

I. BACKGROUND OF THE FACTS

On 28 November 2023, the Commission proposed a legislative package to modernise the legal framework to counter migrant smuggling and to put in place the necessary legal and operational tools to respond to the new *modi operandi* of migrant smugglers, as set out in the Commission Work Programme 2024 of 17 October 2023¹.

This package included:

- (i) a proposal for a Directive laying down minimum rules to prevent and counter the facilitation of unauthorised entry, transit and stay in the Union² defining the relevant criminal offences and the penalties, in order to support the investigation and successful prosecution of migrant smuggling;
- (ii) a proposal for a Regulation on enhancing police cooperation in relation to the prevention, detection and investigation of migrant smuggling and trafficking in human beings, and on enhancing Europol's support to preventing and combating such crimes and amending Regulation (EU) 2016/7949³, aiming to strengthen operational cooperation by reinforcing the role of Europol, as well as EU-level information exchange and interagency cooperation.

The proposals were not accompanied by formal impact assessments. Where an impact assessment is not possible due to reasons of urgency, in line with the better regulation guidelines, the evidence supporting the proposals and the cost estimates are set out in an analytical document presented in the form of a Staff Working Document (SWD).

In the case at hand, following the adoption of the two proposals, two SWDs⁴ were prepared to provide the necessary evidence and estimated costs.

II. THE COMPLAINT TO THE EUROPEAN OMBUDSMAN

On 7 February 2024, the Commission received a letter on behalf of European Digital Rights (EDRi), where concerns were expressed regarding the absence of an impact assessment in relation to the aforementioned legislative proposals.

In the reply dated 9 April 2024, the Commission explained that it decided to proceed without impact assessments due to the urgency of acting swiftly to counter migrant smuggling and to prepare the two legislative proposals.

¹ COM(2023) 638 final of 17.10.2023 Commission Work Programme 2024 - “Delivering today and preparing for tomorrow”.

² COM(2023) 755 final of 28.11.2023.

³ COM(2023) 754 final of 28.11.2023.

⁴ SWD(2024) 94 final of 15.4.2024, and SWD(2024)134 final of 14.5.2024.

In line with the better regulation guidelines, following the adoption of the two initiatives, the Commission was (at the time of the reply) preparing two Staff Working Documents (SWDs) to present the evidence and estimated costs for each proposal. These SWDs were issued in the spring of 2024. In these, the Commission elaborated on how available evidence was assessed and used to underpin the two proposals.

In particular, SWD(2024)134 explained that the proposal for the Directive was based, among others, on the evidence gathered through the 2017 REFIT evaluation of the Facilitators Package⁵; the targeted consultations carried out in the preparation of the 2020 Commission Guidance on the implementation of EU rules on the definition and prevention of the facilitation of unauthorised entry, transit and residence;⁶ and the public consultation carried out on the renewed EU action plan against migrant smuggling (2021-2025)⁷. This included information and evidence provided by Europol, Eurojust and Frontex, as well as information gathered through the Commission's continuous engagement with the Member States and civil society stakeholders in the process of monitoring the implementation of the current EU legal framework, including an external study on the implementation of the Facilitators Package⁸. Moreover, the SWD noted that the policy choices were limited by the legal basis set by the Treaty (Article 83(1) TFEU), the latest standards in the EU criminal law and the instruments tackling organised crime, as well as by the need to further align EU legislation with the UN Protocol against the smuggling of migrants by land, sea and air⁹ with a view to providing further legal clarity to Member States in navigating the multi-layered legal framework on countering migrant smuggling.

As regards the Regulation, SWD(2024)94 provided data highlighting the relatively low number of cases and other operational activities supported by Europol in the area of migrant smuggling, especially if compared to other crime areas. This was a consequence of the low level of information exchanged by Member States with Europol and between EU agencies, as well as the limited processing of information from third countries.

III. EUROPEAN OMBUDSMAN'S INQUIRY

Following the correspondence referred to in Section II, on 23 June 2025 the European Ombudswoman wrote to the Commission communicating her decision to open an inquiry. This was based on a complaint submitted on 4 November 2024 by the European Digital Rights (EDRi) and PICUM (Platform for International Cooperation on Undocumented Migrants) on behalf of the ProtectNotSurveil coalition (<https://protectnotsurveil.eu/>). It concerns the Commission's alleged failure to comply with its 'Better Regulation Guidelines' in preparing the two proposals to strengthen EU legislation on preventing and countering migrant smuggling.

As a first step, the European Ombudswoman requested to receive from the European

⁵ SWD(2017) 117 final of 22.3.2017.

⁶ Communication from the Commission: Commission Guidance on the implementation of EU rules on definition and prevention of the facilitation of unauthorised entry, transit and residence (2020/C 323/01) of 1.10.2020.

⁷ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A renewed EU action plan against migrant smuggling (2021-2025) COM(2021) 591 final of 29.9.2021.

⁸ Milieu Law and Policy Consulting, Study supporting the implementation of the Facilitators Package, Final report, September 2023, ISBN: 978-92-68-15676-6.

⁹ Protocol against the Smuggling of Migrants by Land, Sea and Air, supplementing the United Nations Convention against Transnational Organized Crime, 15.11.2000.

Commission any documentation related to the decision not to perform impact assessments for the two legislative proposals in this case, including any relevant information entered in the Decide IT platform and any approval sought and granted from the Vice-President responsible for ‘better regulation’ or the Director responsible for ‘better regulation’ in the Secretariat-General.

As a second step, she requested to receive a written reply from the Commission to the questions listed in the Annex to her letter to the Commission.

IV. THE REPLY OF THE EUROPEAN COMMISSION

The Commission reiterates from the outset that the Commission’s better regulation practices are specified in the better regulation guidelines and the accompanying toolbox. The better regulation guidelines clearly state:

‘These guidelines are internal instructions for the Commission staff in order to deliver the objectives of ‘better regulation’; in so far as they formulate ‘requirements’ and/or ‘mandatory’ instructions, they cannot be construed as legally binding rules or legal commitments towards outside actors and stakeholders’.

These guidelines are also designed to account for urgencies and to allow the Commission to propose legislation in a short time frame, if necessary.

This being said, the Commission would like to respond to the questions raised as follows:

Proposal for a Regulation on enhancing police cooperation in relation to the prevention, detection and investigation of migrant smuggling and trafficking in human beings, and on enhancing Europol’s support to preventing and combating such crimes

1. *Could the Commission please elaborate on the reasons for its decision not to carry out an impact assessment? In particular, could the Commission clarify the exact nature of the urgency and at what point in time it became aware of the circumstances that triggered this urgency?*

In line with the better regulation guidelines, the Commission conducts impact assessments whenever there is a political choice to be made, and the potential impacts of that choice are likely to be significant. In principle, where an impact assessment is required, but it is not possible to carry out one for reasons such as urgency, an analytical document in the form of a staff working document should be prepared within three months of the initiative’s adoption presenting the evidence behind the proposal and cost estimates.

This is a possibility provided by the guidelines, which is designed to cater for urgencies and to allow the Commission to propose needed legislation in a short time frame. Given the urgency to prepare the two legislative proposals in question, and in order to act swiftly to tackle migrant smuggling, carrying out a full impact assessment would not have been feasible as this requires substantial time.

In her speech regarding the State of the Union¹⁰ on 13 September 2023, the President of the Commission stressed that the EU legislation on countering migrant smuggling is over twenty

¹⁰ https://commission.europa.eu/strategy-and-policy/state-union/state-union-2023_en.

years old and needs an urgent update; that the way smugglers operate is continuously evolving; that new legislation and a new governance structure are needed with stronger law enforcement, prosecution and a more prominent role for EU agencies – Europol, Eurojust and Frontex. The President of the Commission also highlighted the need to strengthen the work with EU partners to tackle the global plague of human trafficking. In that context, the organisation of an International Conference on countering migrant smuggling was also announced.

In the letter of 13 September 2023 to the European Parliament¹¹, the President of the Commission confirmed the intention to prioritise work on a legislative package on countering migrant smuggling, with a limited number of initiatives, which “reflect existing commitments or respond to emerging challenges”.

This announcement was followed up in the Commission Work Programme 2024 adopted on 17 October 2023. The package to modernise the legal framework to counter migrant smuggling and to ensure that the necessary legal and operational tools effectively and efficiently respond to the new *modi operandi* of migrant smugglers featured in Annex I to the Commission Work Programme 2024, with Q4 2023 indicated as adoption date for the Commission’s proposal.

In addition, the Commission Work Programme 2024 reiterated the commitment for the organisation of “an international conference on fighting people smuggling, considering the need for international cooperation and a strong global alliance in this area”.

A call to action¹² to counter migrant smuggling was prepared building also on the conclusions of the Ministerial Conference on the 20th Anniversary of the Palermo Convention on 29 September 2023, with a view to further strengthening the concerted multi-dimensional effort to prevent and respond to smuggling activities, through protection and alternatives to irregular migration, including by addressing the root causes of irregular migration.

In light of these commitments and events, the President of the Commission and the Commissioner for Home Affairs convened an International Conference on a Global Alliance to Counter Migrant Smuggling on 28 November 2023.

As part of the Commission’s commitment and active engagement for immediate and decisive action to combat migrant smuggling, the President of the Commission presented the legislative proposals adopted on the same morning of the Conference, as a key measure to reduce irregular migration into the EU and facilitate legal pathways.

The urgency of these initiatives was demonstrated by the explicit political commitments and further confirmed by the political support showed during the preparation of the proposals with which “this Commission made sure that Member States have the right legal framework and the necessary operational tools when dealing with irregular migration”¹³.

¹¹ <https://webgate.ec.europa.eu/circabc-ewpp/d/d/workspace/SpacesStore/3b8fb651-1ad8-45cc-9bc1-c1c0cc080a99/download>.

¹² https://home-affairs.ec.europa.eu/system/files/2023-11/Call-to-action-global-alliance-to-counter-migrant-smuggling_en_1.pdf.

¹³ RCC(2023) 193 OJ 2475 of 26 November 2023.

The continuous flow of information about the rapidly-developing smuggling activities, as recorded by the EU Agencies supported the urgency of preparing and tabling the proposals, and informed the statements delivered by the President of the Commission during her opening speech at the Global Alliance Conference¹⁴.

The focus on the migrant smuggling phenomenon and its consequences - the rise of irregular migration and organised crime networks' operations - and the need to tackle the increasing smuggling activities has been highlighted by several sources. For example, the report from Europol's European Migrant Smuggling Centre (EMSC) "Spotlight Report on migrant smuggling networks and their methods"¹⁵ showed the sustained migrant smuggling dynamics in 2022. The upward trend was then corroborated, among others, in the 2023 EMSC report "Tackling threats, addressing challenges"¹⁶ and Frontex Annual Brief¹⁷. While these reports were published after the legislative package was presented, the underlying developments were already observed by the Agencies and reflected in the regular exchanges and reporting, including to the Commission.

Moreover, on 17 September 2023, after more than 8,000 migrants had arrived on the Italian island of Lampedusa in just three days, the Commission President visited the island, and presented a 10-point action plan¹⁸ to reduce irregular migration and provide immediate EU assistance, including the urgent need to step up the efforts to investigate and dismantle the criminal networks involved in migrant smuggling. All these developments¹⁹ as well as the

¹⁴ https://north-africa-middle-east-gulf.ec.europa.eu/news/keynote-speech-president-von-der-leyen-international-conference-global-alliance-counter-smuggling-2023-11-28_en.

¹⁵ <https://www.europol.europa.eu/media-press/newsroom/news/spotlight-report-migrant-smuggling-networks-and-their-methods>.

¹⁶ <https://www.europol.europa.eu/publications-events/publications/emsc-report-tackling-threats-addressing-challenges#downloads>.

¹⁷ https://www.frontex.europa.eu/assets/Publications/General/Annual_Brief_2023.pdf.

¹⁸ https://ec.europa.eu/commission/presscorner/api/files/document/print/en/ip_23_4503/IP_23_4503_EN.pdf.

¹⁹ In 2023, irregular migration experienced significant pressure, with over 442,000 irregular border crossings (IBCs) at the EU's external borders, marking a 17% increase from the 2022 figures and representing the highest annual total since the 2015-2016 migration crisis. This increase was largely driven by geopolitical instabilities, particularly in West Africa, leading to a substantial rise in arrivals across several key migration routes. The Western African route experienced a record-breaking 40,000 irregular border crossings, a whopping 161% rise from 2022, largely fuelled by large cayucos from Senegal. The Western Mediterranean also observed a 12% increase in arrivals by sea. The Central Mediterranean route saw a substantial influx, totalling almost 158,000 irregular border crossings, an approximate 50% uptick from the previous year. On this route, migrants primarily departed using very dangerous makeshift metal boats from Tunisia and wooden or large-capacity fishing vessels from Libya to cross the sea. Meanwhile, the Eastern Mediterranean route also experienced a resurgence, reaching about 60,000 irregular border crossings, driven by increased Syrian, Afghan, and Palestinian movements. At the same time, the EU+ received 1.1 million asylum applications, an 18% increase from 2022 and the highest since the migration crisis in 2015/2016. Importantly, 2023 also witnessed a rise in the number of vulnerable migrants, with women and children constituting more than 10% of the overall flow. Notably, unaccompanied minors increased by 28%, raising protection challenges for authorities, with women and children constituting more than 10% of the overall flow. At least 8,565 people died on migration routes worldwide in 2023, making it the deadliest year on record, according to data collected by IOM's Missing Migrants Project. The 2023 death toll represents a tragic increase of 20 per cent compared to 2022. The 2023 totals surpassed the number of dead and missing reported globally in the previous, record year of 2016, when 8,084 people died during migration, making it the deadliest year since the organisation's Missing Migrants Project's inception in 2014. The Mediterranean crossing was the deadliest route for migrants on record, with at least 3,129 deaths and disappearances. 2023 remains the year with the highest death toll recorded in the Mediterranean since 2017. Notably, unaccompanied minors increased by 28%, raising protection challenges for authorities. In this context, 2023 also saw increased law enforcement actions against migrant smuggling compared to 2022. As a result of coordinated action under EMPACT and its dedicated Operational Action Plan on Migrant Smuggling, 6,801

knowledge and expertise gathered over the previous years, including in the implementation of the EU Action Plans against migrant smuggling (2015-2020 and 2021-2025), through extensive cooperation with Europol, EU Member States, Agencies and partners, reports (such as from the European Court of Auditors²⁰ and Europol²¹) and stakeholders' consultations further supported the need for urgent action to effectively respond to smuggling activities including by modernising the legislative framework and add legal certainty to Europol's support to Member States.

In summary, 2023 presented significant developments as regards migration, from irregular arrivals, including vulnerable migrants, applications for international protection, irregular border crossings externally and within Schengen, and sustained law enforcement actions against migrant smuggling and human trafficking networks operating across the EU. Tragically these increases were reflected equally in the numbers of irregular migrants missing, making 2023, reportedly, the deadliest year on record.

Shortly after its adoption by the Commission, the legislative proposals were presented to Member States in the relevant Council Working Groups (LEWP on 1 December and COPEN on 20 December), where Member States acknowledged the trends discussed above and the importance of countering migrant smuggling.

In its conclusions of 15 December 2023, the European Council also held a strategic discussion on migration and concluded, among others, that “the European Union will continue to pursue a comprehensive approach to migration which combines increased external action, mutually beneficial comprehensive partnerships with countries of origin and transit, addressing the root causes of migration, opportunities for legal migration, more effective protection of EU external borders, resolutely fighting organised crime, human trafficking and smuggling, instrumentalisation of migration as a hybrid threat and stepping up returns”.

2. Could the Commission clarify why it considers that the need urgently to improve Europol's support to the Member States implies that the Commission had little or no choice available in preparing the Proposal? While urgency could justify taking expedited actions in the preparation of a proposal, it is not immediately clear how it would limit the Commission's discretion as to the actual content of the proposal.

The Commission acknowledges the importance of clarifying the relationship between the urgency of improving Europol's support to Member States and the degree of discretion it exercised in drafting the Proposal.

In this case, the Commission considered that the rapidly evolving security landscape, showing the increasingly complex nature of multifaceted activities of criminal networks behind migrant smuggling and increasing operational demands on Europol, **required a swift and decisive response with targeted measures having immediate impact.**

facilitators were arrested in 2023, indicating a near doubling from the previous year's 3,646 arrests. Furthermore, 243 key facilitators were identified and arrested, emphasizing a focused approach on critical criminal elements. The law enforcement response included the seizure of €1,549,246 in cash and assets, alongside 7,296 forged documents. Notably, the number of supported international investigations surged to 4,690 in 2023 compared to 3,285 investigations the previous year thus further illustrating the need to increase strategic and coordinated law enforcement efforts against organized crime networks.

²⁰ https://www.eca.europa.eu/Lists/ECADocuments/SR21_19/SR_migrant_smuggling_EN.pdf.

²¹ For example, the Serious Organised Crime Threat Assessment (SOCTA) 2021 available at https://www.europol.europa.eu/cms/sites/default/files/documents/socta2021_1.pdf.

The proposal was shaped by the need to address specific operational gaps identified by Member States and Europol, building on the intensification of the use of tools already available by improving the conditions of their implementation. The proposal intended to bring added value with a strong EU intervention strengthening existing structures and enhancing inter-Agency engagement, cooperation among Agencies and Member States, with a view to delivering results that other initiatives could not achieve in the same timeframe.

As explained in the SWD, other choices such as soft law measures were discarded for two main reasons. On the one hand, they would not have been sufficiently effective to address the implementation and legal gaps concerning the exchange of information. The evidence and consultation carried out demonstrated the need to move from voluntary cooperation towards mandatory participation, which could not be imposed through non-binding legal instruments. On the other hand, non-legislative interventions would fall short of removing legal obstacles and uncertainty underlying the low level of processing certain types of data, such as biometrics. A more ambitious approach would not have been realistically and politically feasible in the same short term.

The targeted technical improvements proposed were thus the viable solution to complement and strengthen the effects of political choices.

3. *How and by whom was the decision taken not to carry out an impact assessment?*

Please see replies to questions 1 and 2 above. Please note that the two legislative proposals were prepared together and are both covered by the Staff Working Documents issued in the spring of 2024, as per references under footnote 3. The process for obtaining exemption from the impact assessment is embedded in the 2019 working methods of the Commission. Accordingly, the Vice-President for Interinstitutional Relations and Foresight is responsible for validating exemptions from impact assessments. Such exemptions can be requested either at the planning stage (and then this entry planning is encoded in the Commission's decision-making IT tool Decide) or at a later stage if this becomes necessary.

In the present case, however, there was no planning of the initiative due to urgency and hence, no formal request for a derogation from the impact assessment requirement was made at that stage by DG HOME and therefore no documentation to that effect exists. The decision to act in urgency was a political decision, taken in reaction to the sharp and sudden increase of migratory trends and the need to respond to the urgency of the situation, as explained above in the replies to questions 1 and 2.

4. *Could the Commission describe the workflow for the preparation and finalisation of the Staff Working Document substituting the impact assessment for this Proposal? Why was the document not published within three months of the adoption of the Proposal, as set out in the Better Regulation Guidelines? Please provide the Ombudsman with a detailed timeline of the Commission's work on the Staff Working Document.*

Although the SWDs were not issued within 3-months after the adoption of the proposal, they included targeted information addressing queries from Member States in an effort to support further the interinstitutional negotiations on the texts, which had already started in December 2023. More importantly, they reflected the results of discussions at the 25 January 2024 Informal Justice and Home Affairs meeting, the 4 March 2024 Justice and Home Affairs Council meeting and the results of 21-22 March 2024 European Council meeting.

Accordingly, the interservice consultation was launched on 9 April 2024, and the Commission services issued the SWD(2024) 94 final supporting the proposed Regulation on 15 April 2024.

Proposal for a Directive laying down minimum rules to prevent and counter the facilitation of unauthorised entry, transit and stay in the Union

1. *Could the Commission clarify why the proposal was presented without an impact assessment? If the reason was the urgency referred to above, could the Commission clarify the exact nature of the urgency and at what point in time it became aware of the circumstances that triggered this urgency? Could the Commission also clarify why this was not indicated in the relevant section of the explanatory memorandum to the Proposal?*

The proposal highlighted several challenges related to the implementation and monitoring of the 2002 Facilitators Package,²² some of which were already mentioned in the 2017 REFIT evaluation²³ as well as in the renewed EU action plan against migrant smuggling (2021-2025)²⁴. The proposal noted the challenges linked to the broad definition of the offence and its lack of exemptions, such as in relation to the distinction between the facilitation of irregular migration and the provision of humanitarian assistance.

The reasons why the proposal for a Directive was not accompanied by the impact assessment were presented above in reply to the questions on the proposal for a Regulation. These include the pressing need for immediate and decisive action to counter migrant smuggling more effectively, as this is one of the key elements for reducing irregular migration into the EU. The proposal was presented according to the timeline set out in the Commission Work Programme 2024 and in line with the announcements of the President of the Commission. It relied on evidence from the 2017 REFIT evaluation of the facilitators package;²⁵ the 2021 public consultation on the new EU action plan against migrant smuggling;²⁶ contributions from Europol, Eurojust (the EU Agency for Criminal Justice Cooperation) and Frontex; and on the results of the engagement with Member States and civil society stakeholders in the framework of monitoring the implementation of the current legal framework.

Furthermore, in 2023, at the time this proposal was being developed, the EU faced a surge in irregular migration, a year-on-year increase, with over 442,000 irregular border crossings detected at its external borders, a 17% increase compared to 2022²⁷. This sharp rise, coupled with increased loss of life and violence associated to migrant smuggling in a geo-politically unstable and rapidly shifting context, signaled a worrying trend requiring a robust policy intervention.

²² Council Directive 2002/90/EC of 28 November 2002 defining the facilitation of unauthorised entry, transit and residence (OJ L 328); and Council framework Decision 2002/946/JHA of 28 November 2002 on the strengthening of the penal framework to prevent the facilitation of unauthorised entry, transit and residence (OJ L 328).

²³ SWD(2017) 117 final of 22.3.2017.

²⁴ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A renewed EU action plan against migrant smuggling (2021-2025) COM(2021) 591 final of 29.9.2021.

²⁵ SWD(2017) 117 final of 22.3.2017.

²⁶ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A renewed EU action plan against migrant smuggling (2021-2025) COM(2021) 591 final of 29.9.2021.

²⁷ See above footnote 17.

As indicated above, it is estimated that more than 90% of irregular migrants use the services of smugglers to reach the EU, highlighting the extent of involvement of criminal networks. The 2023 European Union Serious and Organised Crime Interim Threat Assessment (EU SOCTA-interim)²⁸ further underscored the urgency, mentioning that migrant smuggling is likely to further increase in the future due to the continued demand for smuggling services driven by emerging and deepening crises, most notably economic recessions, environmental emergencies caused by climate change, as well as conflicts and demographic pressure in third countries. In addition, smuggling activities generate substantial profits for the criminal networks, with an annual turnover estimated between at least EUR 4.7 and 6 billion, making migrant smuggling a low risk–high profit crime. A strong and rapid policy response was essential to address the urgency of the situation with immediate legislative measures to disrupt migrant smuggling routes and reduce irregular migration.

In view of this, in the September 2023 State of the Union address, the President of the Commission stressed the need to further strengthen EU tools to better respond to the global challenge of migrant smuggling. The President of the Commission called for an update of the current EU legal framework; the strengthening of the governance on countering migrant smuggling and of the role of EU Agencies, in particular of Europol; and the intensification of cooperation between Justice and Home Affairs Agencies and Member States, as well as with partner countries to tackle this issue globally.

Moreover, **the scope for policy choices was limited** by the legal basis set by the Treaty on the Functioning of the European Union, specifically Article 83(1) TFEU and the latest standards in EU criminal law, including addressing organised crime. These include harmonised provisions on incitement, aiding, abetting and attempt; liability and sanctions for legal persons; limitation periods for criminal offences; resources; training; investigative tools and data collection. As a result, the proposal largely reflects a codification and alignment with existing legal and policy standards in an effort to further stress the importance of effective implementation of the existing framework, while ensuring its gradual adaptation to respond effectively to emerging challenges.

Furthermore, the proposal responds to a clear need to align EU rules more closely with international obligations under the UN Protocol against the smuggling of migrants by land, sea and air²⁹, thereby enhancing legal clarity for Member States and facilitating more coherent implementation across the Union.

As outlined in the SWDs issued in the spring of 2024, the proposal for the Directive is based on a robust foundation of existing evidence and stakeholder input. This body of evidence and consultation provides a solid analytical underpinning that informs and validates the policy direction taken. Please refer to the statements above in the replies to the questions on the Regulation proposal.

2. *How and by whom was the decision taken not to carry out an impact assessment?*

Please see response to questions 1 and 2 of the previous section as the proposed Regulation and the proposed Directive were prepared together.

²⁸ Not public (RESTREINT UE/EU RESTRICTED), presented to the Council of the European Union on 9 June 2023.

²⁹ Protocol against the Smuggling of Migrants by Land, Sea and Air, supplementing the United Nations Convention against Transnational Organized Crime, 15.11.2000.

3. *Could the Commission please describe the workflow for the preparation and finalisation of the Staff Working Document substituting the impact assessment for this Proposal? Why was the document not published within three months of the adoption of the Proposal, as set out in the Better Regulation Guidelines? Please provide the Ombudsman with a detailed timeline of the Commission's work on the Staff Working Document.*

Please note that the Staff Working Document SWD(2024) 134 final issued on 14 May 2024 supporting the proposed Directive, provided useful information and substantial evidence in support of both legislative proposals, mutually reinforcing their content and explaining the policy choices.

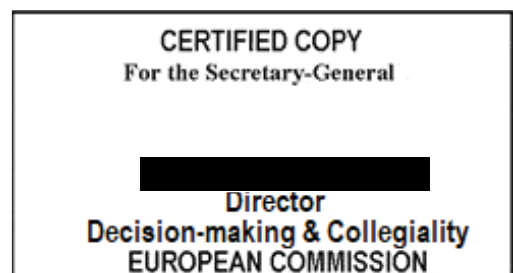
Please also refer to the reply given to question 4 under the section referring to the proposed Regulation.

The interservice consultation was launched on 2 May 2024, and the Commission services issued the SWD(2024) 134 final supporting the proposed Regulation on 14 May 2024.

V. CONCLUSION

The Commission is committed to upholding evidence-based policy making and better regulation standards. The urgency of the situation showed by the developments in the field, as well as the targeted scope of the measures required, did justify accelerating the procedure. Despite the urgency, the Commission did provide analytical documentation (in the form of staff working documents), taking into consideration the evidence available and the consultations already carried out on the matter at stake. This is in line with the better regulation guidelines to facilitate the Commission's swift action when it is necessary to respond to urgent circumstances.

For the Commission
Magnus BRUNNER
Member of the Commission



List of enclosures

Annex 1: A list of data on smuggling activities showing in summary information presented by Europol which fed into the analysis, facts and figures presented in the two SWDs is attached to the present reply to the inquiry of the Ombudsman. This information is available also in the consolidated Annual Activity Report 2024 (page 19 - summary of Europol's support to migrant smuggling and trafficking in human beings investigations) and the SOCTA 2025, which are both relevant as they provide a retrospective analysis on migrant smuggling and trafficking in human beings, including trends observed during the 2021-2024 period which served as a basis for the Commission proposals.

Europol Reports:

EMSC responses and results in 2023		AP Migrant smuggling	AP Phoenix
Operational support	Number of operations supported	164	59
	Number of Action Days	45	23
	OTFs supported	8	3
	Number of Joint Investigation Teams (JITs) where EMSC participated	3	3
Information exchange	Number of accepted contributions	14 738	2 878
Analytical support	Operational reports	999	232

EMSC in 2022 - Activities and performance indicators	
Migrant smuggling	
AP MIGRANT SMUGGLING	2022
Number of accepted contributions ¹	13 988
Operational reports	966
Number of Operations	131
Active Operational Task Forces ²	6
On-the-spot Action Days	31
Active High Value Targets ³	49
Trafficking in human beings	
AP PHOENIX	2022
Number of accepted contributions	3 104
Operational reports	247
Number of Operations	64
Active Operational Task Forces	2
On-the-spot Action Days	22
Active High Value Targets	6

Spotlight Report – Migrant Smuggling Criminal Networks (2023 – assessment of the modus operandi and migrant smuggling dynamics on main entry corridors)

<https://www.europol.europa.eu/media-press/newsroom/news/spotlight-report-migrant-smuggling-networks-and-their-methods>

Consolidated Annual Activity Report 2023 (page 20 - summary of Europol’s support to migrant smuggling and THB investigations)

<https://www.europol.europa.eu/cms/sites/default/files/documents/Consolidated-Annual-Activity-Report-2023.PDF>

EMSC Annual Activity Report (2024 – reports on activities performed during 2023)

<https://www.europol.europa.eu/publications-events/publications/emsc-report-tackling-threats-addressing-challenges>

Consolidated Annual Activity Report 2024 (page 19 - summary of Europol’s support to migrant smuggling and THB investigations)

[https://www.europol.europa.eu/cms/sites/default/files/documents/Consolidated Annual Activity Report 2024.PDF](https://www.europol.europa.eu/cms/sites/default/files/documents/Consolidated%20Annual%20Activity%20Report%202024.PDF)

SOCTA 2025 (relevant as it provides a retrospective analysis on migrant smuggling and THB including trends observed during the 2021-2024 period)

<https://www.europol.europa.eu/publication-events/main-reports/changing-dna-of-serious-and-organised-crime>

Europol Press Releases – Concluded Action Days and Joint Action Days (JADs):

Combatting THB:

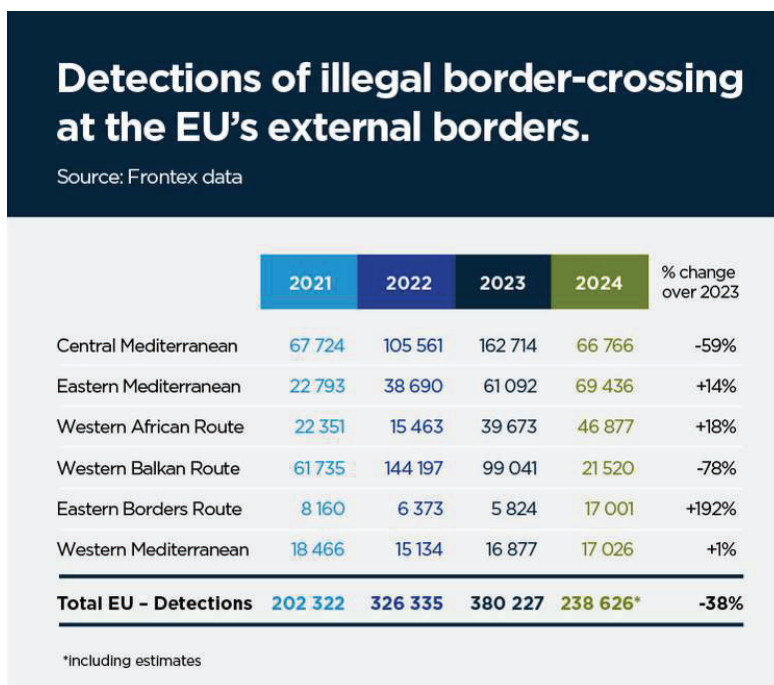
1. <https://www.europol.europa.eu/media-press/newsroom/news/prolific-love-fourteen-young-victims-of-lover-boys-saved-in-spain>
2. <https://www.europol.europa.eu/media-press/newsroom/news/10-arrested-for-abusing-venezuelan-victims-in-greece>

3. <https://www.europol.europa.eu/media-press/newsroom/news/targeted-human-traffickers-luring-victims-online>
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6. <https://www.europol.europa.eu/media-press/newsroom/news/21-arrested-for-labour-exploitation-and-261-victims-identified>
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9. <https://www.europol.europa.eu/media-press/newsroom/news/90-victims-of-sexual-exploitation-identified>
10. <https://www.europol.europa.eu/media-press/newsroom/news/28-arrested-europes-biggest-chinese-prostitution-ring-dismantled>

Combatting Migrant Smuggling :

1. Joint Action Days : <https://www.europol.europa.eu/media-press/newsroom/news/566-arrests-in-week-of-coordinated-actions-in-southern-europe>
2. <https://www.europol.europa.eu/media-press/newsroom/news/eleven-arrested-for-smuggling-migrants-greece-to-northern-europe>
3. Joint Action Days : <https://www.europol.europa.eu/media-press/newsroom/news/operation-mobile-6-puts-brakes-car-thieves>
4. <https://www.europol.europa.eu/media-press/newsroom/news/targeting-logistics-drivers-migrant-smuggling-cell-dismantled-in-bulgaria>
5. <https://www.europol.europa.eu/media-press/newsroom/news/19-arrests-for-smuggling-migrants-within-eu>
6. Europol-Interpol common investigation & action day
<https://www.europol.europa.eu/media-press/newsroom/news/62-transcontinental-migrant-smugglers-arrested>
7. <https://www.europol.europa.eu/media-press/newsroom/news/end-of-road-for-6-suspects-smuggling-migrants-in-rental-cars>
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9. <https://www.europol.europa.eu/media-press/newsroom/news/joint-raids-balkan-route-see-migrant-smugglers-halted>
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13. <https://www.europol.europa.eu/media-press/newsroom/news/92-charged-in-bust-targeting-migrant-smugglers-in-bulgaria>

FRONTEX reports & analyses:



Source:

https://www.frontex.europa.eu/thumb/Migratory_routes/2025/Detection_map.prop_750x_d6648f6385.png

Annual Risk Analysis 2024/2025

https://www.frontex.europa.eu/assets/Publications/Risk_Analysis/Annual_Risk_Analysis_2024-2025.pdf

Annual Brief 2024 (with comparative data for 2022 and 2023, showcasing 2023 as the year with the highest migratory pressure since 2015/2015) [Annual_Brief_2024.pdf](#)

Strategic Risk Analysis 2024

[frontex.europa.eu/assets/Publications/Risk_Analysis/Risk_Analysis/Strategic_Risk_Analysis_2024_Report.pdf](https://www.frontex.europa.eu/assets/Publications/Risk_Analysis/Risk_Analysis/Strategic_Risk_Analysis_2024_Report.pdf)

Annual Brief 2023 (interactive & leaflet – quote: “In 2023, the number of irregular border crossings at the EU’s external borders reached a total of 380 000. **This marks the highest level since 2016** and constitutes a **17% increase from the figures in 2022.**”) [Frontex | 2023 Digital Leaflet Annual Brief 2023](#)

Annual Risk Analysis 2023/2024

https://www.frontex.europa.eu/assets/Publications/General/ARA_2023.pdf

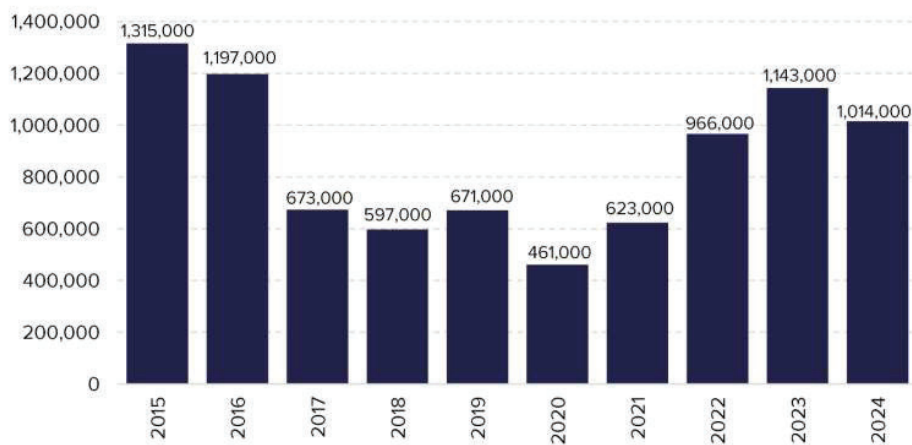
Annual Risk Analysis 2022/2023 [ARA_2022_Public_Web.pdf](#)

EU Asylum Agency – reports and analyses:



In 2024, applications for international protection declined by 11% compared to 2023, with just over 1 million applications received by EU+ countries for the second consecutive year (see Figure 1).

Figure 1. Number of applications for asylum in EU+ countries, 2015-2024



Source: EUAA EPS data as of 3 February 2025.

Asylum Report 2025 (executive summary): <https://euaa.europa.eu/publications/asylum-report-2025-executive-summary>

[Latest Asylum Trends: Mid-Year Review 2024](#)

Asylum Report 2024 (quote: “In 2023, asylum applications rose to levels reminiscent of the 2015-2016 refugee crisis.”): <https://euaa.europa.eu/publications/asylum-report-2024>

Asylum Report 2024 (executive summary): <https://euaa.europa.eu/publications/asylum-report-2024-0>

Latest Asylum Trends 2023 - <https://euaa.europa.eu/publications/latest-asylum-trends-2023-annual-analysis>

Asylum Report 2023 (quote: EU+ countries were faced with an exceptional number of people in need of protection in 2022 as a result of sharply increasing asylum applications lodged in Europe) <https://euaa.europa.eu/publications/asylum-report-2023>

EMPACT



EMPACT Factsheet 2022 -

https://www.europol.europa.eu/cms/sites/default/files/documents/2023_225_empact-factsheets-2022_web-final.pdf

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<https://www.europol.europa.eu/cms/sites/default/files/documents/empact-factsheet-2023.pdf>