

Regulation (EU) No 386/2012 of the European Parliament and of the Council of 19 April 2012 on entrusting the Office for Harmonization in the Internal Market (Trade Marks and Designs) with tasks related to the enforcement of intellectual property rights, including the assembling of public and private-sector representatives as a European Observatory on Infringements of Intellectual Property Rights (Text with EEA relevance)

REGULATION (EU) No 386/2012 OF THE  
EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 19 April 2012

on entrusting the Office for Harmonization in the Internal Market (Trade Marks and Designs) with tasks related to the enforcement of intellectual property rights, including the assembling of public and private-sector representatives as a European Observatory on Infringements of Intellectual Property Rights

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 and the first paragraph of Article 118 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee<sup>(1)</sup>,

Acting in accordance with the ordinary legislative procedure<sup>(2)</sup>,

Whereas:

- (1) The economic well-being of the Union relies on sustained creativity and innovation. Therefore, measures for their effective protection are indispensable in ensuring its future prosperity.
- (2) Intellectual property rights are vital business assets that help to ensure that creators and innovators get a fair return for their work and that their investment in research and new ideas is protected.
- (3) A sound, harmonised and progressive approach to intellectual property rights is fundamental in the endeavour to fulfil the ambitions of the Europe 2020 Strategy including A Digital Agenda for Europe.
- (4) The constant increase in infringements of intellectual property rights constitutes a genuine threat not only to the Union economy, but also, in many cases, to the health and safety of Union consumers. Therefore, effective, immediate and coordinated action at national, European and global levels is needed to successfully combat this phenomenon.

---

**Changes to legislation:** Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

---

- (5) In the context of the overall intellectual property rights strategy envisaged by the Council Resolution of 25 September 2008 on a comprehensive European anti-counterfeiting and anti-piracy plan<sup>(3)</sup>, the Council called on the Commission to set up a European Observatory on Counterfeiting and Piracy. The Commission therefore formed a network of experts from the public and the private sectors and described the tasks of that network in its Communication entitled ‘Enhancing the enforcement of intellectual property rights in the internal market’. The name of the European Observatory on Counterfeiting and Piracy should be changed to the European Observatory on Infringements of Intellectual Property Rights (‘the Observatory’).
- (6) That Communication stated that the Observatory should serve as the central resource for gathering, monitoring and reporting information and data related to all infringements of intellectual property rights. It should be used as a platform for cooperation between representatives from national authorities and stakeholders to exchange ideas and expertise on best practices and make recommendations to policymakers for joint enforcement strategies. The Communication specified that the Observatory would be hosted and managed by the services of the Commission.
- (7) In its Resolution of 1 March 2010 on the enforcement of intellectual property rights in the internal market<sup>(4)</sup>, the Council invited the Commission, the Member States and industry to provide the Observatory with available reliable and comparable data on counterfeiting and piracy and to jointly develop and agree, in the context of the Observatory, on plans to collect further information. The Council also invited the Observatory to publish each year a comprehensive annual report covering the scope, scale and principal characteristics of counterfeiting and piracy as well as its impact on the internal market. That annual report should be prepared using the relevant information provided in that regard by the authorities of the Member States, the Commission and the private sector within the limits of data protection law. The Council also recognised the importance of developing new competitive business models enlarging the legal offer of cultural and creative content and at the same time preventing and combating infringements of intellectual property rights as necessary means for fostering economic growth, employment and cultural diversity.
- (8) In its Conclusions of 25 May 2010 on the future revision of the Trade Mark system in the European Union<sup>(5)</sup>, the Council called on the Commission to establish a legal basis for the involvement of the Office for Harmonization in the Internal Market (Trade Marks and Designs) (‘the Office’) in enforcement-related activities, including the fight against counterfeiting, in particular through fostering its cooperation with the national trade mark offices and the Observatory. In that respect, Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights<sup>(6)</sup> provides, inter alia, for certain measures to promote cooperation, including the exchange of information, among Member States and between Member States and the Commission.
- (9) In its Recommendation of 26 March 2009 on strengthening security and fundamental freedoms on the internet<sup>(7)</sup>, the European Parliament recommended that the Council

---

**Changes to legislation:** Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

---

preserve full and safe access to the internet while encouraging private/public cooperation in enhancing law enforcement cooperation.

- (10) In its Resolution of 22 September 2010 on enforcement of intellectual property rights in the internal market<sup>(8)</sup>, the European Parliament called on the Member States and the Commission to extend the cooperation between the Office and national intellectual property offices so as to include the fight against infringements of intellectual property rights.
- (11) In its Resolution of 12 May 2011 on unlocking the potential of cultural and creative industries<sup>(9)</sup>, the European Parliament urged the Commission to take into account the specific problems encountered by small and medium-sized enterprises when it comes to asserting their intellectual property rights and to promote best practice and effective methods to respect those rights.
- (12) In its Resolution of 6 July 2011 on a comprehensive approach on personal data protection in the European Union<sup>(10)</sup>, the European Parliament called on the Commission to ensure full harmonisation and legal certainty, providing a uniform and high level of protection of individuals in all circumstances.
- (13) In view of the range of tasks assigned to the Observatory, a solution is needed to ensure an adequate and sustainable infrastructure for the fulfilment of its tasks.
- (14) Council Regulation (EC) No 207/2009 of 26 February 2009 on the Community trade mark<sup>(11)</sup> provides for administrative cooperation between the Office and the courts or authorities of the Member States, and the exchange of publications between the Office and the central industrial property offices of the Member States. On that basis, the Office has established cooperation with national offices that are active in the field of protection of intellectual property rights. Consequently, the Office already possesses, to a considerable extent, the necessary experience and expertise to provide an adequate and sustainable infrastructure in the field of the Observatory's tasks.
- (15) The Office is therefore well placed to be entrusted with carrying out those tasks.
- (16) Those tasks should relate to all intellectual property rights covered by Directive 2004/48/EC, since in many cases, infringing acts affect a bundle of intellectual property rights. Furthermore, data and the exchange of best practices are needed on the entire abovementioned range of intellectual property rights, in order to obtain a complete picture of the situation and to enable comprehensive strategies to be devised with a view to reducing infringements of intellectual property rights.
- (17) The tasks that the Office should carry out can be linked to the enforcement and reporting measures laid down by Directive 2004/48/EC. Thus, the Office should provide services to national authorities or operators which affect, in particular, the homogenous implementation of the Directive and which are likely to facilitate its application. The Office's tasks should therefore be considered as closely linked to the subject matter of acts approximating the laws, regulations and administrative provisions of the Member States.

---

**Changes to legislation:** Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

- (18) Assembled by the Office, the Observatory should become a centre of excellence on information and data relating to infringements of intellectual property rights, by benefiting from the Office's expertise, experience and resources.
- (19) The Office should offer a forum that brings together public authorities and the private sector, ensuring the collection, analysis and dissemination of relevant objective, comparable and reliable data regarding the value of intellectual property rights and infringements of those rights, identifying and promoting best practices and strategies to enforce intellectual property rights, and raising public awareness of the impact of infringements of intellectual property rights. Furthermore, the Office should fulfil additional tasks, such as improving the understanding of the value of intellectual property rights, fostering the exchange of information on new competitive business models which enlarge the legal offer of cultural and creative content, enhancing the expertise of persons involved in the enforcement of intellectual property rights by appropriate training measures, increasing knowledge of techniques to prevent counterfeiting, and improving cooperation with third countries and international organisations. The Commission should be associated with the activities undertaken by the Office under this Regulation.
- (20) The Office should thus facilitate and support the activities of national authorities, the private sector and the Union institutions relating to the enforcement of intellectual property rights and in particular their activities in the fight against infringements of those rights. The exercise by the Office of its powers under this Regulation does not prevent Member States from exercising their competences. The Office's tasks and activities under this Regulation do not extend to participation in individual operations or investigations carried out by the competent authorities.
- (21) In order to fulfil those tasks in the most efficient manner, the Office should consult and cooperate with other authorities at national, European and, where appropriate, international levels, create synergies with the activities carried out by such authorities and avoid any duplication of measures.
- (22) The Office should implement the tasks and activities relating to the enforcement of intellectual property rights by making use of its own budgetary means.
- (23) With regard to representatives of the private sector, the Office should, when assembling the Observatory in the context of its activities, involve a representative selection of the economic sectors — including the creative industries — most concerned by or most experienced in the fight against infringements of intellectual property rights, in particular representatives of right holders, including authors and other creators, as well as internet intermediaries. Also, a proper representation of consumers and of small and medium-sized enterprises should be ensured.
- (24) The information obligations imposed by this Regulation on the Member States and on the private sector should not create unnecessary administrative burdens and should endeavour to avoid duplication as regards data already provided by Member States and private-sector representatives to Union institutions under existing Union reporting requirements.

---

*Changes to legislation:* Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

---

- (25) Since the objective of this Regulation, namely to entrust the Office with tasks related to the enforcement of intellectual property rights, cannot be sufficiently achieved by the Member States and can therefore, by reason of its effect, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS REGULATION:

#### *Article 1*

##### **Subject matter and scope**

This Regulation entrusts the Office for Harmonization in the Internal Market (Trade Marks and Designs) ('the Office') with tasks aimed at facilitating and supporting the activities of national authorities, the private sector and the Union institutions in the fight against infringements of the intellectual property rights covered by Directive 2004/48/EC. In carrying out these tasks the Office shall organise, administer and support the gathering of experts, authorities and stakeholders assembled under the name 'European Observatory on Infringements of Intellectual Property Rights' ('the Observatory').

The tasks and activities of the Office under this Regulation do not extend to participation in individual operations or investigations carried out by the competent authorities.

#### *Article 2*

##### **Tasks and activities**

- 1 The Office shall have the following tasks:
  - a improving understanding of the value of intellectual property;
  - b improving understanding of the scope and impact of infringements of intellectual property rights;
  - c enhancing knowledge of best public and private sector practices to protect intellectual property rights;
  - d assisting in raising citizens' awareness of the impact of infringements of intellectual property rights;
  - e enhancing the expertise of persons involved in the enforcement of intellectual property rights;
  - f enhancing knowledge of technical tools to prevent and tackle infringements of intellectual property rights, including tracking and tracing systems which help to distinguish genuine products from counterfeit ones;
  - g providing mechanisms which help to improve the online exchange, between Member States' authorities working in the field of intellectual property rights, of information relating to the enforcement of such rights, and fostering cooperation with and between those authorities;
  - h working, in consultation with Member States, to foster international cooperation with intellectual property offices in third countries so as to build strategies and develop techniques, skills and tools for the enforcement of intellectual property rights.

---

**Changes to legislation:** Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

---

2 In the fulfilment of the tasks set out in paragraph 1, the Office shall carry out the following activities in accordance with the work programme adopted pursuant to Article 7, and in line with Union law:

- a establishing a transparent methodology for the collection, analysis and reporting of independent, objective, comparable and reliable data relating to infringements of intellectual property rights;
- b collecting, analysing and disseminating relevant objective, comparable and reliable data regarding infringements of intellectual property rights;
- c collecting, analysing and disseminating relevant objective, comparable and reliable data regarding the economic value of intellectual property and its contribution to economic growth, welfare, innovation, creativity, cultural diversity, the creation of high-quality jobs and the development of high quality products and services within the Union;
- d providing regular assessments and specific reports by economic sector, geographic area and type of intellectual property right infringed, which evaluate, inter alia, the impact of infringements of intellectual property rights on society and the economy, including an assessment of the effects on small and medium-sized enterprises, as well as on health, the environment, safety and security;
- e collecting, analysing and disseminating information regarding best practices between the representatives meeting as the Observatory, and, if applicable, making recommendations for strategies based on such practices;
- f drawing up reports and publications to raise awareness amongst Union citizens of the impact of infringements of intellectual property rights and to that end, organising conferences, events and meetings at European and international levels as well as assisting national and Europe-wide actions, including online and offline campaigns, principally by providing data and information;
- g monitoring the development of new competitive business models which enlarge the legal offer of cultural and creative content, and encouraging the exchange of information and raising consumer awareness in this respect;
- h developing and organising online and other forms of training for national officials involved in the protection of intellectual property rights;
- i organising ad hoc meetings of experts, including academic experts and relevant representatives of civil society, to support its work under this Regulation;
- j identifying and promoting technical tools for professionals and benchmark techniques, including tracking and tracing systems which help to distinguish genuine products from counterfeit ones;
- k working with national authorities and the Commission to develop an online network facilitating the exchange of information on infringements of intellectual property rights between public administrations, bodies and organisations in the Member States dealing with the protection and enforcement of those rights;
- l working in cooperation with, and building synergies between, the central industrial property offices of the Member States, including the Benelux Office for Intellectual Property and other Member States' authorities working in the field of intellectual property rights, with a view to developing and promoting techniques, skills and tools relating to the enforcement of intellectual property rights, including training programmes and awareness campaigns;
- m developing, in consultation with the Member States, programmes for the provision of technical assistance to third countries as well as developing and delivering specific training programmes and events for officials from third countries who are involved in the protection of intellectual property rights;

---

**Changes to legislation:** Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

---

- n making recommendations to the Commission on issues falling within the scope of this Regulation, on the basis of a request from the Commission;
- o carrying out similar activities necessary in order to enable the Office to fulfil the tasks set out in paragraph 1.

3 In carrying out the tasks and activities referred to in paragraphs 1 and 2, the Office shall comply with existing provisions of Union law on data protection.

### *Article 3*

#### **Financing**

The Office shall at all times ensure that the activities entrusted to it by this Regulation are carried out by making use of its own budgetary means.

### *Article 4*

#### **Meetings of the Observatory**

1 In order to carry out the activities referred to in Article 2(2), the Office shall at least once per year invite to meetings of the Observatory representatives from public administrations, bodies and organisations in the Member States dealing with intellectual property rights and representatives from the private sector, for the purpose of their participation in the Office's work under this Regulation.

2 Private-sector representatives invited to meetings of the Observatory shall include a broad, representative and balanced range of Union and national bodies representing the different economic sectors, including the creative industries, most concerned by or most experienced in the fight against infringements of intellectual property rights.

Consumer organisations, small and medium-sized enterprises, authors and other creators shall be properly represented.

3 The Office shall invite each Member State to send at least one representative from its public administration to meetings of the Observatory. In that context, Member States shall ensure continuity in the Observatory's work.

4 The meetings referred to in paragraph 1 may be complemented by working groups within the Observatory made up of representatives from Member States and representatives from the private sector.

5 Where appropriate, and in addition to the meetings referred to in paragraph 1, the Office shall organise meetings consisting of:

- a representatives from the public administrations, bodies and organisations in the Member States; or
- b private-sector representatives.

6 Members or other representatives of the European Parliament and representatives from the Commission shall be invited to any of the meetings covered by this Article, either as participants or observers, as appropriate.

7 The names of the representatives attending, the agenda and the minutes of the meetings referred to in this Article shall be published on the Office's website.

---

*Changes to legislation: Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

---

## Article 5

### Information obligations

1 As appropriate, in accordance with national law, including the law governing the processing of personal data, Member States shall, at the request of the Office or on their own initiative:

- a inform the Office of their overall policies and strategies on the enforcement of intellectual property rights and any changes thereto;
- b provide available statistical data on infringements of intellectual property rights;
- c inform the Office of important case-law.

2 Without prejudice to the law governing the processing of personal data and to the protection of confidential information, private-sector representatives meeting as the Observatory shall, when possible, at the request of the Office:

- a inform the Office of policies and strategies in their field of activity on the enforcement of intellectual property rights and any changes thereto;
- b provide statistical data on infringements of intellectual property rights in their field of activity.

## Article 6

### The Office

1 The relevant provisions of Title XII of Regulation (EC) No 207/2009 shall apply to the carrying-out of the tasks and activities provided for under this Regulation.

2 Using the powers conferred by Article 124 of Regulation (EC) No 207/2009, the President of the Office shall adopt the internal administrative instructions and shall publish the notices that are necessary for the fulfilment of all the tasks entrusted to the Office by this Regulation.

## Article 7

### Content of the work programme and of the management report

1 The Office shall draw up an annual work programme that appropriately prioritises the activities under this Regulation and for the meetings of the Observatory, in line with the Union's policies and priorities in the field of protection of intellectual property rights and in cooperation with the representatives referred to in point (a) of Article 4(5).

2 The work programme referred to in paragraph 1 shall be submitted to the Office's Administrative Board for information.

3 The management report provided for in point (d) of Article 124(2) of Regulation (EC) No 207/2009 shall contain at least the following information concerning the Office's tasks and activities under this Regulation:

- a a review of the main activities carried out during the preceding calendar year;



---

**Changes to legislation:** Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

---

- b the results achieved during the preceding calendar year, accompanied, where appropriate, by sectoral reports analysing the situation in the different industry and product sectors;
- c an overall assessment of the fulfilment of the Office's tasks as provided for in this Regulation and in the work programme drawn up in accordance with paragraph 1;
- d an overview of the activities that the Office intends to undertake in the future;
- e observations on the enforcement of intellectual property rights and potential future policies and strategies, including on how to enhance effective cooperation with and between Member States;
- f an overall assessment of the proper representation in the Observatory of all the actors mentioned in Article 4(2).

Before submitting the management report to the European Parliament, the Commission and the Administrative Board, the President of the Office shall consult the representatives referred to in point (a) of Article 4(5) on the relevant parts of the report.

#### *Article 8*

#### **Evaluation**

- 1 The Commission shall adopt a report evaluating the application of this Regulation by 6 June 2017.
- 2 The evaluation report shall assess the operation of this Regulation, in particular as regards its impact on the enforcement of intellectual property rights in the internal market.
- 3 The Commission shall, when preparing the evaluation report, consult the Office, the Member States and the representatives meeting as the Observatory on the issues referred to in paragraph 2.
- 4 The Commission shall transmit the evaluation report to the European Parliament, the Council and the European Economic and Social Committee and shall undertake a broad consultation among stakeholders on the evaluation report.

#### *Article 9*

#### **Entry into force**

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

---

**Changes to legislation:** Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

Done at Strasbourg, 19 April 2012.

*For the European Parliament*

*The President*

M. SCHULZ

*For the Council*

*The President*

M. BØDSKOV

---

**Changes to legislation:** Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

---

- (1) [OJ C 376, 22.12.2011, p. 62.](#)
- (2) Position of the European Parliament of 14 February 2012 (not yet published in the Official Journal) and decision of the Council of 22 March 2012 (not yet published in the Official Journal).
- (3) [OJ C 253, 4.10.2008, p. 1.](#)
- (4) [OJ C 56, 6.3.2010, p. 1.](#)
- (5) [OJ C 140, 29.5.2010, p. 22.](#)
- (6) [OJ L 157, 30.4.2004, p. 45.](#) Corrected version in [OJ L 195, 2.6.2004, p. 16.](#)
- (7) [OJ C 117 E, 6.5.2010, p. 206.](#)
- (8) [OJ C 50 E, 21.2.2012, p. 48.](#)
- (9) Not yet published in the Official Journal.
- (10) Not yet published in the Official Journal.
- (11) [OJ L 78, 24.3.2009, p. 1.](#)

**Changes to legislation:**

Regulation (EU) No 386/2012 of the European Parliament and of the Council is up to date with all changes known to be in force on or before 12 July 2023. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.

[View outstanding changes](#)

**Changes and effects yet to be applied to :**

- Regulation revoked by [2023 c. 28 Sch. 1 Pt. 2](#)