



NIT 2018 IN

OTTAWA, October 5, 2018

## STATEMENT OF REASONS

Concerning the Initiation of an Investigation into the Dumping of

CERTAIN NITISINONE CAPSULES  
FROM SWEDEN

## DECISION

Pursuant to subsection 31(1) of the *Special Import Measures Act*, the Canada Border Services Agency initiated an investigation on September 21, 2018 respecting the alleged injurious dumping of certain nitisinone capsules from Sweden.

Cet *Énoncé des motifs* est également disponible en français.  
This *Statement of Reasons* is also available in French.

---

## TABLE OF CONTENTS

<b>SUMMARY</b> .....	1
<b>INTERESTED PARTIES</b> .....	1
COMPLAINANT .....	1
TRADE UNIONS .....	2
EXPORTERS .....	2
IMPORTERS.....	2
<b>PRODUCT INFORMATION</b> .....	3
DEFINITION .....	3
ADDITIONAL PRODUCT INFORMATION .....	3
PRODUCTION PROCESS.....	3
CLASSIFICATION OF IMPORTS.....	4
<b>LIKE GOODS AND SINGLE CLASS OF GOODS</b> .....	4
<b>THE CANADIAN INDUSTRY</b> .....	5
STANDING .....	5
<b>CANADIAN MARKET</b> .....	5
<b>EVIDENCE OF DUMPING</b> .....	6
NORMAL VALUES.....	7
EXPORT PRICE.....	8
ESTIMATED MARGINS OF DUMPING .....	9
<b>EVIDENCE OF INJURY</b> .....	9
PRICE UNDERCUTTING .....	9
LOSS OF SALES.....	10
REDUCED PROFITABILITY AND DECLINE IN PRODUCTION .....	10
NEGATIVE RETURNS ON INVESTMENT.....	11
UNDERUTILIZATION OF PRODUCTION CAPACITY .....	11
NEGATIVE EFFECTS ON GROWTH.....	12
CBSA'S CONCLUSION – INJURY .....	12
<b>THREAT OF INJURY</b> .....	12
CAPACITY OF THE FOREIGN PRODUCER .....	12
RISK OF FURTHER PRICE UNDERCUTTING .....	13
CBSA'S CONCLUSION – THREAT OF INJURY.....	13
<b>CAUSAL LINK – DUMPING, INJURY AND THREAT OF INJURY</b> .....	13
<b>CONCLUSION</b> .....	14
<b>SCOPE OF THE INVESTIGATION</b> .....	14
<b>FUTURE ACTION</b> .....	14
<b>RETROACTIVE DUTY ON MASSIVE IMPORTATIONS</b> .....	15
<b>UNDERTAKINGS</b> .....	16
<b>PUBLICATION</b> .....	16
<b>INFORMATION</b> .....	16

## **SUMMARY**

[1] On August 2, 2018, the Canada Border Services Agency (CBSA) received a written complaint from Laboratoires KABS Inc. and its associated company MendeliKABS Inc. of Saint-Hubert, Quebec, (hereinafter, “the complainant”), alleging that imports of certain nitisinone capsules (NIT) from Sweden are being dumped. The complainant alleged that the dumping has caused injury and is threatening to cause injury to the Canadian industry producing like goods.

[2] On August 23, 2018, pursuant to paragraph 32(1)(a) of the *Special Import Measures Act* (SIMA), the CBSA informed the complainant that the complaint was properly documented. The CBSA also notified the government of Sweden that a properly documented complaint had been received.

[3] The complainant provided evidence to support the allegation that NIT from Sweden has been dumped. The evidence also discloses a reasonable indication that the dumping has caused injury and is threatening to cause injury to the Canadian industry producing like goods.

[4] On September 21, 2018, pursuant to subsection 31(1) of SIMA, the CBSA initiated an investigation respecting the dumping of NIT from Sweden.

## **INTERESTED PARTIES**

### **Complainant**

[5] Founded in 1997, Laboratoires KABS Inc. is a company that specializes in drug development and contract manufacturing. The head office and production facilities of Laboratoires KABS Inc. are located in Longueuil, Quebec. MendeliKABS Inc. is an affiliated company that is the promoter of NIT produced by Laboratoires KABS Inc. and has been granted market authorization and accreditation by Health Canada. The complainant is the only producer of NIT in Canada.

[6] The contact information of the complainant is as follows:

Laboratoires KABS Inc.  
4500, rue de Tonnancour  
Saint-Hubert, Quebec  
J3Y 9G2

MendeliKABS Inc.  
4601, rue de Tonnancour  
Saint-Hubert, Quebec  
J3Y 9J3

## **Trade Unions**

[7] The complainant has indicated that there are no trade unions that represent persons employed in the production of NIT in Canada.

## **Exporters**

[8] The complainant identified a single exporter of the subject goods and a contract manufacturer that produces the subject goods. An examination of CBSA import documentation has confirmed the identity of the exporter identified by the complainant.

Exporter:

Swedish Orphan Biovitrum AB (Sobi)  
Tomtebodavägen 23A  
SE-112 76 Stockholm  
Sweden

Producer:

Apotek Produktion & Laboratorier (Apotek)  
Box 5071  
141 05 Kungens Kurva  
Sweden

[9] In addition to the complainant, there are only two parties that are approved by Health Canada to sell NIT in Canada. Sobi, the exporter located in Sweden, has approval to sell NIT produced by Apotek through its subsidiary Swedish Orphan Biovitrum Canada, Inc. (Sobi Canada). The other party approved by Health Canada is Cycle Pharmaceuticals, a British company that produces like goods through a contract manufacturer in Switzerland.<sup>1</sup>

## **Importers**

[10] The CBSA identified five potential importers of the subject goods from CBSA import documentation and from information submitted in the complaint.

---

<sup>1</sup> NIT Complaint (NC) – Para 107.

## **PRODUCT INFORMATION**

### **Definition<sup>2</sup>**

[11] For the purpose of this investigation, subject goods are defined as:

*Capsules and tablets of nitisinone with a dosage of 2 mg, 5 mg, 10 mg and 20 mg, whether or not they are packaged for retail, originating in or exported from the Kingdom of Sweden.*

### **Additional Product Information<sup>3</sup>**

[12] The goods in question are commonly called nitisinone capsules (NIT). The chemical name and the active molecule of nitisinone is 2 (2 Nitro 4 Trifluoromethylbenzoyl) 1, 3 Cyclohexanedione (“NTBC”) and its molecular form is C<sub>14</sub>H<sub>10</sub>F<sub>3</sub>NO<sub>5</sub>.

[13] Nitisinone is a drug approved for the treatment of hepatorenal tyrosinemia type 1 (HT-1). HT-1 is a rare metabolic disease affecting approximately 1000 persons worldwide. Prevalence of this disease is particularly in Quebec, where approximately 100 persons receive NIT as treatment for HT-1.

[14] NIT is an orally administered drug. The capsules contain a powder of nitisinone and a pharmacologically inert substance. These drugs are sold in hospital and community pharmacies by prescription.

[15] The product definition includes nitisinone that is packaged for retail consumption at the time it is imported, that is, packaged in plastic or glass containers with an exact unit count of the capsules. In general, these containers contain sixty (60) capsule units with the same dosage. Blister pack-type containers are also included, as well as containers containing more or less than 60 capsules.

[16] The product definition also includes nitisinone that is not packaged for retail consumption at the time it was imported, that is, in bulk containers intended for bottling or packaging in Canada.

[17] The product definition does not include nitisinone in liquid suspension.

### **Production Process**

[18] The NIT production process can be subdivided into two elements; the production of the medicinal ingredient nitisinone and the assembly of the ingredients into a capsule.

---

<sup>2</sup> NIT Complaint (NC) – Para 38 and amendment to the product definition received on August 21, 2018.

<sup>3</sup> NIT Complaint (NC) – Para 42-70.

[19] First, the chemical compound nitisinone is synthesized under controlled laboratory conditions. It is then combined with an inert substance and encapsulated in the desired proportions. The non-medicinal ingredients used by the complainant include corn starch, titanium dioxide, gelatin, shellac and iron oxide. The non-medicinal ingredients used by the manufacturer of the subject goods differ slightly, however, this does not affect the substitutability of the products. The assembled capsules are then bottled in plastic containers, each containing 60 units of the specified dosage.

### **Classification of Imports**

[20] The allegedly dumped goods are normally classified under the following tariff classification numbers (tariff numbers):

3003.90.00.90  
3004.90.00.79  
3004.90.00.90

[21] The listing of tariff numbers is for convenience of reference only. The tariff numbers include non-subject goods. Also, subject goods may fall under tariff numbers that are not listed. Refer to the product definition for authoritative details regarding the subject goods.

### **LIKE GOODS AND SINGLE CLASS OF GOODS**

[22] Subsection 2(1) of SIMA defines “like goods” in relation to any other goods as goods that are identical in all respects to the other goods, or in the absence of any identical goods, goods the uses and other characteristics of which closely resemble those of the other goods.

[23] According to the complainant, with respect to subject goods, like goods consist of domestically produced NIT which falls within the product definition.

[24] NIT produced by the complainant has the same physical characteristics and end uses as the subject goods imported from Sweden. The goods produced in Canada and Sweden are bioequivalent products that compete directly with each other in the Canadian market, and are fully interchangeable.

[25] After considering questions of use, physical characteristics and all other relevant factors, the CBSA is of the opinion that domestically produced NIT are like goods to the subject goods. Further, the CBSA is of the opinion that subject goods and like goods constitute only one class of goods.

## **THE CANADIAN INDUSTRY**

[26] The complainant is the only producer of NIT in Canada and accounts for all of the domestic production of the like goods.<sup>4</sup>

### **Standing**

[27] Subsection 31(2) of SIMA requires that the following conditions for standing be met in order to initiate an investigation:

- a. the complaint is supported by domestic producers whose production represents more than 50% of the total production of like goods by those domestic producers who express either support for or opposition to the complaint; and
- b. the production of the domestic producers who support the complaint represents 25% or more of the total production of like goods by the domestic industry.

[28] As the complainant is the only producer in Canada, the conditions for standing have been met.

## **CANADIAN MARKET**

[29] The complainant provided estimates of imports into Canada and their own annual production and sales of like goods.

[30] Sales of NIT in Quebec represent over 88% of the total Canadian domestic market by volume. The purchasing and distribution of NIT to all patients in Quebec is performed by the pharmacy of the Ste-Justine Hospital in Montreal. The pharmacy of the Ste-Justine Hospital acquires pharmaceutical products, medical supplies and services by means of a non-profit buying group called SigmaSanté. SigmaSanté is responsible for issuing tenders and managing the resulting supply contracts. The SigmaSanté tender number 2018-4777-00-01 published on September 27, 2017 covers the exclusive supply of NIT to all Quebec patients for a period of three years beginning on April 1, 2018. The complainant lost this supply contract to the allegedly dumped goods from Sweden.<sup>5</sup> The complainant continues to supply NIT to the majority of patients located outside of the province of Quebec.

[31] The complainant indicates that the imports of the subject goods represent nearly all imports of NIT originating from all countries during the period from July 1, 2017 to June 30, 2018.<sup>6</sup> The complainant states that a single other exporter has received Health Canada approval for NIT produced in Switzerland, however, it has not supplied the drug in Canada in significant commercial quantities at this time.

---

<sup>4</sup> NIT Complaint (NC) – Para 108.

<sup>5</sup> NIT Complaint (NC) – Para 131.

<sup>6</sup> NIT Complaint (NC) – Para 107.



[32] The CBSA conducted its own analysis of imports of the goods based on the CBSA's import data and based on commercial intelligence provided in the complaint.

[33] Detailed information regarding the volume and value of imports of NIT and domestic production cannot be divulged for confidentiality reasons. The CBSA, however, has reviewed the import data and validated the information provided by the complainant with respect to the quantity and relative share of imports from Sweden and Switzerland.

[34] The CBSA will continue to gather and analyze information on the volume of imports during the period of investigation (POI) of January 1, 2018 to June 30, 2018 as part of the preliminary phase of the dumping investigation and will refine these estimates.

### **EVIDENCE OF DUMPING**

[35] The complainant alleged that NIT from Sweden has been injuriously dumped into Canada. Dumping occurs when the normal value of the goods exceeds the export price to importers in Canada.

[36] Normal values are generally based on the domestic selling price of like goods in the country of export where competitive market conditions exist or as the aggregate of the cost of production of the goods, a reasonable amount for administrative, selling and all other costs, and a reasonable amount for profits.

[37] The export price of goods sold to importers in Canada is generally the lesser of the exporter's selling price and the importer's purchase price, less all costs, charges and expenses resulting from the exportation of the goods.

[38] Estimates of normal values and export prices are discussed below.



## Normal Values

[39] The complainant estimated normal values according to the methodology of section 15 of SIMA based on publically available information regarding the selling prices of NIT between distributors and producers to pharmacies in the Swedish domestic market. The Swedish healthcare system provides reimbursement of pharmaceutical products to residents under certain conditions. For drugs that have generic competition, the suppliers must compete on a monthly process to be selected as the “product of the month”.<sup>7</sup> This process will determine which drug will be covered for reimbursement by the Swedish Dental and Pharmaceutical Benefits Agency and can be dispensed by pharmacies.

[40] This information is made available and updated monthly through website of the Dental and Pharmaceutical Benefits Agency of Sweden.<sup>8</sup> The complainant reported the most recent monthly selling price of NIT in dosages of 2, 5 and 10 mg as of June 30, 2018. These prices were converted to Canadian dollars using the monthly average exchange rate quoted by the Bank of Canada for the period.<sup>9</sup> While both the complainant and the exporter produce and have Health Canada approval to market NIT with a dosage of 20 mg in Canada, this product has not been subject to a public tender.

[41] Based on the information available at this time, the CBSA found the complainant’s section 15 normal value estimates to be reasonable and representative. As such, the CBSA adopted the same methodology.

---

<sup>7</sup> PPRI Pharma Profile

[https://www.tlv.se/download/18.1d85645215ec7dc284611ebd/1510316381520/ppri\\_pharma\\_profile\\_sweden\\_2017.pdf](https://www.tlv.se/download/18.1d85645215ec7dc284611ebd/1510316381520/ppri_pharma_profile_sweden_2017.pdf)

<sup>8</sup> The Dental and Pharmaceutical Benefits Agency of Sweden price database

<https://www.tlv.se/beslut/sok-i-databasen.html>

<sup>9</sup> NIT Complaint (NC) – Para 157-176.

[42] The estimated normal values that were used in the CBSA's estimated margin of dumping calculation are summarized in Table 1 below.

**Table 1**  
***CBSA and Complainant's Estimates of Normal Values (Price per 60 count bottle)***

<b>Dosage</b>	<b>Normal Value (CAD)</b>
2 mg	\$1,029.36
5 mg	\$2,058.66
10 mg	\$3,656.05
20 mg	N/A

### **Export Price**

[43] The export price of goods sold to an importer in Canada is generally determined in accordance with section 24 of SIMA as being an amount equal to the lesser of the exporter's sale price for the goods and the price at which the importer has purchased or agreed to purchase the goods adjusted by deducting all costs, charges, expenses, and duties and taxes resulting from the exportation of the goods.

[44] The complainant estimated export prices using the methodology of section 24 of SIMA based on market intelligence respecting the exporter's selling prices to Canada for the SigmaSanté tender number 2018-4777-00-01. However, the complainant is of the opinion that the export prices estimated under section 24 should not be used because a party related to the exporter is likely the importer for SIMA purposes. As such, the complainant also estimated export prices using the methodology of paragraph 25(1)(c) of SIMA by deducting an amount for freight, selling expenses and an amount for profit from the selling price of the goods in Canada based on the SigmaSanté tender.<sup>10</sup>

[45] The CBSA reviewed the customs entry documentation and reports generated through the Facility for Information Retrieval Management for each individual importation from January 1, 2018 to June 30, 2018. After reviewing all customs entries relating to the imports of the subject goods and examining elements in the complaint, the CBSA was not able to conclude that the likely importer of the goods for the purposes of SIMA is related to the exporter. As such, based on the information available at this time, the CBSA finds the complainant's proposed methodology of estimating export prices using the methodology of section 24 of SIMA based on market intelligence respecting the exporter's selling prices to Canada to be an appropriate and conservative approach. As required under paragraph 24(a)(iii) of SIMA, the CBSA deducted an amount for costs, charges and expenses resulting from the exportation of the goods based on actual expenses recorded in the import documentation for the subject goods.

---

<sup>10</sup> NIT Complaint (NC) – Para. 177-187.

## **Estimated Margins of Dumping**

[46] The CBSA estimated the margin of dumping by comparing the weighted average estimated normal value with the weighted average estimated export price of the subject goods imported during the period of January 1, 2018 to June 30, 2018. Based on this analysis, it is estimated that NIT imported into Canada from Sweden was dumped.

[47] The margin of dumping is estimated to be 592.8%, expressed as a percentage of export price.

## **EVIDENCE OF INJURY**

[48] The complainant alleged that the subject goods have been dumped and that such dumping has caused material injury and is threatening to cause material injury to the domestic industry producing like goods in Canada.

[49] SIMA refers to material injury caused to the domestic producers of like goods in Canada. The CBSA has concluded that NIT produced by the complainant is like goods to the subject goods from Sweden.

[50] In 1994, Sobi became the only supplier of NIT in Canada and was granted market authorization for the drug Orfadin under a special access program. This special access program ended on September 20, 2016, the date which the complainant obtained Health Canada approval for the like goods produced in Canada. The complainant briefly became the only authorized supplier of NIT in Canada until the approval by Health Canada of NIT sold by Cycle pharmaceuticals in November of 2016 and the approval of Sobi's drug Orfadin in December of 2016.

[51] In January of 2017, SigmaSanté issued the first public tender number 2015 777 00 10 covering the supply of NIT for all Quebec patients until March 31, 2018. This supply contract was awarded to the complainant. The subsequent tender number 2018 4777 01 01 covering the supply of NIT from April 1, 2018 to March 31, 2021 was won by Sobi due to bids that were submitted at alleged dumped prices. The complainant has remained the primary supplier of NIT to patients outside of Quebec since September 20, 2016.

[52] In support of their allegations of injury, the complainant provided evidence of price undercutting, lost sales, reduced profitability, a decline in production, negative returns on investments, underutilization of production capacity and negative effects on growth.

## **Price Undercutting**

[53] The complainant submitted that the allegedly dumped goods from Sweden have captured sales by undercutting their prices. To support this allegation, the complainant provided specific examples of subject goods at prices well below that of the complainant for the SigmaSanté tender number 2018-4777-00-01.

[54] Based the CBSA's analysis of the information contained in the complaint, the CBSA finds the claim of price undercutting to be supported and sufficiently linked to the allegedly dumped goods.

### **Loss of Sales**

[55] The complainant indicates that it held 99% of the Canadian market in 2017 and through the first quarter of 2018.<sup>11</sup> The complainant states that the loss of the SigmaSanté tender number 2018-4777-00-01 to the allegedly dumped goods from Sweden has represented a loss of sales to over 88% of the Canadian market by volume for the three year period between April 1, 2018 and March 31, 2021.<sup>12</sup>

[56] The CBSA has reviewed the evidence and recognizes that the loss of the SigmaSanté contract represents lost sales to almost the entire Canadian market for NIT for the period from April 1, 2018 to March 31, 2021.

[57] Based on the above, and the CBSA's analysis of the information contained in the complaint, the CBSA finds the claim of lost sales to be supported and sufficiently linked to the allegedly dumped goods.

### **Reduced Profitability and Decline in Production**

[58] The complainant indicates that with the loss of the SigmaSanté contract, MendeliKABS Inc. cannot remain profitable.<sup>13</sup> The complainant explains that given this context, MendeliKABS Inc., and potentially Labortaires KABS Inc., will be shuttered before the Canadian industry is provided the opportunity to bid on the next tender covering the three year period beginning on April 1, 2021. As a result, production of NIT in Canada will cease entirely.<sup>14</sup>

[59] The CBSA finds it reasonable to conclude that the presence of the injury factors described above and in the previous sections would have a significant impact on the financial results of the domestic industry, and that the information in the complaint has sufficiently linked the allegedly dumped goods to the complainant's impacted financial results.

---

<sup>11</sup> NIT Complaint (NC) – Para. 196.

<sup>12</sup> NIT Complaint (NC) – Para. 246.

<sup>13</sup> NIT Complaint (NC) – Para. 263.

<sup>14</sup> NIT Complaint (NC) – Para. 248.

### **Negative Returns on Investment**

[60] The complainant states that the presence of allegedly dumped goods has severely impacted its return on recent investments. The complainant has invested in the construction of a new plant in Asbestos, Quebec to supply the Canadian and international markets for NIT.<sup>15</sup> Due to the presence of the allegedly dumped goods the complainant has suspended further investments required to make the plant operational, negating any potential returns on this investment. The complainant also claims that significant investments had been made in developing the like goods.<sup>16</sup>

[61] The CBSA finds that there is a reasonable link between the presence of the allegedly dumped goods and the complainant's negative returns on investments.

### **Underutilization of Production Capacity**

[62] The complainant states that due to the significant loss of sales to the entire Quebec market, which represents 88% of the total Canadian market, it plans to completely cease the production of the like goods.<sup>17</sup>

[63] The CBSA finds that there is a link between the presence of the allegedly dumped goods and the complainant's capacity underutilization with respect to NIT.

---

<sup>15</sup> NIT Complaint (NC) – Para. 224-228.

<sup>16</sup> NIT Complaint (NC) – Para. 260-261.

<sup>17</sup> NIT Complaint (NC) – Para. 249.

## **Negative Effects on Growth**

[64] The complainant claims that the presence of the allegedly dumped goods in the Canadian market has caused it to postpone its plans to expand its production facilities. The complainant asserts that while the building of the Asbestos plant is completed, the plant remains vacant and unused due to the decision to suspend the hiring of personnel and the acquisition of equipment required to render it operational.<sup>18</sup> The complainant also states that it had intended to invest in the development of medicines for the treatment of other rare diseases. These investments will not be made due to the financial injury sustained as a result of the presence of the allegedly dumped goods in the Canadian NIT market.<sup>19</sup>

[65] Based on the CBSA's analysis of the information contained in the complaint, the CBSA finds the claim of negative effects on growth to be supported and sufficiently linked to the allegedly dumped goods.

## **CBSA's Conclusion – Injury**

[66] Based on the evidence provided in the complaint, and supplementary data available to the CBSA through its own research and customs documentation, the CBSA is satisfied that the evidence discloses a reasonable indication that the dumping of the subject goods from Sweden has caused injury. The injury factors specifically suffered by the domestic industry include price undercutting, lost sales, reduced profitability, a decline in production, negative returns on investments, underutilization of production capacity and negative effects on growth.

## **THREAT OF INJURY**

[67] The complainant states that allegedly dumped subject goods from Sweden threaten to cause further material injury to the Canadian domestic industry. The complainant submits that there is sufficient evidence to draw the conclusion that there is a threat of injury posed by the subject goods due to the excess capacity of the foreign producer and evidence of the risk of further price undercutting of the dumped goods from Sweden into the rest of the Canadian market for NIT.

[68] The complainant provided the following information to support the allegation that subject goods from Sweden threatens to cause further material injury to the Canadian domestic industry.

## **Capacity of the Foreign Producer**

[69] As previously outlined, the market for NIT in the rest of Canada is relatively small in comparison to the Quebec market. The complainant alleges that Sobi can easily supply the entire Canadian market.<sup>20</sup>

---

<sup>18</sup> NIT Complaint (NC) – Para. 228.

<sup>19</sup> NIT Complaint (NC) – Para. 265.

<sup>20</sup> NIT Complaint (NC) – Para. 300.



[70] The CBSA recognizes that Sobi could satisfy the entire Canadian market for NIT and result in an increase in the volume of subject goods from Sweden.

#### **Risk of Further Price Undercutting**

[71] The complainant states that due to the transparency of prices within the review process for pharmaceuticals in Canada there is a high likelihood that Sobi will choose to continue to undercut prices in order to supply the entire Canadian market.<sup>21</sup> The tender process for the supply of NIT to patients outside of Quebec will be held at the end of 2018.<sup>22</sup>

[72] Based on the CBSA's analysis of the information provided in the complaint, the CBSA finds that the market conditions, as described above, may render the Canadian domestic industry particularly vulnerable to an increase in import volumes from Sweden.

#### **CBSA's Conclusion – Threat of Injury**

[73] The CBSA is of the view that the evidence discloses a reasonable indication that there is a threat of material injury to the NIT industry in Canada posed by imports of allegedly dumped subject goods from Sweden.

#### **CAUSAL LINK – DUMPING, INJURY AND THREAT OF INJURY**

[74] The CBSA finds that the complainant has sufficiently linked the injury suffered by the domestic industry, in the form of price undercutting, lost sales, reduced profitability, a decline in production, negative returns on investments, underutilization of production capacity and negative effects on growth, to the alleged dumping of subject goods from Sweden. The CBSA is satisfied that the injury suffered by the domestic industry is directly related to the price advantage produced by the alleged dumping of subject goods from Sweden. Sufficient evidence has been provided to establish this link.

[75] The complainant submitted that the continued dumping of goods from Sweden will cause further injury to the Canadian domestic industry in the future. As discussed above, the CBSA is of the opinion that this allegation of threat of injury is reasonably supported.

[76] In summary, the CBSA is of the opinion that the information provided in the complaint has disclosed a reasonable indication that the alleged dumping has caused injury and is threatening to cause injury to the Canadian domestic industry.

---

<sup>21</sup> NIT Complaint (NC) – Attachments 81 and 82.

<sup>22</sup> NIT Complaint (NC) – Para. 247.



## **CONCLUSION**

[77] Based on information provided in the complaint, other available information, and the CBSA's import documentation, the CBSA is of the opinion that there is evidence that NIT originating in or exported from Sweden has been dumped. Further, there is evidence that discloses a reasonable indication that the dumping of the subject goods from Sweden has caused injury and is threatening to cause injury to the Canadian industry. As a result, pursuant to subsection 31(1) of SIMA, a dumping investigation was initiated on September 21, 2018.

## **SCOPE OF THE INVESTIGATION**

[78] The CBSA is conducting an investigation to determine whether the subject goods have been dumped.

[79] The CBSA has requested information from all potential exporters and importers to determine whether or not subject goods imported into Canada during the POI of January 1, 2018 to June 30, 2018, were dumped. The information requested will be used to determine the normal values, export prices and margins of dumping, if any.

[80] While the CBSA generally selects a POI covering a period of one year, examination of FIRM data has not shown any imports of the subject goods in 2017. In addition, the injury allegations presented by the complainant pertain to the loss of the SigmaSanté tender for the supply of NIT to the Canadian market for a period commencing on April 1, 2018. As such, the CBSA proposes that an appropriate POI for this dumping investigation is the period of January 1, 2018 through June 30, 2018.

[81] All parties have been clearly advised of the CBSA's information requirements and the time frames for providing their responses.

## **FUTURE ACTION**

[82] The Canadian International Trade Tribunal (CITT) will conduct a preliminary inquiry to determine whether the evidence discloses a reasonable indication that the alleged dumping of the goods has caused or is threatening to cause material injury to the Canadian industry. The CITT must make its decision on or before the 60<sup>th</sup> day after the date of the initiation of the investigation. If the CITT concludes that the evidence does not disclose a reasonable indication of injury to the Canadian industry, the investigation will be terminated.

[83] Under section 35 of SIMA, if, at any time before making a preliminary determination, the CBSA is satisfied that the volume of goods of a country is negligible, the investigation will be terminated with respect to the goods of that country.

[84] If the CITT finds that the evidence discloses a reasonable indication of injury to the Canadian industry and the CBSA has not terminated the investigation in accordance with section 35 of SIMA, the CBSA will make a preliminary determination of dumping within 90 days after the date of the initiation of the investigation, by December 20, 2018. Where circumstances warrant, this period may be extended to 135 days from the date of the initiation of the investigation.

[85] Imports of subject goods released by the CBSA on and after the date of a preliminary determination of dumping, other than goods of the same description as goods in respect of which a determination was made that the margin of dumping of the goods is insignificant, may be subject to provisional duty in an amount not greater than the estimated margin of dumping on the imported goods.

[86] Should the CBSA make a preliminary determination of dumping, the investigation will be continued for the purpose of making a final decision within 90 days after the date of the preliminary determination.

[87] After the preliminary determination, if, in respect of goods of a particular exporter, the CBSA's investigation reveals that imports of the subject goods from that exporter have not been dumped, or that the margin of dumping is insignificant, the investigation will be terminated in respect of those goods.

[88] If a final determination of dumping is made, the CITT will continue its inquiry and hold public hearings into the question of material injury to the Canadian industry. The CITT is required to make a finding with respect to the goods to which the final determination of dumping apply, not later than 120 days after the CBSA's preliminary determination.

[89] In the event of an injury finding by the CITT, imports of subject goods released by the CBSA after that date will be subject to anti-dumping duty equal to the applicable margin of dumping on the imported goods.

#### **RETROACTIVE DUTY ON MASSIVE IMPORTATIONS**

[90] When the CITT conducts an inquiry concerning material injury to the Canadian industry, it may consider if dumped goods that were imported close to or after the initiation of an investigation constitute massive importations over a relatively short period of time and have caused injury to the Canadian industry.

[91] Should the CITT issue such a finding, anti-dumping duties may be imposed retroactively on subject goods imported into Canada and released by the CBSA during the period of 90 days preceding the day of the CBSA making a preliminary determination of dumping.

## **UNDERTAKINGS**

[92] After a preliminary determination of dumping by the CBSA, other than a preliminary determination in which a determination was made that the margin of dumping of the goods is insignificant, an exporter may submit a written undertaking to revise selling prices to Canada so that the margin of dumping or the injury caused by the dumping is eliminated.

[93] An acceptable undertaking must account for all or substantially all of the exports to Canada of the dumped goods. Interested parties may provide comments regarding the acceptability of undertakings within nine days of the receipt of an undertaking by the CBSA. The CBSA will maintain a list of parties who wish to be notified should an undertaking proposal be received. Those who are interested in being notified should provide their name, telephone and fax numbers, mailing address and e-mail address to one of the officers identified in the “Information” section of this document.

[94] If undertakings were to be accepted, the investigation and the collection of provisional duties would be suspended. Notwithstanding the acceptance of an undertaking, an exporter may request that the CBSA’s investigation be completed and that the CITT complete its injury inquiry.

## **PUBLICATION**

[95] Notice of the initiation of this investigation is being published in the Canada Gazette pursuant to subparagraph 34(1)(a)(ii) of SIMA.

## **INFORMATION**

[96] Interested parties are invited to file written submissions presenting facts, arguments, and evidence that they feel are relevant to the alleged dumping. Written submissions should be forwarded to the attention of the SIMA Registry and Disclosure Unit.

[97] To be given consideration in this phase of the investigation, all information should be received by the CBSA by October 30, 2018.

[98] Any information submitted to the CBSA by interested parties concerning this investigation is considered to be public information unless clearly marked “confidential”. Where the submission by an interested party is confidential, a non-confidential version of the submission must be provided at the same time. This non-confidential version will be made available to other interested parties upon request.

[99] Confidential information submitted to the CBSA will be disclosed on written request to independent counsel for parties to this proceeding, subject to conditions to protect the confidentiality of the information. Confidential information may also be released to the CITT, any court in Canada, or a WTO/NAFTA dispute settlement panel. Additional information respecting the Directorate's policy on the disclosure of information under SIMA may be obtained by contacting one of the officers identified below or by visiting the CBSA's website.

[100] The schedule of investigation and a complete listing of all exhibits and information are available at: [www.cbsa-asfc.gc.ca/sima-lmsi/i-e/menu-eng.html](http://www.cbsa-asfc.gc.ca/sima-lmsi/i-e/menu-eng.html). The exhibits listing will be updated as new exhibits and information are made available.

[101] This *Statement of Reasons* has been provided to persons directly interested in these proceedings. It is also available through the CBSA's website at the address below. For further information, please contact the officers identified as follows:

**Mail:** SIMA Registry and Disclosure Unit  
Trade and Anti-dumping Programs Directorate  
Canada Border Services Agency  
100 Metcalfe Street, 11<sup>th</sup> floor  
Ottawa, Ontario K1A 0L8  
Canada

**Telephone:** Hugo Dumas 613-954-7262  
Matthew Lurette 613-954-7410

**Fax:** 613-948-4844

**E-mail:** [simaregistry@cbsa-asfc.gc.ca](mailto:simaregistry@cbsa-asfc.gc.ca)

**Website:** [www.cbsa-asfc.gc.ca/sima-lmsi](http://www.cbsa-asfc.gc.ca/sima-lmsi)



Doug Band  
Director General  
Trade and Anti-dumping Programs Directorate