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No. 12091/2022 REGISTER OF COLLEGIATE COURT MEASURES
No. 02897/2022 REGISTER OF PROCEEDINGS

I T A L I A N R E P U B L I C

IN THE NAME OF THE ITALIAN PEOPLE

The Regional Administrative Court of Lazio (TAR)

(Section Two)

Issued the following

JUDGMENT

On the proceeding under General Register number 2897 of 2022, filed by JT International Italia S.r.l., in the person of its *pro tempore* legal representative, represented and defended by Attorney Maurizio Zoppolato, with digital address for service as per the certified e-mail address (PEC) in the Court Records and physical domicile elected at its office in Rome, Via Properzio no. 5;

Against

The Customs and Monopolies Agency and the Ministry of Health, in the person of their respective *pro tempore*, legal representatives, represented and defended by the Attorney General's Office, statutorily domiciled in Rome, Via dei Portoghesi, 12;

for the annulment

- of the Directorial Determination of March 14, 2022, reg. 113025/RU, by which the Excise, Customs and Monopolies Agency ordered the radiation of the respective sale tariff, with the consequent sale ban, except for the supplies already stocked at tobacco shops, of manufactured tobacco brands "*3468 - Camel Activate" and "3543 - Winston Expand*";

of any other pre-established, presumed, consequential and/or anyhow related action, herein included the notice of start of the proceeding to the EU Commission of November 19, 2021 and the Notice to the JTI requesting submission of observations by December 30, 2021.

Having regard to the proceeding and its respective annexes;
Having regard to the entry of appearance by pleadings filed by the Customs and Monopolies Agency and of the Ministry of Health;
Having regard to all the pleadings filed in this lawsuit;
Mr. Michele Tecchia, in his capacity as Rapporteur for the public hearing of September 21, 2022 and having heard the defense counsels for the parties as specified in the Court report; Having considered in fact and in law as follows.

STATEMENT OF FACTS

The Plaintiff - a multinational company operating in the tobacco products distribution industry - hereby requests the annulment of the Directorial Determination of March 14, 2022, reg. 113025/RU, by which the Customs and Monopolies Agency (hereinafter also referred to as "ADM") ordered the elimination of the sale tariff, with the consequent sale ban of "*Camel Activate*" and "*Winston Expand*" manufactured tobacco brands, as they contain "characterizing flavors" whose sale to the public is banned pursuant to Art. 8 of Legislative Decree no. 6/2016.

The objections summarized hereinafter support the motion for annulment:

(i) Failure to comply with the EU procedure provided for this purpose by Regulation EU 2016/779, in order to establish whether a tobacco product actually contains a «*characterizing flavor*»;

(ii) Failure to suspend the administrative proceeding preluding the adoption of the appealed Directorial Determination, even if an identical procedure for the same products had already been started in another EU country (Sweden), which is in breach of article 5,

Paragraph 2 of the above-mentioned Regulation EU 2016/779, pursuant to which «*if a Member State has started a procedure, all other Member States shall abstain from starting a parallel procedure for the same product. If any procedures pertaining to the same product have been started in two or more Member States, only the Member State where the procedure was first started may continue with the procedure. ... All procedures started in Member States other than the Member State that starts the procedure are suspended awaiting the adoption of the decision of the Member State that starts the procedure*»;

(iii) Failure to comply - during the laboratory analysis phase of the flavors contained in the manufactured tobacco brands "*Camel Activate*" and "*Winston Expand*" - of the analysis methodology with the EU procedure provided for this purpose;

(iv) inaccurate assessment of the presence of characterizing flavors in "*Camel Activate*" and "*Winston Expand*" manufactured tobacco brands.

ADM appeared before the Court according to standard procedure, seeking that the proceeding be dismissed.

The outcome of the judges chamber of April 6, 2022 scheduled for the enforcement of the precautionary motion, with a preliminary Court Order published on April 14, 2022 the Court, having deemed necessary to verify whether the products released on the Swedish market, subject of the assessment in that Member State, could be qualified as "*the same product*", pursuant to Art. 2 of Implementing Regulation 2016/779, with regard to products released on the Italian market and subject to the ADM assessment - ordered ADM to create a detailed preliminary report with documentary evidence (Art. 63 Code of Administrative Procedure (CPA)), which would substantiate the evidence of the preliminary findings implemented by the Italian Authority in order to rule out that the products being verified in Italy, could be qualified as the "*same product*" with reference to the products being verified in Sweden.

In the course of the term for the filing of the above-mentioned preliminary report, with a motion *ex* Art. 116, paragraph two, Code of Administrative Procedure (CPA), filed on May 4, 2022, the Plaintiff filed a petition for the verification of the right to access all the documents requested to the ADM, after declaration of illegality of the implicit denial arising after ADM failed to respond to the motion to access filed by the plaintiff on March 25, 2022.

Subsequently, following additional submissions by ADM, with a brief filed on June 27, 2022 the Plaintiff acknowledged that "*only in view of the upcoming Judges Chambers to rule on the precautionary motion, the Excise, Customs and Monopolies Agency (hereinafter "ADM" or "Agency") produced the documents, concurrently filing a brief where ADM: a) states that it has "always" promptly produced the requested documents; b) states that there is no other documentation in the folder for this lawsuit and, in particular, no document exchange occurred between ADM and the Commission; c) persists in stating that the Motion to access by JT INTERNATIONAL Italia S.r.l. (hereinafter "JTI Italia" or "the Company") has a generic significance, aiming to monitor the overall conduct of the Public Administration. In light of the new document production, as well as the stated absence of any other document, JTI Italia acknowledges the discontinuance of the matter at issue pertaining to the motion to access and without prejudice to the lawsuit in the caption herein*".

On July 7, 2022, the ADM filed in the records the preliminary report ordered by the Court.

With a brief filed on September 1, 2022, accompanied by the authorization application to the late filing of documents, the Plaintiff filed in the records the decision by which the European Commission had authorized - only on August 10, 2022 - access to the correspondence between ADM and the actual European Commission in relation to the contentious administrative proceeding (for which access the Plaintiff lodged a motion in Europe

on March 24, 2022, relying of the so-called FOIA), as well as some letters comprised in the correspondence, specifically the ADM letter of March 17, 2021 and the European Commission note of April 16, 2021.

At the public hearing of September 21, 2022 the Court - after discussing the lawsuit - entered the latter in the decision.

LAW

In limine litis, all the Court can do is to acknowledge the supervening termination of the matter at issue with reference to motion to access intra-proceeding documentation filed by the Plaintiff *ex* Art. 116, paragraph two, Code of Administrative Procedure (CPA), just express statement provided in this connection by the actual plaintiff with a brief filed on June 27, 2022, which shows that the requested documents were disclosed.

As pertaining to the Plaintiff's motion requesting authorization to the late filing of certain documents that were only provided on September 1, 2022 (namely, the European Commission decision of August 10, 2022, the ADM letter of March 17, 2021 and the European Commission note of April 16, 2021), this Court deems that this motion may be granted, recognizing the grounds for relief from the time limit *ex* Art. 37 Code of Administrative Procedure (CPA), as the *de quibus* documents were drafted and/or produced only after the document submission deadline *ex* Art. 73, paragraph 1, Code of Administrative Procedure (CPA).

Now therefore, procedurally, the Court deems it essential - before scrutinizing the merit of the grounds for an appeal - a brief systematic overview of the EU and national legislation framework where the *de qua* matter.

The contentious matter is that of the ban imposed at the European and Italian national level, on the trade of tobacco products containing "characterizing flavors" (case in point, the matter pertained to the presence of **menthol** in the product composition), discussing more specifically the

procedure suitable to establish when a product may or may not be deemed to contain "*characterizing flavors*".

In Europe, the matter is governed first and foremost by the 2014/40/EU Directive of April 3, 2014 of the European Parliament and of the European Council (hereinafter also the "Directive"), whose implementation was then regulated by European Commission Implementing Regulation no. 2016/779 of May 18, 2016.

The Directive intervenes on the alignment/reconciliation of legislative, regulatory and administrative provisions of the Member States, pertaining to the processing, presentation and sale of tobacco products and related products.

In particular, the Directive prohibits the sale of tobacco products containing excessive additive flavors of tobacco, as those flavors - where they are excessive and other than tobacco - they end up being "characterizing" and, therefore, «*they could encourage the initiation of tobacco consumption or could affect consumption models*» (Consideration no. 16).

In summary, the presence of flavors such as **menthol** in our case in point, is not absolutely barred, as the Directive is seeking to avoid a content thereof that is such as to flavor to a characterizing extent the product in relation to the tobacco.

In this perspective, in «*taking into account the potential attractiveness of such products on young people and non-smokers*» (Consideration no. 47), and assuming that the prevalence of a flavor other than tobacco may induce a greater consumption, the Directive provides that the Member States ban the release on the market of products featuring said "*characterizing flavor*", referring the Commission to the discipline of the procedure aiming to establish when a product actually contains a characterizing flavor.

In detail, Art. 7, paragraph 1, of the Directive provides that "*Member States shall prohibit the placing on the market of tobacco products with a characterising flavour*", while Art. 7, paragraph 3, provides that "*[t]he*

Commission shall adopt implementing acts laying down uniform rules for the procedures for determining whether a tobacco product falls within the scope of paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 25(2)".

As mentioned earlier, Regulation EU 2016/779 of May 18, 2016 (hereinafter also the "Regulation") intervened in the implementation of the Directive, governing - insofar as the *de quo* case is concerned - the specific procedure that shall be complied with by each Member State before banning the trade of a tobacco product whose characterizing flavor content has been detected.

The procedure unravels through the following essential steps:

- the Member State, first and foremost, must notify the manufacturer that one of its tobacco products could contain a characterizing flavor, also requesting the manufacturer to submit its assessment (see Art. 4, par. 1 of the Regulation);
- the manufacturer may in turn submit any written observations within a 4-weeks deadline from the date of receipt of the initial notice (see Art. 4, par. 2 of the Regulation);
- the Member State must mandatorily notify the start of the procedure - as well as all information received by the manufacturer - also to the European Commission and to all other Member States (see Art. 5, par. 1 of the Regulation);
- if the manufacturer disputes the presence of any characterizing flavors inside its own tobacco product, the procedure continues pursuant to articles 7 and 8 of the Regulation (see Art. 6, par. 2 of the Regulation), thus the relevant Member State may request additional information to the manufacturer, which must in turn provide them in compliance with the term specified in the request of the Member State (see Art. 7, par. 1 of the Regulation);
- the Member State that requested additional information to the manufacturer pursuant to article 7 of the Regulation and that, duly taking this

information into account, should deem that a product has a characterizing flavor, before adopting a decision, allows the manufacturer the possibility to submit additional written observations (see Art. 8, par. 1 of the Regulation). In particular, the relevant Member State submits to the manufacturer a summary of the reasons why the proposed decision should be adopted. In turn, the manufacturer has four weeks to submit its observations thereof;

- lastly, the relevant Member State drafts, based on its available information, a decision-making project aimed to establish whether the product should be deemed as actually having a banned characterizing flavor. The relevant Member State submits said decision project to the Commission and to the other Member States. The final decision may be adopted only after the lapsing of a four-weeks period from the submission of a decision project. This period may be extended by mutual agreement between the Member State that starts the procedure and the Commission (see Art. 9, par. 1 of the Regulation);

- the Commission and the other Member States may submit comments on the decision project within a three-weeks period from its submission. Any objections to the conclusions contained in the decision project are duly motivated (see Art. 9, par. 2 of the Regulation).

The involvement of the European Commission and of the other Member States in the above-mentioned Italian national procedure, is aimed to guarantee the even application of the EU rules in the entire territory of the European Union, in order to ward off any inequalities and differential treatment that may be potentially prejudicial to freedom of trade in the European Single Market.

As far as what concerns the specific analysis methodologies of the substances contained in the tobacco product, the European Commission - pursuant to Art. 7, paragraph 3, of the Directive (actually referring to

Execution proceedings of the European Commission, the scientific assessment procedure for the presence of characterizing flavors) - governed said aspect by execution proceeding of March 11, 2021 (decision 2021/C 89 I/01), by which it approved "*a method for the technical assessment of products being tested helping to identify tobacco products with a characterizing flavor*".

As to the scope of application in the EU and at Italian national level, said European Directive has been duly recognized by Legislative Decree no. 6 of 2016 that:

- defined as characterizing flavor «*a smell or taste that is clearly distinguishable, other than tobacco flavor, resulting from an additive or a combination of additives, including, but not limited to fruit, spice, herb, alcohol, candy,* ***menthol*** *or vanilla, which is noticeable before or during the consumption of tobacco* product» (Art. 2, letter dd);

- allowed «*the use of additives essential to the processing of tobacco products, such as sugar to replace the sugar lost during the curing process, unless said additives should result in a product with characterizing flavor that significantly and quantifiably increase the addictiveness potential and toxicity of tobacco products, or its, CMR (Carcinogenic, Mutagenic, Reprotoxic) properties as specified by the decree issued pursuant to article 26, paragraph 2*» (Art. 8, paragraph 2);

- banned the release on the market of tobacco products with characterizing flavor *«identified by decree issued pursuant to article 26, paragraph 2»* (Art. 8, paragraph 1).

In summary, the Italian legislator relied on a *ministerial decree* whose duty was to define the analysis methodology to detect the presence of characterizing flavors in tobacco products.

However, the above-mentioned Ministerial Decree was never issued, consequently, the only regulatory source that ended up governing the analysis methodology of characterizing flavors is the one

approved - at the European level - with the above-mentioned Decision of the European Commission no. 2021/C 89 I/01 of March 11, 2021.
Having reconstructed the general regulatory framework, at this point we may scrutinize the merit of the grounds for an appeal.

The Court deems both the first and the third grounds for appeal to be well-founded.
The Court actually recognizes, on the one hand, the breach of the EU procedure provided for this purpose by Regulation EU 2016/779 (see the first ground for appeal) and, on the other hand, the failure to comply - in the phase of laboratory analysis of the flavors contained in "*Camel Activate*" and "*Winston Expand*" products - of the method of analysis equally established by the EU (see third ground for appeal).
Regarding the first aspect, documentary (*per tabulas)* evidence attest that ADM procedure was actually implemented as follows:
- on November 19, 2021 ADM notified the European Commission and the Member States (see Art. 5, par. 1 of the Regulation) about its intention to start a proceeding against the Plaintiff for the purpose of banning the sale of "*Camel Activate*" and "*Winston Expand*" manufactured tobacco brands, because of the possible presence of characterizing flavors in their contents;
- on December 30, 2021 ADM notified the plaintiff company about the start of the proceeding (see Art. 4, par. 1 of the Regulation);
- on January 24, 2022 the Plaintiff company filed a counterclaim in defense within the 4-weeks established deadline granted thereof (see Art. 4, par. 2 of the Regulation), disputing the presence of characterizing flavors and seeking access to laboratory analysis certificates used by ADM, as well as requesting suspension of the proceeding in light of the fact that an identical proceeding had already been lodged in Sweden and, lastly, nonetheless, invoking a proceeding extension through March 7, 2022 because of the need to examine any laboratory certificates provided by ADM;
- on February 2, 2022 ADM only granted access to some of the documents

requested, while it instead rejected the request to suspend the procedure stating that the products subject to Swedish investigation were different than the Italian products. No response was instead provided to the request for an extension of the conclusion term of the procedure;

- on February 15, 2022 the Plaintiff company reiterated again that the procedure be suspended and also stated that the presence of characterizing flavors has not been ascertained in compliance with the official procedure established by the European Commission;

- on March 10, 2022 ADM adopted the sales tariff elimination resolution that was appealed.

So, the historical timeline of the main procedural steps actually implemented by ADM demonstrates the omission of at least one essential requirement prescribed by Regulation EU 2016/779, namely, submission of the final decision project to the other Member States and to the European Commission, after which submission at least 4 weeks should have lapsed before adoption of the sales tariff elimination provision (see Art. 9, par. 1 of the Regulation).

It further appears that ADM had notified to the other Member States - in breach of the provision of Art. 5, par. 1, of the Regulation - the information received by the plaintiff company during the course of the proceeding.

Therefore, both the obligation to submit to the European Commission and to the other Member States the information received by the plaintiff company during the course of the proceeding, as well as the obligation to submit to said entities the final decision project have been breached.

Moving to the pathological profile, conveyed with the third ground of appeal, - at the time when the presence of characterizing flavor was assessed - the official analysis method established for that purpose by the EU appears not to have been applied.

It is undisputed that in the month of February 2021 - well before the official start of the procedure against the plaintiff company - ADM relied on the Laboratory in Palermo for the chemical analysis of the contentious products. The laboratory clearly could not have relied on the EU protocols as they had only been approved the following month (see European Commission Decision no. 2021/C 89 I/01 of March 11, 2021).

In consideration of the official start of the procedure to verify the presence of characterizing flavors, implemented with ADM notes of November 19, 2021 and December 30, 2021 (the first addressed to the European Commission and the second addressed to the Plaintiff) and that at that time the analysis method approved by the European Commission had by then come into effect (see European Commission Decision no. 2021/C 89 I/01 of March 11, 2021), ADM should have implemented said analysis method on the *de quibus* products.

It should be noted that said method was not just a “good practice” recommended by the European Commission within the scope of a *soft law*, but rather a *modus operandi* binding and mandatory *ex* Art. 7, paragraph 3, of the Directive that actually refers to execution proceedings by the European Commission - such as for instance the above-mentioned Decision no. 2021/C 89 I/01 of March 11, 2021 - the procedure to assess the presence of characterizing flavors.

ADM has not observed the above-mentioned *modus operandi* and preferred to rely instead on the scientific analyses made by the Laboratory in Palermo in the month of February 2021, made well before the start of the proceeding in November 2021.

It also emerged that the analysis method used by ADM at the Laboratory in Palermo was much less structured and thorough in relation to the analysis approved by the European Commission by Decision no. 2021/C 89 I/01 on March 11, 2021 since the first method takes into account a single assessment (rather than the two phases provided by the European methodology), assessing products based on 6 sensory attributes (rather than 51 sensory attributes provided by the European methodology).

For the sake of thoroughness, it should be added that if on the one hand it is absolutely legitimate for ADM to implement certain *preliminary* and *early* laboratory analyses in the month of February 2021 rather than at the official start time of the sales tariff elimination procedure in the month of November 2021, - analyses whose aim was understandably to sieve through *ex ante* the "soundness" of a possible objection for characterizing flavors - nonetheless, the subsequent approval in the month of March 2021 (*id est* however eight months *before* the official start of the proceeding in November) of a different methodology within the EU, made a preliminary investigation supplement necessary consisting in the audit of the findings of said analyses in Palermo, in light of the supervening EU protocol.

Not just because said protocol was mandated by the Directive, but also - and even earlier - because this is the only way that ADM could have thoroughly complied with the underlying objective of the entire EU subject matter legislation protocol, namely, to apply in all Member States *even* and *homogeneous* detection methods of the presence of characterizing flavors in tobacco products.

The need for the above-mentioned preliminary investigation supplement is further confirmed if one takes into account - in a perspective of balancing opposing interests - also the serious economic impact that may arise from the appealed injunction proceeding.

The significant procedural breaches described herein - that undoubtedly integrate preliminary investigation shortcomings - may only result in the Annulment of the appealed provision, as the remedy mechanism set forth in Art. 21-*octies*, paragraph two, law 241/1990 is not applicable for relief herein.

It is actually well-known that Art. 21-*octies*, paragraph two, law no. 241 of 1990, establishes that - except in content-bound provision - voidability of a discretionary proceeding for breach of procedural standards may be avoided during legal proceedings, by demonstrating that its content could not have been any different, only if the standard is breached requiring the mandatory notification of the start of the proceeding.

As a result thereof, in the presence of discretionary proceedings, the breach of any other procedural standards - other than the standard mandating notification of the start of the proceeding - may not benefit from the special remedying regime for content-bound proceedings *ex* Art. 21 *octies*, paragraph two, law no. 241 of 1990.

In this specific case, it is clear that the assessment on the presence of characterizing flavors implies technical discretion, whose content is not predetermined by law to resorting to prerequisites that may be measured objectively, thus the defect consisting in not having complied with the proper procedure, may only result in the Annulment of the proceeding.

To all of the above, for the sake of thoroughness, it should be added that even if the appealed provision was of a content-bound nature, it would have nonetheless be exempt from formal defects de-quotation regimen of Art. 21-*octies*, paragraph two, law no. 241 of 1990, whereas that regimen implies that "*it is clear that its enacting content could not have been anything other than the one concretely adopted*".

In this specific case, it is absolutely not clear that - in case of adoption of the official analysis method approved by the European Commission

- the enacting content of the provision would have been the same.

In conclusion, the first and the thirds ground for appeal shall be granted as well-founded, with consequent deletion of any additional objection claims arising from the second and fourth ground for appeal (herein including the ground stating the failure to suspend the Italian procedure because of the parallel pending proceeding in Sweden).

The result thereof is the annulment of the Directorial Determination appealed for lack of preliminary investigation, without prejudice to the Administration ability to reiterate the *de quo* power in compliance with the compliance restriction arising from this judgment.

Litigation costs and expenses shall be borne by the losing party and are settled as stated in the judgment.

FOR THESE REASONS

The Regional Administrative Court of Lazio (Section Two), issues a final judgment on the legal action, as indicated in the caption, orders as follows:

a) declares the termination of the matter at issue in relation to the motion for access *ex* Art. 116, paragraph two, Code of Administrative Procedure (CPA);

b) grants the motion for annulment according to the terms indicated in the grounds, with consequent annulment of the Directorial Determination of the Customs and Monopolies Agency of March 14, 2022, reg. 113025/RU. Sentences the Customs and Monopolies Agency to remit payment to the Plaintiff of Court and legal fees, in the amount of Euro 2,000.00 (two-thousand/00), plus statutory incidental expenses and reimbursement of the standard Court fee, if remitted.

Orders the enforcement of this judgment by the Administrative Authority.

So ordered in the judge's chambers in Rome, on September 21, 2022, with the following judges:

Francesco Riccio, Presiding Judge

Eleonora Monica, Counselor

Michele Tecchia, Rapporteur, Reporting Judge

DRAFTING JUDGE	PRESIDING JUDGE
Michele Tecchia	**Francesco Riccio**

MAGISTRATE CLERK