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6

Datum 16 juli 2026
Betreft Rapportage ministerie EZK wetgevingsonderhandelingen en raadplegingen EU vierde kwartaal 2025

Geachte Voorzitter,

In de afspraken met de Kamer over EU-informatievoorziening is afgesproken dat elk ministerie ieder kwartaal de EU-kwartaalrapportage, met daarin de stand van zaken van de onderhandelingen over EU-wetgevingsdossiers en de stand van zaken betreffende EU-raadplegingen naar de Kamer stuurt. Hierbij doe ik dat voor dossiers en raadplegingen op het terrein van het ministerie van Economische Zaken. Het overzicht van het vierde kwartaal van 2025 vindt u in de bijlage.

In deze periode is vanuit EZK op de volgende raadplegingen gereageerd:
- Chips Act 2
- Europese biotechwet
- Normalisatierichtlijn
- Richtsnoeren voor reddings- en herstructureringssteun (staatssteun)
- Diensten van algemeen economisch belang (DAEB) (staatssteun)

Deze vindt u ook bijgevoegd.

Heleen Herbert
Minister van Economische Zaken en Klimaat

EU-wetgevingsonderhandelingen EZ
Kwartaalrapportage, vierde kwartaal 2025

Titel	Document nummer	Korte beschrijving	Stand van Zaken
Verordening betreffende Europese statistieken over bevolking en huisvesting	COM(2023)31	Het voorstel betreft een verordening voor een gemeenschappelijk rechtskader voor de ontwikkeling, productie en verspreiding van Europese statistieken over bevolking en huisvesting.	Dit voorstel is gepubliceerd en afgerond.
Verordeningen aanvullende beschermingscertificaten (ABC's)	COM(2023)221, COM(2023)222, COM(2023)223, COM(2023)231	Aanvullende beschermingscertificaten (ABC's) zijn intellectuele eigendomsrechten die de beschermingsduur van octrooien voor geneesmiddelen of gewasbeschermingsmiddelen met maximaal 5 jaar verlengen. Dit pakket beoogt het ABC-systeem van de EU te vereenvoudigen, evenals de transparantie en efficiëntie ervan te verbeteren, door een gecentraliseerde procedure en een unitair ABC voor genees- en gewasbeschermingsmiddelen te creëren.	Voorstel wordt besproken op ambtelijk EU-niveau in Raadskader.
Verordening dwanglicenties voor crisisbeheersing	COM(2023)224	Het voorstel beoogt de EU in staat te stellen dwanglicenties te verlenen in het kader van de EU-crisisinstrumenten, waarbij de levering en het vrije verkeer op de interne markt gegarandeerd kan worden van producten of processen die onmisbaar zijn voor het reageren op een crisis of noodsituatie, of voor het aanpakken van de gevolgen van een noodsituatie.	Dit voorstel is gepubliceerd en afgerond.
Verordening inzake bestrijding van late betalingen in handelstransacties	COM(2023)533	De Commissie stelt dat de huidige Richtlijn onvoldoende in staat is om het probleem van late betalingen in de Europese Unie aan te pakken. Het voorstel voor een Verordening pakt deze tekortkomingen aan, met als voornaamste doel de betaaldiscipline van alle betrokken partijen (overheidsinstanties, grote bedrijven en mkb'ers) te verbeteren en bedrijven te beschermen tegen de negatieve effecten van betalingsachterstanden bij commerciële transacties.	Dit voorstel is ingetrokken door de Commissie.
Herziening richtlijn pakketreizen	COM(2023)905	De herziening van de Pakketreizenrichtlijn heeft als doel om consumentenbescherming, ook in tijden van crisis, te versterken en de werking van de interne markt in de pakketreissector te verbeteren. Dit sluit aan bij het doel van de huidige richtlijn, die in 2015 is vastgesteld. De Commissie beoogt dit te doen door definities	De onderhandelingen in triloog zijn afgerond en er is een politiek akkoord bereikt tussen de Commissie, de Raad en het Europees Parlement. Het voorstel zit in de afrondende procedurele fase.

		aan te passen, regels toe te voegen over betalingen en vouchers en de regels rondom annuleringen in uitzonderlijke situaties nader uit te leggen.	
FDI-verordening	COM(2024)23	Het Commissievoorstel tot herziening van de huidige verordening ten aanzien van toetsing van buitenlandse directe investeringen (*foreign direct investments*, FDI) heeft als doel de verbetering van samenwerking en coördinatie en meer harmonisatie (zowel inhoudelijk als procedureel) tussen lidstaten op het gebied van FDI-screening.	De onderhandelingen in triloog zijn afgerond en er is een politiek akkoord bereikt tussen de Commissie, de Raad en het Europees Parlement. Het voorstel zit in de afrondende procedurele fase.
Herziening meetinstrumenten-richtlijn	COM(2024)561	Het voorstel is een gerichte herziening van een aantal annexen van meetinstrumentenrichtlijn, onder andere om deze uit te breiden naar laadpalen voor elektrisch rijden en waterstofdispensers.	De onderhandelingen in triloog zijn afgerond en er is een politiek akkoord bereikt tussen de Commissie, de Raad en het Europees Parlement. Het voorstel zit in de afrondende procedurele fase.
Omnibus InvestEU	COM(2025)84	Het voorstel beoogt de efficiëntie van rapportagevereisten voor EU garanties onder het InvestEU programma te vergroten door vereenvoudiging.	De onderhandelingen in triloog zijn afgerond en er is een politiek akkoord bereikt tussen de Commissie, de Raad en het Europees Parlement. Het voorstel zit in de afrondende procedurele fase.
Verordening niet-financiële statistieken over zakelijk ontroerend goed	COM(2025)100	Het voorstel betreffende een verordening van het Europees Parlement en de Raad betreffende niet-financiële statistieken over zakelijk onroerend goed.	De Raad heeft een algemene oriëntatie bereikt. Het Europees Parlement heeft nog geen positie ingenomen. Zodra dit wel het geval is, start de triloogfase met onderhandelingen tussen de Commissie, de Raad en het Europees Parlement.
Wijziging van verordeningen om bepaalde steunmaatregelen voor	COM(2025)501, COM(2025)502,	De Europese Commissie heeft op 21 mei 2025 een vierde Omnibuspakket gepresenteerd om regeldruk voor bedrijven te verminderen, met als kern de introductie van een geharmoniseerde definitie voor small mid-cap bedrijven (SMC's), gericht op proportioneelere regelgeving. Deze nieuwe categorie bedrijven krijgt	De Raad heeft een algemene oriëntatie bereikt. Het Europees Parlement heeft nog geen positie ingenomen. Zodra dit wel het geval is, start de triloogfase met

het mkb uit te breiden naar small mid-cap ondernemingen en aanvullende vereenvoudigingsmaatregelen		toegang tot versoepelingen die voorheen enkel voor het mkb golden, in wetgeving zoals de AVG, MiFID II en de Prospectusverordening.	onderhandelingen tussen de Commissie, de Raad en het Europees Parlement.
Wijziging van verordeningen voor de digitalisering van productinformatie en gemeenschappelijke specificaties	COM(2025)503, COM(2025)504	Dit voorstel maakt onderdeel uit van het vierde omnibuspakket. Centraal staat het vereenvoudigen van productregels door fabrikanten te verplichten productinformatie, conformiteitsverklaringen en gebruiksinstructies digitaal aan te leveren, en een digitaal contactpunt toe te voegen. Daarnaast introduceert de Commissie een mechanisme om zelf tijdelijke productnormen (gemeenschappelijke specificaties) vast te stellen wanneer Europese normen ontbreken, om productveiligheid en innovatie te bevorderen.	De Raad heeft een algemene oriëntatie bereikt. Het Europees Parlement heeft nog geen positie ingenomen. Zodra dit wel het geval is, start de triloogfase met onderhandelingen tussen de Commissie, de Raad en het Europees Parlement.
Verordening tot vaststelling van het ruimtevaartprogramma van de Unie, tot oprichting van het Agentschap van de Europese Unie voor het ruimtevaartprogramma en tot wijziging van enkele verordeningen	COM(2025)335	Het voorstel beoogt om tegen 2050 de EU te positioneren als wereldleider in de ruimtevaartsector een geharmoniseerd juridisch kader te creëren voor ruimtevaartactiviteiten binnen de Europese Unie. Concreter omvat het doel de juridische en technische versnippering binnen de interne markt te verminderen en tegelijkertijd de veiligheid, duurzaamheid en weerbaarheid van ruimtevaartactiviteiten te versterken. Het voorstel introduceert daartoe een gemeenschappelijk regelgevend kader op drie hoofdthema's: (1) veiligheid en ruimteverkeersbeheer, (2) cyber- en fysieke weerbaarheid van ruimte-infrastructuur, en (3) milieu-impact en duurzaamheid van ruimteactiviteiten.	Voorstel wordt besproken op ambtelijk EU-niveau in Raadskader.
Europese Concurrentiekrachtfonds (ECF)	COM(2025)555	Het Europese Concurrentiekrachtfonds (ECF, het Fonds) maakt deel uit van het pakket voor het Meerjarig Financieel Kader (MFK) na 2027. Het heeft als doel om 12 afzonderlijke financieringsinstrumenten uit het huidige MFK te bundelen in één kader dat functioneert als investeringscapaciteit ter versterking van de Europese concurrentievermogen op het gebied van technologieën en strategische sectoren die van essentieel belang zijn voor het concurrentievermogen van de EU.	Voorstel wordt besproken op ambtelijk EU-niveau in Raadskader.
Horizon 2028-2034	COM(2025)543, COM (2025)544	Het voorstel van de Europese Commissie betreft het tiende kaderprogramma voor onderzoek en innovatie (2028–2034), met een voorziene begroting van 175 miljard euro, onder de naam Horizon Europe. Het programma wil strategische focus, vereenvoudigde	Voorstel wordt besproken op ambtelijk EU-niveau in Raadskader.

		toegang en snellere uitvoering combineren met steun voor de hele innovatieketen – van fundamenteel onderzoek tot markttoepassing. Het bestaat uit vier pijlers: excellente wetenschap, concurrentievermogen & maatschappij, innovatie, en de Europese Onderzoeksruimte, waarbij onder meer wordt ingezet op samenwerking met het Concurrentievermogenfonds (ECF), publiek-private partnerschappen en versterking van SGW. Er is ook ruimte voorzien voor dual-use-projecten, deelname van niet-EU-landen, en een sterkere koppeling tussen EU- en nationale investeringen in O&I.	
Europees Fonds voor Regionale Ontwikkeling (EFRO) met inbegrip van Europese Territoriale Samenwerking (Interreg) en het Cohesiefonds 2028-2034	COM (2025)552	De Commissie stelt voor om de Europese fondsen onder het cohesiebeleid — EFRO, Interreg en het Cohesiefonds — in het volgende MFK onder de pijler 'National and Regional Partnership Plans' (NRPP) te plaatsen. Daarbij worden EFRO en het Cohesiefonds geïntegreerd in één plan per lidstaat, maar wordt Interreg buiten deze nationale plannen geplaatst, via een zogeheten Interreg Plan.	Voorstel wordt besproken op ambtelijk EU-niveau in Raadskader.
Verordening statistieken inzake visserij en aquacultuur	COM(2025)435	Het voorstel beoogt een geïntegreerd rechtskader voor Europese statistieken over de instandhouding van mariene biologische hulpbronnen door visserijactiviteiten en het in de handel brengen daarvan, alsmede over de visserijvloot van de Europese Unie, de aquacultuurproductie en aquacultuurinrichtingen.	Voorstel wordt besproken op ambtelijk EU-niveau in Raadskader.
Interne markt en douane programma voor de periode 2028-2034	COM(2025)590	Het voorstel beoogt vijf programma's onder het huidige MFK samen te voegen tot één programma met als overkoepelend doel het versterken van de interne markt en douane-unie, het beschermen van de financiële en economische belangen en de veiligheid van de Unie en haar lidstaten. Het voorstel bestaat uit vier verschillende beleidsonderdelen: interne markt, douane, samenwerking op het gebied van belastingen en fraudebestrijding.	De Raad heeft een algemene oriëntatie bereikt. Het voorstel bevindt zich in de triloogfase met onderhandelingen tussen de Commissie, de Raad en het Europees Parlement.
Omnibus Digitaal	COM(2025) 837	Het voorstel voor een Omnibus Digitaal wijzigt verschillende Europese verordeningen en richtlijnen, met name met betrekking tot data en cybersecurity.	Voorstel wordt besproken op ambtelijk EU-niveau in Raadskader.
Omnibus AI	COM(2025) 836	Het voorstel voor een Omnibus AI wijzigt de AI-verordening[1]. Een belangrijke voorgestelde wijziging is dat de datum waarop de bepalingen van de AI-verordening met betrekking tot hoog-risico AI-systemen van toepassing worden wordt uitgesteld.	Voorstel wordt besproken op ambtelijk EU-niveau in Raadskader.

[1] Verordening (EU) 2024/1689

Contribution ID: f0754ced-5176-4cbc-855c-45e1fa7b3f75
Date: 14/11/2025 15:16:03

Public Consultation Questionnaire - Revision of the Rescue and Restructuring Guidelines

Fields marked with * are mandatory.

Introduction

The Rescue and Restructuring Guidelines and the need to revise them

The currently applicable Rescue and Restructuring Guidelines were adopted in 2014 and are based on the 2004 Rescue and Restructuring Guidelines. However, the basic principles of the Rescue and Restructuring Guidelines were laid down long before, as the European Commission at least since the 1970s allowed State aid to Undertakings in Difficulty and specific guidelines were adopted in 1994, 1997, 1999 and 2004.

Financial distress at the company level plays a signaling role in an economy, indicating that a firm is not making optimal use of its resources. While financial distress and consequent market exit plays a key role in ensuring an efficient allocation of resources, they can have negative economic consequences, which can justify public support. There is general consent that rescue and restructuring aid is distortive and detrimental to productivity and should be allowed only under strict conditions.

The Rescue and Restructuring Guidelines set out the conditions under which the Commission deems State aid granted to rescue or restructure Undertakings in Difficulty to be compatible with the internal market. Besides few exceptions, rescue or restructuring support is the only aid Undertakings in Difficulty can receive.

Since the last revision of the Rescue and Restructuring Guidelines in 2014, the Commission has applied them in a large number of cases covering various sectors of the economy. The Commission practice and the case law of the EU Courts show that the Rescue and Restructuring Guidelines in general work well. Moreover, this view was supported by the results of an evaluation conducted in the context of the Fitness Check of the 2012 State aid modernisation package, railways guidelines and short-term export credit insurance published in 2020. The Fitness Check focused in particular on the Undertaking in Difficulty definition and came to the conclusion that the Undertaking in Difficulty criterion largely meets its objective to identify companies in difficulties correctly, but it is not entirely clear and easy to apply for national authorities and guidance and/or clarification might be needed.

Based on its case practice, the evaluation in context of the Fitness Check and ad hoc contributions received since the conclusion of the Fitness Check, the Commission considers that there is considerable evidence

available to allow revising the Rescue and Restructuring Guidelines.

The purpose of this public consultation is to collect feedback on the key revisions on substance envisaged by the Commission to take better into account the challenges faced by companies in the EU. In particular, the Commission is envisaging updating the scope of the guidelines. It is considering lifting the exclusion of the steel sector and to review the parameters defining an Undertaking in Difficulty.

The results of this public consultation will be summarised in a factual report, which will be published on the Have Your Say website. At the end of the survey, you can upload a file with a more detailed contribution.

About you

* Language of my contribution

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Head of

* Surname

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  - Local
  - (•) National
  - Regional

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- ○ Agency

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255 character(s) maximum

Ministry of Economic Affairs

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- Somalia
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- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan

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- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
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- Comoros
- Congo
- Guinea
- Guinea-Bissau
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- Ireland
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- United Kingdom
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- Latvia
- Lebanon
- Lesotho
- Liberia
- Puerto Rico
- Qatar
- Réunion
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- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
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The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

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The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

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1. Sectorial Scope of the Rescue and Restructuring Guidelines

The questions in this section aim at assessing whether the current state of the EU economy would justify a change in the sectors covered by the Rescue and Restructuring Guidelines.

Background

Currently all sectors can benefit from aid under the Rescue and Restructuring Guidelines except the coal and steel sectors and the financial sector. Concerning the steel sector, its exclusion from the scope of the Rescue and Restructuring Guidelines had been historically motivated by the existence of significant overcapacities globally and in the EU market. The current exclusion of the steel sector means that if a steel company is under financial distress (considered an Undertaking in Difficulty) it cannot receive any State aid, including State aid under the Rescue and Restructuring Guidelines, unlike undertakings active in other metal sectors, such as aluminium.

Global overcapacity still affects European producers and their employees. Moreover, the pressure on the EU steel industry from imports is taking place against the background of decarbonisation and new challenges to the global trade system. Due to the challenges faced, the Commission adopted an Action Plan for Steel and Metals, which outlines the importance of the steel sector which is among the most vulnerable sectors in transition.

Within the EU market overcapacities have decreased and EU production can cover most of the EU's domestic demand in steel (90%). Between 2014 and 2023, EU steel industry production capacity has decreased significantly (crude steel production has decreased by around 20%). In the same vein, employment in the sector decreased by around 10%. At the same time, in 2024, global overcapacity was estimated to be more than four and a half times the EU's yearly consumption. The EU steel industry went from a substantial trade surplus to a significant deficit.

Question 1

In your experience, has the exclusion of the steel sector from the Rescue and Restructuring Guidelines had a positive impact on:

	Yes	No	I do not know / no opinion
Competition within the EU steel sector	○	○	◉
Competitiveness of the EU steel sector	○	○	◉
Both	○	○	◉
There has been no positive impact at all	○	○	◉

Please justify your answer:

2000 character(s) maximum

The EU steel market is fairly integrated, but competition is asymmetric between small group of large companies, depending on national conditions, energy mix in countries and delay in the green transition.

The global steel sector is viewed as having structural overcapacity in its production. However, the EU steel sector's production capacity is diminishing. Overcapacity is driven by international competition from third countries that offer steel against prices that not in conformity with market prices in EU. This overcapacity can be attributed by distorting subsidies in third countries. This has a negative impact on competitiveness in the EU steel sector, but is not necessarily solved with rescue and restructering aid, as it is more a trade related issue. Excluding the sector has not had a negative nor positive effect on the sector so far.

Question 2

In your experience, has the situation of the steel sector changed compared to 2014?

	has improved	has worsened	is unchanged	I do not know / no opinion
The situation	○	◉	○	○

Please justify your answer:

2000 character(s) maximum

The current EU steel market is fairly integrated, but competition is asymmetric between small group of large companies, depending on national conditions, energy mix in countries and delay in the green transition. However, the EU steel sector's production capacity is diminishing while the global steel sector is having structural overcapacity in its production. This overcapacity is created by third countries that offer steel against low prices. Thia leads to diminishing competiitveness of the EU steel sector, which is considered strategic.
In addition, the green transition creates a need for investments but puts pressure on the business case of steel sector undertakings, and COVID-19 had an impact (temporary drop in demand, but also price increases). Therefore, at this moment the steel sector knows more international competition, higher operation costs and a stricter regulatory framework necessary for the green transition compared to 2014. See: https://www.oecd.org

/en/publications/oecd-steel-outlook-2025_28b61a5e-en.html
These market changes have an impact on the viablity of undertakings in this sector, which is at odds with the aim of an automous EU steel stector. The general focus on improving EU resilience and meeting NATO budget accords supports the importance of an autonomous EU steel sector.

Question 3

Based on your reply to the question above, do you consider the exclusion of the steel sector from the scope of the Rescue and Restructuring Guidelines still justified?

- ○ Yes
- ○ No
- ◉ I do not know / no opinion

Please justify your answer:

2000 character(s) maximum

The guidelines explicitly exclude the steel sector because at the time, the EU and international market were characterized by substantial overcapacity.
The Dutch authorities are of the opinion that the EU should strive to autonomously produce steel. (See: https://www.rijksoverheid.nl/documenten/publicaties/2025/04/25/bnc-fiche-mededeling-staal-en-metaal-actieplan). This is in line with the European Steel and Metals Action Plan. The steel sector plays a pivotal role in strategic sectors such as the defense industry, the construction sector, automotive and the energy transition.
In the current market, these objectives of common interest could very well arise in the light of autonomy of the steel sector. The global steel sector is viewed as having structural overcapacity in its production. However, the EU steel sector's production capacity is diminishing, as can be seen in OECD steel outlook 2025. The global steel market is currently in a precarious state. Excess capacity is growing from unsustainably high levels, fueled by market-distorting subsidies and other non-market practices, mainly in countries outside the OECD. This trend has the potential risk of dumping into the EU market, because of a competition disadvantage. While it is important this issue is addressed and the EU should support the competitiveness of the steel sector in the EU, we have reasonable doubt whether state aid rules are the right instrument. Most of the problems stem from trade related problems and should be addressed by other instruments in the EU toolbox

Question 4

In your view, would an inclusion of the steel sector in the Rescue and Restructuring Guidelines have:

	Yes	No	I do not know / no opinion
A positive impact on competition within the EU steel sector	○	◉	○
A positive impact on competitiveness of the EU steel sector	○	○	◉
A positive impact on both	○	◉	○

no positive impact	○	○	◉
Negative impact on competition within the sector	○	○	◉
Negative impact on competitiveness of the sector	○	○	◉
Negative impact on both	○	○	◉

Please justify your answer:

2000 character(s) maximum

State aid support should be fit for purpose and should go hand in hand with sustainability measures and EU coördinated measures to strengthen the sector. This should lead to a competititve steel sector ecosystem that is able to compete with third countries, but maintains its competitiveness in the internal market. Therefore, trade related instruments might be more suitable to solve the problems in the steel market, instead of rescue and restructering aid.

Question 5

In your view, would an inclusion of the steel sector in the Rescue and Restructuring Guidelines have an impact on other industries relying on steel products as input?

	a positive impact	a negative impact	no impact	I do not know / no opinion
There would be	○	○	○	◉

Please justify your answer:

2000 character(s) maximum

See answer under 4. It is important to protect competitiveness and resilience of the European steel sector and reduce dependencies on import. If European undertakings are pushed out from the market through unfair competition, dependency on imports rises and uncertainties increase in other industries that are dependent on steel (energy transition, defense industry). It is important to create certainty for European producers and security of supply for downstream buyers.

2. Material Scope of the Rescue and Restructuring Guidelines

The questions in this section aim at assessing whether the current definition of Undertaking in Difficulty would need to be amended to address certain deficiencies raised previously by stakeholders.

Background

For undertakings that meet the criteria to be defined as Undertakings in Difficulty, rescue and restructuring aid is in principle the only route available to grant State aid. This is because rescue and restructuring aid is among the most distortive types of State aid, as it interrupts the normal competitive process leading inefficient undertakings to exit the market. The Undertaking in Difficulty concept is thus of a horizontal relevance as it is

applied not only as an inclusion criterion in the Rescue and Restructuring Guidelines, but also as an exclusion criterion preventing companies from receiving aid under other guidelines.

An undertaking is considered to be in difficulty when, without intervention by the State, it will almost certainly be condemned to going out of business in the short or medium term. Whether an undertaking fulfils this definition is assessed based on four quantitative criteria in the Rescue and Restructuring Guidelines ((i) the loss of more than half of the subscribed capital in case of limited liability companies, (ii) the loss of more than half of the book capital for companies with at least some members with unlimited liability, (iii) undertakings under collective insolvency proceedings or fulfilling the criteria for being placed in collective insolvency proceedings at the request of its creditors, (iv) undertakings that are not SMEs with a book debt to equity ratio above 7.5 and an EBITDA interest coverage ratio below 1.0 for the past 2 years).

Start-ups and scale-ups

The Rescue and Restructuring Guidelines provide that an SME that has been in existence for less than three years will not be considered to be in difficulty unless it is subject to collective insolvency proceedings or fulfils the criteria under its domestic law for being placed in collective insolvency proceedings at the request of its creditors.

However, in recent years it has come to the Commission's attention that the quantitative criteria of the Undertaking in Difficulty definition may have the effect of qualifying certain start-ups or scale-ups that have a specific capital-intensive growth model and that have not yet had the time to achieve Balance Sheet growth as Undertaking in Difficulty. Although those undertakings would not be condemned to going out of business in the short or medium term, and thus barring them from receiving other forms of State aid.

The Commission reminds that the following questions concern the Undertaking in Difficulty definition of the Rescue and Restructuring Guidelines and of all other State aid rules using that term. The General Block Exemption Regulation (EU) 651/2014 ("GBER") includes also a definition for Undertakings in Difficulty in Article 2(18) of the GBER. Aid to undertakings that fulfil the definition set out in Article 2(18) of the GBER can, in principle, not be block exempted (Article 1(4)(c)) GBER). The Undertaking in Difficulty definition of the Rescue and Restructuring Guidelines does not concern the GBER, hence no potential change to the definition in the Rescue and Restructuring Guidelines will impact the possibility of undertakings concerned to receive aid that has been block exempted.

Question 6

In your experience, is the current exemption for SMEs that have been in existence for less than three years sufficient to allow start-ups to benefit from other forms of aid?

- ○ Yes
- ◉ No
- ○ I do not know / no opinion

Please justify your answer:

2000 character(s) maximum

The current exemption for SMEs is not sufficient to allow start-ups to benefit from other forms of aid. However, it is important that young SMEs, such as start-up or scale-up companies, especially in (deeptech) innovation, founded in the past 10 years (Young Innovative Companies: YIC), can benefit from aid because of the fundamental role of these undertakings in the transition to a green industry and open strategic autonomy in Europe. Investing in YICs is essential for innovation in these areas.
Currently, the exemption limits aid in the following way. YICs in general face a start-up investment period of R&D of 3 to 7 years, followed by a scale-up investment period of 5-7 years. It generally takes 8 to 10 years before the scale up of production is in line with market demand. This results in substantial negative operational cashflows. To sustain itself, the undertaking attracts funding by investors during this period through multiple funding rounds (SEED, A, B, etc.). Most of these loans are hybrid: the loan has the characteristic that it can be converted into shareholders capital in time.

R&D investments often result in accumulated negative reserves that reach higher than 50% of the shareholders capital plus the share premium reserves. This results in an UiD-qualification under the current criteria, which prevents the start- and scale-up receiving state funding. At the moment, it excludes 40 to 80% of the YICs applying for state funding in the Netherlands from receiving it. The Dutch authorities emphasize that state funding is an essential factor for successful innovation development. Absence thereof leads to innovation drain of these undertakings to more investment-ready economies.

Question 7

If your answer to Question 6 was “no”, which of the following options would be sufficient to address the shortcomings:

	Yes	No	I do not know / no opinion
Extend the exemption period to five years	○	◉	○
Exempt all undertakings that fulfil the definition of start-up laid down in Article 22(2) of the GBER	○	◉	○
Extend the exemption period to ten years	◉	○	○

If the proposed extension period is not relevant, please provide a proposition and specify your industrial sector:

2000 character(s) maximum

The extension should not be limited to five years because YICs starts to decrease its accumulated negative reserves by expected positive results only after ten years or more. At this point, YIC generally are not making profit. A longer period of exemption is therefore needed

Others (please specify)

2000 character(s) maximum

Exempting all start-ups defined in the GBER would include a too broad category of companies, opening up the possibility to fund undertakings that do not have potential and are almost certainly condemned to go out of business in the short or medium term, because they are not secured by investments and not backed by investors. This amendment would therefore not be fit for purpose.

Please justify your answer:

2000 character(s) maximum

The current exemption should be extended to 10 years for SMEs that qualify as an YIC.
This amendment is fit for purpose because it aligns with the common interest to stimulate innovation while keeping harmful uses of state aid restricted by providing a strict definition of the category of undertakings that will be able to make use of this exception to YICs.

The definition of YIC should include:
SMEs founded in the past 10 years, investing in (expensive complex technological) innovations, with a horizon of introduction on the public market.

It is important to realize that in some sectors, such as Deeptech and Life Science & Health, extending the exemption to ten years could still be problematic, because of its long-term development window (>10 years) and an capital intensive nature resulting in above average high negative results in start- and scale up phase.

Question 8

Under the current rules, scale-ups fall under the definition of an Undertaking in Difficulty which prevents them from receiving aid under other State aid rules. In your view, is this specific scale-ups situation justified?

- ○ Yes
- ◉ No
- ○ I do not know / no opinion

Please justify your answer:

2000 character(s) maximum

During the scale up period, undertakings test scaling up their business model before engaging in full market introduction. This period takes (average) 5 to 7 years and requires a considerable amount of investment. Only after this, the level of production has reached market demand and the scale-up starts to make positive returns. Before that, the undertaking already knows severe cash out financed by investors (could be issued shares and /or convertible loans). These forms of invested external capital, can be characterized as commitment by investors as well as investors acknowledgement of the perceived market potential of the product in development during the start up fase. The capability of the start- scale up to attract funding, still determines its continuity perspective regardless of the form in which the funding is raised (see Question 7). First, allowing specific types of external funding to be classified as ‘own funds’. This classification should at least include ‘near-equity’ capital (such as subordinated or convertible loans) as own funds (see Question 12). Secondly, an

exception should be introduced for SME's, permitting them to exceed the current threshold by allowing situations where more than 70% of its subscribed share capital may be lost as a result of accumulated losses. The existing 50% threshold does not correspond with the financial realities commonly faced by start- and scale-ups. The threshold ensures a low but acceptable solvency ratio appropriate for SMEs. This exception maintains the requirement to have a positive balance sheet position for the total equity amount. The threshold of 70% creates the opportunity to better align conversion periods on convertible bonds. This means that the SME, in collaboration with the investor, has the opportunity to anticipate to the subsidy requirements in the loan agreement (see similar EC approach in the financial capacity assessment of tenders (see the Financial capacity self-check in the EU Funding Portal).

Question 9

In your view, what would be the impact of an exemption of start-ups and/or scale-ups from the definition of Undertaking in Difficulty on the administrative burden and costs for authorities?

	Yes	No	I do not know / no opinion
It would decrease the administrative burden with respect to start-ups	◉	○	○
It would decrease the administrative burden with respect to scale-ups	◉	○	○
It would not decrease the administrative burden	○	○	◉

Please justify your answer:

2000 character(s) maximum

In case of total exemption of start- and scale-ups from the definition of UiD, the administrative burden would decrease substantially. However, the Dutch Authorities are not in favor of this proposal because it is not targeted and not fit for purpose for the reasons given under Question 7 b.

Question 10

In your view, what would be the impact of exempting start-ups and/or scale-ups from the definition of Undertaking in Difficulty on competition between undertakings within the internal market and the competitiveness of the EU economy in a global context?

	Yes	No	I do not know / no opinion
Increase competition within the EU	◉	○	○
Increase Competitiveness of the EU	◉	○	○
Increase both	◉	○	○

Decrease competition within the EU	○	◉	○
Decrease Competitiveness of the EU	○	◉	○
Decrease both	○	◉	○

Please justify your answer:

2000 character(s) maximum

The start- and scale-ups targeted in this questionnaire are not companies that are in real financial difficulty. Current investment practices have evolved and the legislation is not up to date. Successfully attracting external funding is often a strong indicator of the economic potential of a start-up or scale-up. Furthermore, investors use specific risk analysis methods which are more thorough than the UiD criteria test. Research shows investor support is a strong determining factor in the continuity perspective in the start- and scale-up. Therefore, aiding these companies does not create market disruptions because they keep non-competitive undertakings afloat. To the contrary, it increases competition because state aid can provide an extra impulse for companies to settle in the EU and be innovative. Supporting start-ups and scale-ups is also crucial in order to enhance the EU economy in a global context and secure fair competition in the future. Innovative companies are the basis for the autonomy of the EU and EU global competition.

The definition of "own funds"

The term "own funds" (which represents a literal translation of the French term "fonds propres" into English) is used in the definition of Undertaking in Difficulty and serves as a benchmark against which accumulated losses of a limited liability company must be evaluated, in order to establish whether such a company is in difficulty. That term is not defined in the Rescue and Restructuring Guidelines, which may create in some language versions of the Guidelines confusion as to which parts of a company's equity and which financial instruments are covered by the term "own funds".

Question 11

In your opinion, does the term "own funds" need to be further clarified?

- ◉ Yes
- ○ No
- ○ I do not know / no opinion

Please justify your answer:

2000 character(s) maximum

The term 'own funds' instead of 'equity' causes confusion and therefore needs to be clarified. Furthermore, various forms of external funding are, according to Dutch jurisprudence on the GBER definition, not classified as 'own funds' ('eigen vermogen' in Dutch, which translates to equity) (Paragraph 20, subsection a, of the guidelines and see judgment of April 2024 the Court of Appeal for trade and industry (College van Beroep voor het Bedrijfsleven, which is the highest administrative Court of Appeal in The Netherlands for administrative law

concerning economic instruments), ruled that ‘eigen vermogen’ in the GBER definition should be interpreted uniformly and independently and therefore according to Directive 2013/34/EU. Please see point 8.2 and 8.3 of the judgement: ECLI:NL:CBB:2024:289, College van Beroep voor het bedrijfsleven, 22/2178)) and, therefore, negatively impact the UiD assessment. This is illogical, as successfully attracting external funding in most cases is a strong indicator of the economic potential of a start-up or scale-up.
According to the Dutch Authorities, the term ”own funds” is preferred over “equity” as “equity” has a specific meaning in the Dutch financial administration practice, while “own funds” is a more general term, that the EC should define in the guidelines.

Question 12

If your answer to Question 11 was “yes”, what would, in your opinion, be the necessary clarification of the term “own funds”?

2000 character(s) maximum

The Dutch government proposes the following three types of external funding to be included as ‘own funds’ in the definition of UiD: 1) subordinated loans
2) convertible loans
3) loans provided by national and European (semi-)governmental institutions, such as InvestNL and the European Investment Bank.

The Dutch government also proposes two conditions to these types of external funding.
Firstly, the (remaining) duration of the loan must be at least equal to the duration of the period over which aid is given.
Secondly, the loan may not be withdrawn during the project period. In this way, the loan will take on the character of (semi) permanent capital (commitment), thereby ensuring the realization of the project for which aid is granted.
If a loan is withdrawn during the project period, it should be reassessed whether the undertaking would qualify as an UiD. In case an undertaking would classify as an UiD, it should be treated as such, meaning that the provided state aid must be recovered

Please justify your answer:

2000 character(s) maximum

The reasoning behind our proposal to add these three forms of external funding, lies primarily in the characteristic of the loans as ‘near-equity’ due to the absence of solid collateral for the loan (commitment) and in the thorough risk assessment on the SME's continuity perspectives, conducted by investors prior to their investment. These continuity assessments are performed on a professional level, given the risk of default and low collateral coverage on the loan.
A positive outcome of the continuity assessment is decisive for the provision of risk financing, similar to what the UiD test aims to determine in the public domain. Following these market practices and including these forms in the definition of “own funds” is a necessary and fit for purpose solution to the problem of false qualification of innovative undertakings as UiD’s.

Question 13

In your opinion, using “equity” instead of “own funds” would contribute to simplifying the assessment of this criterion, given that a company’s equity is readily available from its balance sheet?

- (●) Yes
- ( ) No
- ( ) I do not know / no opinion

Please justify your answer:

2000 character(s) maximum

This would exclude different interpretations, but would be too limited as a definition (see question 11). The Dutch authorities prefer a specific definition of ‘own funds’.

Other comments on the definition of Undertaking in Difficulty

Question 14

Do you have any other comments concerning the definition of Undertaking in Difficulty for the purposes of the Rescue and Restructuring Guidelines or other State aid rules.

- (●) Yes
- ( ) No

If yes, please elaborate:

2000 character(s) maximum

The Dutch authorities would welcome a clarification in the definition in GBER and other guidelines than these guidelines that UiD should only be assessed at the level of the group an aid applicant belongs to (if any).
In a judgement of December 2024, the Court of Appeal for trade and industry (College van Beroep voor het Bedrijfsleven, which is the highest administrative Court of Appeal in The Netherlands for administrative law concerning economic instruments), ruled that the requirement of UiD only applies on the level of the (international) group to which the aid applicant belongs and not both at the level of the group and the aid applicant. Please see point 6 and further of the judgment: https://uitspraken.rechtspraak.nl/details?id=ECLI:NL:CBB:2024:923&showbutton=true&keyword=tvl&idx=2.
The Dutch authorities are aware that this is not in line with the point of view of the EC (as follows from state aid wiki entries and bilateral contacts with the EC, which were shared with the Court with consent of the Commission services). However, the Dutch authorities consider that, as the Court concluded, the point of view of the Commission is not supported by the text of the GBER itself and is not in line with the notion of ‘one single undertaking’. The Netherlands would welcome if the EC clarified this in GBER. It is important to note that the situation is not entirely similar when the definition is used for the purposes of the guidelines of rescue and restructurering aid as in that case aid for large undertakings is the exception and arbitrary allocation of costs within the group should be avoided. In case of application in GBER the situation is opposite because if the undertaking

3. Additional information

Question 15

Do you want to raise any other points which may be relevant for the revision of the Rescue and Restructuring Guidelines?

- (●) Yes
- ( ) No

If yes, please elaborate:

2000 character(s) maximum

The Dutch authorities believe this revision should be adopted and take effect as soon as possible, preferably at the start of 2026. Implementation in GBER is also very urgent. Delaying the new rules would deny innovative companies a fair assessment and erode start-up confidence in the member states' business climate. Implementing the changes early 2026 provides a clear, harmonised basis for aid.

Additional documents

If you want to share any document (e.g. data, research paper, position paper, etc.) that may be relevant for the revision of the Rescue and Restructuring Guidelines, please upload it here. Please make sure not to include any personal data in the file you upload if you wish to remain anonymous.

Please upload your file(s)

Only files of the type pdf,txt,doc,docx,odt,rtf are allowed

Please upload your file(s)

Only files of the type xls,xlsx,ods are allowed

Contact

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Ministerie van Economische Zaken

HT.6515 Dutch response to the public consultation on the revised SGEI Decision

The Hague, 4 November 2025

This response reflects the views of the Dutch 'Interdepartementaal Staatssteun Overleg (hereafter: ISO)'. The ISO is a central State aid coordination body composed of all Dutch ministries and representatives of the regional and local authorities. The Minister of Economic Affairs is responsible for competition policy in the Netherlands and, in that context, the ministry of Economic Affairs chairs the ISO.

This is the Netherlands' response to the public consultation on the revised Commission Decision on the application of Article 106(2) of the Treaty on the Functioning of the European Union to State aid in the form of public service compensation granted to certain undertakings entrusted with the operation of services of general economic interest (hereafter: the SGEI Decision).

The proposed revised SGEI Decision aims to introduce new rules for affordable-housing SGEIs which should prevent undue distortion in the private housing sector and bring sufficient legal certainty to Member States and public authorities, while at the same time allowing them to tailor the rules to their specific national and local housing contexts. The new SGEI Decision also proposes introducing sectorial changes concerning critical medicine, aviation and maritime sectors as well as changes aimed at updating and simplifying the rules.

General comments

Robust State aid control is essential for ensuring a level playing field and well-functioning, competitive internal market. At the same time, State aid intervention may be needed to address certain market failures and/ or to accomplish the goals of European Union interests.

The revision of the SGEI Decision is welcomed, as it enables compensation for SGEIs to speed up the construction of affordable housing, addressing the urgent needs of the housing sector and the challenges European citizens face in having access to affordable housing. Moreover, the Netherlands welcomes the increase in the general threshold set out in Article 2 paragraph 1 under a) for non-specific SGEIs to EUR 20 million and the proposed simplification of administrative requirements, particularly with regard to the calculation of overcompensation. The Netherlands also endorses the provisions as set out in Article 7, paragraph 3 of the draft SGEI Decision. This stipulates that EU Member States will no longer have to calculate the amount of compensation ex post if the provider is obliged to reinvest all profits in the SGEI. Especially for local and regional authorities these alterations are important improvements, decreasing administrative burdens and providing more flexibility for the financing of SGEIs at a local and regional level.

Specific comments on social and affordable housing SGEI

The Netherlands welcomes the proposed amendments to the SGEI Decision. These changes provide much-needed flexibility within the State aid legal framework to support undertakings entrusted with providing affordable housing. The Netherlands, like many other EU Member States, is facing a shortage of affordable

homes. The targeted revision of the SGEI Decision on affordable housing, without a notification threshold, is therefore particularly welcome. Furthermore, we welcome the conditions outlined in the Annex regarding the combination of social and affordable housing. The proposed requirements for SGEIs for social and affordable housing leave sufficient discretion for EU Member States to design, finance and implement SGEIs for social and affordable housing within their national contexts, in accordance with the principles of subsidiarity and proportionality.

The draft SGEI Decision also correctly considers in recital 28 that a longer timeframe than 10 years is necessary for social and affordable housing projects. In practice, this can be more than 25 years, as is the case with social housing.

While the draft SGEI Decision provides flexibility regarding the criteria that EU Member States can apply to affordable and/or social housing projects, the Netherlands would like to draw the Commission's attention to two criteria mentioned in the draft SGEI Decision:

The criterion of 'already owning residential property' as a possible exclusion ground for the SGEI target group of beneficiaries, as mentioned in recital 15, can lead to excessive administrative burdens. Very few households that own residential property seek to rent affordable housing. Yet all households would be required to prove that they do not own property, which would lead to implementation problems in the national practice.[1] In some cases, property ownership may also be temporary or incidental, such as inheriting a home in a different region. This should be treated with flexibility and fall under the discretion of EU Member States.

The criterion to verify eligibility of affordable housing beneficiaries at regular intervals should not result in an obligation for EU Member States to adopt regulations that would terminate rental contracts in such cases. For example, gradually raising the rent to market levels for households that are no longer eligible would address the issue and prevent them from instantly losing their home if their income increases.

Finally, the Netherlands proposes introducing a turnover threshold in Article 7, paragraph 3 of the SGEI Decision. For instance, if a provider engages in non-SGEI activity related to the SGEI[2], and this activity accounts for only [5] % of the provider's annual turnover, the provider should still be eligible for the exemption. This would help to avoid excessive administrative burdens, such as the need to track and precisely allocate multiple revenue streams. It would also prevent the creation of unintended barriers to new housing developments containing both SGEI and a small non-SGEI component, for example as a result of city planning or

[1] In social housing in the Netherlands 19.000 households of 2,1 million households own property.
[2] For example, an operator rents out the ground floor of an apartment building in an inner city to a store

architectural reasons.[3] Please see also our request under 'Other comments' regarding SGEI's in relation to non-economic SGI-activities.

Specific comments on critical medicines SGEI

The Netherlands welcomes the explicit inclusion of critical medicines in the draft SGEI Decision. However, the Netherlands has two concerns relating to critical medicines in the draft SGEI decision. Firstly, it is important that the definition of critical medicine aligns with the definitions in the Critical Medicines Act and the revision of the Pharmaceutical Package. Currently, this is not the case. These legislative acts are currently under negotiation in the Working Party on the Critical Medicines Act and in the Trilogue (the revision of the Pharmaceutical Package). We therefore urge the Commission to align the definition in the revised SGEI decision with the final definitions of these pieces of legislation.
Secondly, there is the paragraph concerning market failure and the vulnerability assessment. In the draft SGEI Decision, market failure must be substantiated by a vulnerability assessment. In the Netherlands, we are exploring several instruments relating to the concept market of failure with regard to the SGEI, e.g. stockpiling (medicines/APIs), technology transfer for final registrations ,and scalable production. Market failure is assessed based on the fact that financial margins are too low for (certain) generic medicines for a return on investment in these examples (stockpiling, production registrations and keeping capacity available for times of shortages/crisis). Could the Commission please clarify what a vulnerability assessment entails and whether an assessment of return on investment would be sufficient to establish a market failure?

Specific comments on the maritime and air transport SGEI

The Netherlands welcomes the proposed amendments to Article 2, paragraph 1, sub d) and sub e) of the draft SGEI Decision for the aviation sector (air links and airports).

The Netherlands also welcomes the proposed amendments to Article 2, paragraph 1, sub e) of the draft SGEI Decision for the maritime sector (ports).
However, it is unclear how 'freight' can be defined in terms of linear meters in Article 2, paragraph 1, sub d) of the draft SGEI Decision. Clarification on this matter would be welcomed.

Other comments

To ensure a careful revision of the SGEI Decision and the necessary internal coordination of the response to the public consultation, the Netherlands would have preferred a regular consultation period to an accelerated one. The Netherlands requests that the Commission take this into account in future public State aid consultations.

[3] For example, an operator in an inner city development needs to allocate the ground floor for offices and stores, since they are not suitable for homes, but this operator is not able to finance the non-SGEI activity because of the obligation to reinvest all profits in the SGEI.

With regard to the scope of the SGEI Decision, the Netherlands welcomes in Article 2, paragraph 1, point (a) of the draft SGEI Decision, the increase in the annual amount from EUR 15 million to EUR 20 million for the provision of SGEI in areas other than transport and transport infrastructure, including social services not referred to in Article 2, paragraph 1, point (c) and critical medicines.

With regard to transparency, the Netherlands notes that the requirement for the entrustment act shall to include a reference to the SGEI Decision has been removed. In our view, it is important to refer to the SGEI Decision in order to ensure transparency and provide an overview of the measures based on it. At the same time, however, we do not object to the deletion of this requirement.

The Netherlands is not in favor of the introduction of the transparency obligation (Article 8 of the draft SGEI Decision). We question the effectiveness of the transparency obligation and the added value next to a reporting obligation (of which the results are integrally published), However, we believe that if this requirement is introduced, it is important for the transparency obligation to include a reference to SGEI aid. The Netherlands considers it important to distinguish between 'regular' State aid and aid granted in the context of an SGEI.

Finally, the Commission is asked to consider whether the rules can be clarified and simplified in situations where SGEI activities and non-economic SGI-activities might overlap. This is particularly relevant when assessing overcompensation, especially in relation to separate accounting.

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Date: 01/10/2025 16:31:00

Public Questionnaire informing the European Biotech Act

Fields marked with * are mandatory.

Introduction

The European Biotech Act

Biotechnology and biomanufacturing hold great promise for advancing competitiveness and innovation within the European Union (EU). As previously acknowledged in the Communication on Biotechnology and Biomanufacturing (March 2024) and the reports by Enrico Letta (April 2024) and Mario Draghi (September 2024), it is necessary to address the challenges faced by European companies, users and consumers, and all stakeholders involved to boost the technological advancement, competitiveness and economic growth of the EU.

To this end, the Commission has announced in the 2024-2029 political guidelines a new European Biotech Act, aimed at creating an enabling environment to make it easier to bring biotech products from the laboratory to the factory and then onto the market, while maintaining the highest safety standards for the protection of the population and the environment.

EU policy initiatives relevant for this sector are for example the Strategy for European Life Sciences, the Competitiveness Compass, new EU Bioeconomy Strategy, the AI in science Strategy, the Vision for Agriculture and Food, the European Innovation Act, the EU Start-Up and Scale-up Strategy, the Union of Skills and the Savings and Investment Union. Some of these are currently still under development and the European Biotech Act will be defined in synergies with them.

The public consultation

The European Commission is launching a **public consultation** on the European Biotech Act in the form of an online questionnaire. The aim is to gather evidence and views from stakeholders across all relevant sectors of biotechnology and biomanufacturing, including the medical and pharmaceutical, agricultural, food and feed, industrial, environmental and marine sectors. Your feedback is crucial for identifying the most important challenges and barriers that could be addressed by the Act and for shaping targeted policy actions.

Instructions

The first section of the questionnaire contains questions about you or the organisation you represent, which is then followed by questions on the regulatory and non-regulatory environment in the EU to inform the policy-

making process of the European Biotech Act.

Whenever possible, please substantiate your replies with data and sources of information or practical examples.

This questionnaire is available in all EU official languages and you can reply in any EU official language. You can pause at any time and continue later. You can download your contribution once you have submitted your answers.

About you

* Language of my contribution

- ○ Bulgarian
- ○ Croatian
- ○ Czech
- ○ Danish
- ○ Dutch
- ◉ English
- ○ Estonian
- ○ Finnish
- ○ French
- ○ German
- ○ Greek
- ○ Hungarian
- ○ Irish
- ○ Italian
- ○ Latvian
- ○ Lithuanian
- ○ Maltese
- ○ Polish
- ○ Portuguese
- ○ Romanian
- ○ Slovak
- ○ Slovenian

- ○ Spanish
- ○ Swedish

* I am giving my contribution as
  - ○ Academic/research institution
  - ○ Business association
  - ○ Company/business
  - ○ Consumer organisation
  - ○ EU citizen
  - ○ Environmental organisation
  - ○ Non-EU citizen
  - ○ Non-governmental organisation (NGO)
  - ◉ Public authority
  - ○ Trade union
  - ○ Other

Do you identify yourself as a private investor (e.g. venture capitalist, business angel)?
- ○ Yes
- ◉ No
- ○ I don't know/I'd rather not say

* This questionnaire covers **all areas of biotechnologies.** Please indicate the **sector s** that are relevant to you or the organisation you represent, or which you have most knowledge on.

You can select multiple sectors.

Please note that your answers to the questionnaire will be analysed in relation to the sector(s) you have selected.
- ☑ Medical/pharmaceutical
- ☑ Agricultural
- ☑ Food/feed
- ☑ Industrial

- [x] Environmental
- [ ] Marine
- [ ] Bioinformatics
- [ ] Biotechnology for defence and security
- [ ] Other areas of biotechnology
- [ ] Not applicable

If a different sector of biotechnology is relevant to you or the organisation you represent, please specify.

*First name

*Surname

*Email (this won't be published)

*Scope

- ( ) International
- ( ) Local
- (•) National
- ( ) Regional

*Level of governance

- ( ) Parliament
- (•) Authority
- ( ) Agency

*Organisation name

255 character(s) maximum

From the Dutch government on behalf of the Dutch Ministry of Economic Affairs

* Organisation size

- Micro (1 to 9 employees)
- Small (10 to 49 employees)
- Medium (50 to 249 employees)
- Large (250 or more)

Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

* Country of origin

Please add your country of origin, or that of your organisation.

This list does not represent the official position of the European institutions with regard to the legal status or policy of the entities mentioned. It is a harmonisation of often divergent lists and practices.

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Saint Martin
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles

- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia

- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d’Ivoire
- Croatia
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan
- Turks and Caicos Islands
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam

- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- **Anonymous**

  Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

- **Public**

  Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

☑ I agree with the personal data protection provisions

Questions regarding a future European Biotech Act

*Mandatory questions are indicated with an *.*

Please note that the answers to the questionnaire will be analysed in relation to the area(s) you have selected in the 'About you' section.

Section 1 - General views on biotechnology

Biotechnology can be defined as the application of science and technology to living organisms, as well as parts, products and models of them, to alter living or non-living materials for the production of knowledge, goods and services.

Biomanufacturing is the use and conversion of biotechnology and biological resources into chemicals, products and energy.

Q1. Considering **biotechnology and biomanufacturing products overall,** to what extent do you agree with the following:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
* Biotechnology and biomanufacturing products can **positively impact the EU economy**	○	○	○	○	◉	○
* Biotechnology and biomanufacturing can **positively impact the EU society**	○	○	○	○	◉	○
* Biotechnology and biomanufacturing can **positively impact the environment**	○	○	○	○	◉	○
* Biotechnology and biomanufacturing products that reach the EU market are **safe and secure**	○	○	○	◉	○	○
* **Information to users and consumers** on biotechnology and biomanufacturing is available and accessible	○	○	○	◉	○	○
* Consumes are **willing to pay a price premium** for biotechnology and biomanufacturing products	○	○	○	○	○	◉

Section 2 - The regulatory environment in the EU

The following questions seek to collect views on the regulatory environment in the EU, in particular the perceived regulatory barriers.

Q1. Taking into account recent initiatives and legislation adopted or under discussion at EU level, to what extent do you agree with the following statement: **EU rules lead to regulatory barriers for biotechnology and biomanufacturing products to reach the market in the following phases:**

Not all phases may be applicable to all biotechnology and biomanufacturing products.

This specific question covers EU rules, i.e. legislation stemming from the European Union.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
* In early-stage or pre-clinical development	○	○	◉	○	○	○
* In product development	○	○	○	◉	○	○
* In pre-commercial testing or clinical trials	○	○	○	◉	○	○
* In the assessment and in obtaining authorisation to market products	○	○	○	○	◉	○
* In techno-economics (outside of health) or health technology assessment	○	○	○	○	○	◉
* In commercialising products	○	○	○	○	◉	○
* In scaling-up production or manufacturing	○	○	○	○	◉	○
* In post-market activities, including monitoring and surveillance	○	○	○	○	○	◉

Q2. Please indicate **other phases of the innovation and manufacturing cycle** where there are **regulatory barriers** caused by EU rules.

600 character(s) maximum

There are multiple examples where biotech innovations have to comply with more than one regulations. The Netherlands calls for a coherent, flexible EU framework that aligns overlapping rules and eliminates contradictions. For instance regarding GMO and Novel Food legislation. In the assessment and in obtaining authorization to market products, an specific example is green pesticides as market product. The Commission could provide more guidance and support to applicants, through a contact point that they can approach for general questions and specific questions about and during the procedure.

Q3. Please substantiate your statements with **additional evidence** on the **challenge s** resulting from the **EU regulatory environment**.

600 character(s) maximum

Currently EU plant protection product regulations are primarily designed for chemical substances and are ill-suited for biological alternatives, resulting in unpredictable and excessively long lead times. The approval of low-risk biological substances and authorization of corresponding market products can take up to 10 years. The approval procedures for novel foods, sometimes produced with GMOs such as cellular food production or precision fermentation, are currently perceived by companies as non-transparent, costly and slow, and therefore hampering commercializing products.

The following questions seek to collect views on possible ways forward to simplify and streamline the EU regulatory environment applicable to biotechnology and biomanufacturing products.

* **Q4.** In your view, what **actions at EU level** are necessary to **improve the regulatory environment for biotechnology and biomanufacturing** in the EU? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

Given the rapid developments in biotechnology and new insights in safety, regulations should be forward-looking and resilient: developing adaptable regulations while ensuring harmonisation and maintaining the highest safety standards. Especially the 2009/41 (CU) and 2001/18 (DR) could merit from more adaptability to the latest scientific developments. For example, revising the GMO-definition should help to properly assess new applications and whether they fall under the scope of the GMO legislation. Also, the differentiation in procedures should be risk- instead of containment-based (CU/DR).

The following questions refer to views or experience with regulatory environments in countries outside of the EU and of the EEA (Norway, Iceland and Liechtenstein).

Q5. To what extent do you agree that the EU regulatory environment in comparison with some of the countries outside of the EU...:

For each statement, you will have the possibility to indicate the third country(ies) your answer refers to.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
... is more **predictable**	○	○	○	○	○	◉
... is **less complex and clearer**	○	○	○	○	○	◉
... leads to lower **costs** for **complying** with the regulation	○	○	○	○	○	◉
... **enables** biotechnology and biomanufacturing products to **reach the market faster**	○	○	○	○	○	◉
... ensures a **higher level of safety and security**	○	○	○	○	◉	○

Q5e. Regarding the level of safety and security: Please indicate the reasons why, and in which third-country(ies) this applies.

600 character(s) maximum

Where the EU applies the precautionary principle – meaning that if there is scientific uncertainty about potential risks, approval is withheld until safety can be assured – non-EU countries like the US/Canada regulate using a product-based approach regardless of whether the product is a GMO. This means GMO's in the phase before market-authorisation are not assessed and possibly dangerous when released into the environment. GMOs can spread uncontrollably and irreversibly and may cause lasting damage and severe diseases in humans and the environment – GMOs multiply and may grow exponentially.

Q6. Please indicate any **other relevant factors that characterise the regulations in non-EU countries** and that are applicable to biotechnology and biomanufacturing products.

600 character(s) maximum

It is important that national and EU regulations should align with the latest scientific findings. The regulatory framework within Europe should be harmonised and forward-looking. The procedures associated with legislation and regulations must be transparent, effective and predictable.

Section 3 - Access to capital

The following questions seek to collect views on access to public and private capital and related barriers.

Q1. To what extent do you agree it is **easy to access the following types of public investments in the EU:**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Grants and subsidies (e.g. at EU level: HORIZON, EU4Health)	○	○	○	○	○	◉
* Debt and equity instruments (e.g. European Innovation Council, European Investment Bank, Strategic Technologies for Europe Platform)	○	○	○	○	○	◉
* Commercialisation support	○	○	○	○	○	◉
* Support to capacity expansion	○	○	○	○	○	◉

Q2. To what extent do you agree it is **easy to access the following types of private investments in the EU:**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable/I don't know
* Angel investors	○	○	○	◉	○	○
* Venture capital: Start-up/early stage (Series A)	○	○	○	◉	○	○
* Venture capital: Expansion stage (Series B)	○	○	◉	○	○	○
* Venture capital: Growth stage (Series C, etc)	○	◉	○	○	○	○
* Debt financing	○	○	◉	○	○	○
* Private equity	○	○	◉	○	○	○
* Strategic research or sales partnerships and collaborations	○	○	◉	○	○	○
* Publicly listing (Initial Public Offering (IPO))	◉	○	○	○	○	○
* Capital markets/shareholders	○	○	○	◉	○	○
* Corporate funding (from other companies in the market)	○	○	◉	○	○	○

* **Q3.** In your views, are there **other financial instruments** relevant for the biotechnology sector in the EU?

- (●) Yes
- ( ) No
- ( ) I don't know

Q3a. Please indicate **other relevant private and public financial instruments**.

600 character(s) maximum

Seed capital

Q4. Based on your experience, to what extent do you agree that the following factors **drive investment in a biotechnology company**?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Innovative science	( )	( )	( )	( )	(●)	( )
* Groundbreaking technology (e.g. health biotech: a breakthrough that significantly improves upon existing therapies or addresses unmet medical needs; food biotech: solution that can boost food security)	( )	( )	( )	( )	(●)	( )
* Scientific evidence, including data, concerning innovation	( )	( )	( )	( )	(●)	( )
* Access to data held by public sector bodies	( )	( )	( )	( )	(●)	( )
* Experienced management team	( )	( )	( )	( )	( )	(●)
* Robust supply chain	( )	( )	( )	(●)	( )	( )

* Regulatory certainty (e.g. length and predictability of authorisation process)	○	○	○	○	◉	○
* Sufficient protection of intellectual property	○	○	○	○	◉	○
* Financial health and projections	○	○	○	○	○	◉

Q5. Please indicate **other factors that drive investment** in a biotechnology and/or biomanufacturing company here.

1000 character(s) maximum

In order to offer a level playing field and prospects to developers and financiers of biotechnological innovations in Europe the Netherlands calls for proportional and future-oriented European legislation and regulations with transparent, efficient and predictable approval procedures. Thereby Europe can optimally use these innovations in our society, while maintaining a high level of safety guarantee. In the field of green and industrial biotechnology a factor that drives investment is market demand. Without market demand for green and sustainable products, the business case is not competitive. Creating market demand on a EU-level green and circular biotech products will improve the business case.

Q8. Please substantiate your statements with **additional evidence** on the **challenge s** related to **access to finance in the EU**.

600 character(s) maximum

As an example, there is a medical company in the Netherlands that wants to build a new plant and has the ambition to make their process circular. This is because they are using a rare earth metal in their process. They need to use mercury, a metal that is phased out, in order to make it circular. They asked for a 'exception position' at DG ENV. However, there is no specific reaction period to take this into consideration. Companies that want to start a plant can experience this (possibly long waiting time) as a bottleneck. Additional evidence on challenges can be found in section 9.

The following questions seek to collect views on possible ways forward to support access to finance in the EU.

* **Q9.** In your view, what **actions at EU level** are necessary for the public sector **to attract/derisk private investments in biotechnology and/or biomanufacturing**? Please substantiate your statements with views and evidence on the ways forward.

You can provide references of successful schemes existing at EU level, national level or in other jurisdictions to attract private capital in biotechnology.

600 character(s) maximum

Availability of public-private research and technology infrastructure and access to facilities for experimentation and scaling are important prerequisites for SME, start-up and scale-up for strategic innovation. (Long term) funding for pilot- to -demo infrastructure is a prerequisite for exploitation of these facilities. The Netherlands are in favor for public support mechanisms to derisk and attract private capital. The Netherlands also promotes to make existing shared facilities better accessible for innovative SMEs, start-up and scale-up.

* **Q10.** In your view, what **actions at EU level** are necessary to prioritise **funding for high-risk and high-reward biotechnology research and innovation?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The Netherlands calls for tailored instruments in the next MFF to close funding gaps for scaling and commercialization of innovations, because SMEs in industrial biotech or cultivated meat often lack access to late-stage finance and must rely on foreign investors to grow. Therefore, the ECF and the new Horizon Europe must offer tailored instruments - such as grants, direct and indirect equity, venture debt, guarantees, and blended finance – as well as the right framework conditions such as focus on the most strategic technologies and sectors, including biotech, based on excellence and impact.

* **Q11.** In your view, what **other actions** are necessary at EU level? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The Netherlands welcomes the announcement in the Start-up and Scale-up strategy to revise the definition of Undertakings in financial Difficulty (UiD), which is also relevant for the biotechnology sector. The Netherlands calls on EC DG COMP, to collaborate with other EC DGs (CLIMA, SANTE, RTD, REGIO) to ensure that the State aid rules are fit fur purpose for aid measures for the biotechnology industry, particularly with respect to the definition of UiD, taking into account the specific characteristics of this sector.

Section 4 - Biotechnology clusters and/or cluster organisations

The following questions seek to collect views on biotechnology clusters and/or cluster organisations in the EU.

'**Clusters** are groups of firms, related economic actors, and institutions located near each other and with sufficient scale to develop specialised expertise, services, resources, suppliers and skills.' [**link to definition of clusters**]

'**Cluster organisations** are the legal entities that support the strengthening of collaboration, networking and learning in innovation clusters and act as innovation support providers by providing or channelling specialised

and customised business support services to stimulate innovation activities, especially in SMEs. They are usually the actors that facilitate strategic partnering across clusters.' [**link to definition of cluster organisations**]

Q1. To what extent do you agree that biotechnology clusters and/or cluster organisations in the EU face the **following barriers** in order to reach their full potential?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Insufficient number of academic institutions with long standing expertise in the area of biotechnology	◉	○	○	○	○	○
* Insufficient presence of industrial players	○	◉	○	○	○	○
* Insufficient higher education or vocational training institutions	◉	○	○	○	○	○
* Insufficient startup incubators or business support infrastructure (providing for example regulatory affair support)	○	○	○	◉	○	○
* Lack of technology transfer offices	◉	○	○	○	○	○
* Incapacity to reach a critical mass of stakeholders	○	○	○	○	◉	○
* Insufficient public support	○	○	◉	○	○	○
* Insufficient collaboration among existing clusters	○	○	○	◉	○	○
* Insufficient financial support	○	○	○	○	◉	○

Q2. Please indicate **other factors impacting biotechnology clusters and/or cluster organisations** in the EU.

1000 character(s) maximum

Not applicable

Q3. Please substantiate your statements with **additional evidence** on the **challenges** faced by **biotechnology clusters and/or cluster organisations** in the EU.

600 character(s) maximum

Competition for national and international funding does not often encourage formation of (national) centres of excellence (and critical mass). There is insufficient integration of existing TTOs best practices on a national /international level. There is insufficient finance available for spinouts and young innovative companies arising from national biotechnology clusters. Seed finance is available. Availability of finances for growing companies is insufficient. For example, of corporate finance is limited, partly due to lack of critical mass on national level.

The following questions seek to collect views on possible ways forward to support biotechnology clusters and/or cluster organisations in the EU.

* **Q4.** In your view, what **actions at EU level** are necessary to **enhance the impact of biotechnology clusters and/or cluster organisations in the EU**? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The Netherlands calls for improvement of the knowledge and technology transfer between academia and industry and upscaling of innovations (specifically SMEs). To create centres of excellence and critical mass within Biotechnology, better collaboration between leading European biotech clusters is needed. The Netherlands offers several best practices such as: Leiden Bio Science Park hosts a high concentration of R&D-intensive companies and public-private research infrastructure, while the ecosystem around Wageningen University & Research foster innovation in agri-food and cellular agriculture.

* **Q5.** In your view, what **actions at EU level** are necessary to create more **synergies** between existing clusters and/or cluster organisations and facilitate **pooling of expertise and resources** in the EU? Please substantiate your statements with views and evidence on the ways forward here.

600 character(s) maximum

The Biotech Booster is an example of a national cluster in The Netherlands. Effective ways to improve synergies in EU is to create networking opportunities (e.g. the EU Cluster Collaboration) and to finance strategic cross-border partnerships. Long-term investment is needed for sustainability. Successful pilots can be financed for longer periods (10 years), until such cross-border clusters can generate sustainable self-finance. Cluster formation should integrate of life sciences with emerging hi-tech.

Section 5 - Biotechnology manufacturing

The following questions seek to collect views on biotechnology manufacturing in the EU.

Q1. To what extent do you agree that biotechnology manufacturing in the EU faces the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Length and/or complexity of permitting processes for new facilities	○	○	○	○	○	◉
* High cost of raw material and/or of the operations	○	○	○	○	○	◉
* High energy costs	○	○	○	◉	○	○
* Other operational costs	○	○	○	○	○	◉
* Limitations in logistics and physical infrastructure	○	○	○	○	○	◉
* Vulnerabilities in supply chains and strategic dependencies	○	○	○	○	○	◉
* Labour costs	○	○	○	◉	○	○
* Inconsistent environmental and sustainability policies or lack of a policy	○	○	○	○	○	◉
* Taxation and customs barriers (e.g. tax credits, import duties)	○	○	○	○	○	◉
* Global competition	○	○	○	○	◉	○
* Difficulty scaling up from pilot to industrial production	○	○	○	○	◉	○
* Maintaining product quality and consistency at scale	○	○	○	○	○	◉

Q2. Please indicate **other challenges impacting biotechnology manufacturing in the EU**.

600 character(s) maximum

Commercial producers/economic operators would like to have the opportunity to test their product in the development phase before applying for an authorisation. For these kind of 'taste tests', there is currently no possibility within the frame of the legislation. This concerns for example innovative fermentation products, or food produced by cellular agriculture. We are currently investigating the possibilities for facilitating taste testing for innovative fermentation products (on a national level). For cellular food production, the Netherlands has already facilitated some taste testing.

Q3. Please substantiate your statements with **additional evidence** on the **challenges impacting biotechnology manufacturing in the EU**.

600 character(s) maximum

Market demand is lacking in the field of industrial biotechnology. Without market demand for green and sustainable products, the business case is not competitive. Creating market demand on a EU-level green and circular biotech products will improve the business case.

The following question seeks to collect views on possible ways forward to support biotechnology manufacturing in the EU.

* **Q4.** In your view, what **actions at EU level** are necessary to **enhance the impact of biotechnology manufacturing in the EU?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The Dutch government welcomes the European Commission’s proposal to update the Bioeconomy Strategy and supports the objective to create and protect European lead markets for biobased products. Furthermore we support the Commission’s aim to secure the competitive and sustainable supply of biomass.

Section 6 - Availability, upskilling and reskilling the biotechnology workforce

The following questions seek to collect views on the needs of the workforce in biotechnology in the EU.

Q1. To what extent do you agree that **the EU workforce for biotechnology** faces the following **challenges?**

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Shortage of vocational skills especially for biotechnology and biomanufacturing (e.g. lab technicians, operators, etc.)	○	○	○	◉	○	○
* Insufficient STEM education graduates (STEM: Science, Technology, Engineering, Mathematics)	○	○	○	◉	○	○
* Insufficient research and technical skills	○	○	○	◉	○	○
* Insufficient regulatory and quality assurance expertise	○	○	◉	○	○	○
* Insufficient digital and data science skills	○	○	○	◉	○	○
* Insufficient intellectual property skills	○	○	◉	○	○	○
* Limited financial, entrepreneurial skills and mindsets	○	○	○	◉	○	○
* Other	○	○	○	○	○	◉

Q2. Please indicate **other challenges faced by the workforce for biotechnology in the EU**.

600 character(s) maximum

The demand for workers in general is high. Filling vacancies at the vocational and higher professional levels is becoming increasingly difficult in NL. This also applies to the biotechnology sector. In addition the enrollment of students in science and technology education is a factor that contributes to reducing labor market shortages in the Netherlands. We are committed to increasing the enrollment of students in science and technology education at universities of applied sciences and research universities and to reducing unnecessary student dropouts from these programs.

Q3. To what extent do you agree that **the following factors** lead to the EU workforce facing the above-mentioned challenges?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Difficulty in attracting, developing and retaining global talent	○	○	◉	○	○	○
* Misalignment between education and industry needs	○	◉	○	○	○	○
* Regional disparities in the availability of skilled workers in the EU (for example as a result of brain drain or lack of availability of training courses)	○	○	○	◉	○	○
* Insufficient public and private investment in skilled workforce	○	○	○	○	◉	○

Q4. Please indicate **other factors** leading to the **EU workforce facing the above-mentioned challenges**.

1000 character(s) maximum

Continued and smart commitment to lifelong learning (LLD) is also necessary to reduce labor market shortages and increase labor productivity. LLD can increase the adaptability of individuals and companies, which is crucial in the context of rapid biotechnological developments. LLD requires structural and cultural changes, requiring both public and private commitment and investment. This should lead to a strong learning culture, in which it is clear to everyone that investing in learning and development is rewarding.

Q5. Please substantiate your statements with **additional evidence on the challenges faced by the workforce for biotechnology in the EU**.

600 character(s) maximum

In Biotech Talent Unlocked, knowledge institutions from the Netherlands and Germany in the Eems Dollard Region (EDR) border region are committed to organizing sufficient and appropriately trained talent for the circular and biobased economy. The consortium focuses on increasing the visibility of career prospects in this region for young German and Dutch talent (MBO, BSc, MSc) with a background in biotech or related fields. Techkwadraat is a program that provides primary- and secondary schools with the opportunity to introduce their students to biotech, as part of the broader themes of STEM.

* **Q6.** In your view, what **actions at EU level** are necessary to **enhance specialised training programmes/curricula?** Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

The provision of research funds dedicated towards ecosystems that surround fundamental scientific questions which can be related to involved industries, similar to initiatives around quantum.

* **Q7.** In your view, what **actions at EU level** are necessary to **enhance support for scientists to launch a business** (e.g. through incubators, pilot facilities for knowledge transfer and idea testing, etc.)? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

To accelerate innovation in new breeding techniques (genetic modification, synthetic biology), breakthroughs in biotechnological applications (such as the new DNA technology CRISPR/Cas9), robotization and virtualization, crop adaptations in response to climate change (including increased heat and salt tolerance), and shifts in food-producing regions worldwide. Staying ahead of the curve requires strong collaboration between businesses, education, and government, developing knowledge. Sufficient and highly trained personnel are essential.

* **Q8.** In your view, what **actions at EU level** are necessary to support **programmes to attract talent from other geographical areas**? Please substantiate your answers with views and evidence on the ways forward.

600 character(s) maximum

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* **Q9.** In your view, what **other actions at EU level** are necessary for the availability, upskilling and reskilling of the biotechnology workforce? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

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Section 7 - Data and Artificial Intelligence

The following questions seek to collect views on the challenges related to access to data and on the development, deployment and use of Artificial Intelligence (AI) in biotechnology.

* **Q1.** Are you or the organisation you represent having difficulties in **accessing or using relevant data** for the development of biotechnology or biomanufacturing products?

- ○ Yes
- ○ No
- ○ Partially
- ◉ Not applicable/I don't know

* **Q2.** Are you or the organisation you represent relying on **data sourced from outside of the EU/EEA** for the development of biotechnology and biomanufacturing products and services?

- ○ Yes
- ○ No
- ◉ Not applicable/I don't know

Q3. To what extent do you agree that **data synthetisation** is a viable means to overcome data scarcity in the EU?

- ○ Strongly disagree
- ○ Disagree
- ○ Neutral
- ◉

Agree

- Strongly agree
- Not applicable/I don't know

The next set of questions specifically cover the implementation of the European Health Data Space (EHDS) and consequently focus on health data.

In the health domain, the EHDS aims to alleviate challenges in accessing data for secondary use by establishing a legal framework facilitating the reuse of health data for research and innovation, including in the biotechnology sector. The EHDS Regulation entered into force on 26 March 2025 and its key provisions will enter into application and be operational by March 2029.

Q4. Regarding the health biotechnology sector, are you or the organisation you represent **actively preparing for the entry into application of the EHDS?**

- Yes
- No
- Not applicable/I don't know

Q5. Which types of services of research and health data infrastructures (e.g. biobank research infrastructures) are currently used in the biotechnology sector?

600 character(s) maximum

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The following questions specifically concern the transformative potential of AI for biotechnology.

In the following questions, a distinction is made between two categories of AI use in biotechnology, representing different phases of the innovation cycle:

1. Use of AI in Research and Development (R&D): Biotech companies using AI toolsto support or accelerate their R&D processes (e.g. using AI to identify drug targets or design new molecules, applying machine learning to analyse omics data, etc).

2. Deployment and scale-up of AI-based Biotechnology Products: Biotech companies developing AI-powered products or services and deploying these products into real-world settings (e.g.AI-powered

biomanufacturing platforms aimed to be integrated in production facilities, AI powered diagnostic tool that analyses blood based biomarkers to detect early stage cancer using a biological model of tumour progression, etc).

Q6. To what extent do you agree that **the use of AI in R&D** is facing the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* **Technological challenges, access and use of data** (e.g. outdated infrastructure to support the integration of AI tools, lack of interoperability, lack of local validation (performance testing), lack of post-deployment monitoring mechanisms, lack of AI transparency and explainability etc)	○	○	○	○	○	◉
* **Challenges in the implementation of regulatory frameworks** (e.g. complex regulatory landscapes for AI users and/or deployers, concerns over liability, concerns surrounding data security and privacy etc)	○	○	○	○	○	◉
* **Organisational and business challenges** (e.g. lack of end-user involvement in the development and deployment of AI tools, lack of added value assessment in deploying AI, lack of AI strategy for use/deployment in the entity)	○	○	○	○	○	◉
* **Social and cultural challenges** (e.g. lack of trust in AI tools, lack of digital literacy among users/deployers/the public, concerns on job security, concerns surrounding overreliance on AI tools, etc	○	○	○	○	○	◉

Q7. To what extent do you agree that **the deployment of AI-based biotech products** is facing the following challenges:

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* **Technological challenges, access and use of data** (e.g. outdated infrastructure to support the integration of AI tools, lack of interoperability, lack of local validation (performance testing), lack of post-deployment monitoring mechanisms, lack of AI transparency and explainability etc)	○	○	○	○	◉	○
* **Challenges in the implementation of regulatory frameworks** (e.g. complex regulatory landscapes for AI users and/or deployers, concerns over liability, concerns surrounding data security and privacy etc)	○	○	○	○	◉	○
* **Organisational and business challenges** (e.g. lack of end-user involvement in the development and deployment of AI tools, lack of added value assessment in deploying AI, lack of AI strategy for use/deployment in the entity)	○	○	○	◉	○	○
* **Social and cultural challenges** (e.g. lack of trust in AI tools, lack of digital literacy among users/deployers/the public, concerns on job security, concerns surrounding overreliance on AI tools, etc	○	○	○	◉	○	○

Q8. Please substantiate your statements with **additional evidence** on **access to data, the use of AI in R&D,** and **deployment of AI-based biotech products in the EU biotechnology sector** here.

600 character(s) maximum

Generally, technological challenges are low (AI-)cloud adoption/a lack of compute, fragmented data systems and a lack of standardization, which combined undermine data utility and the machine-learning readiness of data models. A challenge in the implementation of regulatory frameworks is the lack of adequate security controls for the protection of intellectual property (IP) as well as sensitive personal data. Social challenges faced include the lack of digital skills and the competitive labor market for hiring AI/ML talent.

The following questions seek to collect views on possible ways forward to support the deployment and use of AI and data in biotech.

* **Q9.** In your view, what **actions at EU level** are necessary to enhance **the use of AI in R&D in biotechnology** in the EU?

600 character(s) maximum

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* **Q10.** In your view, what **actions at EU level** are necessary to enhance the **deployment of AI-based biotechnology products** in the EU?

600 character(s) maximum

-

Q11. In your view, what **other actions** should be prioritised **at EU level** related to **data and AI in the field of biotechnology and biomanufacturing** (e.g. on data, on use of high-performance computers (HPC), etc.)?

600 character(s) maximum

- Promoting availability, sharing of and access to high quality data - Support for the biotechnology and biomanufacting field connecting with EuroHPC and new high performance computing facilities in Europe (e.g. AI factories)

Q12. The European Commission is supporting the creation of **AI Factories** to accelerate trustworthy AI development. AI Factories are dynamic ecosystems bringing together computing power, data, and talent to create cutting-edge AI models and applications across various sectors (e.g. health, manufacturing, climate etc.).

In your views, how can the AI factories be leveraged to advance biotechnology innovation in Europe?

	Yes	No	Not applicable /I don't know
* Host public-private AI model development for biotech use cases	○	◉	○
* Support validation and certification of AI tools in the biotech field	◉	○	○
* Secure and high-performance processing of health data made available through the EHDS for development of innovative products and tools for the biotech sector	◉	○	○
* Provide access and/or facilitate the use of high-quality datasets through 'data labs'	◉	○	○
* Other	○	○	◉

Q13. To what extent do you agree that the following types of support would help biotech companies, particularly SMEs, **develop and deploy AI solutions more effectively** in the EU?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Dedicated funding instruments for biotech-related AI research and development	○	○	○	◉	○	○
* Access to annotated datasets (e. g. biological, clinical, genomic data)	○	○	○	○	◉	○
* Access to synthetic datasets	○	○	○	◉	○	○
*						

Regulatory sandboxes for testing biotech-related AI models	○	○	◉	○	○	○
* Partnerships with public research institutions or AI hubs /factories	○	○	○	○	◉	○
* Simplified IP and data-sharing frameworks	○	○	○	◉	○	○
* Skills development and AI training for biotech personnel	○	○	○	◉	○	○
* Roadmaps for implementation and scalability of AI tools in the EU ecosystem	○	○	◉	○	○	○
* Other	○	○	○	○	○	◉

Q14. If you would like to substantiate any of your statements with additional evidence on **the ways forward** to **support the deployment and use of data and AI in biotechnology,** you can do so here.

600 character(s) maximum

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Section 8 - Defence and security

Advanced biotechnological possibilities including development of synthetic pathogens, aided by AI-driven software systems, are creating new risks related to future health preparedness and potential of weaponisation by State or non-State actors (Sauli Niinistö report, October 2024).

The following questions seek to collect views on biotechnology for defence and security in the EU.

Q1. To what extent do you agree that application of **biotechnology in defence and security related areas** faces the following **challenges in the EU**?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Threats related to biosecurity and biosafety, including misuse of biotechnology	○	○	○	○	○	◉
* Risks to strategic autonomy in biomanufacturing, and availability of medical and non-medical countermeasures	○	○	○	○	○	◉
* Vulnerabilities in the resilience of biotech supply chains	○	○	○	○	○	◉
* Insufficient civil military cooperation in biotechnology sector	○	○	○	○	○	◉
* Cybersecurity risks to biotech infrastructure and AI tools used in biotechnology	○	○	○	○	○	◉
* Other	○	○	○	○	○	◉

* **Q2.** Please indicate **other challenges** impacting biotechnology for defence and security in the EU.

600 character(s) maximum

-

Q3. To what extent do you agree that **biotechnology for defence and security** is creating the following **opportunities in the EU**?

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree	Not applicable /I don't know
* Facilitate detecting biological and chemical threats, including via availability of biosensors	○	○	○	○	○	◉
* Opportunity to revolutionise defence logistics with biotechnology products (including food) manufacturing close to its point of use	○	○	○	○	○	◉
* Development of new innovative medical countermeasures including vaccines and antidotes	○	○	○	○	○	◉
* Developments of materials with new functions and/or improved characteristic	○	○	○	○	○	◉
* Increased food security	○	○	○	○	○	◉
* Other	○	○	○	○	○	◉

The following questions seek to collect views on possible ways forward to support biotechnology for defence and security in the EU.

* **Q4.** In your view, what **other actions at EU level** are necessary to **enhance the impact of biotechnology for defence and security in the EU**? Please substantiate your statements with views and evidence on the ways forward.

600 character(s) maximum

-

Section 9 - Additional information

Is there anything else you would like to add that has not been covered by this consultation?

To add on actions at EU level that are necessary to improve the regulatory environment for biotechnology and biomanufacturing: The biotech-regulations could merit from an integrated-approach by taking all related legislation into account. Having different legislation and involved bodies at different levels within the EU and between Member States can lead to overlapping or conflicting requirements, which further complicates the permitting process. An example of conflicting rules is the over pressure that must prevail in clean rooms according to Good Manufacturing Practice (GMP), while the GMO regulations require negative pressure. Another example is the Working Conditions Act. We have several attachments: - To support our suggestions at Section 2 Q4 on forward-looking and resilient legislation. COGEM (Dutch Commission on Genetic Modification) research report: “Towards resilient regulations for rapid technological change.”: which can be found on the following website https://cogem.net/app/uploads/2025/02/CGM-2025-1-Grijze-gebieden-in-de-regulering-van-groene-en-rode-biotechnologie.pdf - Dutch government-wide vision on biotechnology: https://www.rijksoverheid.nl/documenten/rapporten/2025/04/11/kabinetsvisie-op-biotechnologie, we also uploaded the english translation in the attachment. - Dutch non-paper in relation to the EU Biotech Act, - Notes to section 8, - Notes to section 6. For additional evidence on the challenges related to access to finance in the EU we kindly refer to: - (Dutch) https://www.rijksoverheid.nl/documenten/rapporten/2024/06/26/kies-voor-baten-ibo-bedrijfsfinanciering - Meta analysis of dutch risk capital policy instruments https://www.rijksoverheid.nl/documenten/rapporten/2024/07/17/eindrapportage-meta-evaluatie-risicokapitaalinstrumentarium - State of European tech https://www.stateofeuropeantech.com/ Section 2 - Q2 additional information: There are multiple examples where biotech innovations have to comply with more than one regulation. For example, if a food additive contains, consists or is produced from GMOs, two regulatory frameworks apply: one for food additives (Regulation 1333/2008) and a second for genetically modified food and feed (Regulation 1829/2003). Each regulation requires a case specific risk assessment, which do not necessarily align. Section 2 - Q3 additional information: EU regulation cannot only be seen as a barrier, but serves a purpose. For example: GMO legislation ensures environmental safety. Another example: novel food regulation ensures food safety. Acquiring approval can take a long time which may cause for promising innovations a struggle to secure the necessary funding for large-scale implementation. The legislation on genetically modified food and feed has a broader scope of products than those commercially intended at the time of writing of the legislation. In the early 2000's GMO plants were the primary focus of this

legislation, though nowadays other type of GMO's are seen as part of the scope of this legislation (e.g. GM micro-organisms - GMMs). This raises questions/differences in interpretations between member states, which makes it difficult for food safety authorities to enforce the legislation and for commercial producers it threatens their current licence to operate. Section 2 – Q4 additional information: Regulatory procedures should be rendered more transparent and predictable. The Commission could provide more guidance to applicants, through a contact point that they can approach for general questions and specific questions about the procedure. For the legislation on genetically modified food and feed in order to solve interpretation issues, it would be beneficial to review the scope of the legislation, specifically on definitions of a GMO and the limitation of use of detection results. Section 6 - Q4 additional information: It remains crucial that training programs meet the needs of the labor market and society. Educational institutions have the authority to further develop and adjust their training programs (where necessary). Labor market relevance and the distribution of training programs are key principles. We continue to offer educational institutions, in collaboration with companies, the opportunity to broaden and renew current training programs where possible to accommodate new technological developments (and consideration for ethical aspects). Where necessary, they can launch new programs. In the context of training for the labor market of the future, we encourage and, where possible, make agreements about training programs focused on societal challenges and strategic shortage sectors such as technology.

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Contact

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Date: 28/11/2025 12:41:10

Public consultation of the review of the Chips Act

Fields marked with * are mandatory.

Introduction

Consolidated public consultation of the review of the Chips Act

This public consultation is part of the evaluation and review of the Chips Act foreseen for September 2026. The overall objective of the public consultation is to firstly identify the adequacy of the current Chips Act and to seek stakeholders' views on potential improvements, shortcomings and new avenues for action. The consultation will aim at collecting the views of industry, SMEs, Research and Technology Organisations (RTOs), academia, Member States, and any other relevant actors. The draft public consultation is structured around four sections.

Section 1: questions concerning the identity of the respondents that will trigger different sets of follow-on questions in Section 4, depending on the type of stakeholder.

Section 2: questions for all respondents that are designed to capture all stakeholders' views on the progress and functioning of the current Chips Act. **Section 3:** questions for all respondents that are designed to capture all stakeholders' views on next steps considering a potential "Chips Act 2.0". **Section 4:** questions very specific to the stakeholder group selected: Research and Technology Organisation, Academia/university, Foundry & Integrated Device Manufacturer (IDMs), Fabless company, Intellectual property & Electronic Design Automation (EDA) vendor, Equipment manufacturer, Material provider, Assembly, Packaging and Test (OSAT), Photonics companies, Quantum companies, and the User industry (Automotive, Defence /aerospace, Health/Medical devices; Telecommunications/digital networks))

Section 5: space for uploading supporting and comprehensive documentation by any participant to the questionnaire.

Other stakeholders such as business associations and user associations are included under the 'Other' category. This layered structure will make it possible to capture the different sets of stakeholders.

Section 1: General information on the organisation

* Language of my contribution

- ○ Bulgarian
- ○ Croatian
- ○ Czech
- ○ Danish

- Dutch
- English
- Estonian
- Finnish
- French
- German
- Greek
- Hungarian
- Irish
- Italian
- Latvian
- Lithuanian
- Maltese
- Polish
- Portuguese
- Romanian
- Slovak
- Slovenian
- Spanish
- Swedish

* Do you represent one or more organisations (e.g. industry organisation or civil society organisation) or are you acting in your own personal capacity (e.g. independent expert)?

- organisation(s)
- personal capacity

* First name

* Surname

* Email (this won't be published)

* Please choose the type of stakeholder you represent

- ○ Research and Technology Organisation
- ○ Education institutions and training providers
- ○ Foundry & Integrated Device Manufacturer (IDMs)
- ○ Fabless company
- ○ Intellectual property & Electronic Design Automation (EDA) vendor
- ○ Equipment manufacturer
- ○ Material provider
- ○ Assembly, Packaging and Test (OSAT)
- ○ Photonics company
- ○ Quantum company
- ○ User industry - automotive
- ○ User industry - defence/aerospace
- ○ User industry - health/Medical devices
- ○ User industry - telecommunications/digital networks
- ○ User industry - energy
- ○ User industry - other
- ◉ Public administration (local, regional and national public administrations as well as EU public bodies involved in semiconductor policy, such as R&D&I and/or industrial policy).
- ○ Financial institution, investor, fund, etc.
- ○ Business association
- ○ Other (e.g. NGOs, customer association, etc.)
- ○ Individual citizen

* Organisation name

255 character(s) maximum

Government of the Netherlands

* Scope

- ○ International
- ○ Local
- ◉ National
- ○ Regional

* Level of governance

- ◉ Parliament
- ○ Authority
- ○ Agency

* Organisation size

- ○ Micro (1 to 9 employees)
- ○ Small (10 to 49 employees)
- ○ Medium (50 to 249 employees)
- ◉ Large (250 or more)

Transparency register number

Check if your organisation is on the transparency register. It's a voluntary database for organisations seeking to influence EU decision-making.

* Is your organisation headquartered in the EU?

- ◉ Yes
- ○ No
- ○ Other

* Is your parent company headquartered in the EU?

- ◉ Yes
- ○ No

* Do you have a research and development department?

- ○ Yes
- ◉ No

* Country of origin

Please add your country of origin, or that of your organisation.

This list does not represent the official position of the European institutions with regard to the legal status or policy of the entities mentioned. It is a harmonisation of often divergent lists and practices.

- Afghanistan
- Åland Islands
- Albania
- Algeria
- American Samoa
- Andorra
- Angola
- Anguilla
- Antarctica
- Antigua and Barbuda
- Argentina
- Armenia
- Aruba
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Eswatini
- Ethiopia
- Falkland Islands
- Faroe Islands
- Fiji
- Finland
- France
- French Guiana
- French Polynesia
- French Southern and Antarctic Lands
- Gabon
- Georgia
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Macau
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Martinique
- Mauritania
- Mauritius
- Mayotte
- Mexico
- Micronesia
- Moldova
- Monaco
- Mongolia
- Saint Martin
- Saint Pierre and Miquelon
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- São Tomé and Príncipe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Sint Maarten
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Georgia and the South Sandwich Islands
- South Korea
- South Sudan

- Belgium
- Belize
- Benin
- Bermuda
- Bhutan
- Bolivia
- Bonaire Saint Eustatius and Saba
- Bosnia and Herzegovina
- Botswana
- Bouvet Island
- Brazil
- British Indian Ocean Territory
- British Virgin Islands
- Brunei
- Bulgaria
- Burkina Faso
- Burundi
- Cambodia
- Cameroon
- Canada
- Cape Verde
- Cayman Islands
- Germany
- Ghana
- Gibraltar
- Greece
- Greenland
- Grenada
- Guadeloupe
- Guam
- Guatemala
- Guernsey
- Guinea
- Guinea-Bissau
- Guyana
- Haiti
- Heard Island and McDonald Islands
- Honduras
- Hong Kong
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Montenegro
- Montserrat
- Morocco
- Mozambique
- Myanmar/Burma
- Namibia
- Nauru
- Nepal
- Netherlands
- New Caledonia
- New Zealand
- Nicaragua
- Niger
- Nigeria
- Niue
- Norfolk Island
- Northern Mariana Islands
- North Korea
- North Macedonia
- Norway
- Oman
- Pakistan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Svalbard and Jan Mayen
- Sweden
- Switzerland
- Syria
- Taiwan
- Tajikistan
- Tanzania
- Thailand
- The Gambia
- Timor-Leste
- Togo
- Tokelau
- Tonga
- Trinidad and Tobago
- Tunisia
- Türkiye
- Turkmenistan
- Turks and Caicos Islands

- Central African Republic
- Chad
- Chile
- China
- Christmas Island
- Clipperton
- Cocos (Keeling) Islands
- Colombia
- Comoros
- Congo
- Cook Islands
- Costa Rica
- Côte d'Ivoire
- Croatia
- Cuba
- Curaçao
- Cyprus
- Czechia
- Democratic Republic of the Congo
- Denmark
- Iraq
- Ireland
- Isle of Man
- Israel
- Italy
- Jamaica
- Japan
- Jersey
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kosovo
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Palau
- Palestine
- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Pitcairn Islands
- Poland
- Portugal
- Puerto Rico
- Qatar
- Réunion
- Romania
- Russia
- Rwanda
- Saint Barthélemy
- Saint Helena Ascension and Tristan da Cunha
- Saint Kitts and Nevis
- Saint Lucia
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States
- United States Minor Outlying Islands
- Uruguay
- US Virgin Islands
- Uzbekistan
- Vanuatu
- Vatican City
- Venezuela
- Vietnam
- Wallis and Futuna
- Western Sahara
- Yemen
- Zambia
- Zimbabwe

* Do you have an office or other kind of representation in the EU?

- (•) Yes (we have a subsidiary, branch office or similar representation in the EU)

- ○ Yes (other)
- ○ No

* We may wish to contact you for clarification or further discussion if your submission prompts additional interest. Do you agree to be contacted by the Commission for clarification or discussion further to your submission?

- ◉ Yes
- ○ No

The Commission will publish all contributions to this public consultation. You can choose whether you would prefer to have your details published or to remain anonymous when your contribution is published. **For the purpose of transparency, the type of respondent (for example, 'business association, 'consumer association', 'EU citizen') country of origin, organisation name and size, and its transparency register number, are always published. Your e-mail address will never be published.** Opt in to select the privacy option that best suits you. Privacy options default based on the type of respondent selected

* Contribution publication privacy settings

The Commission will publish the responses to this public consultation. You can choose whether you would like your details to be made public or to remain anonymous.

- ○ **Anonymous**

  Only organisation details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published as received. Your name will not be published. Please do not include any personal data in the contribution itself if you want to remain anonymous.

- ◉ **Public**

  Organisation details and respondent details are published: The type of respondent that you responded to this consultation as, the name of the organisation on whose behalf you reply as well as its transparency number, its size, its country of origin and your contribution will be published. Your name will also be published.

☑ I agree with the personal data protection provisions

Section 2: Questions on the progress and functioning of the current Chips Act

This consultation will gather insights that will aid evaluating the progress and well-functioning of the current Chips Act.

Section 2.1 Questions on pillar 1 of the Chips Act

To what extent does pillar 1 'Chips for Europe Initiative' of the Chips Act deliver on its objectives?

Note: The general objective of the Chips for Europe Initiative is to achieve large-scale technological capacity building and support related research and innovation activities throughout the Union's semiconductor value chain to enable development and deployment of cutting-edge semiconductor technologies, next-generation semiconductor technologies and cutting-edge quantum technologies and the innovation of established technologies that will reinforce advanced design, systems integration and chip production capabilities in the Union, thereby increasing the competitiveness of the Union. It shall also contribute to the achievement of the green and digital transitions, in particular by reducing the climate impact of electronic systems, improving the sustainability of next-generation chips and strengthening the circular economy processes, contribute to quality jobs within the semiconductor ecosystem and address security-by-design principles, which provide protection against cybersecurity threats.

To achieve large-scale technological capacity building.

- ○ Fully meets the objectives
- ◉ Partially meets the objectives
- ○ Does not meet the objectives
- ○ Don't know / Not involved

Additional comments:

In general, NL has positive experiences with pillar 1 in achieving technological capacity building, with regard to innovation. The terminology 'capacity building' could also refer to production capacity, and that objective has not been met:

- The 20% goal has by far not been reached
- The EU investments are quite moderate in size compared to other blocks in the world.
- Design capabilities for leading edge chips are still lacking in Europe
- In addition, the focus of pillar 1 is not on capacity building, but on novel technology development. The step towards increasing production capacity or towards the maturity of companies is not a part of this.

To support related research and innovation activities throughout the Union's semiconductor value chain.

- ◉ Fully meets the objectives

- ○ Partially meets the objectives
- ○ Does not meet the objectives
- ○ Don’t know / Not involved

Additional comments:

NL acknowledges that pillar 1 has been able to support research and innovation activities throughout the Union’ s semiconductor value chain. The support for R&D projects in the Chip JU and its predecessors has been quite considerable. Precompetitive R&D cooperation is a European strength which is quite well supported .

To enable development and deployment of cutting-edge semiconductor technologies, next-generation semiconductor technologies and cutting-edge quantum technologies and the innovation of established technologies.

- ○ Fully meets the objectives
- ◉ Partially meets the objectives
- ○ Does not meet the objectives
- ○ Don’t know / Not involved

Additional comments:

Pillar 1 manages to fund novel technology development quite well, as long as it fits reasonably well in the technology roadmaps of European companies. However, it does not truly incentivize disruptive innovation that could lead to new positions of global excellence and has not lead to a sustainable position for cutting-edge semiconductors.

To reinforce advanced design, systems integration and chip production capabilities in the Union, thereby increasing the competitiveness of the Union.

- ○ Fully meets the objectives
- ○ Partially meets the objectives
- ◉ Does not meet the objectives
- ○ Don’t know / Not involved

Additional comments:

Activities on design such as the design platform have only just started so can not yet be evaluated, however it has not yet lead to reinforcement of advanced design. Furthermore, for advanced chip production capabilities we are still far behind on other players such as the US.

To contribute to the achievement of the green and digital transitions, in particular by reducing the climate impact of electronic systems, improving the sustainability of next-generation chips and strengthening the circular economy processes.

- ○ Fully meets the objectives
- ◉ Partially meets the objectives
- ○ Does not meet the objectives
- ○ Don’t know / Not involved

To contribute to quality jobs within the semiconductor ecosystem and address security-by-design principles.

- ○ Fully meets the objectives
- ○ Partially meets the objectives
- ◉ Does not meet the objectives
- ○ Don’t know / Not involved

To address security-by-design principles, which provide protection against cybersecurity threats.

- ○ Fully meets the objectives
- ○ Partially meets the objectives
- ◉ Does not meet the objectives
- ○ Don’t know / Not involved

To what extent do the five selected pilot lines support the transition from “Lab to fab”?

Note: ‘Pilot line’ means an experimental project or action addressing higher technology readiness levels from levels 3 to 8 to further develop an enabling infrastructure necessary to test, demonstrate, validate and calibrate a product or system with the model assumptions.

“Lab to fab" means turning scientific discoveries made in research labs into technologies that can be produced at scale in factories. It helps ensure that promising innovations become real products we can use in everyday life.]

- ○ Fully meets the objectives
- ◉

Partially meets the objectives

- ○ Does not meet the objectives
- ○ Don’t know / Not involved

Please provide suggestions on how these pilot lines could be industrialised

NL is generally supportive of the pilot lines and has positive experience in setting these up. We have to ensure that the R&D-investments result into actual production value within Europe. Otherwise we remain the continent of excellent research, but do not decrease our dependence on foreign production capacity. Especially the areas of the pilot lines could become the new areas in which Europe leads globally. Pilot lines could be improved by involving companies and SMEs already at an early stage in the setting up of pilot lines. With regard to public financing, it is important that the State aid frameworks are fit for purpose. The NL therefore welcomes the revision of the General Block Exemption Regulation (GBER). In our view it is important to consider the latest digitalization and technologies developments, and we call on the European Commission to verify, among others, whether the articles on investment aid for research infrastructures and for testing and experimentation infrastructures need to be revised taking into account the specific characteristics of the [Chips sector, including semiconductors]. The NL would, for example, also welcome certain additions to the GBER for innovation projects involving technologies at higher TRL levels. In doing so, it should take into consideration the fact that semiconductor markets are global, and that competition is too. The NL calls on the Commission to organize expert meetings to review these aid categories.

The Chips Fund is a financial instrument supporting the growth of Europe’s semiconductor sector. It aims to make it easier for start-ups, scale-ups, SMEs, and small mid-caps to access debt and equity financing, helping them bring innovations to market and scale up production. The Fund is implemented by the European Innovation Council and InvestEU. Have you applied to be a beneficiary of the Chips Fund?

- ○ Yes, I successfully applied
- ○ Yes, I applied but the application was unsuccessful
- ○ No but will in the future
- ◉ No and I won’t

In your view, how did the Competence Centres help to achieve the Chips Act objectives?

Note: Under the Chips for Europe Initiative, a European Network of Competence Centres is being implemented. This network comprises at least one Competence

Centre per Member State, whose objectives are to provide access to technical expertise in the area of semiconductors, helping companies to improve their semiconductor capabilities and developing skills.

Competence centres are still in the early stages, therefore it is too early to provide a sufficient answer. One note is that the recently launched ChipNL Competence Center has announced that it will offer support in obtaining funding through the EU Chip Fund. It is too early to share their experiences. However, other experience suggests that larger scale projects are too big for the Chips Fund. An expanded budget for the Chips Fund seems in order.

Should the scope of the Competence Centres be extended to cover more activities /areas than currently defined, and if yes, what would you suggest adding under their remit?

The Competence Centres should also be active towards like-minded countries outside of Europe. This helps in connecting other global ecosystems to our European system in a coordinated matter, instead of just bilaterally.

What other capacities could the Initiative focus on in addition to the five components of the Initiative (Design Platform, pilot lines, development of Quantum chips, network of competence centres and the Chips Fund)?

400 character(s) maximum

Please see our replies to questions related to chips act 2.0 under section 3. With regards to the present day Chips Fund: it is mainly aimed at scale ups, start ups and smaller SMEs. Its not very suitable for larger SMEs, given the size of the funding needed for larger SMEs . In future, this should be addressed in order to speed up business growth and industrialization in Europe.

In your view, how effective has the Important Project of Common European Interest (IPCEI) instrument been in addressing strategic EU industrial priorities?

The IPCEI instrument in general is vital, as it currently is the only tool we have for supporting First Industrial Deployment. The political momentum it has created for investments cannot be underestimated. It has proven its value for the European position in the global semiconductors value chain, however, there is room for improvement.
In the first place, the instrument fully relies for funding on national budgets. Even when there is coordination between member states and the Commission on priorities and project selection, there is a risk that the IPCEI instrument leads to sub-optimal outcomes when the delineation values for projects are determined by budget source and geography. A possible avenue to remedy this situation could be to explore European co-funding with a larger emphasis on the strategic value for Europe as a whole.
Another element of improvement is timing. Currently, an element of luck is involved with the conception of projects within the timeframe of IPCEI. To address projects with great urgency that could be addressed by IPCEI's, more flexibility or even the possibility of a permanent or 'rolling IPCEI' for semiconductors could be explored.

In your view, how effective has the Important Project of Common European Interest (IPCEI) State aid instrument been in supporting research, development and innovation in the semiconductor value chain?

> The IPCEI instrument generates a lot of political momentum for investments in this crucial sector. The IPCEI ME /CT and ME are often seen as just generic roadmap support for European semiconductor companies, without too much focus on truly disruptive innovation that leapfrogs the international competition. This is something that the IPCEI AST intends to tackle by a clearer technological focus aimed at those areas where Europe can excel.

Section 2.2 Questions on pillar 2 of the Chips Act

In your view, is the pillar 2 'Security of supply and resilience' of the Chips Act successful in delivering on its objectives?

Note: The objective is to improve the functioning of the internal market by laying down a uniform Union legal framework for increasing the Union's long-term resilience and its ability to innovate and provide security of supply in the field of semiconductor technologies with a view to increasing robustness in order to counter disruptions.

- ○ Fully meets the objectives
- ○ Partially meets the objectives
- ◉ Does not meet the objectives
- ○ Don't know / Not involved

Additional comments:

> Efforts under Pillar II have not yet resulted in meeting the set targets of 20% production capacity in the EU. This target however should not be the main goal, Pillar II should focus on building prosperity, indispensability and resilience in our Semiconductor supply chains. Pillar II is currently insufficiently focused on the type of fabs and chips the EU needs to provide security of supply. To improve resilience, it is key to focus our capacity building on strategic sectors and end-markets crucial for the Union and know where the EU demand is.

To what extent are "integrated production facilities and open EU foundries" contributing to the security of supply of semiconductors and the resilience of the Union's semiconductor ecosystem?

- ○ Fully contribute to the security of supply
- ◉ Partially contribute to the security of supply
- ○ Does not contribute to the security of supply
- ○ Don't know / Not involved

Additional comments:

The IPF's and Open foundries have helped in locating production facilities in the EU, it is however yet unclear how they will contribute in supplying our critical sectors, also in crisis situations. As we have recently seen, we are still highly vulnerable in terms of supply shortages. We should make sure that production in Europe fits our local demand, and aim for a certain degree of flexibility in European fabs.

Has the Chips Act sped up permits for planning, construction and operation of first-of-a-kind facilities, integrated production facilities and open EU foundries?

Unsure whether this process is sped up under the Chips Act. Permit procedures are still notably long in the EU.

To what extent has the European Chips Act pillar 2 ‘Security of supply and resilience’ made the EU a more attractive location for semiconductor manufacturing?

- ○ Fully
- ◉ Partially
- ○ Not at all
- ○ Don’t know

Additional comments:

Chips Act has contributed to Europe's attraction as a location for production, it has been made easier to contribute to a facility by member states. However, we are in a global competition and commercial actors will locate in places where all prerequisites, such as for example energy costs, regulatory processes and talent are in order, the current Chips Act does not sufficiently address these challenges.
In addition, we should work on increasing (desirable) demand for chips within Europe, as this will improve the attractiveness of Europe as a production location. Production facilities to a considerable extent follow the market. The Chips Act 2.0 could therefore focus more on establishing and promoting end markets in Europe, An EU preference principle within public procurement in critical and strategic sectors (such as AI) could also have its effect to more chips being produced in Europe, when sufficiently substantiated and delineated in terms of time, proportionality and suitability. In selected core and critical strategic sectors working towards an EU preference principle should only be done when no less invasive measures are available and when the expected benefits of such a scheme outweigh the associated costs, including the expected increase in price and administrative burden and the trade distorting impact on (likeminded) partners of the EU.

Section 2.3 Questions on pillar 3 “Monitoring and crisis response” of the Chips Act

To what extent does pillar 3 "Monitoring and crisis response" of the Chips Act deliver on its objectives?

Note: Pillar 3 of the European Chips Act establishes a coordination mechanism between the Member States and the Commission to strengthen collaboration on

monitoring and crisis response. The governance mechanism of the European Chips Act is ensured by the European Semiconductor Board (ESB), which includes representatives of the Member States and is chaired by the Commission.

- ○ Fully meets the objectives
- ○ Partially meets the objectives
- ◉ Does not meet the objectives
- ○ Don’t know / Not involved

Additional comments:

> Pillar 3 and also the Risk Assessment are the basis of several different requests to member states and semicon companies to compile data, answer questionnaires and provide detailed information on sometimes sensitive topics. It is not always clear why certain information is being gathered and what is being done with the collected info. This often leads to information that is not very usable, but it is being presented as such. Part of the monitoring is being delegated to a market research company, which can certainly be helpful, whereas the methodology and actual contributions to the monitoring task remain unclear for now. When talking about crisis response, it remains to be seen if the advisory role of the ESB has any meaningful weight in dealing with these situations. Furthermore, the instrument of priority-rated orders still requires an act to be implemented and the procedure to decide on a PRO is extensive and might not be quick enough to react to an urgent situation.

Have you developed or implemented a monitoring system for the semiconductor supply chain in your organization?

- ◉ Yes
- ○ No

How does it work? Does your organisation have a mechanism for reporting or communicating updates and information?

> In general, NL is in constant contact with our sector and regularly proactively inquire about any concerns in this regard through national bodies, like our Semiconductor Board.

Which early warning indicators should the EU monitor to define the onset of a semiconductor crisis in a clear and predictable manner (e.g. percentage increase in lead times, specific price thresholds, unavailability of a non-substitutable component)?

> Monitoring should move beyond generic indicators in the current Chips Act, to monitor deep-level, measurable, and predictable early warning indicators to define the onset of a crisis. The most critical indicators are those related to Geopolitical and structural concentration indicators.
> These are vital for anticipating risks stemming from concentrated dependencies, especially at Tier-2 and Tier-3 of the supply chain. The Commission needs to define clear, aggregated thresholds without demanding confidential corporate data. For example, by linking to current initiatives on the EU Critical Raw Materials Centre or establishing a monitor relating to the percentage of EU's total fabrication capacity that depends on a

single non-EU region for non-substitutable, critical input materials, and quantifying the EU's reliance on external, high-risk production sites for specific strategic chips such as advanced nodes and Chips for AI, as well as chips that are vital for our most important industrial sectors.

Have you ever reported or received alerts about potential semiconductor supply chain disruptions?

- (●) Yes
- ( ) No

How and to whom? Please elaborate

We remain in constant contact with our sector on this matter.

Have you ever received alerts about potential semiconductors supply chain disruptions?

- (●) Yes
- ( ) No

From/to whom? Please elaborate

We remain in constant contact with our sector on this matter.

What are some of the recent threats or obstacles your organisation has faced to secure the supply of chips?

- [ ] Geopolitical risks (e.g., war, conflicts, political instability)
- [x] New trade barriers (e.g., tariffs, export controls from third countries)
- [ ] Natural hazards
- [ ] Logistic bottlenecks
- [x] Other

Please, specify:

Our national sector has mostly been impacted by new trade barriers and relating uncertainty. A new Chips Act should entail a more coordinated European approach to these issues.

In which segments of the semiconductor supply chain have you experienced shortages in the past 12 - 24 months? Please specify the main products and the reason for the shortage.

- [ ]

Raw material (Silicon, gallium, germanium, tungsten, REEs, etc.)

- [ ] Inputs (materials, chemicals, gases)
- [ ] Wafers
- [ ] Equipment
- [ ] Final chips
- [x] Other
- [ ] None

Specify (products and reason):

Risks in various parts of the supply chain can be distinguished. Companies are best placed to reply to this question from their experience.

Section 2.4 Other evaluation and review questions

What resources have been necessary on your organisation's side to contribute to the implementation of the Chips Act?

There has been financial contribution for co-financing projects, mainly focused on Pillar 1. In addition, we have provided personnel resources, with teams involved in coordination of EU projects, ESB participation and risk assessment analysis.

Are the efforts invested at EU level proportionate to the expected or observed impacts, such as the aim to strengthen the EU semiconductor ecosystem?

The EU has established a strong foundation, but realizing a resilient and leading European semiconductor ecosystem requires acceleration and deepening of commitment on both the financial and regulatory fronts. The current investments mobilized, contrast sharply with the massive subsidy packages in the US (CHIPS Act) and Asia. While it is questionable whether we can and should mirror the subsidy levels of other continents, given the extreme capital intensity of the sector, a consistent, scaled-up, and long-term funding framework at the EU level is essential to close the gap. Besides, efforts at EU level to strengthen the EU semiconductor ecosystem should address necessary preconditions in which companies can innovate, grow and excel, such as access to talent, infrastructure and overcoming regulatory obstacles.

How well has the implementation of the Chips Act been communicated within your relevant Member State(s)?

- ( ) Very well
- ( ) Well
- (•) Adequately
- ( ) Poorly

- ○ Very poorly

Please provide specific examples if relevant.

This is up to our sector to evaluate.

Does your organisation have any sustainable practices/policies in place for the semiconductor sector?

- ◉ Yes
- ○ No

Please, specify:

NL has general sustainability policies in place for all companies and industry players. Specifically for the semiconductor industry supports initiatives to make the semiconductor more sustainable, like in the IPCEI ME /CT that contains a sustainability/ energy-efficiency pillar for example.

To what extent has the Chips Act contributed to increase the governance and coordination between different national and regional authorities and agencies?

- ○ Very well
- ○ Well
- ◉ Adequately
- ○ Poorly
- ○ Very poorly

How would you improve it?

See below

How would you judge the coordination of semiconductor policies across EU Member States through the European Semiconductor Board?

The ESB has not reached its full potential in coordinating semiconductor policies across Member States. While the ESB is a valuable institutional platform for formal dialogue and information exchange between the Commission and the 27 Member States, its current impact feels more administrative than strategic. The ESB has produced few publicly visible, concrete results in harmonizing national strategies or correcting market distortions resulting from varying national subsidies. It primarily serves to discuss plans, to communicate about contributions/development in international fora/programs, and to present national semicon strategies, rather than to actively streamline, integrate, or compel a unified European industrial strategy. It often focusses a disproportionate amount of time and effort on pillar 3 related topics (such as Risk Assessment), which is distracting from discussions on how to further propel the European industry in terms of promote. Furthermore, the ESB still struggles to overcome the inherent fragmentation of national interests preventing the translation of

the EU's ambition into sharp, cohesive strategic choices for the entire bloc.
On top of that the ESB currently lacks formal authority, to enhance coordination and strategic resilience, the ESB lacks the independent analytical capacity and enforcement mandate necessary to effectively police critical issues, such as ensuring "First-of-a-Kind" projects meet a collective European need rather than just a local one.

To what extent do you agree with the following statement: "The current framework of the Chips Act, which includes initiatives such as investment in manufacturing facilities, support for research and development, and enhanced international cooperation, provides a sufficiently robust approach to address Europe's supply-side vulnerabilities, such as shortages of semiconductor products and dependence on non-European suppliers"

- ○ Strongly agree
- ○ Agree
- ◉ Neutral
- ○ Disagree
- ○ Strongly disagree

Please explain your answer.

The current chips act lacks a clear strategic focus. For current investments in capacity, it is unclear how it will contribute to supplying our critical sectors and is mostly focused on building new strengths instead of also reinforcing current strong positions.
The R&D component of the Act, the "Chips for Europe Initiative" (Pillar I), is a strong element focusing on advanced pilot lines and the development of a virtual design platform. However, bridging the full lab-to-fab gap remains difficult and needs additional regulatory (and possibly financial) support as already touched upon. This step is crucial for materializing Europe's efforts in this initiative.
Furthermore, the current framework lacks a coordinated international approach to mitigating vulnerabilities and dependencies on non-EU players. The current risk mitigation for critical parts of the supply chain remains too often fragmented and bilateral among Member States. There is a need for a more concerted European approach regarding international trade and export barriers. The EU must act as a unified bloc to pursue a robust diplomatic and economic strategy that ensures supply chain access. This includes jointly negotiating with like-minded partners to guarantee the flow of essential materials and components, and collectively protecting the European industrial base from unilateral trade barriers imposed by third countries.
This fragmented approach is also reflected in the investments made under Pillar II of the Chips Act. There is no clear, collective analysis and strategy for which production facilities are necessary to reduce the most important vulnerabilities of Europe. Instead, Pillar II is used as a 'bottom-up' instrument that individual Member States can use to fund projects they consider desirable, but coordination and collaboration is missing.

Section 3: Questions on new ideas for a future 'Chips Act 2.0'

Europe's competitiveness is tied to semiconductors. The Chips Act aims to contribute to attracting manufacturing investments and initiate efforts to bridge the gap between research and industrial deployment.

However, the EU still faces strong tech dependencies, particularly in advanced manufacturing and design. Furthermore, European companies face unfair market access conditions in third countries with respect to mature-node chips. These countries often have established infrastructures and government support that enable them to dominate the market. This situation poses a risk to the EU's strategic autonomy and to its ambition of becoming a leader in technology innovation. Addressing these dependencies and developing a more competitive and self-sufficient technology ecosystem is crucial for the EU to reduce its reliance on external sources and strengthen its position in the global market.

"The EU's semiconductor manufacturing ecosystem is lagging, notably in cutting-edge semiconductor manufacturing. It is therefore vital that Europe becomes a more attractive destination for foreign and domestic industrial actors to produce the next generation chips in Europe."

Do you agree with the above statement and call for further Union actions?

- ○ Strongly agree
- ◉ Agree
- ○ Neutral
- ○ Disagree
- ○ Strongly disagree

Please clarify your answer:

NL agrees that Europe's current cutting-edge semiconductor manufacturing, ecosystem is not sufficiently developed. However, our manufacturing ecosystem is also lagging in terms of legacy chips as we have seen during the pandemic but also now with current supply chain disruptions, which underscores Europe's overall supply chain vulnerability. This reliance on non-EU sources for both advanced and legacy chips (essential for sectors like automotive and healthcare) poses a significant economic and security risk.
Regarding cutting-edge manufacturing, in our view, Europe does not necessarily have to be the new production hub for cutting-edge chips in large volumes but we do need access to a secure supply chain for our critical sectors. Europe should focus on our strengths for R&D, equipment and low-volume high diversity production. In this area of expertise, Europe can truly excel towards a position of global technological leadership.
Europe has a notably thin ecosystem for cutting-edge chip design and a smaller internal demand from large hyperscale end-markets (like high-end cloud, AI, and premium smartphones) compared to the US and Asia. This creates a risk where new, subsidized European fabs could lack a guaranteed stream of local demand, making the push for massive production inefficient and unsustainable. Union actions should focus on the whole value chain, for example with demand side instruments, and not only on attracting production facilities.

"High barriers" to entry discourage fabless companies and new innovative semiconductor firms to emerge. The Union must therefore lower the barriers for innovative companies to grow."

Do you agree with the above statement and call for further Union actions?

- ○ Strongly agree

- (●) Agree
- ( ) Neutral
- ( ) Disagree
- ( ) Strongly disagree

Please clarify your answer:

The European Union must address the significant entry barriers that currently stifle the growth of innovative semiconductor companies within Europe. The most pressing obstacles are the capital intensity, the acute challenge of talent acquisition, permitting and infrastructural issues. Any new, innovative chip firm faces high costs for Electronic Design Automation (EDA) tools and securing IP licenses, which can also lead to incredibly long waiting times and high upfront fees. Furthermore, the search for a highly specialized workforce is complicated by a global industry-wide talent scarcity. Finally, the process of establishing new facilities is hampered by the need to streamline long permitting processes and bureaucratic procedures, alongside local infrastructural issues like grid congestion.

“The European semiconductor industry faces serious talent shortages, posing a major bottleneck for growth and innovation. This requires investment in attraction, skilling, reskilling, and training policies.”

Do you agree with the above statement?

- ( ) Strongly agree
- (●) Agree
- ( ) Neutral
- ( ) Disagree
- ( ) Strongly disagree

Please clarify your answer:

The semiconductor industry is facing a global talent shortage because demand for skilled workers is increasing, while the pipeline of qualified graduates is shrinking, and the existing workforce is aging and retiring. Solutions can be found in partnerships between educational institutions and companies (such as bringing industry into the classroom or the classroom to company facilities), recruiting from adjacent industries with transferable skills, recruiting students from other countries, and implementing training and upskilling programs for current employees.

“Dispersed national strategies require EU-level coordination strategies to ensure that Member States contribute efficiently to the strengthening of the EU’s semiconductor value chain in a coherent and complementary fashion.”

Do you agree with the above statement and call for further Union actions?

- ( )

Strongly agree

- Agree
- Neutral
- Disagree
- Strongly disagree

Please clarify your answer:

EU-level coordination could be valuable to prevent duplication of efforts across Member States. However, such coordination should not lead to over-centralisation or undermine existing national strengths. Rather, it should recognise and build on the strengths of each member state, ensuring that coordination leads to complementary value chains. More than currently is the case, member states should closely align their strategies to increase their collective impact. The ESB could be a suitable format for this, with the Commission taking up a coordinating role rather than a decision making role.

Section 3.1 Questions on new ideas for pillar 1 of the Chips Act

What gaps in capacities and infrastructures remain unaddressed by the Chips Act, and which would require additional support?

The present day Chips Fund is mainly aimed at scale ups, start ups and smaller SMEs. It is not very suitable for larger SMEs, given the size of the funding needed for their projects. Besides we observe a gap in the access for companies and SMEs in the setting up of pilot lines (see question below). We support establishing new pilot lines in the future for new emerging technologies, to maintain the pipeline of innovation and creating the strengths of tomorrow. Also, the definition of an undertaking in difficulty is hampering investment and involvement of key companies as Semiconductor companies are faced with high start-up costs and often fall under this definition. This point is further addressed elsewhere in the consultation.

To address the gaps in the landscape of and access to pilot lines and testing facilities the Netherlands support the actions as presented in the recent EU Strategy on Research and Technology Infrastructures and ERA Action 16 (Developing a European Approach to Technology Infrastructures). For impact and success, a link should be made in the Chips Act to foster these important new actions. Aspects that should be taken into account are integrating the digital infrastructure of the design platforms and competence centers, possibly nurturing technological cross-overs.
Another important point is to ensure a more sustainable and structural framework, including finance for investments in new or scaling facilities to ensure pilotline capabilities can be scaled and industrialized.

How could pilot lines under the Chips for Europe Initiative ensure a timely technology transfer to industry and deliver on the 'lab-to-fab' approach?

Pilot lines could be improved by involving companies and SMEs already at an early stage in the setting up of pilot lines. Securing industry involvement and buy-in from the initiation phase of pilot lines should be envisaged in order to establish a close collaboration with the research institutes. Do not envisage a pilot line as a research infrastructure, but design it with full commercial operation from the onset. Allow industry players to do full commercial wafer runs during the development phase of the line, In this context, we also call on the European

Commission to verify whether the current State aid frameworks are fit for purpose to facilitate commercialization. Furthermore, encourage (parts of) pilot lines to be spun out to industrial players after the pilot phase is completed and adapt the rules accordingly.

Which broader technological trends or gaps should be prioritized in the review of the Chips Act?

Semiconductor technology continues to evolve at a highly rapid pace. The industry is gradually moving from 2D to 3D solutions, meaning that new technologies in heterogeneous integration and in chip architectures, but also in metrology will increase in importance. We need to anticipate these trends and focus on building upon existing strengths, for instance in equipment manufacturing or systems engineering, to establish new strongholds in these novel fields.

In particular, the AI revolution will be key for our technological sovereignty. It will provide the key (high)-endmarkets for the semiconductor industry. The deployment of advanced semiconductor technologies could be a key enabler of smarter, more automated and energy-efficient industrial processes. Bridging the gap between chip development and industrial adoption will therefore be important. Therefore, the Chips Act should also be linked to other European initiatives such as the Cloud and AI Development Act, the CRMA and the Quantum act and the proposals for a new governance for Technology Infrastructures which include a prioritization of new and important technologies.

Additionally, the relatively small end market for (certain types of) semiconductors also decreases the attractiveness of Europe as a place for investments. The revision should explore ways to stimulate the creation of stronger European end markets and in this way focus more on demand driven support than production driven support also taking into account our demand for legacy Chips andnot merely focussing on cutting edge production.

Next to or building upon the Design Platform set up through the Chips Act, what additional measures or actions could strengthen the semiconductor design ecosystem in the EU?

Note: The design platform proposed in the Chips Act is a cloud-based virtual environment to be made available across the Union, integrating a wide range of design facilities, from IP libraries to Electronic Design Automation (EDA) tools, as well as support services.

The design platform took a long time to launch, given the fact that also (as layer 2) commercial design software should be made available, which complicated procedures. It is too early to comment on the design platform and its possible additions. As mentioned earlier, a link could be made to the European Strategy Forum on Research Infrastructures (ESFRI).
Additionally, it is crucial that chip designers retain access to low-volume manufacturing processes within Europe. Proximity to production facilities can contribute to faster learning cycles. Furthermore, especially for start- and scale-ups, new chip designs are usually only produced in relatively small batches. It is not economically attractive for large fabs to produce these chips, which hampers the learning and innovation processes of these smaller chip designers.

What next steps should be taken to ensure effective collaboration and knowledge exchange across the European network of Chips Competence Centres?

This is the main responsibility of the dedicated CSA for the Chips Competence Centres. It is essential that this becomes a truly European network and the CSA acts as a central access point, also addressing matchmaking and cross border use of competence center expertise throughout Europe.
Besides, the competence centers could be extended to relevant countries outside the EU.

How can the Chips Competence Centres best support SMEs and start-ups in the future?

It is essential that the Chips Competence Centres provide to SME's and start ups an easy access to the Centres' areas of expertise either for free or at affordable rates while keeping the administrative burden at a minimal level. For example, through voucher systems for access to its services.

The Chips Act is setting up 6 pilots in quantum chip technologies. What next steps should be taken with respect to these pilots?

Secure funding for the next scale-up phase and ensure close industry involvement in adopting the pilot lines, and even a full take over in order to embark on full commercial operation. Furthermore, encourage cooperation between pilot lines.
Additionally, to maintain the pipeline of innovation and creating the strengths of tommorow, pilot lines should in the future also be established for new emerging technologies.

Section 3.2 Questions on new ideas for pillar 2 of the Chips Act

What are, within 5 to 10 years, the most important barriers to the development of an AI chip value chain in the EU?

- [x] Lack of manufacturing capability for AI chips
- [x] Lack of design capability
- [x] Lack of skilled workforce
- [x] Low demand from domestic hyperscale's or AI companies in the EU
- [x] Lack of public/private investment instruments

Other (please specify):

The vulnerability across the full value chain is best defined by the synergistic impact of three key barriers: Low Domestic Demand, Lack of Specialized Design Capability, and the Skilled Workforce shortage. Low Demand from Domestic Hyperscalers or AI Companies in the EU (The Demand Pull Barrier) is arguably the single most constraining factor. The AI chip ecosystems in the US and Asia are fundamentally driven by massive "anchor demand" from local tech giants (Google, Meta, Amazon, Tencent). These companies co-design chips with fabricators, guaranteeing the necessary volume and providing the immediate feedback loop required for rapid innovation. Regarding Design capabilities, Europe has strong research in next-generation AI architectures

(neuromorphic, in-memory computing), the pipeline for commercializing this into effective silicon products is weak and we completely lack GPU capabilities. The talent shortage acts as a ceiling on the growth of the entire value chain, hindering both design and manufacturing ambitions simultaneously. The lack of manufacturing capability for AI Chips is a significant barrier, especially for leading-edge mass-volume chips (sub-3nm), the gap is enormous. However, for more specialized areas (e.g., chips leveraging European strengths like photonics, Quantum, inference and edge, AI , and specialized packaging), the manufacturing challenge is less about having the technology and more about making it easily accessible and scalable for new AI startups.

In which segments of the value chain do you think the EU has the potential to gain or to further reinforce its leadership in the coming years?

- [ ] Software for chip design
- [x] Basic IP Inputs (materials, chemicals, gases)
- [x] Semiconductor manufacturing equipment
- [ ] Manufacturing of Mainstream chips (> 28 nanometres)
- [x] Packaging, testing and Assembly of chips
- [ ] Manufacturing of Advanced chips (<10 nanometres)

How can the EU establish an effective framework to stimulate greater demand for advanced semiconductors? (<10 nanometres)

EU should actively stimulate demand for advanced semiconductors. Governments can make use of smart public procurement policies. An EU preference in procurement could stimulate the use of EU-designed of EU-manufactured chips in strategic applications when they are essential for our European resilience and other less intrusive policies are insufficient to stimulate European demand..
Also Europe should leverage our current strengths and stimulate downstream industries, for example by supporting the transition to autonomous driving and Industrial Internet of Things (IIoT) / Industry 4.0, which rely heavily on Edge AI and high-performance, energy-efficient chips, the EU creates organic demand for advanced nodes. Furthermore, integrating advanced semiconductor requirements into EU regulatory frameworks (cybersecurity, energy efficiency) can accelerate industrial uptake by making high performance chips the default option.

In which segments of the value chain do you think the EU has the potential to gain or to further reinforce its leadership in the coming years?

- [ ] Software for chip design
- [x] Basic IP Inputs (materials, chemicals, gases)
- [x] Semiconductor manufacturing equipment
- [ ] Manufacturing of Advanced chips (<10 nanometres)
- [ ] Manufacturing of Mainstream chips (> 28 nanometres)
- [x]

Packaging, testing and Assembly of chips

Should the status of Integrated Production Facility and/or OpenEU foundry be modified to better meet the production needs of the market?

The status of IPF's and Open EU foundries should be fit for purpose to ensure production capacity building within the EU to ensure our resilience for critical sectors and end-markets. So far, also in light of the current crisis this goal has not been reached. To do so we need:

- Stronger alignment with industrial demand and offtake commitment could help end-market creation. For example by requiring or encouraging binding offtake or purchase commitments from downstream users (e.g. chip designers, OEMs) to ensure that capacity will be used, reducing risk of overcapacity or stranded assets.
- Use demand-side signals (e.g. public procurement, defense, critical infrastructure) to guide which facilities get priority.
- Investigate whether relaxing the “first-of-a-kind” constraint will allow incremental expansions under strict conditions, while introducing limits to prevent over production and ensure necessity and proportionality of potential state support in light of the objective of strategic autonomy and resilience.
- enable established fabs and for example pilot lines, to upgrade or expand and still reap the benefits of the IPF/Open EU status (when justified by supply-demand tightness or strategic importance.) for example by Introducing a “next-of-a-kind” or “scale-up” status,

What are your expectations from the future European Competitiveness Fund to support semi-conductors?

The objective of the ECF should be to strengthen the Union’s competitiveness. The Netherlands pleads for a stronger focus in the ECF on the most strategic technologies and sectors. This includes the whole semiconductor valuechain, in particular under its Digital Leadership window.

Should certain projects receive the status of ‘strategic project’ in the sense of the draft European Competitiveness Fund and receive a Competitiveness Seal?

Note: See draft regulation for a European Competitiveness Fund, article 8: a Competitiveness Seal may be awarded to high-quality actions which shall comply at least with the following conditions: (a) they have been assessed in an award procedure under the ECF; (b) they comply with the minimum quality requirements of that award procedure. Strategic projects identified in Union legislation that fulfil these conditions will be directly granted the Competitiveness Seal.

Granting certain projects a strategic project status or a Competitiveness Seal could be useful, if the awarding of a Seal is selective enough. This means that clear and well-defined criteria should be established to determine whether a project is truly strategic. It could potentially provide an important signal to the market on the quality of a project. However, a Seal on its own has limited value if it does not lead to prioritized approvals or fast-track financing, without prejudice to the applicable State aid rules and selection of the best project under open and

competitive procedures as much as possible. The EU should therefore ensure that the designation is not merely symbolic but tied to tangible benefits and clarity on selection process. For each such strategic project, a broader approach on how to strengthen the business climate is needed, considering not only subsidies but also for example access to talent, (energy) infrastructure and grid capacity.

Should the EU support certain projects for production capacity and in which sectors?

The Netherlands recognizes that the EU is facing competitive challenges. It is clear the Europe needs production capacity in the semiconductor value chain in Europe in the light of open strategic autonomy. This is mainly driven by intense global competition. Major economies, notably the United States and China, are aggressively deploying massive subsidy programs to secure their own supply chains and technological leadership. If the EU fails to act decisively, its industrial base will continue to rely heavily on external suppliers, risking future economic disruption and the loss of its technological sovereignty. To safeguard its economy and deliver on the green and digital transitions, the EU must regain a significant, resilient share of high-tech production for which there is sufficient demand. In response to these competitive challenges, the EU should focus on strategic sectors and technologies.

We need to create the right policy mix to ensure a resilient and competitive Union. With regard to financing projects for production capacity, it is crucial to encourage private investment. With regard to public support, The NL is reluctant in allowing for EU or national subsidies for building production capacity, since this support can be highly distortive.

For public support for projects for production capacity, It is important to set clear conditions to ensure that public support is necessary in the context of open strategic autonomy and no-less distortive instruments are available. Positive effects of the aid should outweigh the negative effects on trade and competition, based on market analysis and competition assessments. Should new possibilities for public support be introduced, projects must operate under a principle of broad-based European benefit, and clear spillovers. Funding decisions should not only consider the economic viability of the project but also its significant contribution to the entire European ecosystem and its strategic autonomy, for instance, by ensuring that new production facilities grant fair access to companies and researchers from all Member States.

It is crucial that potential centralized EU programs must provide support for the most promising projects, based on a selection of excellence and impact. Caution is needed with regard to State aid. We need an evidence-based approach and a long-term EU strategy for strategic sectors. As part of the policy mix, the State aid rules should be targeted and proportionate in order to strike the right balance between allowing necessary State aid and preserving a level playing field in the EU. The State aid rules should be fit for purpose. In that context we welcome the revision of the General Block Exemption Regulation, to take into account the latest technological developments, and the revision of the Rescue and Restructuring Guidelines with its definition of Undertaking in Difficulty. We urge the Commission to speed up the revision of this definition. Please also refer to our comments on the IPCEI framework.

Should the selection and set-up of such strategic projects be coordinated at EU level?

- ○ Yes
- ○ No
- ◉ Don't know

How should such projects be financed?

- [ ] From EU funds
- [ ] From national funds
- [ ] From private funds
- [x] A combination of funds

Please clarify your response.

For strategic projects in the semicon sector, a unified, combination-of-funds approach is most suitable. Strategic projects should still entail a viable businesscase also taking into account geopolitical tensions, public funding should be used to close the gaps o and clear market failure.

- Private Funds: Incentives should be designed to reduce risk for investors in "first-of-a-kind" facilities, ensuring that public resources leverage the maximum possible industrial commitment.
- EU Funds: Centralized EU programs must provide support for the most promising projects, based on a selection of excellence and impact. This ensures that projects of highest European importance are prioritized and guarantees a basic level of support regardless of the host country's fiscal capacity. After all, if Europe truly wants to compete at the global stage, it should make sure that the developments that are most promising from a technological and market perspective can be adequately supported.
- Member State Funds: National support (including from the NRPPs) should be permitted and encouraged, within a clearly defined fit-for purpose State aid framework, as also discussed above.
- Additionally, Europe could seek to encourage customers of chips to invest in European production capacity as a means of supply chain resilience, as we can for instance see happening in Japan with the Rapidus initiative.

Regarding coordination; EU level coordination can offer added value if it ensures better alignment between industrial, research, and innovation policy approaches and contributes to strengthening European strategic ecosystems and a level playing field in the European market. The coordination should align national and EU policy priorities and serve as a facilitator rather than an additional administrative burden. Overlaps with existing bodies (JEF-IPCEI) and instruments should be avoided. The set-up of such coordination should be in close cooperation between the Commission and Member States.

Which obligations related to obtaining the status of integrated production facility and /or Open EU foundry would you add or remove?

See earlier questions. While the benefits (State aid, fast permits) are powerful incentives, they are still bleak compared to other regions. Additionally, the obligation to accept "priority-rated orders" is widely viewed as a commercial risk and a potential hindrance because of it. These obligations should be revised for example by adding cost compensations, capping production volumes for priority rated orders and pre-negotiate framework contracts for crisis obligations to provide companies with more predictability, rather than starting complex negotiations during crisis.

Section 3.3 Questions on new ideas for pillar 3 of the Chips Act

Do you anticipate any disruptions in the semiconductor supply chain over the next 2 or 3 years?

- (●) Yes
- ( ) No

If yes, please specify the types of disruptions you anticipate:

> It is clear that in the current geopolitical context further disruptions of any kind in the semiconductor supply chain cannot be ruled out and should be anticipated.

Which risk mitigation measures should be considered to prevent product shortages?

- [x] Increase stocks and inventories
- [x] Diversify trade partners
- [x] Investing in innovation for recycling, advanced materials, or substitutes
- [ ] Reporting to national authorities on potential shortages
- [ ] Reporting to national authorities on ongoing shortages
- [ ] Reporting to EU authorities on potential shortages
- [ ] Reporting to EU authorities on ongoing shortages
- [ ] Other:

Specify:

> Diversifying trade partners is paramount because it insulates supply chains from geopolitical friction and single-source failure, a resilience that is institutionalized through effective trade agreements. Additionally, the short-term measures of increasing safety stock and managing inventories is in the first place the responsibility of commercial actors in the market, while the long-term goal must be to also boost innovation for recycling and advanced material substitutes

Given the high differentiation of semiconductors, for which specific product categories (e.g., memory, power semiconductors) could a joint purchasing mechanism be useful?

> A joint purchasing mechanism could be most useful when it is used as a demand pull for EU manufacturing capacity rather than from a supply perspective. A Joint Purchasing Agreement, executed by the EU and its Member States, offers a guaranteed demand floor. If a consortium of EU public buyers (governments, defense, healthcare, public institutions) commits to purchasing a significant percentage of a new European fab's output for, say, five years, that guaranteed volume drastically reduces the financial uncertainty for the private company.

In the event of a semiconductor crisis and in case of a market situation which corresponds to a significant shortage of an essential product pursuant to Regulation

(EU) 2015/479, would you consider it useful to impose protective measures on the Union’s semiconductor sector?

- ○ Yes
- ◉ No

Please specify:

This is very dependant on the crisis and what kind of protective measures, in case of shortage more promotional measures should be taken.Furthermore these measures might need to be taken before a crisis instead of during.

To prevent future disruptions (e.g. shortages) in the supply chain, should the European Commission/National Competent Authorities be given the mandate to request information from undertakings along the semiconductor supply chain?

- ○ Yes, for information from all companies along the semiconductor supply chain
- ○ Yes, for information from semiconductor producing companies only
- ○ Yes, for information from end user industry companies only
- ◉ No
- ○ Don’t know

If not, please specify what other measures should be put in place to identify potential upcoming disruptions?

Authorities should be able to request this information, however this should remain on a voluntary basis and with respect to confidentiality/company secrecy. Imposing mandatory obligations should remain linked to the crisis stage, expanding these to non-crisis scenario's is inappropriate because of the sensitivity of business information and could have negative effects on private investments in EU manufacturing capacity.

To prevent future supply chain vulnerabilities (e.g. overcapacities, dependencies on other parts of the world), should the European Commission/ National Competent Authorities be given the mandate to request information from undertakings along the semiconductor supply chain?

- ○ Yes, for information from all companies along the semiconductor supply chain
- ○ Yes, for information from semiconductor producing companies only
- ○ Yes, for information from end user industry companies only
- ◉ No
- ○ Don’t know

If not, please specify what other measures should be put in place to identify potential supply chain vulnerabilities?

Authorities should be able to request this information, however this should remain on a voluntary basis and with respect to confidentiality/company secrecy. Imposing mandatory obligations should remain linked to the crisis stage, expanding these to non-crisis scenario's is inappropriate because of the sensitivity of business information and could have negative effects on private investments in EU manufacturing capacity.

Do you have any suggestions for additions or changes to the pillar 3?

Pillar 3 needs to evolve from being just a shortage management tool and focus more on geopolitical disruptions such as trade barriers and export controls.
Pillar 3 currently focuses on supply shortage indicators. It must expand its monitoring to formally track foreign subsidies, export controls, and non-market-based trade barriers imposed by third countries. Additionally, and perhaps most importantly, it should investigate overdependencies on single-source suppliers. This early intelligence is necessary to anticipate economic coercion, rather than just reacting to shortages.

When it comes to addressing shortages/disruptions, the crisis mechanism as a tool is likely not efficient enough to make a timely difference. Without sacrificing current safeguards and lessening the focus on proportionality, the governance structure of this mechanism should be simplified and a direct role for the industry could be considered to better align any measures with actual needs within the affected sectors.
The intelligence gathered by the European Semiconductor Board (ESB) should mandate a timely, unified EU diplomatic response to external trade threats. This ensures that the Commission and Member States push back against foreign coercion with a single, coordinated, and consistent voice, maximizing the EU's leverage in global trade disputes.

Section 3.4 Other questions on new ideas for a future Chips Act '2.0'

To what extent would you put emphasis in the Chips Act on demand considerations from the following semiconductor end-user industries?

	1 (not very important)	2	3	4	5 (very important)
Automotive	○	○	◉	○	○
Defence/aerospace	○	○	○	○	◉
Health/Medical devices	○	○	○	○	○
Telecommunications	○	○	○	◉	○
Industrial automation	○	○	◉	○	○
Data centre infrastructure	○	○	○	◉	○
Energy	○	○	○	○	◉
Others	○	○	○	○	○

Please explain your answer:

Demand focus is essential in the new Chips Act. recognizing that different end-user sectors fulfill distinct strategic goals for the EU. The overall emphasis should be strong and coordinated across all seven sectors, but the type of support should be differentiated:

National Security and Resilience: A foundational emphasis is required on sectors vital for state function and public safety: Defence/Aerospace, Health/Medical devices, and Energy. These are critical sectors where supply security is non-negotiable, justifying measures like the Act's provisions for priority-rated orders during a supply crisis (Pillar 3).

Innovation Drivers (Highest Requirements): High emphasis must be placed on Data Centre Infrastructure and advanced Telecommunications. These sectors drive demand for the most cutting-edge chips. Supporting their requirements directly fuels R&D and ensures Europe remains technologically competitive, meeting the goal of boosting innovation (Pillar 1).

European Industrial Capacity: In the context of the digitalisation transition, significant emphasis should be placed on Automotive and Industrial Automation. These sectors are where Europe holds global manufacturing leadership. Focusing on their chip supply, particularly for mature and specialty nodes, secures large existing industrial value chains, anchors manufacturing capacity in Europe, supports local job growth, boost productivity and provides a solid foundation for digital transformation.

Through international cooperation, what types of actions could be taken to strengthen the EU’s ecosystem, and in which specific areas?

- [x] Collaborative R&D and innovation
- [x] Cooperation on supply chain diversification and security of supply
- [x] Workforce development and talent exchange
- [x] Cooperation on standardisation
- [ ] Cooperation on energy-efficient manufacturing techniques and recycling programs for semiconductor materials.
- [x] Other actions

How could the overall governance between different organisations be strengthened to ensure better alignment and cohesion among Commission, Member States (national, regional, local authorities) and industry representatives?

The governance must be strengthened by establishing formal, permanent mechanisms for industry input directly within the European Semiconductor Board (ESB). Industry representatives (across the entire value chain, including end-users like automotive and data centers) must be mandated to co-develop strategies and technical standards. This structural, continuous involvement ensures that policies and public investments remain market-relevant, aligning the Commission and Member States toward commercially viable, industrial goals.

What policy approaches could drive sustainability in chip design, fabrication, materials, equipment, and packaging? What steps could policymakers take to promote sustainability throughout the semiconductor industry?

Europe should support the development of semiconductors and electronic components and systems that contribute to the green transition, including energy-efficient chips, chips designed for green energy applications and circularity, integrated photonics, heterogeneous integration, and the use of advanced sustainable materials. Promote cleaner semiconductor manufacturing by encouraging the substitution of hazardous substances, the use of renewable energy, improved water efficiency, and the circular use of residual materials in production processes and throughout the whole value chain.

Section 4: Questions only for specific stakeholder groups

Please specify

Section 4.12 Public administration (local, regional, and national public administrations as well as EU public bodies involved in semiconductor policy, such as R&D&I and/or industrial policy)

Does your authority provide specific incentives to the semiconductor value chain, such as dedicated aid schemes, tax incentives, regulatory facilitations, or other support measures?

- [x] Yes
- [ ] No

If yes, please describe the instruments used and (briefly) the conditions under which they are granted. (Open-ended)

The Netherlands has specific policies for the semiconductor industry as described in our letter to parliament of May this year and is currently developping a new sectoragenda together with its industry presenting an analysis and outlook towards 2035.

From your perspective, what are the key challenges to attracting large-scale semiconductor production projects to your region/country?

- [x] Site availability and permitting
- [x] Skilled labour availability
- [x] Infrastructure (Energy, Water, Connectivity, Other)
- [x] Access to financing or aid
- [x]

Other

Please specify which ones

Investment decisions in the semiconductor industry are not solely determined by technological or market-related factors, but are strongly influenced by the overall climate in which companies operate. This includes fiscal regulations, energy costs, rapid access to necessary infrastructure, and a predictable and stable policy framework. Given the enormous capital investments, long payback periods, and the unequal global playing field, creating optimal preconditions for Europe is not a luxury, but a strategic necessity. The sector is currently hampered by multiple, long-term resource scarcities, including labor shortages, limited electricity grid capacity, restrictions on nitrogen/environmental space, housing shortages, and strained infrastructure. These bottlenecks severely delay or outright prevent the realization of corporate investments.

Has your authority supported or been involved in the identification, attraction, facilitation, or authorisation of first-of-a-kind facility investments?

- [ ] Yes
- [x] No

Has your authority been involved in a state aid notification process relating to semiconductor manufacturing investments (under Pillar II of the Chips Act)?

- ( ) Yes
- (•) No

If no, please specify areas of improvement:

See below

What other suggestions would you have for future semiconductor-related State aid procedures?

In our view, caution is needed with regard to the State aid instrument due to the level playing field on the EU internal market. At the same time, however, the NL recognizes the importance of revising the State aid rules to support the digital and green transitions, among other things. In this regard the NL welcomes the revision of the GBER to take account of the latest developments of digitalization and new technologies. In our view it is important to verify whether the section on aid to support research, development and innovation activities is fit for purpose. The NL would, for example, welcome certain additions in the GBER for innovation projects of technologies in higher TRL levels. A fit for- purpose GBER would consider the specific characteristics of these sectors, including semiconductors.

Furthermore, the Netherlands is particularly concerned about the definition of UiD as it does not adequately consider the business model of startups and scale-ups, especially those operating in strategic (deep) technologies. Technological startups may require many years of investment in advanced innovations and may therefore be loss-making for a considerable period of time, until a commercial product is developed. However, this does not mean that these companies are not economically viable. In fact, they have disproportionately high

potential, which is why professional investors fund the R&D losses. The NL, therefore, welcomes the public consultation for the revision of the R&R Guidelines with its definition of UiD and calls on the Commission . The NL calls on the Commission to address this issue as a matter of priority, working together with the Member States and financial experts to redefine the UiD definition.

Has your authority developed a national, regional or local semiconductor strategy?

- [x] Yes, my own authority has developed a semiconductor strategy
- [ ] No, but another national, regional and/or local authority/authorities in my Member State has or have developed a semiconductor strategy
- [ ] No, to my knowledge there is no semiconductor strategy developed in my Member State

Is your authority interested in supporting strategic projects in the area of semiconductors in the sense of the Commission proposal for a European Competitiveness Fund?

- (•) Yes
- ( ) No

If yes, please specify what should be the criteria for such projects and how they should be financed and coordinated at EU level

The Netherlands pleads for a stronger focus in the ECF on the most strategic technologies and sectors. This includes the semiconductor sector, in particular under its Digital Leadership window. We welcome the strategic projects in the area of semiconductors but much remains unclear how strategic projects will be defined and what benefits it will entail to be a strategic project.
Disclaimer as this question implies additional national support for strategic projects, the Netherlands cannot anticipate any future funding decisions at this moment.

Has your authority implemented measures that fall outside of the Chips Act semiconductor crisis response framework?

- [x] Yes
- [ ] No

If yes, please specify which measures your authority has implemented.

Yes, in recent events the Netherlands has taken measures outside of the Chips Act, this has further been discussed within the ESB

Does your authority engage in bilateral or multilateral cooperation with third countries in the field of semiconductors (e.g. in R&D&I, industrial development, or investment)?

- [x] Yes
- [ ] No

If yes, please indicate the countries and provide a brief description of the nature and objectives of the cooperation.

The Netherlands has extensive multi and bilateral collaboration with third countries such as R&D collaborations, talent exchange and strategic dialogues. As mentioned before, the semicondsctor supply chains are inherently global. International partnerships with like-minded countries are crucial to ensure an open, connected and secure semiconductor supply chain and strengthening the innovation ecosystem.
Europe could take a role in these collaborations. Europe should: 1) Foster global collaboration with like-minded international partners (from governments to industry) to create mutually beneficial dependencies, thereby building a resilient global supply chain. 2) Enable companies from like-minded partners from outside the EU to form joint ventures with EU firms and access EU-funded R&D infrastructures in line with open strategic autonomy. 3) Attract strategic capabilities from outside the EU to complement and reinforce the European ecosystem.

What role do you see for your national competence centre(s) in enabling participation in an expanded European design ecosystem? Please specify.

The Competence Centres' mission includes facilitating access to the EU Design platform acting as a bridge between entrepreneurs and the EDP; they play a vital role in this process.

Through which mechanism(s) could first-of-a-kind investments be coordinated among Member States?

The ESB should be the main platform under which more directed projects can be coordinated by the Member States. With increased coordination a subsidy race between Member States should be prevented. Most importantly projects and investments should be coordinated based on European local demand to ensure secure supply chains for our most critical sectors.

Through which mechanism(s) could strategic projects investments be coordinated among Member States?

The ESB should be the main platform under which more directed projects can be coordinated by the Member States. With increased coordination a subsidy race between Member States should be prevented. Most importantly projects and investments should be coordinated based on European local demand to ensure secure supply chains for our most critical sectors.

What specific policies by public authorities on regional, national and/or EU level could promote the uptake of European semiconductor products?

Governments can make use of smart public procurement policies and act as launching customers. , An EU preference principle within public procurement in critical and strategic sectors (such as AI) could also have its effect to more chips being produced in Europe, when sufficiently substantiated and delineated in terms of time, proportionality and suitability. In selected core and critical strategic sectors working towards an EU preference principle should only be done when no less invasive measures are available and when the expected benefits of such a scheme outweigh the associated costs, including the expected increase in price and administrative burden and the trade distorting impact on (likeminded) partners of the EU.

In your view, which targets, or Key Performance Indicators (KPIs) should be established to effectively monitor and evaluate the progress and resilience of the European semiconductor ecosystem?

The primary KPIs for the EU semiconductor strategy should focus on the Semicon Coalition's three core goals:

Prosperity: Measuring economic growth and value creation within the European ecosystem (e.g., increase in market share and R&D investment).

Indispensability: Measuring technological leadership and strategic autonomy in critical value chain control points (e.g., market share in essential production equipment or advanced design).

Resilience: Measuring supply security and the ability to absorb disruptions in critical sectors (e.g., increase in local production capacity and supply chain diversification).

What mechanisms and/or platforms can be considered to integrate regional semiconductor clusters and ecosystems more systematically into implementation of EU semiconductor policy?

Regional semiconductor clusters and ecosystems are a prime driver of the European semiconductor ecosystem development in general. There is already a structural discussion platform between the European semiconductor regions. It would be good to stay in close contact with regards to implementation and execution of EU semiconductor policies.

How should the measures on priority rated orders be adjusted in order to increase their effectiveness?

Priority rated orders are now seen as a barrier for commercial actors. These obligations should be revised for example by adding cost compensations, capping production volumes for priority rated orders and pre-negotiate framework contracts for crisis obligations to provide companies with more predictability, rather than starting complex negotiations during crisis.

Please add any additional information

This consultation shows a clear focus on leading-edge and AI developments reflecting the ambition for future technological sovereignty. However, a singular focus on cutting edge overlooks the need to address immediate vulnerabilities and to build on existing strengths.
While focussing on advanced nodes is important, the recent supply chain crises have painfully demonstrated

that Europe's industry is very dependent on legacy chips , which form the backbone of many sectors, including, automotive, industrial, and healthcare. The dependency is especially large when it comes to the back-end segment of the chip production. Neglecting this existing legacy capacity fails to address our current resilience gap.
Therefore, the EU’s strategy must be two-pronged: attract investment in advanced fabs and/or design capacity on advanced nodes, and simultaneously incentivize the expansion and modernization of existing legacy production within Europe to secure immediate supply and to lessen our dependencies.

Furthermore, we must actively build upon Europe's world-class strengths in the semiconductor equipment and materials sector (e.g., lithography and metrology). Leveraging these established capabilities is crucial for building a robust, balanced, and strategically autonomous European ecosystem across the entire value chain.

Europe should focus on segments for High-Variety, Low Volume production which align with Europe’s industrial base (e.g., automotive, industrial IoT). By focusing on specialized niches, Europe can benefit significantly from technological crossovers, using advancements in one area to build ecosystems and gain a competitive edge in related domains (e.g., specialized chips for quantum or photonics). Given the fierce international competition, it is not feasible to build up areas of global technological leadership without building on preexisting capabilities.

Section 5: Supporting documentation

In this last session you may upload any separate document such as position papers, background documents that accompany or support your responses (up to four documents, as per the number of sections). You may specify the sections addressed by each document.

Please upload your file(s)

Contact

Contact Form

16 December, 2025

Input NL on the public consultation for Regulation 1025/2012

Introduction

The European Standardisation System (ESS), with Regulation 1025/2012 as the main basis, is a key pillar of the European single market. The ESS is unique in its inclusive, consensus-based approach and balanced stakeholder representation, which results in high quality standards. The system creates a level playing field for businesses, facilitates international trade, and supports and enables innovation. Consumers equally benefit from the ESS through enhanced safety and reliability of products and services.

The revision of Regulation 1025/2012 provides a timely opportunity to address current challenges. Aligning this revision with the revision of the New Legislative Framework and the Market Surveillance Regulation in a European Product Act creates synergies and strengthens coherence across the quality infrastructure system. This document outlines the current Dutch position and key recommendations for the four main themes identified by the European Commission in the revision of Regulation 1025/2012.

1. **Speed and responsiveness to innovation: What is needed is 1) a more critical stance towards when standardisation should be used, 2) process improvements within the current system, 3) considering the possibility of other (normative) documents instead of the classical approach, and 4) exploring the possibility to use the added value of other actors beyond the existing ESOs.**

- There is not one solution to develop EU harmonised standards faster. It is important to that several different elements are explored in parallel.
  A) NL has two main suggestions when it comes to improving the speed and responsiveness given the current ESS:
     i. *A more critical ex-ante stance towards using standardisation:* Taking a more critical stance when standardisation is used as an instrument to make sure ESO's only work on those requests that they are equipped for. If standardisation is not expected to be a the right instrument, we should refrain from using it. This can be achieved by introducing a formal assessment framework to determine the most suitable instrument.
        - This framework should clarify which instrument (e.g. standards, "agile specifications", or (fast-track) legislation) is best suited for which policy objective.
        - An 'advisory institute' should play a central role in creating, implementing and monitoring this assessment.
     ii. *Improve processes within current system:* Improvements within the current system if standards are considered to be the most suitable instrument. This may be, among other ways, achieved by:
        - A second formal assessment in addition to the initial assessment, for example by the advisory institute as mentioned above, to determine that the legal requirements are unambiguous and clear in the underlying legislation. That will result in a clearer task for the ESO's and as a consequence a smoother and faster process.
        - Improving the process of drafting the standardisation requests by involving the ESO's earlier in the process and setting realistic deadlines for both the ESO's and Commission;
        - Examining the possibilities to accelerate the process by developing standards with less strict criteria for consensus, for instance majority voting. In a light form this can also be phased standardisation by developing preliminary standards with less consensus.
        - Improving digitalisation, for example in the standard development, standard maintenance and standard application systems.

B) NL suggests two other points that go beyond the current ESS and need a more in-depth analysis:

i. Consider other (normative) documents instead of the classical harmonised standards approach:

- Make it easier for existing (inter)national standards developed outside the existing ESOs to be assessed in meeting the EU requirements and be published as European Standards via the existing ESS. The European Agile Specifications (EAS) project should be seen as a promising pilot.
- Consider giving temporary status to other documents to demonstrate the presumption of conformity while harmonised standards are still in the process of being developed. This can be for example technical specifications.

ii. Explore the possibility to use the added value of other actors beyond the existing ESOs:

- To reduce pressure on the ESS, the possibility to make better use of the added value provided by other relevant actors beyond the existing ESOs should be explored.
- NL is also open to exploring more far-reaching, out-of-the-box adjustments to the current system. For example, increased cooperation between NSBs. In the future, models with increased thematic or regional coordination between individual NSBs within the EU could be assessed.

- NL attaches great importance to the concept of 'presumption of conformity' within the European quality infrastructure. This is a key pillar in the European quality infrastructure and important to keep in mind when exploring the above-mentioned options.

2. Inclusiveness of the standardisation process: Regulation 1025/2012 provides a solid legal basis. Better implementation in practice is needed according to the recommendations of HLF workstream 3 on inclusiveness.

- The current wording of Regulation 1025/2012 provides a solid legal basis for a transparent and inclusive standardisation process where all relevant stakeholders are represented.
- However, achieving this inclusiveness in practice is challenging in the Netherlands due to limited expert capacity, long-term project commitment and lack of knowledge of the standardisation process.
- We fully support the findings and recommendations of workstream 3 on NSBs peer-review under the High Level Forum on standardisation (HLF). It is important that the Commission, NSB's, Member States and other relevant organisations implement the recommendations.
- We also encourage the Commission to keep supporting the development of the pan European standardisation certificate for capacity building and the exchange of best practices among member states. The HLF can be used as a platform for this exchange.

3. Access to standards: the current business model of the ESS is under pressure: 1) NSBs should be encouraged and facilitated by the Commission in developing a future-proof business model and 2) a legal basis should be created to (partly) compensate NSBs for the loss of fees.

- NL proposes two points on the access to standards and a future-proof business model for the ESS:
  1) NSBs should be stimulated and facilitated by the Commission to work towards a future-proof business model that is no longer solely dependent on selling standards.
     - The Dutch NSB NEN has already been exploring new ways to shift towards an amended business model for many years and is actively sharing best practices.
     - The HLF can be used as a platform to exchange best practices for future-proof business models for NSB's.
     - It is important to set realistic timelines for NSBs to amend their business model.

2) The Commission should consider (partially) compensating the NSBs (or the NSBs via the ESOs) for the missed license-fees of European harmonised standards that are published in the Official Journal of the EU. The legal basis for such compensation should be adopted in regulation 1025/2012.
    - The Netherlands works with a license-fee compensation for NEN for mandatory national standards under Dutch law since 2016.
    - The methodology to calculate (partial) compensation should take technological developments (AI, smart standards, open source) and the transition to a future-proof business model by NSB's into account.

4. EU's role in global standard-setting: the EU needs to remain competitive in global standardisation by strategically prioritising, enhancing cooperation on EU-level and building capacity.

- Two recently published reports from the Dutch research institute Clingendael on the geopolitical power of standards confirm that the EU is losing influence on standardisation internationally: 'Standardisation with Chinese Characteristics' and 'Raising the Standard'.
- The Commission's Standardisation Strategy from 2022 already addressed this and introduced several important recommendations. While these measures are significant in using standards as a strategic instrument, it remains essential to maintain this strategic focus and strengthen it where possible. NL therefore encourages to focus on:
    - Identifying and prioritizing strategic sectors for standardisation. The HLF should be used as platform to set strategic priorities on a political level;
    - Enhancing cooperation and coordination between EU stakeholders to participate in international standardisation;
    - Investing in capacity building to train more standardisation experts;
    - Encouraging member states and the private sector to financially support experts to participate in international technical committees.

Ministerie van Economische Zaken

Directie Europese en Internationale Zaken

Aan de Minister van Economische Zaken en Klimaat

Auteur

[redacted]

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Kopie aan

Bijlage(n)

nota
TER BESLISSING

Beslisnota rapportage ministerie EZK wetgevingsonderhandelingen en raadplegingen EU vierde kwartaal 2025

Parafenroute

[redacted]

Aanleiding

Elk vakdepartement brengt periodiek de Eerste en Tweede Kamer op de hoogte van de lopende EU-wetgevingsonderhandelingen en de reacties op raadplegingen van de Europese Commissie. Dit is conform de afspraken met de Kamers over EU-informatievoorziening. U informeert met de bijgaande brieven beide Kamers over de stand van zaken betreffende EU-wetgevingsonderhandelingen en de EU-raadplegingen op het beleidsterrein van Economische Zaken en Klimaat (EZK) in het vierde kwartaal van 2025. Met deze brieven stuurt u conform de afspraken een afschrift van de Nederlandse inbreng op vijf EU-raadplegingen als bijlage mee. Per abuis heeft het uitsturen van deze kwartaalrapportage eerder dit jaar vertraging opgelopen waardoor deze verlaat wordt uitgestuurd.

Geadviseerd besluit

U kunt akkoord gaan met de bijgevoegde brieven aan de Eerste en Tweede Kamer en deze ondertekenen.

Kernpunten

Overzicht EU-wetgevingsonderhandelingen.

Ten opzichte van het derde kwartaal van 2025 zijn de volgende voorstellen nieuw gepubliceerd en worden besproken op ambtelijk EU-niveau in Raadskader:

- Omnibus digitaal
- Omnibus AI

Ten opzichte van het derde kwartaal van 2025 zijn de volgende voorstellen in de triloogfase beland:

- Interne markt en douaneprogramma voor de periode 2028-2034

Ten opzichte van het derde kwartaal van 2025 zijn voor de volgende voorstellen de trilogen afgerond maar zijn de voorstellen nog niet procedureel afgerond:

- Herziening richtlijn pakketreizen
- FDI-verordening
- Herziening meetinstrumenten-richtlijn

Ten opzichte van het derde kwartaal van 2025 zijn de volgende voorstellen gepubliceerd en daarmee afgerond:

- Verordening betreffende Europese statistieken over bevolking en huisvesting
- Verordening dwanglicenties voor crisisbeheersing

<u>EU-raadplegingen</u>
Door EZK is er in het vierde kwartaal van 2025 op de volgende EU-raadplegingen gereageerd:

- Chips Act 2
- Europese biotechwet
- Normalisatierichtlijn
- Richtsnoeren voor reddings- en herstructureringssteun (staatssteun)
- Diensten van algemeen economisch belang (DAEB) (staatssteun)

Deze consultatiereacties zijn bijgevoegd.