banking Union	▶ improving consistency between the deposit guarantee schemes Directive and the payment service and e-money Directives
Combating late payments	▶ clarifying certain terminologies, such as the concept of 'grossly unfair' terms and practices
Ambient air quality	▶ ensuring consistency between policies to close the gaps on emission sources

Labelling, authorisation and permitting procedures

Efficient labelling, authorisation and permitting procedures were also in the Platform's annual work programme in 2021. The Platform also delivered on reporting obligations necessary to assess the performance of EU legislation and whether the 'once only principle' had been met. Examples from the Platform's 2021 opinions include:

Computer reservation system	▶ updating reporting requirements under the corresponding regulation to reflect new market realities
Union Customs Code	▶ exploring the possibilities for flexible implementation of the rules in emergencies
Industrial emissions	▶ implementing a uniform electronic reporting format
Patient rights in cross-border healthcare	▶ tying prior authorisation to direct billing
State aid in agricultural and forestry sectors and in rural areas and the agricultural	▶ simplifying aid to small farmers by further reducing the administrative burden

exemption regulation

Package travel

- providing better information on the identity of the contract partners and contact details, and better enforcing rules

Local and regional levels - the RegHub special report⁷⁷

As part of the Platform's annual work programme, the Committee of the Regions' RegHub network worked in 2021 on a special report on the obstacles that local and regional administrations encounter in rolling out infrastructure projects and proposed solutions. This responded to a special request by the Fit for Future Platform's chair, Vice-President Maroš Šefčovič, given the importance of this issue for mastering the green and digital transitions and achieving the EU objectives of the Green Deal, Digital Decade, and Sustainable and Smart Mobility.

To identify the infrastructure projects of high interest, the RegHub carried out two consultations in the spring and autumn of 2021. The network of regional hubs highlighted the types of infrastructure that are key for the development of their cities and regions and the link to the EU laws which oversee the rollout of that infrastructure. The report's analysis focusses on issues related to transport infrastructure, broadband deployment as well as environmental impact assessments and green infrastructure.

Regarding **transport infrastructure**, the Hubs support the objectives of the EU's Sustainable and Smart Mobility Strategy. The conclusions of the report point, however, to the need to pay attention to the following issues: (i) avoiding disparities between regional railway infrastructure and mainline networks; (ii) increasing the legal certainty of state aid and its role in facilitating infrastructure investment; and (iii) increasing synergies in cross-border areas and making approvals by the European Rail Agency smoother.

Regarding **green infrastructure** and EU environmental law, the report draws further attention to the frequent changes of documents relating to the implementation of the Directives on environmental impact assessment⁷⁸ and strategic environmental assessment⁷⁹. Such changes may also occur at national or at the regional level, when legislation and guidelines are transposed in their respective context. The report notes that it is necessary to effectively reduce information requirements, increase local and regional authorities' awareness of guidance documents, and allocate funding to digitisation of plans, platforms and training of municipal staff. The Commission's 'one-in-one-out approach' is seen by the Hubs as an opportunity to lighten administrative burden and simplify legislation by avoiding duplication and inconsistencies, if certain conditions are met.

⁷⁷ European Committee of the Regions (2022) RegHub Special Report on "21st Century Rules for 21st Century Infrastructure" – Overcoming obstacles to transport, digital, and green infrastructure deployment, available at <https://cor.europa.eu/en/our-work/Pages/RegHub-Special-Report-on-21st-Century-Rules-for-21st-Century-Infrastructure.aspx>

⁷⁸ [Directive 2021/92/EU, EUR-Lex - 32011L0092 - EN - EUR-Lex \(europa.eu\)](#)

⁷⁹ [Directive 2001/42/EC, EUR-Lex - 32001L0042 - EN - EUR-Lex \(europa.eu\)](#)

Regarding **digital infrastructure**, the report acknowledges that the current rules on the provision of state aid for deployment of non-terrestrial (fixed wireless) connections are well-functioning. The Hubs view the current revisions of (i) the state aid general block exemption Regulation ⁸⁰ and (ii) the Guidelines on state aid for broadband networks⁸¹ as a step in the right direction but flag that additional efforts on simplification and clarification are still needed. It proposes to improve the interoperability of ledgers also in the areas such as transport and energy management, and to envisage a close interconnection of all public registers.

The report further discusses the role of the **public acceptance and participation** as important factors when it comes to infrastructure projects. It outlines, amongst other things, the need for a better involvement of local and regional authorities in infrastructure development and rollout.

Following up on the opinions

The Platform's opinions complete the evidence base and inform the Commission's ongoing and planned analyses for evaluations and impact assessments, as well as other initiatives, including implementing acts, preparation of guidelines and training activities.

All 2021 opinions have been considered in the Commission's preparatory work. Annex III provides a summary of all opinions and the follow-up given by the Commission, while the REFIT scoreboard presents further details of this.

The follow-up can take various forms. For instance, the Platform's opinions can **help to prepare and be taken up by legislative proposals**.

In the case of the single permit for non-EU nationals, the Platform tabled suggestions in its opinion to streamline and digitise the single permit application and visa applications as well as the procedures for changing employer and increasing ownership of workers.

The suggestions have been addressed in the Commission's proposal⁸² to review the directive. The Commission proposed changes stipulating that the Member States allow the application for a single permit to be made both in the Member State of destination and from a non-EU country, and requiring Member States to issue the requisite visa where the requirements specified by EU or national law are fulfilled⁸³.

⁸⁰ Regulation (EU) No 651/2014 of 17 June 2014

⁸¹ EU Guidelines for the application of State aid rules in relation to the rapid deployment of broadband networks, [2013/C 25/01](#)

⁸² COM(2022)655 of 27 April 2022

⁸³ Article 4 of COM(2022)655

The Commission also specified in its proposal⁸⁴ that the time limit of four months laid down in the directive covers the issuance of the requisite visa. This time limit must also cover the time needed by the authorities to check the labour market situation before a decision on the single permit is adopted.

Regarding the procedures around employment under a single permit, the Commission's proposal ensures that (i) the single permit shall not be withdrawn in the event of unemployment of its holder, and (ii) that Member States will allow the non-EU worker to remain on their territory for at least three months during the validity of the permit. The Commission will carry out technical work within its relevant networks to address the Platform's suggestion about digitising the various procedures.

The Platform's opinions can also provide **input to evaluations**, where the input from representatives of national local and regional authorities as well as stakeholders gives concrete insights into how the legislation impacts them on the ground.

For example, the Platform's opinion on patient rights in cross-border healthcare was informed by significant contributions from the local and regional level. The Commission assessed these aspects in its evaluation of the directive⁸⁵. They concern in particular (i) a lack of awareness about the opportunities created by the directive among healthcare professionals and the public at large; (ii) challenges in accessing information on care options abroad; and (iii) obstacles stemming from prior authorisation procedures and price transparency.

The evaluation's findings point to similar conclusions as reached by the Platform in its opinion: the evaluation found that the directive has been moderately effective in delivering its objectives to facilitate access to safe and high-quality healthcare in another EU country.

Based on the evaluation findings, the Commission committed⁸⁶ to boost cooperation with the national contact points and to organise knowledge and capacity-building workshops. The Commission will also organise new bilateral dialogues with Member States about prior authorisation and help Member States share good practice on price transparency for cross-border patients and the estimated level of reimbursement. The Commission will further help Member States share knowledge on streamlining procedures for accessing cross-border healthcare through digitisation.

In addition, the Commission will support awareness events in the Member States, in cooperation with national contact points and with participation by regional healthcare projects and relevant stakeholders, as suggested by the Platform. At the same time, the creation of a European Health Data Space will ensure that citizens have greater access to and control over their own health data, including across borders, and will facilitate its reuse for purposes such as research, innovation, policy-making and regulatory activities.

In its opinion on the public e-procurement, the Platform tabled suggestions to simplify, modernise and reduce potential burdens in the area of e-procurement. This concerned, for

⁸⁴ Article 5 of COM(2022)655

⁸⁵ SWD(2022)200 of 12 May 2022.

⁸⁶ COM(2022)210 of 12 May 2022.

example, the European single procurement document, eCertis and the interoperability of the various platforms used in procurement procedures to further support the transition to e-procurement.

In line with the Platform's suggestions, the Commission aims to fully integrate the European single procurement document with the existing e-procurement landscape and meet the once-only principle. For instance, the Commission supports a technical data model to allow buyers to provide information on individual criteria, and it engages regularly with stakeholders to further improve the integration of the European single procurement document into other systems and the new eForms, including eCertis. While the Commission provides the technical documentation, it is in the remit of the Member States and its solution providers to integrate the different solutions.

The Commission also plans to make a standardisation request to help organisations in Europe to make their eProcurement solution interoperable. Improving technical capacity, as recommended by the Platform, represents a key aspect of supporting the use of e-procurement and the Commission plans to use the future national workshops to highlight this to the Member States and overcome the complexity of different national set-ups.

The Commission also initiated actions to help small and medium-sized businesses and small contracting authorities to transition to e-procurement. The upcoming launch of procurement notices eForms is an important step as it is for the first time possible with the coming notices to indicate business opportunities which are particularly suitable for SMEs.

5. Conclusions

The economic uncertainty and turmoil caused by the Covid-19 pandemic, and more recently because of Russia's invasion of Ukraine, have caused significant challenges for citizens and businesses in the EU. This context underlines the importance of avoiding unnecessary costs and burdens while ensuring that EU legislation achieves its objectives. The Commission is regularly examining how unnecessary burdens can be avoided, especially for medium-sized and smaller companies. We will further revitalise the work of the SME network and support similar initiatives in this regard.

The **regulatory fitness and performance programme** (REFIT) continues to play a key role as it aims to maximise benefits for people, businesses and society at large, while removing unnecessary burden. Under this programme, the Commission systematically screens existing legislation for opportunities to simplify and reduce burden, while preserving the attained benefits, and considering digital solutions.

In 2022, the Commission's focus will be placed on fully implementing the **'one in, one out' approach**. The lessons learnt from the 10 pilot projects from 2021 have informed the full deployment of the approach that started in January 2022. It includes initiatives listed in the Commission work programme that have cost implications for, or otherwise affect, citizens and businesses. The next annual burden survey will report on the offsetting of all relevant initiatives adopted in 2022 and provide a first full picture in implementing this milestone of the new better regulation generation.

Moreover, the Commission will further consolidate the integration and implementation of REFIT throughout the full policy-making cycle. This entails improving the understanding that regulatory fitness and performance is **not just cutting red tape but securing maximised benefits for citizens and businesses** in the most efficient manner. Ambitions such as the European Green Deal and digitalisation remain solidly at the core of the Commission agenda.

The **Fit for Future Platform** will continue to provide valuable input to this process. After having agreed on improved working methods to increase transparency and efficiency, the Platform has already managed to adopt its new annual work programme in January 2022 – giving it three months of additional time to work on its opinions. This includes work in many different areas, such as energy, taxation, access to capital for small and medium-sized enterprises, bio solutions, victims' rights, chemicals and interoperability.

The Commission has addressed the challenges faced and followed up on the suggestions for improvement that it received. The Commission has shown that it implements its commitment to take evidence-based political decisions without creating unnecessary burdens for citizens and businesses.

Annex I: ‘One in, one out’ pilot summary by case

Solvency II Directive

This initiative concerns a review of the directive that, in 2016 provided a uniform framework for supervising insurance and reinsurance companies in the EU. It introduced risk-based capital requirements, stricter governance, risk management rules, improved supervisory reporting and public disclosure. It aims to protect insurers’ clients (‘policyholders’) and preserve the stability of the financial system.

Solvency II contains review clauses requiring the Commission to assess and, where necessary, propose changes to four areas of the framework. These concern: long-term guarantees and measures on equity risk; the standard formula for solvency capital requirements; minimum capital requirements; and group supervision and capital management within a group of insurance or reinsurance companies as well as insurance guarantee schemes.

This review included also additional issues that the Commission has identified in other parts of the Solvency II framework. The proposal introduced proportionality measures in Solvency II. It implies that certain obligations will no longer apply to domestic insurance and reinsurance companies that have revenues between EUR 5 and 15 million and a risk volume between EUR 25 and 50 million. Low-risk insurers will also benefit from the automatic application of certain proportionate rules. These measures will amount to total administrative cost savings of EUR 217.2 million.

‘One in, one out’ administrative costs:

- Recurrent costs: EUR -217.2 million

Ozone layer protection

The evaluation carried out for this initiative showed that the potential for improving the current ozone layer Regulation relates to mostly enhancing its efficiency, consistency and clarity by fine-tuning specific measures.

This initiative consists of both cost-generating and cost-saving elements. This revision removes certain information requirements, such as per-shipment licences, annual quotas and obligations to register (amounting to cost savings of EUR 0.2 million). At the same time, new reporting requirements are introduced, such as for production emissions and sales and purchases of ozone-depleting substances (amounting to costs of EUR 0.1 million).

‘One in, one out’ administrative costs:

- Recurrent costs: EUR -0.1 million

Fluorinated greenhouse gases

This initiative of the second ‘Fit for 55 package’ focuses on fluorinated greenhouse gases (F-gases). These are man-made chemicals used as refrigerants in cooling equipment and heat pumps as well as in foams and asthma sprays. F-gases are powerful greenhouse gases – several thousand times stronger than carbon dioxide. This initiative reviews the rules on F-gases to ensure they comply with the Montreal Protocol (on substances that deplete the ozone layer) and contribute to the European Green Deal targets as well as to improvements in implementation, enforcement, monitoring and reporting.

This initiative implies new costs and removed costs. Total new costs amount to EUR12.1 million, of which EUR 1.9 million relate to alignment with international rules and/or improving enforcement to reduce illegal activities.

Cost savings come from reducing administrative costs for businesses by relaxing and aligning the maximum amounts of products and equipment that importers can place on the market, requiring applications for quotas only every three years rather than annually (for bulk gas importers and EU producers) and introducing an electronic verification process (for reporting companies e.g. bulk and equipment importers, EU producers).

- The 3-year quotas save EUR 1 242 000.
- Aligning reporting and authorised amounts for equipment saves EUR 92 923.
- Relaxing the verification limit for equipment (and laying down the legal basis for electronic verification) saves EUR 3 203 710.
- Total cost savings are EUR 4.5 million.

‘One in, one out’ administrative costs:

- Recurrent costs: EUR 5.7 million
- One-off costs: EUR 3 million

Industrial emissions Directive

The industrial emissions Directive⁸⁷ is the main instrument regulating pollutant emissions from agro-industrial installations (i.e. power plants, refineries, cement producers, steel, non-ferrous metals and glass, intensive rearing of pigs and poultry etc.). Its aim is achieve a high level of protection of human health and the environment as a whole by reducing harmful emissions into air, water and soil from industrial installations and livestock farms across the EU, in particular through the application of Best Available Techniques (BAT). The proposal to revise this directive comes in the context of renewed environmental and climate objectives. While it will substantially reduce negative health and environmental impacts, the initiative will also have costs, including administrative costs, largely because its scope is expanded.

⁸⁷ Directive 2010/75/EU

The directive is the result of a better regulation initiative that merged and simplified seven directives⁸⁸ and streamlined administrative aspects, including cutting reporting requirements by around half⁸⁹. While this limits the potential for further streamlining, stakeholder consultations have identified additional opportunities for clarifications and simplifications. Moreover, the proposal introduces a lighter permitting regime for 20 000 livestock farms currently regulated by the directive, as well for those that will be newly brought within its scope, notably the smallest businesses regulated by the directive. This should reduce the administrative burden by EUR 113 million per year.

The proposal would add EUR 171.5 million in administrative costs (linked to monitoring and reporting requirements) and remove around EUR 40.7 million for industry⁹⁰.

‘One in, one out’ administrative costs:

- Recurrent costs: EUR 130.8 million
- One-off costs: EUR 1 946 million

Energy performance of buildings

Decarbonising buildings is vital for delivering the EU’s 2030 and 2050 climate and energy objectives. Buildings are responsible for 40% of total energy consumption and one third of energy-related greenhouse gas emissions in the EU.

The initiative to revise the Directive on the energy performance of buildings is part of the ‘Fit for 55’ package. It complements the other initiatives to cut net greenhouse gas emissions in the EU by at least 55% by 2030, compared to 1990. Energy efficiency is an essential component and the building sector is one of the key sectors that needs additional efforts. The 2020 ‘Renovation wave’ Communication contains an action plan with regulatory, financing and enabling measures. These aim to at least double the annual energy renovation rate of buildings by 2030. The revision of the directive introduces a new provision to ensure that the worst performing parts of the building stock are upgraded to reach ‘minimum’ energy performance standards. They will need to reach at least an E-rating level by 2030. Therefore, an affected building or building unit will need to be certified once in the next 7 years to certify that it complies with the minimum energy performance standards. This is a one-off cost for each building. This cost is usually part of the overall renovation cost, but is nonetheless included in this summary.

From the 2027/2030 stock of EU buildings, approximately 27% will fall under categories F-G that means approx. 32 million residential buildings and 1.2 million non-residential buildings. These buildings will need to be upgraded and it would have to be certified that they have reached EPC E.

- Cost of certification for residential building units involved –240 /unit – Total cost: EUR 7.68 billion.

⁸⁸ SEC/2007/1679 of 21 December 2007

⁸⁹ SWD(2017)230 of 9 June 2017

⁹⁰ Administrative costs reported in the impact assessment supporting the proposal (SWD(2022) 111 final) are provided in ranges and at a different level of aggregation.

- Cost of certification for non-residential building units involved –Total cost EUR 0.48 billion.

Consequently, the estimated administrative costs will be EUR 8.16 billion (one-off). These costs will be spread over 7 years (from 2023 to 2030), resulting in EUR 1.16 billion per year. These costs are necessary to upgrade Europe's building stock and to enhance energy efficiency and reduce their CO2 emissions.

‘One in, one out’ administrative costs:

- One-off costs: EUR 8.16 billion

Blood, tissues and cells

This proposal is a revision of the Blood Directive 2002/98/EC and the Tissues and cells Directive 2004/23/EC. These rules help to ensure the safety of patients undergoing blood transfusion, tissue transplantation and medically-assisted reproduction.

The legislation sets quality and safety requirements for all steps, from donation to human application, unless the donations are used to manufacture medicines or medical devices. In these cases, the legislation only applies to donation, collection and testing.

The proposal updates the regulation with new scientific and technical developments and addresses identified shortcomings on blood transfusions that were emerging during the COVID-19 pandemic. And it merges two directives into one regulation.

The additional administrative costs come from registrations and authorisations of new establishments, adaptations to safety and quality standards, and reporting and monitoring requirements.

These total additional administrative costs are estimated at EUR 29.6 million per year. The total reduced administrative cost is estimated at EUR 13.7 million per year, leaving a net balance of around EUR 15.9 million of additional costs per year.

‘One in, one out’ administrative costs:

- Recurrent costs: EUR 15.9 million
- One-off costs: EUR 0.58 million

Visa procedures

Applying for Schengen visas and issuing them remains a largely paper-based and cumbersome process. Applicants complete and sign an application form (on paper). They provide supporting documents and travel medical insurance (in original or copy). Finally, they pay the visa fee (in most cases in person). This is a time-consuming and costly procedure for both the applicants and the consulates involved.

This initiative implements the Commission's commitment in its New Pact on Migration and Asylum to make the visa procedure fully digitalised by 2025, with a digital visa and the ability to submit visa applications online.

The impact analysis shows tangible benefits in terms of cost saving and simplification for Member State administrations and for non-EU nationals applying for visas. The proposal is also likely to lead to an increase in visa applicants, which would notably benefit the tourism industry and possibly other business sectors. However, the 'one in, one out' approach does not concern costs and costs savings for national, local and regional authorities and for third country nationals, thus these important costs savings are not recorded.

No 'One in, one out' administrative costs.

Trans-European transport network (TEN-T)

This initiative reviews the EU regulation concerning the guidelines for developing the trans-European transport network (TEN-T). The aim of the TEN-T is to build an EU-wide multimodal transport infrastructure network of roads, rail, inland waterways and maritime routes. These should link to urban nodes, ports, airports and other terminals across the EU.

The measures include the adoption of new, reinforced or clarified standards for all transport modes, to deliver a fully interoperable and functioning EU-wide network. There are also measures to address bottlenecks and insufficient connectivity, notably by targeting urban nodes and furthering the digitalisation of the infrastructure. Furthermore, there are measures to increase the safety and resilience of the network. It also responds to the goals of the European Green Deal and the EU's Sustainable and Smart Mobility Strategy.

The proposed revision is considered to lead to additional administrative costs for businesses, estimated at EUR 1.1 million per year at EU level⁹¹. These costs concern:

1. the participation of transport operators and project promoters in TEN-T governance mechanisms, e.g. corridor fora, workshops and other related coordination activities (EUR 0.3 million per year); and
2. management and operational costs in relation to increased TEN-T requirements for terminal owners/operators (EUR 0.2 million per year), rail operators (EUR 0.5 million per year) and road operators (EUR 0.1 million per year).

The proposal also concerns nine European Transport Corridors (ETCs) that will align the existing Rail Freight Corridors and the TEN-T Core Network Corridors. This is projected to lead to a reduction in the reporting needs for the transport operators and project promoters, estimated at EUR 0.2 million per year⁹².

'One in, one out' administrative costs:

- Recurrent costs: EUR 0.9 million

⁹¹ Expressed as annual averages over a 10 year period.

⁹² Expressed as annual average over a 10 year period.

Designs initiatives

This initiative aims to revise the EU designs legislation that was established two decades ago in the Designs Directive and the Community designs Regulation. The pilot concerns two initiatives (run jointly) that aim, among other things, to ensure that the design protection system becomes substantially more accessible and efficient for individual designers, design-intensive industries and small and medium-sized enterprises, due to streamlined and simplified procedures.

The initiatives follow up on the related evaluation completed in 2020. It concluded that there are two key remaining challenges: 1) the disruption of the single market for spare repair parts for cars; and 2) the continuing discouragement of businesses from seeking design protection at EU or national level. It aims to address these problems while ensuring that the design protection system will be fit for purpose in the digital age and becomes more accessible and efficient. It is a building block of the Commission's intellectual property action plan launched last year.

The initiative is planned to be adopted in the second half of 2022. Preliminary data points to a reduction in recurrent administrative costs in the range of EUR 2 million.

Marketing standards for fishery and aquaculture

Current marketing standards for fishery and aquaculture products have been in place for over 25 years. An evaluation in 2019 identified shortcomings in terms of the ability of current standards to achieve the objectives of the common market organisation. In particular, they do not contribute to the objective of promoting sustainable products for EU markets.

Their contribution to a level playing field in the EU seafood market was also considered limited, because the current standards only apply to a limited share of fisheries products on the market.

The new standards would aim to improve transparency along the supply chain on key sustainability aspects of seafood products sold in the EU. They would improve incentives for good sustainability performance, by helping to reward additional efforts of producers and businesses on sustainability aspects. As such, the marketing standards would lead to fairer competition between operators selling fisheries products in the EU.

The revised fishery marketing standards may have an increased scope (in comparison to the existing standards) and are expected to lead to some administrative costs and burdens. The new standards could introduce product grading, based on key fishery-specific sustainability criteria; the product grading would ideally be visible to both consumers and operators in the supply chain, to inform their purchasing and sourcing decisions.

Some administrative burden is expected due to the necessity to reflect the sustainability information indicators on product labels. As there are other relevant Commission initiatives in the area of food sustainability and labelling, which are currently being prepared, a priority focus was placed on ensuring consistency of fishery marketing standards with other ongoing initiatives. For that purpose, the initiative has been postponed to the end of 2022 or first

quarter 2023, hence too late for this pilot. For this reason, it was not possible to include the costs estimates of this initiative here.

Annex II: ‘One in, one out’ calculator

Calculator of Recurrent Administrative Costs (AC) & Administrative Burdens (AB)

1. Identification of EU Act															
What is the EU legislation you would like to measure the AC-AB for?															
If the act assessed is a delegated or implementing act (or acts), what is the name and reference of that (or these) 'original' acts?															
<input type="radio"/> New act <input type="radio"/> Revision															
<input type="radio"/> CWP initiative <input type="radio"/> non-CWP initiative															
What is the REPT policy area related to this legislation?															
Lead DG?															
Commission priority:															
Adoption year:															
2. New administrative obligations															
Type Of Obligation	Description Of Required Action(s)	Target Group	SMEs Affected	Average Tariff (€ per hour)	Time (minutes)	Price	Frequency (per year)	Override cost per company	Number Of Entities	Equipment Costs (per entity & per year)	Outsourcing Costs (per entity & per year)	Administrative Costs of an obligation	Business & Usual Costs (% of AC)	Administrative Burdens of an obligation (A C - BAU)	Comments
1			<input type="checkbox"/>	25.70 €		0.00...		<input type="checkbox"/>				0.00 €	0	0.00 €	
New one off administrative costs (MC): Duration (years): Discount factor (%):															
Description:															
Total New Administrative Costs (MC): 0.0 <input type="checkbox"/>															
Total New Administrative Burdens (MC): 0.0 <input type="checkbox"/>															
Total New Administrative Costs for SMEs (MC): 0															
Total New Administrative Burdens for SMEs (MC): 0															
3. Removed administrative obligations															
Type Of Obligation	Description Of Required Action(s)	Target Group	SMEs Affected	Average Tariff (€ per hour)	Time (minutes)	Price	Frequency (per year)	Override cost per company	Number Of Entities	Equipment Costs (per entity & per year)	Outsourcing Costs (per entity & per year)	Administrative Costs of an obligation	Business & Usual Costs (% of AC)	Administrative Burdens of an obligation (A C - BAU)	Comments
2			<input type="checkbox"/>	25.70 €		0.0...		<input type="checkbox"/>				0.00 €	0	0.00 €	
Removed one off administrative costs (MC): Duration (years): Discount factor (%):															
Description:															
Total Removed Administrative Costs (MC): 0.0 <input type="checkbox"/>															
Total Removed Administrative Burdens (MC): 0.0 <input type="checkbox"/>															
Total Removed Administrative Costs for SMEs (MC): 0															
Total Removed Administrative Burdens for SMEs (MC): 0															
4. Total net cost / burden															
Total Net Administrative Costs (MC): 0.0		Net indirect costs (MC): 0.0		Corrected net administrative costs (MC): 0.0											
Total Net Administrative Burdens (MC): 0.0		Net indirect burdens (MC): 0.0		Corrected net administrative burdens (MC): 0.0											
Net one-off costs (MC): 0.00															

Note: Screenshot of the Commission’s internal ‘One-in out’ calculator tool for calculating and recording new and removed administrative burden, based on the EU standard cost model that is publicly available (see Tool #58 of the Better Regulation toolbox at https://ec.europa.eu/info/sites/default/files/br_toolbox-nov_2021_en_0.pdf).

Annex III: Summary of the Fit for Future opinions and follow-up

SINGLE PERMIT FOR NON-EU NATIONALS

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Streamline and digitise the single permit application and visa applications
- Simplify procedures for changing employers and increasing ownership of workers

SUMMARY OF COMMISSION FOLLOW-UP

The suggestions have been addressed in the Commission's proposal⁹³ to review the directive⁹⁴.

The Commission proposed changes to the directive (in Article 4), requiring Member States to allow the application for a single permit to be made both in the Member State of destination and from a non-EU country and requiring Member States to issue the requisite visa, if the requirements under EU or national law are fulfilled.

The Commission also explains in its proposal (in Article 5) that the time limit of four months laid down in the directive covers the issuance of the requisite visa. This time limit must also cover the time needed by the authorities to check the labour market situation before a decision on the single permit is adopted.

The Commission proposed changes (in Article 11) on aspects pertaining to procedures. This ensures that the single permit shall not be withdrawn in the event of unemployment of its holder, and Member States allow the non-EU worker to remain on their territory for at least three months during the validity of the permit, after losing their job.

The Commission will carry out technical work within its relevant networks to address the specific Platform's suggestion regarding digitisation of the various procedures.

Further read: REFIT Scoreboard⁹⁵

⁹³ COM(2022)655 of 27 April 2022

⁹⁴ Directive 2011/98/EU on a single application procedure for a single permit for third-country nationals to reside and work in the territory of a Member State and on a common set of rights for third-country workers legally residing in a Member State

⁹⁵ <https://op.europa.eu/webpub/com/refit-scoreboard/en/>

INDUSTRIAL EMISSIONS DIRECTIVE

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Duration of the permit process
- Duration of the BREF process ('best available technique reference documents')
- Enter the digital age for the authorisation and control phases
- Monitoring provisions
- Baseline reports on soil and groundwater
- Overlapping requirements
- Functioning of the BREF process
- Clarity and harmonisation
- Global dimension

SUMMARY OF COMMISSION FOLLOW-UP

The Commission considered the Platform's suggestions in the context of the revision proposal it adopted, as well as part of its ongoing implementation and compliance support activities.

The Commission will, in particular, facilitate the exchange of good practices between Member States, to promote a swift revision of permits.

The Commission proposal aims to modernise and improve the BREF process, including by a provision establishing clear legal rules on the processing of confidential business information. The Commission is likely to review the implementing act on the guidance for drawing up the BREF documents, which could also include the suggested improvements to the monitoring rules. The Commission will also consider the issues raised by the Platform as regards baseline reports on soil and groundwater pollution and the lack of BAT conclusions for some associated activities.

The proposal aims to promote a more consistent approach across Member States by setting up aligned rules to assess compliance of industrial installations with their permits. This should contribute to a more level playing field and reduce divergences of environmental performance of industry across Member States.

Furthermore, the proposed revision of the directive includes a requirement for a digital permit summary, for which the Commission would establish a common format.

Further read: REFIT Scoreboard

LATE PAYMENT DIRECTIVE

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Define 'grossly unfair'
- Explore the reversal of the burden of proof for grossly unfair terms and practices
- Encourage small and medium-sized enterprises to exercise their rights by providing advice and information about payment terms
- Make payment terms transparent
- Self-regulation
- Explore tightening up contractual payment terms to a maximum of 30 days for payments from a large company to a small or medium-sized one
- Automatic offsetting for damages resulting from late payments by government organisations
- E-invoicing
- Governmental supervisor

SUMMARY OF COMMISSION FOLLOW-UP

The creation of an EU Observatory of payments in commercial transactions is one of the flagship Commission initiatives. It will support better transparency about payment terms and payment practices.

The Observatory will monitor the payment performance and behaviour of both public and private organisations, including unfair (and grossly unfair) practices and clauses. It will also include a library of self-regulation codes, codes of conduct and similar best practices from around the EU.

The Commission will also launch a pilot for alternative dispute resolution and mediation schemes to help solve payment disputes. This will respond to the Platform's suggestion to help SMEs exercise their rights by providing information and support about payment terms. Under the pilot, the Commission will look into how the burden of proof is applied and whether it should be reversed in cases that meet the description of 'grossly unfair'.

In its proposal for the directive amending the relevant EU acts on corporate sustainability reporting⁹⁶, the Commission acknowledged the importance of access to information for companies' corporate culture. The proposal includes an obligation to draft specific reporting standards on "the management and quality of relationships with business

⁹⁶ COM(2021)189 of 21 April 2021

partners, including payment practices”.

The Commission is reflecting on the more widespread use of e-invoicing (public authorities are obliged to accept e-invoices from their suppliers⁹⁷, whereas no such obligation is in place for business to business payments). It is carrying out an assessment to study the impacts of making e-invoicing compulsory in business to business transactions across the EU.

Furthermore, the Commission’s assessment of VAT recovery regimes revealed that some of the rules are inconsistent with EU law/case law, as suggested by the Platform. This prompted the Commission to follow up and:

- promote greater understanding of the rules for claiming VAT reimbursements;
- support action to reduce language barriers;
- ensure that claim verification procedures are proportional;
- reduce financial risks for claimants generated by the current regimes; and
- promote systematic data collection by tax administrations.

Further read: REFIT Scoreboard

EUROPEAN FISHERIES STATISTICS

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Greater uniformity in the collection and digitisation of data
- Efficient labelling, authorisation and reporting obligations
- Simplify and streamline EU legislation on fisheries statistics

SUMMARY OF COMMISSION FOLLOW-UP

The Fit for Future Platform’s suggestions on European fisheries statistics have been integrated as potential goals of the upcoming Commission proposal.

Notwithstanding the results of the impact assessment, the Commission’s proposal aims to reduce double reporting, streamline different databases and alleviate potential discrepancies by reusing administrative data and aligning requirements with other organisations, thereby improving data quality.

⁹⁷ Directive 2014/55/EU on e-invoicing

The Commission also aims to clarify and align definitions, classifications, concepts and timings, creating as many synergies as possible between the various fisheries data collections.

Further read: REFIT Scoreboard

UNION CUSTOMS CODE

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Ensure more predictability in the process of rolling out the Union Customs Code
- Explore possibilities of flexible implementation of rules in case of crisis
- Ensure greater coherence of related policy areas to the Union Customs Code
- More benefits for authorised economic operators

SUMMARY OF COMMISSION FOLLOW-UP

The Platform's suggestions were echoed by the interim evaluation of the Code, which acknowledged that the frequent changes to uniform data requirements negatively affected the legal certainty given by the Code.

The evaluation confirmed that the implementation of the Code did not fully tap into the potential synergies with related policies, and was not properly coordinated between customs authorities and other national administrations responsible for applying EU policies at the border. Economic operators were unsatisfied with the benefits brought by the 'authorised economic operator' status.

Building on the Platform's opinion and its evaluation findings, the Commission will analyse the Platform's suggestions as it prepares the revision of the Code. It will reflect on potential improvements for trustworthy operators, possibilities for flexibly implementing the rules in emergencies and how to increase consistency with other related policies to ensure a uniform and efficient response across the EU.

As regards the IT systems, the Commission stabilised them in 2021 and will continue to monitor them closely until 2025, when implementing the remaining IT systems.

Further read: REFIT Scoreboard

COMPUTER RESERVATION SYSTEM

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Ensure that the computer reservation system Regulation is forward looking, relevant and efficient in the light of new challenges and technological progress
- Update the reporting requirements under the Regulation to reflect new market realities
- Strengthen enforcement to ensure relevance and effectiveness
- Ensure access to all (elements of) airfares, so travellers can compare and choose the travel options that best meet their needs
- Use the Regulation to promote multimodality, in line with sustainable development goals and the sustainable mobility strategy
- Maintain the sectoral personal data protection provisions in the Regulation, but review and simplify them where appropriate

SUMMARY OF COMMISSION FOLLOW-UP

The Commission is carrying out preparatory work for the revision of the regulation. One of the objectives is to ensure that the legal framework remains fit for purpose in light of technological and market changes, in line with the Platform's suggestions.

The Commission is considering updating the reporting requirements on the ownership structure and governance model, notably by removing the duplication between these requirements and similar ones that apply in any case to all listed companies.

The Commission also considers effective enforcement as one of the areas for possible improvement and acknowledges it as an essential part of a reliable legislative framework.

Several of the Platform's suggestions will be considered in the context of different initiatives. For example, the ongoing preparatory work on multimodal digital mobility services will specifically aim to address the Platform's suggestion regarding multimodality. It will promote the comparability of travel options within one mode and across modes and facilitate consumer choice and travel, as well as more sustainable travel/transport. The suggestion regarding the transparent communication of information on optional price supplements will be considered in the ongoing work to revise the air services Regulation⁹⁸.

Further read: REFIT Scoreboard

⁹⁸ Regulation (EC) 1008/2008

STATE AID IN THE AGRICULTURAL AND FORESTRY SECTORS AND IN RURAL AREAS

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Simplify the rules and improve their consistency with green policies
- Align the scope of the notion ‘damage’, to achieve a coherent use throughout the guidelines
- Simplify aid to the forestry sector, through more streamlined rules
- Align the risk management loss thresholds with the new CAP requirements
- Simplify aid to small farmers by further reducing administrative burden
- Make the formulation of eligible costs more comprehensive
- Explore possibilities for introducing result-oriented state aid

SUMMARY OF COMMISSION FOLLOW-UP

With the revision of the State aid guidelines in the agricultural and forestry sectors and rural areas, the Commission seeks to establish ambitious state aid rules that contribute to the European Green Deal, the 2030 Biodiversity Strategy, the 2030 Forestry Strategy, and to the targets set out by the European Climate Law.

The Commission proposed to review the aspects regarding investment in agricultural holdings linked to primary production, to follow the Regulation 2021/2115⁹⁹ trend, which raises the maximum aid intensities from 40% to 65%. In addition, when the investment is linked to environmental objectives, the maximum aid intensity can be increased up to 80% for productive investment and up to 100% for non-productive investment.

In the proposed new guidelines, the Commission envisages also making support possible for collective schemes and result-based payment schemes (including carbon farming schemes). To increase the currently low uptake of forest-environment climate services, it is proposed to introduce the possibility of an incentive payment of up to 120% of the eligible costs for biodiversity, climate, water or soil-related services and collective and result-based schemes, such as carbon farming schemes in forestry.

The Commission also proposes a new article in the draft revised guidelines, stating that lost income due to lower yields linked to attacks by protected animals can be considered as an eligible cost. In the draft revised guidelines, the Commission further proposed introducing the option of simplified costs for several types of aid, which could also alleviate the administrative burden for small farmers.

Further read: REFIT Scoreboard

⁹⁹ [Regulation \(EU\) 2021/2115](#)

PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Redesign the National Contact Points (NCPs)
- Tie prior authorisation to direct billing
- Introduce a common EU cross-border health bill template
- Create a network of regional 'Healthcare abroad' points in all EU border regions
- Complement the triennial implementation report with a Cross-Border Healthcare Conference for regional authorities
- Make the use of the European electronic health record (EHR) exchange format mandatory for Member States in cross-border healthcare situations
- Enable truly cross-border emergency care and transport
- Improve information on applicable tariffs

SUMMARY OF COMMISSION FOLLOW-UP

In its evaluation of the directive, the Commission assessed aspects concerning:

- i. citizens' and healthcare professionals' lack of awareness about the opportunities created by the directive
- ii. challenges in accessing information on care options abroad
- iii. obstacles stemming from prior authorisation procedures and price transparency¹⁰⁰.

The evaluation found that the directive has been moderately effective in delivering its objectives of facilitating access to safe and high-quality healthcare in another EU country. This is aligned with the Platform opinion.

Based on the evaluation findings, the Commission committed¹⁰¹ to strengthen cooperation with the national contact points and organise knowledge and capacity-building workshops.

It will also organise new bi-lateral dialogues with Member States regarding prior authorisation and help Member States share good practice on price transparency for cross-border patients and the estimated level of reimbursement.

The Commission will also help the Member States share knowledge on streamlining procedures for accessing cross-border healthcare through digitisation. In addition, the Commission will support awareness events in the Member States organised in cooperation

¹⁰⁰ SWD(2022)200 of 12 May 2022.

¹⁰¹ COM(2022)210 of 12 May 2022.

with the NCPs and attended by regional healthcare projects as well as relevant stakeholders, as suggested by the Platform.

The Commission also evaluated article 14 of the directive, which sets out the European cooperation framework on digital health. This evaluation led to the proposal for a Regulation on the European Health Data Space. Its creation will ensure that citizens have greater access and control over their own health data, including across borders, and will facilitate its reuse for purposes such as research, innovation, policy-making and regulatory activities.

Further read: REFIT Scoreboard

ECO-DESIGN

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Include principles specific to products where changes in design may bring benefits in the short term, in particular for end-use products. However, an expansion of its scope should consider proportionality
- Continue to concentrate on key aspects of the environmental performance of end-use products: energy efficiency, resource efficiency, extending their lifespan (including reparability) and recyclability. All requirements should be proportionate to the complexity of a product
- Ensure overall coherence in order for the rules to be effective and fully implemented
- Ensure that modern information requirements are clear, comprehensible and comparable for consumers
- Ensure legal certainty and make legislation easy to apply
- Use access to information and standardisation as a tool to reduce burden while extending lifespan of products (e.g. quality, durability, reparability and recyclability)
- Software and firmware- dependent products and planned obsolescence: a novel way to adapt to technological progress while considering environmental impact
- Envisage appropriate and proportionate transition periods in any new legislation within the framework of the Eco-design Directive
- Provide further measures for SMEs to assist them with the extension of the scope of the directive

SUMMARY OF COMMISSION FOLLOW-UP

The Commission addressed suggestions raised by the Platform in its proposal on eco-design for sustainable products, such as those regarding proportionality and prioritisation, and considering the end-use products.

The decisions on which products to regulate will be based on clear criteria and a working plan. This will ensure that those products will be prioritised that have the most potential for reducing environmental impact through design changes. The framework will thus be flexible and futureproof, in line with the Platform's suggestion.

The Commission proposal allows for enhanced sustainability requirements, including those noted in the Platform's opinion. Secondary legislation will consider the value added of different measures. By setting sustainability requirements for each product group based on potential benefits and costs, the proposal aims to ensure proportionality.

The Platform pointed to the need to have clear and comprehensive information for consumers. The Commission's proposal considers this aspect and includes the

development of the European Digital Product Passport.

The content of each EU Digital Product Passport will be decided when developing product-specific measures, with the objective of only requiring the most relevant information, additional to what is already requested through existing legislation. To ensure that the Digital Product Passport is flexible, market-driven and evolving in line with business models, markets and innovation, it will be based on a decentralised data system, set up and maintained by economic operators.

In its impact assessment, the Commission has carefully considered the implementation of the legislation. The proposal aims to create a level playing field for businesses operating in the single market by setting EU-wide eco-design requirements. The potential for improving access to information is considered in the proposal, and will be addressed on a product-by-product basis in the subsequent measures. The proposal is part of a package of initiatives presented by the Commission, aiming to make sustainable products the norm. The package includes an initiative to empower consumers in the green transition, through better protection against unfair practices and better information, which should also help ensure consumers have better access to information.

Subsequent measures to establish requirements for specific product groups will be accompanied by impact assessments. These will examine whether the impacts for small and medium-sized enterprises are proportionate, and that will assess the possibility of mitigating measures.

Further read: REFIT Scoreboard

NEW LEGISLATIVE FRAMEWORK FOR PRODUCTS

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Maintain the European system for harmonised standards
- Explain regulatory choices
- Don't fix what isn't broken
- Update the New Legislative Framework to the current and future business environment
- Evaluate Member State's Notified Bodies Suggestion
- Focus supplementary market surveillance activities on compliance processes in companies
- Digital information and documentation
- Fit for crisis situations
- One catalogue of obligations for economic operators

SUMMARY OF COMMISSION FOLLOW-UP

In its evaluation of the new legislative framework for products, the Commission will examine aspects such as technologically neutral essential requirements and rely on uniform standards for presumption of conformity. One of the main aspects of this evaluation will be as well the relevance of the new legislative framework for product legislation, and whether the framework is fit enough to keep up with the ongoing digital and green transition.

The Commission will evaluate whether the lack of an emergency instrument makes the framework less effective or efficient, responding to the Platform's call to make the framework fit for emergencies. Moreover, independently of the work on the product framework, the 2022 Commission work programme includes an initiative for a Single Market Emergency Instrument, which will contain concrete elements to respond to supply chain disruptions and possible future shortages.

The Platform also suggested evaluating (i) the Member States' notified bodies, (ii) the multiple co-existing approaches, and (iii) the awareness and know-how of the EU's accreditation bodies and supervising authorities. The Commission will look into the efficiency and effectiveness of the conformity assessment process in ensuring the safety of products, as well as its relevance to market realities.

Regarding the supplementary market surveillance activities, such a solution – based on joint activities by market surveillance authorities – is already set out in the Commission's Guidelines on Article 9 of Regulation (EU) 2019/1020 (on joint activities to promote compliance, to some extent).

Market surveillance authorities might carry out joint activities with other authorities or

organisations representing economic operators or end users to promote compliance, identify non-compliance, raise awareness and provide guidance on EU harmonisation legislation.

Furthermore, the Commission will evaluate the relevance of the physical label of products currently required by the legislation and its interplay with technological development.

Further read: REFIT Scoreboard

BANKING UNION

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Broadly merge supervisory and early intervention powers
- Clarify Article 16 of the Deposit Guarantee Schemes Directive with regard to periodic information on deposit protection
- Revise Article 32b of the Bank Recovery and Resolution Directive to provide more legal certainty about the management of failed banks for which there is no public interest in a resolution
- Improve legal clarity of Article 32 (5) of the Bank Recovery and Resolution Directive concerning the assessment of the public interest for resolution
- Improve the consistency between the Deposit Guarantee Schemes Directive, payment services and e-Money Directives, and increase the protection of client funds held by e-money institutions (EMIs) and payment institutions (PIs)

SUMMARY OF COMMISSION FOLLOW-UP

The Commission has considered the Platform's opinion, where relevant and feasible, together with other evidence, as part of a wider assessment of policy options to include in a potential legislative proposal for the review of the Crisis Management and Deposit Insurance Framework.

Further read: REFIT Scoreboard

E-PROCUREMENT

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Simplify the European Single Procurement Document
- Ensure that platforms are interoperable and compatible with various national databases – digitise the whole procurement procedure
- Place an emphasis on the needs of small and medium-sized enterprises and small procuring authorities
- Address the missing links with respect to e-signature
- Undertake more targeted efforts to enhance technical capacity to support the transition to e-procurement
- Improve the user-friendliness of eCertis

SUMMARY OF COMMISSION FOLLOW-UP

Among other aspects that the Commission will address regarding the Platform's suggestions, the Commission aims to fully integrate the European single procurement document with the existing e-procurement landscape and meet the once-only principle.

For example, the Commission supports a technical data model to allow buyers to provide information on individual criteria. The integration of the model into national services lies within the remit of the Member State and its solution providers. The Commission engages regularly with stakeholders to further improve the integration of the European single procurement document with other systems and the new eForms, including eCertis.

Through the Connecting European Facility, it supported organisations in Europe making their eProcurement solution interoperable. It also plans to make a standardisation request to further support the interoperability of eProcurement solutions.

Improving technical capacity, as recommended by the Platform, represents a key element for supporting the use of e-procurement. The Commission plans to use the future national workshops to highlight this to the Member States and overcome the complexity of different national set-ups.

The Commission also initiated actions to help small and medium-sized enterprises and small contracting authorities to transition to e-procurement. The upcoming launch of the procurement notices eForms is an important step towards this, as the upcoming forms allow public buyers to indicate if a business opportunity is particularly suitable for SMEs.

Further read: REFIT Scoreboard

AMBIENT AIR QUALITY

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Improve air quality monitoring networks, to diminish discrepancies and enhance comparability across Member States, improve the design of air quality plans and promote local/regional action
- Modernise air quality standards and supplement limit values with regional exposure reduction targets
- Extend monitoring to pollutants not currently covered by the ambient air quality directives, such as ultrafine particles, black carbon and other components of particulate matter, metals, and ammonia
- Enhance the coherence with EU legislation, including urban and road transport, energy efficiency and climate
- Address emission sources such as tyre and brake wear, non-exhaust traffic-related particles, heavy goods vehicle refrigeration units, heating and power emissions and wood burning
- Reinforce governance across all levels of government, to improve the effectiveness of the ambient air quality Directive
- Simplify the legislative framework by bringing together Directives 2008/50/EC and 2004/107/EC into a single directive.

SUMMARY OF COMMISSION FOLLOW-UP

In line with the commitment in the European Green Deal, the Commission's initiative aims to improve the current ambient air quality directives, to:

- I. align more closely EU air quality standards with scientific knowledge, including the latest recommendations from the World Health Organization;
- II. improve the legislative framework on air quality, including rules on penalties and public information, to improve effectiveness, efficiency and consistency; and
- III. strengthen air quality monitoring, modelling and plans.

In its impact assessment, the Commission is looking at monitoring, assessment and governance provisions, to improve the effectiveness of the legislation in delivering air quality objectives, as well as at options for air quality objectives, in line with the latest advice from the World Health Organization.

Some of the Platform's suggestions will be addressed by the ongoing impact assessment work. However, the revision will not change any legislation that controls emissions of air pollutants, because the ambient air quality directives set maximum permissible concentrations of certain air pollutants in ambient air, rather than directly regulating emission sources.

The Commission has announced, in its zero pollution action plan¹⁰² and under the European Green Deal, that it will further tackle air pollution at source. This includes its recent proposal on industrial emissions as well as upcoming measures on emissions from road vehicles and from buildings.

Regarding simplification of legislation through consolidation, there are several legislative techniques to simplify the legal framework, and the Commission is taking these into account, as appropriate.

Further read: REFIT Scoreboard

¹⁰² COM(2021)400

PACKAGE TRAVEL

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Better information on (i) the identity of the contractual partners and (ii) contact details, and a better enforcement of rules
- Clarify the scope and simplify the definitions of ‘package travel’ and ‘linked travel arrangement’
- Clarify the pre-contractual information requirements (in Article 5)
- Clarify uncertainties regarding insolvency protection
- Clarify 'other tourist services'

SUMMARY OF COMMISSION FOLLOW-UP

The Commission is carrying out an evaluation of the ‘package travel’ Directive and an impact assessment for a possible revision. The analysis covers different aspects relating to insolvency protection for travellers, such as the scope of this protection, in particular with regard to vouchers and refund claims, preparedness for a liquidity crisis and possible limitations of pre-payments.

Possible shortcomings in the application of the main concepts in the directive are also being examined, including the potential for clarifying and simplifying the definitions of ‘package’ and ‘linked travel arrangement’, comprising the definition of ‘other tourist services’. Other aspects considered during this exercise include the question of whether and how increased clarity for travellers can be achieved without placing unnecessary burden on businesses. Furthermore, it will be analysed whether simplified information requirements could provide benefits for travellers and companies.

In addition, other related legislation will be taken into account, in particular the parallel review of the passenger rights regulations¹⁰³, to assess the potential for alignment.

The evaluation and the impact assessment will be based on robust data collection as well as the analysis and suggestions from the Platform and input from stakeholders. The impact assessment will address any shortcomings identified or confirmed in the evaluation by analysing the impacts of possible solutions, including legislative amendments, if needed.

Further read: REFIT Scoreboard

¹⁰³ E.g. https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13290-Travel-better-protection-for-passengers-and-their-rights_en
https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13255-Revision-of-the-Air-Services-Regulation_en

INSPIRE (INFRASTRUCTURE FOR SPATIAL INFORMATION)

SUMMARY OF F4F PLATFORM SUGGESTIONS

- Make data specifications less technology-bound, more generic and focused on the purpose.
- Place the focus on defining priorities and clarifying policy needs.
- Put in place mechanisms to improve European legislation on geospatial information, in particular, by having a coordination body in the European Commission (possibly GISCO at Eurostat) to serve as a geospatial hub.
- Fully exploit the potential benefits of INSPIRE beyond environment and for creating positive spill overs in other policy fields.
- Overcome technical and financial barriers by supporting non-legislative initiatives.

SUMMARY OF COMMISSION FOLLOW-UP

The evaluation carried out by the Commission found that the current framework is no longer fit for purpose, as the technical specifications introduced by INSPIRE have become too prescriptive in the context of evolving information requirements, standards and technologies. The Commission will consider in its impact assessment work how to make the legal framework both technology-neutral and future-proof.

The evaluation of INSPIRE also showed that implementation would benefit from a more user-driven approach. The Commission will explore this suggestion notably by identifying common policy needs across administrative levels.

Regarding the mechanisms to improve European legislation, the Commission intends to analyse the best way to align and streamline the existing framework and implementation guidance with recent and emerging EU data legislation (the open data Directive¹⁰⁴ and the implementing regulation on high value datasets, the data governance act¹⁰⁵, the data act¹⁰⁶). Synergies could be better exploited to improve data sharing and minimise burden on data providers in the Member States.

Similarly, the Commission will explore the effectiveness and efficiency of the INSPIRE Directive and the Directive on public access to environmental information as enabling instruments for implementing data sharing in Europe. Building a common European Green Deal data space could be further developed by accommodating new requirements coming from the twin digital and green transitions. The aim would be to maximise data

¹⁰⁴ [Directive \(EU\) 2019/1024](#)

¹⁰⁵ COM(2020)767 of 25 November 2020

¹⁰⁶ COM(2022)68 of 23 February 2022

reuse and avoid duplication in content and data sharing effort.

The Commission will also explore non-legislative actions, in particular, as part of coordinated actions under the multi-annual work programme¹⁰⁷ of the INSPIRE Maintenance and Implementation expert group¹⁰⁸. This includes building capacity in Member States for INSPIRE implementation (e.g. webinars, best practices, presentations, and training) and stakeholder engagement.

Further read: REFIT Scoreboard

¹⁰⁷ [INSPIRE work programme 2021-24 - INSPIRE Maintenance and Implementation Group \(MIG\) - EC Public Wiki \(europa.eu\)](https://wikis.ec.europa.eu/display/InspireMIG/INSPIRE+work+programme+2021-24) (<https://wikis.ec.europa.eu/display/InspireMIG/INSPIRE+work+programme+2021-24>)

¹⁰⁸ <https://inspire.ec.europa.eu/inspire-maintenance-and-implementation/46>