COMMISSION IMPLEMENTING DECISION (EU) 2025/1760

of 19 August 2025

determining under Article 41(1) of Directive 2014/53/EU of the European Parliament and of the Council whether a measure taken by France with respect to Apple iPhone 12 A2403 is justified

(notified under document C(2025) 5736)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC ([1]), and in particular Article 41(1) thereof,

Whereas:

1. PROCEDURE

(1) On 5 October 2023, France, via its relevant market surveillance authority, Agence Nationale des Fréquences ('ANFR'), notified, in accordance with Article 40(4) of Directive 2014/53/EU and via the information and communication system referred to in Article 34(1) of Regulation (EU) 2019/1020 of the European Parliament and of the Council ([2]) ('ICSMS'), a measure to have the mobile phone 'iPhone 12 A2403' manufactured by Apple Inc. ('Apple') withdrawn from the French market ([3]) ('the national measure').

(2) France, via ANFR, adopted the national measure on the grounds that the iPhone 12 A2403 exceeds the limit value of 4 W/kg, the limit value for specific absorption rate (SAR) on limbs set out in harmonised standard EN 50566:2017 ([4]) which reflects the limits established in Council Recommendation 1999/519/EC ([5]). In accordance with Article 16 of Directive 2014/53/EU, that harmonised standard confers, if it is applied by a manufacturer ([6]), a presumption of conformity with the corresponding essential requirements. SAR is the rate at which electromagnetic energy emitted by a wireless device is absorbed by the human body expressed in power absorbed per unit mass of tissue (W/kg) ([7]).

([1]) OJ L 153, 22.5.2014, p. 62, ELI: http://data.europa.eu/eli/dir/2014/53/oj.

([2]) Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1, ELI: http://data.europa.eu/eli/reg/2019/1020/oj).

([3]) Safeguard 2014/53/EU-F-231005-14771 | F | 4678 – Agence Nationale des Fréquences.

([4]) Product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: hand-held and body-mounted devices in close proximity to the human body.

([5]) Council Recommendation 1999/519/EC of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz) (OJ L 199, 30.7.1999, p. 59, ELI: http://data.europa.eu/eli/reco/1999/519/oj). These limit values are taken from those defined by the International Commission on Non-Ionising Radiation Protection (ICNIRP), on the basis of a search for proven health effects (ICNIRP 1998). The ICNIRP is a non-governmental organisation officially recognised by the World Health Organisation (WHO) in the field of non-ionising radiation. It makes recommendations regarding exposure to electromagnetic fields in order to protect the public and workers from their potential health effects.

([6]) Apple's EU declaration of conformity for the iPhone 12 A2403, which is drawn up pursuant to Article 18 of Directive 2014/53/EU, referred to that harmonised standard.

([7]) There are three types of SAR measurements, each one corresponding to a different use case depending on the specific part of the human body where the measurements are conducted: the 'head SAR', which reflects the use of the wireless device next to the ear; the 'trunk SAR' associated with uses where the wireless device is carried close to the torso (i.e., attached to the belt or in the pocket); and the 'limb SAR', in which the wireless device is positioned in direct contact with the limbs, such as when it is held in the hand or carried in an armband or trouser pocket.

(3) ANFR indicated that the non-compliance with that limit value did not affect the iPhone 12 models Mini, Pro and Pro Max. ANFR concluded that the iPhone 12 A2403 is not compliant with the essential requirement set out in Article 3(1), point (a), of Directive 2014/53/EU, relating to the protection of health and safety of persons and domestic animals.

(4) Given that the national measure was communicated to the Commission and to Member States on 5 October 2023, an objection against that measure could be raised until 3 January 2024, in accordance with Article 40(7) of Directive 2014/53/EU.

(5) On 24 October 2023, Ireland, via its relevant market surveillance authority, the Commission for Communications Regulation ('ComReg'), submitted via ICSMS an objection with respect to the national measure.

(6) In that formal objection, ComReg concluded that the iPhone 12 A2403 was compliant with the essential requirements laid down in Directive 2014/53/EU.

(7) Following the objection raised against the national measure in accordance with Article 40(7) of Directive 2014/53/EU, the Commission entered into consultation with ANFR, ComReg and Apple to evaluate the national measure as provided for in Article 41(1), first subparagraph, of that Directive.

(8) In a meeting of the Administrative Cooperation Group of market surveillance authorities in the sector of the radio equipment (ADCO RED) that took place on 18 and 19 October 2023, ANFR presented the national measure to the market surveillance authorities of the Member States. The Commission attended the meeting as an observer.

(9) In the online meeting of the Telecommunication Conformity Assessment and Market Surveillance Committee (TCAM), held on 30 November 2023, ANFR presented an overview of the national measure to the Member States. The Commission provided an explanation of the safeguard clause procedure under Chapter V of Directive 2014/53/EU.

(10) On 30 November and 1 December 2023, an online meeting of the Commission expert group on radio equipment (E03587) was held. Apple was invited to participate in the discussion on the iPhone 12 A2403 that took place during that meeting. More specifically, Apple stated that the tests performed by ANFR do not reflect the intended use of the product and they can lead to potential erroneous results.

(11) On 5 January 2024, ANFR sent a letter to the Commission expressing the view that the objection raised by ComReg in relation to the national measure should not be upheld.

(12) By letter dated 8 March 2024, the Commission invited the ANFR to submit their observations and reply to several questions regarding the national measure. ANFR replied by email on 25 March 2024. Following supplementary questions raised by the Commission on 3 May 2024, ANFR sent additional information by email on 14 May 2024. On the same date, an online meeting took place between the Commission and ANFR, in which the independent laboratory CETECOM ADVANCED GmbH ('CETECOM'), accredited under the standard EN ISO/IEC 17025:2017 ([8]), also participated. During that online meeting, and also by email sent on the same date, the Commission informed ANFR about the validity of the objection raised by ComReg.

(13) By letter of 22 April 2024, the Commission invited Apple to submit its observations on the national measure and to reply to questions in order to clarify its position and observations. Apple submitted its observations and replies by email on 12 May 2024. As a follow-up, the Commission and Apple held an online meeting on 4 June 2024. On 3 June 2024, the Commission sent further questions to Apple on various technical elements to which Apple sent replies and clarifications on 18 June 2024 by email.

([8]) General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017).

(14) On 4 July 2024, the Commission held an online meeting with ComReg to discuss the national measure. ComReg submitted a written statement on 8 July 2024. That statement underlined that the iPhone 12 A2403 had been tested by Apple in cooperation with a notified body and was found to be within the SAR limb limits ([9]).

2. **BACKGROUND**

(15) The iPhone 12 A2403 model was released on the Union market in October 2020. It is the first iPhone model equipped with 5G technology and, when ANFR notified the national measure, it was still sold on the Union market.

(16) Apple incorporated in the iPhone 12 A2403 the so-called 'Body Detect' function. By means of that mechanism, when the device detects movement, it considers that it is being used in contact with the human body, thus setting the 'Body Detect' function to 'on-body' state. The objective is to lead to a reduction of emitted power and, in turn, to a reduction of the average SAR level so that the said device meets the relevant SAR limits set out in harmonised standard EN 50566:2017.

(17) In July 2022, ANFR conducted the first SAR measurements on the iPhone 12 A2403, for determining if the device meets the limits set out in harmonised standard EN 50566:2017.

(18) ANFR concluded, after carrying out the SAR measurement, that the device exceeded the limb SAR limit set out in the relevant harmonised standard. According to harmonised standard EN 50566:2017, the limb SAR limit is set at 4 W/kg. ANFR concluded that the limb SAR measurement presented a retained value of 5,615 W/kg, thus significantly beyond the standard's limit.

(19) Apple disputed those conclusions, by claiming the following:

— The laboratory conducting the test for France had clamped the iPhone 12 A2403 tightly against the SAR phantom ([10]). According to Apple, this configuration might prevent the iPhone 12 A2403 from triggering the 'Body Detect' algorithm and might lead to a potential lack of compliance with the SAR limit.

— Apple's proprietary engineering tools are necessary to ensure that the power control algorithms of the iPhone 12 A2403 do not produce inaccurate results.

(20) Following discussions between ANFR and Apple, the latter suggested to repeat the SAR measurements under a specific testing procedure (so-called 'protocol 1'), which was communicated to ANFR in February 2023.

(21) Protocol 1 had the following characteristics:

— A separation distance of 1 mm between the device and the phantom.

— An external proprietary motorised system attached to the device to produce artificial vibrations in order to properly simulate and trigger the 'Body Detect' function.

— The set-up of a specific testing configuration to carry out a stable and accurate measurement and to ensure that the emission came only from one preselected antenna of the iPhone 12 A2403 under test.

([9]) Apple's EU declaration of conformity for iPhone 12, dated 28 June 2021, mentions the conformity assessment body (notified body) involved.

([10]) Human body model.

(22) ANFR did not accept protocol 1 on the following grounds:

— The maximum SAR emitted by the device is more likely to occur at a distance of 0 mm from the device.

— Attaching a motorised system to the device was considered as an artificial mechanism that might not reflect the real use conditions of the product.

— The testing configuration used to ensure that the emission came only from one preselected antenna of the device could have an undetermined impact on SAR measurements.

(23) In June 2023, due to the lack of agreement between ANFR and Apple on protocol 1, Apple proposed a second measurement procedure (so-called 'protocol 2'), which had the following characteristics:

— A separation distance of 0 mm between the device and the phantom.

— The triggering of the 'Body Detect' algorithm by pressing the volume button of the iPhone 12 A2403 every 20 seconds.

— In order to ensure that the emission came only from one preselected antenna of the iPhone 12 A2403, the use of, two alternative methods: either the one already proposed under protocol 1 or another method involving a specific placing of the network simulator's antenna ([11]).

(24) ANFR accepted the measurement procedure described in protocol 2 and decided to use the method involving a specific placing of the network simulator's antenna.

(25) In August 2023, ANFR requested CETECOM to conduct SAR measurements on the iPhone 12 A2403 in accordance with protocol 2 on different samples. CETECOM concluded that the iPhone 12 A2403 remained non-compliant under protocol 2 (5,740 W/kg).

(26) On 12 September 2023, France, via ANFR, adopted a national decision ordering the withdrawal from the French market of the iPhone 12 A2403. That decision was adopted on the grounds that Apple refused to offer a software update to make the product compliant, as other manufacturers usually do, according to ANFR.

(27) Following the concerns expressed by ANFR and the subsequent adoption of a restrictive measure, Apple indicated it would release a software update for the iPhone 12 A2403 users in France to permanently activate the 'on-body' state of the 'Body Detect' function. That update to the iPhone 12 A2403 would reduce the emitted power, and in turn the SAR level, on a permanent basis. Apple added that that update would not be made available in other Member States since it considered that the iPhone 12 A2403 was compliant with Directive 2014/53/EU and that the national measure was groundless.

(28) New measurements conducted by CETECOM in September 2023 showed the compliance of the iPhone 12 A2403 running the updated software (iOS 17.1) with the SAR limit value set out in harmonised standard EN 50566:2017. Those measurements were carried out with test equipment simulating a mobile network located in France.

(29) Following the release of the software update, ANFR considered that the devices for which the updated software (iOS 17.1) was operational to permanently activate the 'on-body' state of the 'Body Detect' function were in compliance as it was demonstrated that such devices meet the relevant SAR limit set out in harmonised standard EN 50566:2017.

(30) ANFR, however indicated that it was informed by Apple, on 4 October 2023, that the corrective software update would only be operational on the French territory. During the meeting of the Commission services with Apple, held on 4 June 2024, Apple confirmed that the corrective software update would only be operational on the French territory.

([11]) The network simulator is part of the SAR testing equipment.

(31) Article 40(3) of Directive 2014/53/EU requires that a corrective action is taken in respect of non-compliant radio equipment throughout the Union. If the action taken for devices found not to be compliant consists of implementing, for example, a software update, that action can be considered corrective if the software update, i.e. corrective software, is made available and being operational in the entire Union and it is thus made available for all related devices operating in the Union.

(32) In this context, the action taken for the iPhone 12 A2403 devices, to implement a software update to ensure that the 'on-body' state of the 'Body Detect' function is permanently activated, so that the said devices can meet the relevant SAR limits and can thus be compliant, can be considered corrective only when that software update is made available in all the Union territory. Therefore, such devices are considered non-compliant not only when they do not have such a corrective software installed but also when such a software is installed but the permanent activation of the 'Body Detect Function' is operational only in France, and not in the entire Union.

(33) On 5 October 2023, ANFR encoded the national measure on ICSMS, initiating the three-month objection period in relation to iPhones 12 A2403 operating without the software update (iOS 17.1) and as a result the 'on-body' state of the 'Body Detect' function is not permanently activated.

3. **ARGUMENTS OF THE PARTIES**

3.1. **ANFR**

3.1.1. *Procedural point*

(34) By letter of 5 January 2024, sent by ANFR to the Commission, ANFR expressed the view that the objection raised by Ireland, via ComReg, in relation to the national measure should not be upheld.

(35) According to ANFR, that objection is not substantiated and is based only on an analysis of the technical documentation as well as on the measurement reports carried out by a notified body and communicated by the manufacturer. In other words, ANFR stated that the relevant Irish authorities neither conducted a technical investigation nor performed any tests.

3.1.2. *Substantive points*

(36) ANFR first referred to the general context for SAR measurements and explained that the latter are carried out systematically for head, body and limbs for smartphones. Then, ANFR provided an overview of the chain of events and facts, i.e. the specific dates when relevant tests were carried out and measures taken, which are summarised in the previous section.

(37) ANFR underlined that the SAR measurements are carried out through an accredited laboratory and that there are no specific national regulations applicable in France on SAR, outlining that, with respect to SAR measurements, the limits set out in Recommendation 1999/519/EC, which correspond to the limits set out in harmonised standard EN 50566:2017, are applied and followed when a laboratory carries out tests for ANFR. Moreover, it was indicated by ANFR that the tests for the iPhone 12 A2403 were carried out by CETECOM, which is accredited under the standard EN ISO/IEC 17025.

(38) In addition, in reply to questions submitted by the Commission services, ANFR provided the following details concerning the SAR measurements carried out in France:

— Many smartphones incorporate motion sensors, however such information must be included in their technical file.

— Before SAR measurements are carried out, ANFR asks the manufacturer to provide the full technical file, which must include the test reports drawn up by the manufacturer and a description of the operation of the device in question.

— If the device incorporates a motion sensor-based power control device, its algorithm is to be described in the technical file.

— After analysing the algorithm, the latter will be taken into account in the measurements, but only if it can ensure conformity with Directive 2014/53/EU, in particular, for safety, as regards the reasonably foreseeable use of the device, as provided for in Article 17(1) of that Directive.

— Since the devices incorporate power control mechanisms, they need to be tested by using Time Averaged SAR (TAS) procedure.

(39) ANFR indicated that the iPhone 12 A2403 reduces the emitted power when it detects movement because, in such a case, the device considers that it is being used in contact with the human body. That approach reflects the reasonably foreseeable use of the product, according to the manufacturer. ANFR did not challenge the described power control technique as a concept. Nevertheless, ANFR considered that it was not properly configured. More specifically, it was observed by ANFR that the device does not always reduce sufficiently the power when it detects movement.

(40) According to ANFR, CETECOM performed the first SAR measurement on the iPhone 12 A2403 in July 2022, leading to a result that exceeded the limb SAR limit. More specifically, as stated by ANFR, the limb SAR measurement presented a retained value of 5,615 W/kg.

(41) For that SAR measurement, ANFR took the following position:

— The measurement was carried out without taking into consideration the device mechanisms for power control.

— Since the technical documentation submitted by Apple did not mention the presence of a motion sensor, or a specific power control algorithm, those measurements were carried out without taking into account the device mechanisms allowing power control.

(42) ANFR then referred to protocol 1 proposed by Apple. ANFR clarified that the specific configuration to ensure that the maximum power is measured, as proposed under protocol 1, did not represent the reasonably foreseeable use, and it could be considered as an artificial way to pass the test.

(43) ANFR confirmed that, following the rejection of protocol 1, Apple proposed protocol 2. According to ANFR, that protocol was more in line with what is expected from a test taking into consideration the reasonably foreseeable conditions. However, by following protocol 2, ANFR noted that the limb SAR measurement performed by the accredited laboratory CETECOM showed the persistence of the non-compliance. The limit of 4 W/kg was exceeded by simulating the use of the iPhone 12 A2403 in France, more specifically, the limb SAR measured presented a retained value of 5,740 W/kg ([12]) (while the first measurement carried out presented a value of 5,615 W/kg) ([13]). Additional tests performed by ANFR concluded that the limb SAR exceeded the recommended value by simulating the use of the iPhone 12 in two other Member States.

(44) Additionally, ANFR tested in their internal laboratory ([14]) a different sample using the same protocol 2, which also resulted in non-compliance with the limb SAR limit value.

(45) As regards the new updated software offered by Apple, ANFR stated that a national decision taking a provisional measure was adopted ordering the withdrawal from the French market of the iPhone 12 A2403. The national decision was adopted on the grounds that, as stated by ANFR, Apple repeatedly refused to offer a software update to make the product compliant, as other manufacturers usually do.

([12]) The SAR measurement, following measurement protocol 2, carried out in August 2023.
([13]) The first SAR measurement that showed a retained value of 5,615 W/Kg was carried out in August 2022.
([14]) Agence Nationale des Fréquences (ANFR)'s internal laboratory is not accredited to perform measurements under harmonised standard EN 50566:2017.

(46) ANFR confirmed that the corrective software that was finally provided by Apple can be acceptable and can ensure compliance with the health and safety essential requirements set out in Directive 2014/53/EU. More specifically, the concrete measure implemented in this software limits the power of the device in all cases of use, thus restoring compliance and no longer making compliance of the device dependent on its performance in detecting the human body. ANFR noted that Apple provided the corrective software update only for iPhones 12 A2403 that operated on the French market and for this reason the national measure was encoded on ICSMS, initiating the three-month objection period.

3.2. **ComReg**

(47) According to the objection raised by Ireland, via ComReg, a preliminary investigation into the iPhone 12 A2403 was carried out by ComReg, which received documentation and technical testing results from Apple demonstrating that that radio equipment is compliant with the essential requirements set out in Directive 2014/53/EU. More specifically, the objection submitted by Ireland, via ComReg, was as follows:

'*ComReg objects to the measure taken by the ANFR in respect of the Apple iPhone 12 on the 12 September 2023 on the grounds outlined below:*

1. *On the 12 September 2023, the ANFR, the Market Surveillance Authority for Directive 2014/53/EU in France, took a measure to have the Apple iPhone12 withdrawn from the market in France having found that testing measures showed the specific absorption rate (SAR) exceeds the set limits. This is a procedure provided for under Article 40 of the Directive.*

   In accordance with Article 40.4, ANFR informed the Commission and the other Member States of this measure on 5 October 2023 by placing the requisite information on ICSMS.

2. *ComReg has carried out a preliminary investigation into the radio equipment in question. ComReg has received documentation and technical testing results from the economic operator demonstrating that the radio equipment is compliant with the essential requirements of the Directive. In particular, ComReg notes that when the iPhone12 was tested by Apple at a registered Notified Body, the product was found to be within the SAR Limb guidelines. ComReg has not carried out any technical testing on the iPhone12.*

3. *Common standards across the Union ensure interoperability and safety, reduce costs and facilitate companies' integration in the value chain and trade. Under the circumstances, ComReg believes that it would be appropriate for the European Commission to evaluate the national measure in question, and in particular the testing undertaken, and provide a common position to assist MSAs*'.

(48) ComReg noted that, when the iPhone 12 A2403 was tested by Apple in cooperation with a registered notified body ([15]), the device was found to be within the SAR limb limit. ComReg did not, however, carry out any technical testing on the iPhone 12 A2403. Moreover, ComReg did not point to any shortcomings of harmonised standard EN 50566:2017 with respect to its purpose of providing presumption of conformity with the essential requirement that it aims to cover and demonstrating, when that harmonised standard is applied, compliance with the essential requirement under Article 3(1), point (a), of Directive 2014/53/EU.

3.3. **Apple**

(49) According to Apple, the iPhone 12 A2403 is safe to use and has always been so. Particularly, according to Apple, the iPhone 12 A2403, which was launched in 2020, was certified and recognised as compliant with all applicable SAR regulations and standards around the world. Apple added that its power control mechanism has not been updated in any way since its launch.

(50) Apple informed the Commission that the iPhone 12 A2403 is equipped with technical mechanisms which control the emitted power based on certain parameters. The SAR level is, in turn, controlled by those mechanisms. The functioning of the latter is Apple-proprietary and was not disclosed in full to the Commission.

([15]) Conformity assessment body designated under Directive 2014/53/EU.

(51) According to Apple, the finding of ANFR on the iPhone 12 A2403 is not a compliance concern, rather a consequence of an alleged erroneous implementation of the testing protocol. More specifically, Apple considers that the test performed by ANFR does not trigger the power control mechanism in a proper way, leading to a potential lack of compliance with the SAR limb limit. Apple stated that the iPhone 12 A2403 passed a test at 5 mm separation distance (allowed by harmonised standard EN 50566:2017), executed by ANFR on 21 December 2021. Apple stated that the iPhone 12 A2403 did not comply with the test procedure performed by ANFR only for the limb exposure at 0 mm when the phone was clamped tightly to the flat phantom. The latter scenario, according to Apple, does not reflect the intended use of the device since it does not create any movement to activate the 'Body Detect' functionality. In other words, as noted by Apple, in the described scenario, the contact with the human body is not properly simulated.

(52) Apple added that the 'Body Detect' function has been used in all iPhones for over a decade and has been thoroughly tested and certified to be an effective mechanism of power control to comply with SAR requirements. Apple indicated that they provided ANFR with several reports of tests performed by independent third-party laboratories, which proved the appropriate functioning of the 'Body Detect' function, which proved, in turn, the compliance with SAR limb limits.

(53) Apple indicated that it developed a proprietary testing tool to activate the 'Body Detect' function during the tests, underling that such a tool is deemed necessary. Apple also indicated that the use of such tool was recommended by a manufacturer of SAR testing equipment.

(54) Apple considered that the tests performed by or on behalf of ANFR under protocol 2 were erroneous on the following grounds:

— CETECOM added the SAR values of the 4G and 5G bands while the radiation patterns demonstrated that there was no spatial overlapping between these two technologies and, therefore, the values could not be added.

— The iPhone 12 was set in a position that prevented the person performing the test from manually pushing the volume buttons as agreed in protocol 2 and leading to a lack of triggering of the 'Body Detect' function.

4. **COMMISSION'S ASSESSMENT**

4.1. **Procedure**

(55) The Commission first examined the view expressed by ANFR, in its letter of 5 January 2024, that the objection raised by Ireland, via ComReg, in relation to the national measure should not be upheld because of the lack of a deep investigation by the relevant Irish authorities.

(56) Under Article 40(7) of Directive 2014/53/EU, in the case where no objection has been raised by a Member State or the Commission, as specified in that provision, Member States are to ensure that appropriate restrictive measures, such as withdrawal of the radio equipment from the market, are taken in respect of the radio equipment concerned, without delay. However, according to Article 41(1) of Directive 2014/53/EU, if an objection has been raised, the Commission is to without delay enter into consultation with the Member States and the relevant economic operator and is to evaluate the national measure. On the basis of the results of that evaluation, the Commission is to adopt an implementing act determining whether the national measure is justified or not.

(57) While it is not disputed that the objection raised by Ireland, via ComReg, does not include technical details or technical justifications, based on Article 40(6) and (7) of Directive 2014/53/EU and considering the relevant case-law (in particular Case T-349/21 ([16])), the objection raised by Ireland, via ComReg, is sufficient to trigger the Commission's obligation referred to in Articles 40(7) and 41(1) of that Directive to issue an implementing decision under Article 41(1) of that Directive.

([16]) Judgment of 13 September 2023, Federal Republic of Germany v European Commission, T-349/21, ECLI:EU:T:2023:539.

(58) In Case T-349/21 the General Court stated that Directive 2014/33/EU of the European Parliament and of the Council ([17]) does not lay down any particular format requirements as regards the way in which objections may be formulated by a Member State. Similarly, Directive 2014/53/EU does not impose any specific format on how such objections can be formulated, and so the Court's finding can be applied to it.

(59) Under Article 34 of Regulation (EU) 2019/1020, objections raised by Member States in accordance with the applicable safeguard procedure in the Union harmonisation legislation applicable to the product, and any subsequent follow-up are to be entered into the information and communication system referred to in that Article (i.e. the ICSMS). In this respect, Ireland, via ComReg, has entered the objection it raised in relation to the national measure in ICSMS.

(60) During the online meeting of 14 May 2024 with the ANFR, and also by email sent on the same date, the Commission informed ANFR about the validity of the objection raised by ComReg and of the obligation for the Commission to issue an implementing decision.

4.2. **Observations in relation to the corrective software**

(61) Due to the concerns expressed by ANFR, and the subsequent national measure, Apple released a software update for iPhone 12 A2403 users in France to permanently activate the 'on-body' state of the 'Body Detect' function.

(62) The described modifications to the functioning of the 'Body Detect' function only took place on iPhone 12 A2403 devices operating in cellular networks located in France ([18]). According to Apple, the update would not be made available for all Union users since Apple considered that the iPhone was compliant with Directive 2014/53/EU and the national measure was groundless.

(63) The Commission observes that, following the release of the software update, and as confirmed by the additional tests carried out by ANFR, the iPhone 12 A2403's behaviour related to SAR remained unchanged in the rest of the Union. Therefore, the potential lack of compliance would remain in the majority of the Union.

(64) Under Article 40(3) of Directive 2014/53/EU, any corrective action must be available throughout the Union. Therefore, the corrective measures taken by Apple, by making available the new software (iOS 17.1) activating permanently the 'on-body' state of the 'Body Detect' function only on devices operating in cellular networks located in France, are not in line with that Article.

(65) As the national measure in relation to the iPhone 12 A2403 operation without the software update, so that the 'on-body' state of the 'Body Detect' function is being permanently activated, was encoded in the ICSMS and has not been withdrawn by France, the Commission's obligation to issue an implementing decision under Article 41(1) of Directive 2014/53/EU remains.

4.3. **Substantive points**

4.3.1. *Radio Equipment Directive provisions*

(66) Directive 2014/53/EU establishes a regulatory framework for the making available on the market and putting into service of radio equipment in the Union.

(67) Article 6 of Directive 2014/53/EU requires Member States to take appropriate measures to ensure that radio equipment is made available on the market only if it complies with that Directive. In addition, according to Article 9 of Directive 2014/53/EU, Member States are not to impede, for reasons relating to aspects covered by that Directive, the making available on the market in their territory of radio equipment which complies with that Directive.

([17]) Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251, ELI: http://data.europa.eu/eli/dir/2014/33/oj).

([18]) The iPhone 12 can detect the country where it is located. Therefore, its operating system can exhibit a specific behaviour of transmitted power depending on the country.

(68) The obligations of manufacturers when placing on the Union market radio equipment are set out in Article 10 of Directive 2014/53/EU. Article 10 of that Directive requires, among other things, that manufacturers, when placing their radio equipment on the market, ensure that it has been designed and manufactured in accordance with the essential requirements set out in Article 3 of that Directive.

(69) Article 3 of Directive 2014/53/EU sets out essential requirements to ensure the protection of health and safety, as well as of certain other aspects of public interest protection. According to Article 3(1), point (a), of that Directive, radio equipment is to be constructed so as to ensure the protection of health and safety of persons and of domestic animals and the protection of property, including the objectives with respect to safety requirements set out in Directive 2014/35/EU of the European Parliament and of the Council ([19]), but with no voltage limit applying. Under point 2(b) of Annex I to Directive 2014/35/EU measures of technical nature must be taken so that radiation which would cause a danger is not produced.

(70) As provided for in Article 17(1) of Directive 2014/53/EU, a manufacturer is to perform a conformity assessment of the radio equipment with a view to meeting the essential requirements set out in Article 3 of that Directive. The conformity assessment is to take into account all intended operating conditions and, for the essential requirement set out in Article 3(1), point (a), of that Directive, i.e. the essential requirements relating to health and safety, the assessment is also to take into account the reasonably foreseeable conditions. In addition, where the radio equipment is capable of taking different configurations, the conformity assessment is to confirm whether the radio equipment meets the essential requirements set out in Article 3 of that Directive in all possible configurations.

(71) Under Article 40(1) of Directive 2014/53/EU, where the market surveillance authorities of a Member State have sufficient reason to believe that radio equipment covered by that Directive presents a risk to the health or safety of persons or to other aspects of public interest protection covered by that Directive, or following the amendments introduced by Directive (EU) 2022/2380 of the European Parliament and of the Council ([20]) that it does not comply with at least one of the applicable essential requirements set out in Article 3 of Directive 2014/53/EU, they are to carry out an evaluation in relation to the radio equipment concerned covering all relevant requirements laid down in Directive 2014/53/EU. If the market surveillance authorities find that the radio equipment does not comply with the requirements laid down in Directive 2014/53/EU, they are to without delay require the relevant economic operator to take all appropriate corrective actions to bring the radio equipment into compliance with those requirements, to withdraw the radio equipment from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

4.3.2. *SAR limits*

(72) Recommendation 1999/519/EC sets out limits for the exposure of the general public to electromagnetic fields in line with the International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidelines. For radio equipment placed on the Union market and intended for use by the general public, those limits are set out in the harmonised standards drafted in support of Directive 2014/53/EU ([21]) and published in the *Official Journal of the European Union* by Commission Implementing Decision (EU) 2022/2191 ([22]).

(73) Pursuant to Article 16 of Directive 2014/53/EU, radio equipment which conforms with harmonised standards (or parts thereof), of which the references have been published in the *Official Journal of the European Union*, are presumed to be in conformity with the corresponding essential requirements set out in Article 3 of that Directive.

([19]) Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357, ELI: http://data.europa.eu/eli/dir/2014/35/oj).

([20]) Directive (EU) 2022/2380 of the European Parliament and of the Council of 23 November 2022 amending Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment (OJ L 315, 7.12.2022, p. 30, ELI: http://data.europa.eu/eli/dir/2022/2380/oj).

([21]) EN 50566:2017, product standard to demonstrate the compliance of wireless communication devices with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 30 MHz to 6 GHz: handheld and body mounted devices in close proximity to the human body. EN 50360:2017, product standard to demonstrate the compliance of wireless communication devices, with the basic restrictions and exposure limit values related to human exposure to electromagnetic fields in the frequency range from 300 MHz to 6 GHz: devices used next to the ear.

([22]) Commission Implementing Decision (EU) 2022/2191 of 8 November 2022 on the harmonised standards for radio equipment drafted in support of Directive 2014/53/EU of the European Parliament and of the Council (OJ L 289, 10.11.2022, p. 7, ELI: http://data.europa.eu/eli/dec_impl/2022/2191/oj).

(74) Harmonised standard EN 50566:2017, which confers a presumption of conformity with the essential requirement that it aims to cover, sets out the limb SAR limit value at 4W/kg, reflecting the relevant limit established in Council Recommendation 1999/519/EC, for the purpose of demonstrating compliance with the essential requirement relating to human and animal health referred to in Article 3(1), point (a), of Directive 2014/53/EU, as far as the SAR limit value for limb is concerned.

(75) Apple's EU declaration of conformity for the iPhone 12 A2403, which is drawn up pursuant to Article 18 of Directive 2014/53/EU, referred to that harmonised standard and therefore Apple had applied that harmonised standard, which confers a presumption of conformity with the essential requirement that it aims to cover, for demonstrating conformity with the essential requirement in question.

(76) The fact that a device, by meeting the limb SAR limit value set out in harmonised standard EN 50566:2017, which reflects the relevant limit established in Council Recommendation 1999/519/EC, can be in conformity with the essential requirement relating to human and animal health referred to in Article 3(1), point (a), of Directive 2014/53/EU, as far as the SAR limit value for limb is concerned, was not disputed by Member States.

(77) Moreover, during the online meetings held with Apple, mentioned above, the latter has never indicated that the limits, as set out in harmonised standard EN 50566:2017, are disputed. Additionally, Apple has not questioned the fact that that such exceedance for the limb SAR limit would imply non-compliance with the said essential requirement under Article 3(1), point (a), of Directive 2014/53/EU, as such, but focused instead on questioning the way in which the measurement protocol 2 was applied by or on behalf of ANFR.

(78) It is thus undisputed that a device, when it meets the relevant limb SAR limit set out in harmonised standard EN 50566:2017, is in compliance with the essential requirement set out in Article 3(1), point (a), of Directive 2014/53/EU regarding protection of health and safety of persons and domestic animals as far as the SAR limit value for limb is concerned.

(79) It is also unquestionable that a significant exceedance of the limb SAR limit value (over 40 %), as it results from the tests carried out by CETECOM on iPhone 12 A2403, would demonstrate that the device concerned is non-compliant with the essential requirement in question.

(80) As regards the SAR measurements to demonstrate equipment compliance, harmonised standard EN 50566:2017 provides that they are to be performed according to EN 62209-2:2010, Clauses 5 and 6. EN 62209-2:2010 does not, however, set out a measurement methodology for mobile communication devices featuring certain advanced functionalities that can be relevant as regards limb SAR measurement. Since the iPhone 12 A2403 has this kind of features, the development of a specific testing protocol was necessary.

4.3.3. *Tests conducted by ANFR*

(81) Firstly, the Commission agrees with the assessment and conclusion of ANFR, as described in recital 22, that protocol 1 is not an acceptable testing method.

(82) More specifically, Apple stated that SAR measurement requires the use of proprietary testing tools. Apple also indicated that the use of such tools was recommended by a manufacturer of SAR testing equipment. However, the Commission considers that the guidance issued by a testing equipment manufacturer does not have any binding value. Additionally, the Commission observes that the use of proprietary tools, especially when the algorithm governing the tools is not disclosed, is deemed inappropriate for the independent evaluation of SAR. Further, the use of proprietary engineering tools to measure the compliance of radio equipment with the relevant essential requirements not only does not ensure that the device is tested in foreseeable conditions of use, in particular when it comes to limb measurements, but also does not provide the necessary transparency and independence required in the context of market surveillance activities.

(83) Moreover, the Commission considers that the configuration suggested by Apple to ensure that the emission came only from one preselected antenna of the iPhone 12 A2403 was not duly justified.

(84) Additionally, even if harmonised standard EN 50566:2017 allows for a testing distance between 0 and 5 mm, the worst-case scenario should be considered. In other words, should the SAR level be higher at 0 mm than at 5 mm, the former testing distance should be used. Additionally, the Radio Equipment Directive Compliance Association (REDCA), formed pursuant to Article 38 of Directive 2014/53/EU, in its technical guidance note (TGN) 20, titled 'SAR Testing and Assessment Guidance', considers the test separation distance for head SAR, limb SAR and SAR in known accessories to be typically 0 mm or 'contact'.

(85) Secondly, following the agreement of protocol 2 by ANFR and Apple, the Commission has evaluated the tests conducted by ANFR and the details provided by the concerned parties, in relation to iPhone 12 A2403, on the basis of extensive consultations with ANFR, ComReg and Apple.

(86) Both Apple and ANFR agreed to use protocol 2 as an alternative to the use of Apple's proprietary testing tool.

(87) ANFR, using the services of CETECOM and carrying out measurements as set out in protocol 2, concluded that:

— Prior to the software update, the iPhone 12 A2403 exceeded the limb SAR limit value as set out in harmonised standard EN 50566:2017.

— After the software update, the iPhone 12 A2403 no longer exceeded the limb SAR limit value as set out in harmonised standard EN 50566:2017 when operating in cellular networks located in the French territory.

(88) Apple challenged the non-compliance result of the tests performed by CETECOM by stating that the device was set in a position that prevented the person performing the test from manually pushing the volume buttons to trigger the 'Body Detect' function as agreed in protocol 2. However, Apple did not substantiate this statement with any irrefutable evidence. Additionally, CETECOM, which is an accredited laboratory and thus a laboratory independently evaluated by an accreditation body, did not report any issues with pushing the volume button during the test and consequently triggering the 'Body Detect' function during the tests.

(89) Additionally, Apple indicated that CETECOM incorrectly added the SAR values of the 4G and 5G bands. That claim is deemed irrelevant since CETECOM confirmed to the Commission that the iPhone 12 A2403 exceeded the SAR limit in the 4G band alone.

(90) Apart from the concerns raised by Apple on the tests performed by CETECOM, no evidence has been identified to conclude that harmonised standard EN 50566:2017 or those tests had not been correctly applied by CETECOM.

(91) The Commission thus considers that iPhone 12 A2403 devices that do not operate with the software update iOS 17.1 are not compliant with the applicable limb SAR limit values. Therefore, such devices are not compliant with the health and safety essential requirement set out in Article 3(1), point (a), of Directive 2014/53/EU.

(92) The Commission further considers that iPhone 12 A2403 devices that operate with the software update iOS 17.1 are compliant with the applicable limb SAR limit values when the updated functionalities are fully operational, more specifically, when the software update modifies the functioning of the 'Body Detect' algorithm developed by Apple (iOS 17.1), by setting, in practice, the iPhone 12 A2403 in a permanent 'on-body' state. In that way, the software update reduces the device's transmission power.

4.3.4. *The national measure*

(93) According to the Court in its judgment of 13 September 2023, in Case T-349/21 ([23]), in market surveillance investigations and national safeguard measures, the burden of proving that a product is not compliant with the law lies with the Member State. The Commission considers that France has met that burden of proof, as it has demonstrated the need to adopt the national measure, by testing the device and providing documented information and details.

([23]) Judgment of 13 September 2023, *Federal Republic of Germany v European Commission*, T-349/21, ECLI:EU:T:2023:539, para. 83.

(94) Moreover, in light of the principle of proportionality, the seriousness of the identified risks is to be weighed against the cost of the corrective measures to be applied to the product concerned (judgment in case T-152/19 ([24]), paragraph 78). In that respect, it should be noted that iPhone 12 A2403 is an old model and is no longer placed on the Union market by Apple, although some iPhones 12 A2403 devices might still be made available by retailers. In addition, Apple can avoid the cost of withdrawal by ensuring that iPhone 12 A2403 meets the SAR levels for limb according to the protocol 2, by deploying the already developed software ensuring that those limits are respected. That software was, however, made available only for iPhones 12 A2403 operating in France, and not for any iPhone 12 A2403 operating in Member States other than France.

5. **CONCLUSION**

(95) Concerning an area in which the Commission is required to carry out complex technical assessments, in particular in order to assess the justification of national measures taken pursuant to the Union harmonisation legislation, it is allowed a broad discretion with regard to those assessments (judgment in Case T-349/21, paragraph 65).

(96) Based on the evidence available, and following a thorough assessment of the arguments of all involved parties, the technical merits of the case and the principle of proportionality, the Commission concludes that iPhone 12 A2403, when running an operating system without the software activating permanently the 'on-body' state of the 'Body Detect' function, is not compliant with the essential requirement set out in Article 3(1), point (a), of Directive 2014/53/EU.

(97) Therefore, the Commission considers that the national measure is justified.

HAS ADOPTED THIS DECISION:

Article 1

The measure taken by France, via its relevant market surveillance authority, Agence Nationale des Fréquences, notified on 5 October 2023, in accordance with Article 40(4) of Directive 2014/53/EU, via the information and communication system referred to in Article 34(1) of Regulation (EU) 2019/1020 (ICSMS) ([25]), to withdraw iPhone 12 A2403, manufactured by Apple Inc., from the market, is justified.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 19 August 2025.

For the Commission
Stéphane SÉJOURNÉ
Executive Vice-President

([24]) Judgment of the General Court of 8 September 2021, Case T-152/19, Brunswick Bowling Products LLC, formerly Brunswick Bowling & Billiards Corporation, established in Muskegon, Michigan (United States) v European Commission, ECLI:EU:T:2021:539.
([25]) Safeguard clause 2014/53/EU-F-231005-14771 | F | 4678.