Novelty Determination Information Form (NDIF)

NOTES

- Health Canada reserves the right to request additional documentation.
- This form should not be used for Genetically Modified (GM) foods.
- If your product could also be considered a Natural Health Product, please review Health Canada's guidance document *Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats*
- Please answer all the following questions. It is not sufficient to provide a 'yes' or 'no' response. You must provide justification for your answers and details of any reference material accessed in order to answer the questions. Acceptable reference sources include, but are not limited to, scientific publications and patents, non-scientific publications and books, cookbooks, books on the history of food culture, and/or affidavits from two or more independent, reputable authorities that include well-documented accounts of the products use as a food, including information to substantiate their knowledge.
- Health Canada will only consider your inquiry once all of the questions are satisfactorily answered. In recognition that not all questions will be relevant to all products, if a particular question is not applicable to your enquiry, please provide justification.
- Please provide copies of any, and all, references cited as evidence. Where applicable, provide copies in the original language accompanied with a translation in either official language.
- Importers and industry consultants should contact product or ingredient manufacturers and/or suppliers directly to obtain the information required as part of this form.
- Any information provided that is considered to be Confidential Business Information will be respected by Health Canada.
- Part 7 of this form relates to the review and authorisation of products by regulatory agencies outside of Canada. It is recommended that this section be completed for all products.
- Part 8 for this form is for the inclusion of any information that a petitioner may consider relevant to novelty determination and which was not specifically request elsewhere.

  Once completed this Form and any supporting information should be submitted to the Food Directorate's Submission Management and Information Unit (SMIU) via their email address: hc.smiu-ugdi.sc@canada.ca Please use NDIF in the subject line of your email to SMIU.

All non-novel determinations based on requests received after September 30, 2020 will automatically be included in the list of non-novel food products and ingredients, and published on Health Canada's website. This list will contain the following information: the date, the name of the product, a plain language description of the product, and Health Canada's rationale. The identification of the requestor will not be published.

PART 1 – CONTACT INFORMATION

A. APPLICANT

Crush Dynamics Inc			
9201 Shale Avenue			
Summerland	BC	Canada	V0H1Z4

B. SENIOR OFFICIAL (This is the name of the principal contact person for the sponsor company)

7. ☒ Mr. ☐ Ms ☐ Dr ☐ Other Surname: Broddy Given Name: William		8. Title : President	9. Language preferred: ☒ English ☐ French
10. Street/Suite/PO Box:		**11. Address same as "A"** ☒	
12. City – Town:	13. Province – State:	14. Country :	15. Postal/ZIP Code:
16. Telephone No: Ext.:		17. Fax No:	18. E-mail :

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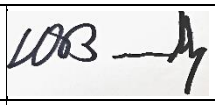
C. CONTACT FOR THIS NOTIFICATION (This is the name of the contact person for product-specific questions)			
19. Contact same as "B" ☒	20. Title :	21. Language preferred: ☐ English ☐ French	
22. ☐ Mr. ☐ Ms ☐ Dr ☒ Other Surname: Cordeiro		Given Name: Michelle	
23. Company Name (If different from Sponsor Company):		24. **Address same as "A"** ☒	
25. Street/Suite/PO Box:			
26. City – Town:	27. Province – State:	28. Country :	29. Postal/ZIP Code:
30. Telephone No: Ext. :	31. Fax No:	32. E-mail: michelle@crushdynamics.com	
D. REPRESENTATIVE IN CANADA (Only required where Address in "A" is not in Canada)			
33. Contact same as "B" ☒ Contact same as "C" ☐		34. Title :	35. Language preferred: ☐ English ☐ French
36. ☐ Mr. ☐ Ms ☐ Dr ☐ Other Surname:		Given Name:	
37. Company Name (* if different from Applicant/Licensee):		38. Contact same as "B" ☐ Contact same as "C" ☐	
39. Street/Suite/PO Box:			
40. City – Town:	41. Province – State:	42. Country :	43. Postal/ZIP Code:
44. Telephone No: Ext. :	45. Fax No:	46. E-mail:	
E. CONTACT TO WHOM THE NOVELTY DETERMINATION OPINION LETTER SHOULD BE SENT			
47. **As Above: B** ☒ **C** ☐ **D** ☐ **Not Applicable**: ☐ Name : _____ (Check only one box)			

F. SIGNING AUTHORITY

I, the undersigned, certify that the information included in this Novelty Determination Information Form is accurate and complete.

I agree to inform Health Canada if there are any changes made with respect to the information provided in this Novelty Determination Information Form.

Name of Authorized Signing Official	**Signature**	**Date**
William Broddy		2024-02-09
Title : **Président**	**Telephone No:** **250-486-4340**	**Fax No:**
Name of Company to which the Authorised Signing Official Belongs: **Crush Dynamics**		

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PART 2 – General Information

A. Product Overview

48. Product or Substance Name:	49. Common Name or chemical name:	50. Scientific Name (plant latin binomial)
Winecrush® Paste	Wine Vinegar Paste	Vitis Vinifera

51. Product or Substance Description (e.g., intended purpose, proposed use level / consumption directions (per serving and per day)):

Is a highly viscose *wine vinegar product* considered novel?

We submit that Winecrush® Paste (a highly viscose wine vinegar product) is not novel as it is made from a Health Canada approved food (Vitis vinifera) using an approved wine vinegar process (Jacques F. BOURGEOIS, François BARJA 2009), which produces a vinegared paste with similar chemical properties to W*ine Vinegar*, when adjusted for dry mass. The Canadian Food and Drug Regulations defines it as: "B.19.003 [S]. Wine Vinegar shall be vinegar made from wine and may contain caramel."

Our product is made by fermenting Vitis vinifera grapes (Merlot, Cabernet Sauvignon, Cabernet Franc, Syrah, Chardonay, Pinot Gris, Reisling, Gewurztraminer) that have been crushed and pressed to remove grape juice during winemaking. The substance is referred to in winemaking as Grape Pomace or Marc in *Health Canada Food & Drug Regulation B.02.058 [S]. Pomace or Marc.*

The fermentation steps are the same as wine vinegar-making and the final product is chemically the same, except for solid mass: wine vinegar is usually less than 2% whereas our paste is 20 - 30% depending on the application. This allows us to deliver more flavour, polyphenols, and fiber. There are no known regulations defining the maximum viscosity of wine vinegar. The manufacturing process is laid out in attached *US Patent 11,584,904*.

Our "vinegar" processing facility was inspected and approved by CFIA in 2023, including the microbial contents and the Vitis vinifera grape sourcing *(attached)*. The process is supervised by onsite rabbis from the *Star K* kosher organization (Baltimore MD). The rabbi ensures that the only approved Vitis vinifera grapes are used and that the Saccharomyces Cerevisiae, Lactobacillus, and Acetobacter are Kosher.

We have developed formulas for Winecrush Paste as a food ingredient in sauces, chocolate, prepared meats, plant-based proteins, pastries, and sports drinks**.**

There are no known health restrictions regarding the consumption of wine vinegar as a beverage, food, or ingredient.

Unfortunately, many large food processing companies want local government confirmation that our product would not be construed as a novel ingredient.

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52. What is the source material of the product? Plant

Crushed Vitis vinifera grapes left over from winemaking

53. From what part of the source material is the product derived? Plant fruit

including seeds, skins, and petiole.

54. What is the form of the final product (e.g., whole, ground, extract, concentrate, isolate, etc.)?

fermented paste (20 – 30% solids)

55. Is this product standardized, or does a standard for this product exist?

USDA regulation requires that Vitis vinifera (wine) vinegar contain at least 4% acetic acid to be labeled as vinegar. However, we do not label it as a vinegar. There are no known regulations on the viscosity of wine vinegar.

Historically, wine vinegar has been regulated by local alcohol tax departments (e.g. US ATF) as there is an interim alcohol substance produced.

56. Is this product an ingredient? ☒ Yes – Proceed to Box 57 ☐ No – Proceed to Part 3.

B. Ingredient Overview (A complete tabular listing of foods and the proposed quantity of the ingredient to be added to should be provided as Appendix B)

57. What is the intended purpose of this ingredient in the final food?

Flavour modulation (specifically to enhance the flavour of salt, sweeteners, and fat, lowering the amount of these ingredients in formula) bulking agent (natural lignocellulose), and food preservation (polyphenols).

58. Please summarize the food products to which this ingredient is intended to be added:

The product has been successfully tested in prepared meats, breads, sauces, dressings, chocolate, cheese and other fermented milks, desserts, and confectionery. Dried paste has been used in sports drink formulas and dried seasoning recipes.

59. Please summarize the proposed quantities of the ingredient that would be used in the food:

Most formulas use .5% = 1.5% of the dry weight as a flavouring ingredient. However, our paste can be used as a mother sauce e.g. Wine Catsup, pasta sauce.

PART 3 – History of Food Use

A. Details of Food Use

60. Does the product have a history of use **as a food** in Canada prior to 1999?

☒ Yes – Complete box 61 and submit form to SMIU. ☐ No – Proceed to Box 62.

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61. Provide a summary of the evidence of food use in Canada prior to 1999 (all references should be provided as Appendix A).

Canadians have been drinking Vitis vinifera wine since the early colonial period. Both Champlain and Cartier our believed to have imported barrels of Vitis vinifera wine during their voyages to New France. Some of this wine eventually would have been infected with wild endobacteria generating Vitis vinifera vinegar. The sediment in the barrel (Lees) would be similar to vinegar paste.

Wine vinegar is called for in many Canadian recipes. *The Canadian Cookbook circa 1923 lists over 70 recipes* that include vinegar as an ingredient. Health Canada lists two recipes that include wine vinegar on its Canada's Food Guide website (attached).

Wine vinegar has been imported from Italy since the 19th century. Although our product has a higher dry matter, it could be used in any of these recipes if they adjust the volume.

62. Does the product have a history of use as a food in a country other than Canada? ☒ Yes – Complete box 63. ☐ No – Skip to Part 4.

Vitis vinifera grapes naturally ferment. This is part of their evolutionary selection process to attract animal distributors. If grapes fall off the vine, they will likely turn into z grape vinegar must that could be blended into a paste. Archaeological evidence shows that primates have eaten fermented fruit (including grapes) for roughly 10 million years, leading to development of receptor genes that positively respond to both phenol-rich fruits and fermented foods.

The first evidence of grape domestication dates back over 11,000 years ago, which show up in the genetics of grape selection from early vine keepers. The earliest examples of Vitis vinifera grape fermentation dates back 8,200 years to multiple winemaking facilities in Georgia and Armenia. As rudimentary winemaking did not involve sealing the container (Amphora) and archaeological evidence shows that crushed grapes were not removed from the fermented wine, there was a vinegary residue (paste) left in the bottom of the amphora.

Vitis vinifera wine, vinegar and even pomace has been regulated by the Judaic Kosher laws of approximately 3,000 years.

There are many references to Vitis vinifera wine and vinegar in Roman texts including Pliny the Elder's "Natural History – Book 14" circa 79 AD.

Wine vinegar has been readily available in modern times. Attached is a Sensory Review of (Italian and Spanish) Wine Vinegars circa 1997.
Although the attached documents prove the existence of wine vinegar, none of them suggest there was, or is, any restriction on viscosity.

63. Provide a summary of the evidence of food use in countries other than Canada, including estimated normal dietary levels (all references should be provided as Appendix A).

Wine vinegar is commonly used as an ingredient or condiment in all wine producing countries. Here are no known restrictions on the use of wine vinegar as a beverage, food, condiment, or ingredient.

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64. Is the proposed use of the food product comparable to the historical use cited above? ☒ Yes – Complete box 65. ☐ No – Skip to Part 4.

65. Provide a comparison of the proposed use to the historical use of this product (complete data and all references to be provided as Appendix C)

The product has been successfully tested in prepared meats, breads, sauces, dressings, chocolate, cheese and other fermented milks, desserts, and confectionery. Dried paste has been used in sports drink formulas and dried seasoning recipes.

66. Has this product been consumed by a population of at least 1 million people as part of the regular diet?

☒ Yes – Complete box 67. ☐ No – Skip to Part 4.

67. Provide a summary of the evidence for this consumption (all references should be provided as Appendix A). Wine and wine vinegar has been consumed by humans for over 8,000 years.

- *Early Neolithic wine of Georgia in the South Caucasus* – Stephen Batiuk et al, 2017.
- *Natural History:* Book 14 - Pliny the Elder circa 79 AD
- The Canadian Cookbook – 1923
- Sensory qualities of Wine Vinegar – 1997
- History of Vinegar – 2024
- US Patent describing our production process for the product.
- Health Canada recipes including vinegar

68. Has the product been consumed by this/these population(s) for at least two generations? ☒ Yes – Complete box. ☐ No – Skip to Part 4.

69. Provide a summary of the evidence for this consumption (all references should be provided as Appendix A) Please see *The history of vinegar and of its acetification systems - Jacques F. BOURGEOIS, François BARJA 2009*

PART 4 – Product Type

A. Information on the final product format

70. Is the product a whole food/whole food ingredient?

☒ Yes – Skip to the Part 7. ☐ No – Complete Box 71.

71. Is the product an extract, concentrate or isolate?

☐ Yes – Skip to the Part 5. ☐ No – Complete Box 72.

72. Is the product a microorganism?

☐ Yes – Skip to the Part 6. ☐ No – Submit Form and Contact SMIU.

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PART 5 – Extracts, Concentrates and Isolates

A. Details of the Intended purpose of the extract, concentrate or isolate ingredients

73. Is the intended purpose of adding this extract, concentrate or isolate to achieve a technical effect in the food?

☐ Yes – Submit Form to SMIU. ☐ No – Proceed to Box 74.

74. Is the intended purpose of adding this extract, concentrate or isolate to provide a potential health benefit to the consumer? ☐ Yes ☐ No

B. Source material of the extract, concentrate or isolate ingredients

75. Is the extract, concentrate and isolate derived from a food with a known history of safe use as demonstrated in Part 3?

☐ Yes – complete Box 76 à 78. ☐ No – Submit Form to SMIU.

76. Common Name of Source material:	77. Scientific Name of Source material:

78. Provide a description of the food use of the source material (All references should be provided as Appendix A).

79. Is the extract, concentrate or isolate derived from a portion of the source material that is normally consumed as food?

☐ Yes – complete Box 80 et 81. ☐ No – Submit Form to SMIU.

80. What portion of the source material is used in the production of this extract, concentrate, or isolate?

81. Provide a description of the food use of this portion of the source material (All references should be provided as Appendix A).

C. Production Process

82. Provide a brief description of the production process used to prepare this extract, concentrate, or isolate (Complete manufacturing details should be provided as Appendix D).

83. Provide the Extraction ratio:	84. Provide the Quantity Crude Equivalent (QCE):

85. Describe the naturally occurring levels of concentrated/extracted/isolated compounds in the source material and compare to the levels present in the final ingredient. (A complete comparison and data should be provided as Appendix E)

D. Dietary Exposure

86. Does the addition of this ingredient at the proposed levels result in a greater dietary exposure to the ingredient, or other naturally occurring substances than from consumption of the source material?

☐ Yes – Box 87. ☐ No – Complete Box 87 and submit form to SMIU.

87. Summarise the available data and compare the dietary exposure from the proposed addition to the dietary exposure of the source material (A complete comparison and data should be provided as Appendix F).

88. Does the ingredient or other naturally occurring substance have a history of dietary exposure at the proposed level from a dietary source other than the source material?

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☐ Yes – complete Box 89. ☐ No – Submit form to SMIU.

89. Summarise the available data and compare the dietary exposure from the proposed addition to the dietary source of exposure (A complete comparison and data should be provided as Appendix G).

PART 6 – Microorganisms

A. History of Use

90. Has this microorganism (*Genus*, *species*) previously been used as a food or food ingredient?

☐ Yes –complete Box 91. ☒ No – Submit form to SMIU

91. Was the previous food use of the microorganism in the same state (e.g., active, dried, etc.) as the proposed use?

☐ Yes – Complete Box 92 and proceed to Section B. ☐ No – Skip to Box 93.

92. Describe the previous use of the microorganism in food (All references should be provided as Appendix A).

93. Was the previous use of this microorganism to produce a substance added to food for a technical effect?

☐ Yes – Submit form to SMIU. ☒ No – Proceed to Section B.

B. Regulatory Status

94. Did the previous food use of this microorganism require Canadian authorisation prior to is use in/as food?

☐ Yes – complete Box 95 then proceed to Section C. ☐ No – complete Box 96.

95. Indicate the *Act* or *Regulations* under which this microorganism was authorised for food use and the purpose of this previous usage (All references should be provided as Appendix A).

96. Is this microorganism included in the European Food Safety Authority (EFSA) list of bacteria with a qualified presumption of safety (QPS)?

☐ Yes – Proceed to Section C. ☐ No – Submit Form to SMIU.

C. Current strain

97. Has this strain of the microorganism been modified, protected or otherwise altered in manner from those strains previously used in food?

☐ Yes – complete Box 98 and submit form to SMIU. ☒ No – Submit form to SMIU.

98. Describe the alteration, modification or protection that has been performed on this strain of the microorganism (complete details and relevant data should be provided as Appendix H. All references should be provided as Appendix A).

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PART 7 – International Status

99. Has this product been previously assessed by another regulatory body for use as food?

☐ Yes – Complete the table below and submit form to SMIU. ☒ No – Submit Form to SMIU.

Country of Assessment	Assessing Regulatory Body	Assessment Outcome	Date of Authorisation (if applicable)

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PART 8 – Additional Information

100. *This Section can be used to provide any additional information that may be relevant to the determination of novelty and has not specifically been requested earlier in the form. Please note that information pertaining to the medicinal usage is not considered relevant to novelty determination.*

Our vinegar processing facility was inspected and approved by the Canadan Food Inspection Aency (CFIA) in 2023, including the microbial contents and the Vitis vinifera grape sourcing. The process is supervised by onsite rabbis from the Star K kosher organization (Baltimore MD). The rabbi ensures that the only approved Vitis vinifera grapes are used and that the Saccharomyces Cerevisiae, Lactobacillus, and Acetobacter are Kosher.

Our process creates nutritious food from derivatives that would otherwise go to waste. The is ~25,000 Tonnes of crushed Vitis vinifera that usually goes to waste in Canada each year, and ~15 million tonnes worldwide. IF left to rot in landfills or compost pile, it will generate up to 50 million tonnes of CFCs each year. If the Vitis Vinifera were converted into paste, it could feed the world for at least a day.

Winecrush® Paste is certified as an upcycled food by the *Upcycled Food Association*. As a result of our efforts at upcycling this nutritious ingredient. we have received numerous grants to assist in the development of our product, including:

- IRAP / NRC
- Agriculture Cleantech Program - AAFC
- Protein Industries Canada
- Natural Products Canada
- Canadian Food Innovation Network – Innovation Canada, AAFC (see recent announcement)

Federal Ministerial Comments include:

Trade Minister Mary Ng met with CrushDynamics on Sept 20, 2022, to review progress to take its recently patented process to all wine regions of the world. "*At scale, CrushDynamics proprietary biomechanical process could materially reduce global methane emissions equivalent to 50 million Tonnes of GHG*."

"Crush Dynamics' new bio-fermentation process offers a concrete solution to address the food and beverage industry's most pressing challenges. This innovative solution will help the industry improve food quality, reduce production costs, and carbon footprints. With this initiative, the Canadian Food Innovation Network promotes sustainability through a circular food economy and creates highly skilled job opportunities for Canadians."

– **The Honourable François-Philippe Champagne**
Minister of Innovation, Science, and Industry

"When it comes to addressing challenges in the FoodTech sector, Canada is leading the charge through innovation. We're proud to support to this effort to develop a unique upcycled food ingredient that will help improve the quality of our food while also reducing emissions."

- **The Honourable Lawrence MacAulay**
Minister of Agriculture and Agri-Food