limit spread of the bacterium. However, this is largely ineffective since it is the spores rather than the bacteria that cause the disease. Therefore, burning of the hive is often the only solution to contain the disease.

[7] Thus, there is a need in the art for safe, effective measures for the control and prevention of American foulbrood disease and other related insect disease. This disclosure satisfies this need and provides related advantages as well.

SUMMARY

[7a] In one aspect, provided herein is a composition comprising whole cells or cell wall fragments of at least one dead, non-disease causing bacterial species of a bacterial genus and a carrier.

[7b] In one aspect, provided herein is use of an effective amount of the composition as described herein in the manufacture of a medicament for vaccinating, treating or immunizing a bee queen or bee larvae against Foulbrood disease, wherein the medicament is to be administered to a bee selected from one or more of worker bees or nurse bees that feed the bee queen, bee larvae or the bee queen, thereby immunizing the queen bee or the bee larvae produced by the queen bee.

[7c] In one aspect, provided herein is use of a composition comprising whole cells or cell wall fragments of at least one dead, non-disease species of *Paenibacillus* in the manufacture of a medicament for preventing or vaccinating against American foulbrood in a population of bees, optionally honeybees, wherein the composition is to be administered to a bee queen.

]7d] In one aspect, provided herein is a method for preparing an insect composition or vaccine comprising isolating whole cells or cell wall fragments from at least one dead, non-disease causing bacterial species of a bacterial *Paenibaccilus*.

[7e] In one aspect, provided herein is a composition prepared by a method as described herein.

[7f] In one aspect, provided herein is a vaccine composition prepared by a method as described herein.

[7g] In one aspect, provided herein is a kit comprising the composition as described herein, and instructions for use.

[7h] In one aspect, provided herein is the composition as described herein for use in therapy.

[7i] In one aspect, provided herein is a composition comprising whole cells or cell wall fragments of at least one dead, non-disease species of *Paenibacillus* for use in therapy.

[8] The disclosure relates to novel compositions, vaccine formulations and methods for raising an immune response to, and/or vaccinating treating and/or for the prevention foulbrood diseases caused by *Paenibacillus sp.* including American Foulbrood diseases (AFB) in bees and other insects caused by *Paenibacillus* larvae, via administration to and/or vaccination of the queen bee with dead non-disease causing *Paenibacillus sp.,* including, but not limited to *Paenibacillus alvei* (PA) and *Paenibacillus dentritiformis* (PD). In one example, the bees are honeybees.

[9] In contrast to what had been known in the art, Applicant describes administration and/or immunization by applying a stimulus from a non-disease pathogen to treat and/or prophylactically immunize the bees against diseases caused by *Paenibacillus sp.* such as Afb. Specific match between the disease pathogen and the vaccine strain is not required.

[10] Thus, in one example, this disclosure provides a method of protecting insects from disease by applying or administering an immunization stimulus derived from a pathogen other than the disease pathogen to provide broad-spectrum generalized protection.

[11] In an exemplary example, provided herein is a composition containing dead *Paenibacillus* such as PD and PA in combination or alone for the protection against infection by *Paenibacillus* larvae (PL). The composition also can contain, for example, bee feed such as honeybee feed.

[12] In other examples, the disclosure provides a method for preventing American foulbrood in a population of bees, e.g., honeybees. The method can include administering or feeding to the queen bee a vaccine formulation consisting of dead PB or PA or a combination of both. In one example, from about 1.5×10^6 to about 1.5×10^8

antigen units/gram of insect food is provided to or fed to the queen bee, worker bees, nurse bees or the larvae.

[13] In one example, provided herein is a composition, comprising, or consisting essentially of, or yet further consisting of, whole cells or cell wall fragments of at least one dead, non-disease causing bacterial species of a bacterial genus, such as dead *Paenibacillus sp.* such as PD or PA or a combination of both, and a carrier. In one example, the composition comprises, or consisting essentially of, or yet further consisting of, whole cells or cell wall fragments of at least two or more, or three or more, of four or more dead, non-disease causing bacterial species of a bacterial genus, such as dead *Paenibacillus* such as PD or PA or a combination of both, and a carrier. Non-limiting examples of the non-disease causing bacterial species for the composition formulation is a species of the genus *Paenibaccilus, Paenibacillus alvei* (PA) or *Paenibacillus dentritiformis* (PD), or a combination thereof. In a further example, the one or more, two or more, three or more, or four or more dead *Paenibaccilus* species is included in the composition, wherein the species is one or more selected from the group consisting of *Paenibacillus alvei*, *Paenibacillus dentritiformis, Paenibacillus amylolyticus*, *Paenibacillus campinasensis*, *Paenibacillus chondroitinus*, *Paenibacillus chungangensis*, *Paenibacillus doosanensis*, *Paenibacillus glucanolyticus*, Paenibacillus humicus, *Paenibacillus lactis*, *Paenibacillus lautus*, *Paenibacillus lentimorbus*, *Paenibacillus maceran*, *Paenibacillus macerans*-like, *Paenibacillus macquariensis*, *Paenibacillus motobuensis, Paenibacillus pabuli, Paenibacillus phoenicis, Paenibacillus polymyxa, Paenibacillus popilliae, Paenibacillus puldeungensis, Paenibacillus residui, Paenibacillus stellife, Paenibacillus thiaminolyticus, Paenibacillus validus,* and *Paenibacillus xylanisolvens*, or a combination thereof. In a further example, the dead *Paenibaccilus* species in the composition comprise, or consist essentially of, or consists of *Paenibacillus alvei* and *Paenibacillus dentritiformis,* alone or in combination with each other.

[14] Non-limiting examples of a carrier can be a solid or a liquid carrier and can include preservatives, insect nutrients, or other coloring agents as necessary. In one specific example, the carrier is an insect food, such as a queen bee wafer or sugar feed.

[15] In one example, the and whole cells or cell wall fragments of the at least one dead, non-disease causing bacterial species of the bacterial genus in the composition are present in a total amount per dose per gram of the composition or food of from about 1.5 x 10^6 to about 1.5 x 10^{11} antigen units, or from about 1.5 x 10^7 to about 1.5 x 10^{11} antigen units, or from about 1.5 x 10^8 to about 1.5 x 10^{11} antigen units, or from about 1.5 x 10^8 to about 1.5 x 10^{10} antigen units, or from about 1.5 x 10^8 to about 1.5 x 10^9 antigen units, or at least 1.5 x 10^7 antigen units, or at least about 1.5 x10^8 antigen units, or at least about 1.5 x 10^9 antigen units, or at least about 1.5 x 10^{10} antigen units.

[16] In an exemplary example, provided herein is a composition containing dead *Paenibacillus* such as PD and PA in combination or individually for the protection of the bee larvae and queen bee progeny against infection by *Paenibacillus larvae* (PL). The composition also can contain, for example, insect feed such as honeybee feed. The range of whole cells or cell wall fragments of the *Paenibacillus* are in the ranges provided herein.

[17] In other examples, the disclosure provides a method for preventing American foulbrood in a population of bees, e.g., honeybees. The method can include administering to the worker bees, larvae, nursing bees and/or the queen bee a composition as disclosed herein and/or a vaccine formulation comprising, or consisting essentially of, or yet further consisting of dead *Paenibacillus* such as PD or PA or a combination of both. As is apparent to the skilled artisan, the queen bee may feed on the food or alternatively the worker or nurse bees will ingest the food and feed the queen. In addition, bee larvae may also feed on the composition. The range of whole cells or cell wall fragments of the *Paenibacillus* are in the ranges provided herein.

[18] In other examples, the disclosure provides a treatment for diseases caused by *Paenibacillus sp.*, such as American foulbrood in a population of bees, e.g., honeybees. The method can include administering to the worker bees, nurse bees, larvae and/or the queen bee a composition or formulation comprising, or consisting essentially of, or yet further consisting of dead non-disease causing *Paenibacillus* such as PD or PA or a combination of both. In one example the composition comprises dead PD or PA to treat

diseases caused by *Paenibacillus larvae*, such as Afb. The range of whole cells or cell wall fragments of the *Paenibacillus* are in the ranges provided herein.

[19] In other examples, the disclosure provides a method for preventing American foulbrood in a population of bees, e.g., honeybee larvae or progeny from a queen treated by the method disclosed herein. The method can include administering to the worker bees, nurse bees and/or the mother queen bee a formulation comprising, or consisting essentially of, or yet further consisting of dead non-disease causing *Paenibacillus* such as PB or PA or a combination of both. The range of whole cells or cell wall fragments of the *Paenibacillus* are in the ranges provided herein.

[20] Also provided herein is a method of treating or immunizing or raising an immune response in a honeybee larvae against a disease caused by *Paenibacillus sp.* such as Foulbrood disease known to cause by PL, the method comprising, or alternatively consisting essentially of, or yet further consisting essentially of, administering an effective amount of the composition as described herein to a nurse bees, worker bees or the honeybee queen, or honey bee larvae thereby immunizing the queen bee, and the honeybee larvae and progeny produced by the queen bee. In one example, the Foulbrood disease is caused by any species belonging to the Family *Paenibacillaceae.* Without being bound by theory, detection of the antigen that will be passed to the larvae can be detected in the ovaries of the queen bee. This vaccinates the larvae from disease.

[21] The method is useful to protect larvae-queen bees and worker bees from Foulbrood disease that is caused by members of the Family *Paenibacillaceae* such as PL, PA and PD to provide a population of larvae that has been immunized against Foulbrood via the queen bee that has ingested the vaccine composition.

[22] Further provided herein is a method for treating and/or preventing foulbrood diseases such as Afb in a population of bee, e.g., honeybees comprising, or alternatively consisting essentially of, or yet further consisting of administering to worker bees and the queen bee, a composition as described herein, wherein in one example the composition comprises, or consists essentially of, or yet consisting of dead non-disease whole or fragments from the species of *Paenibacillus*. In another example, the dead non-disease species of *Paenibacillus* are selected from the group consisting of *Paenibacillus alvei*, *Paenibacillus dentritiformis,*

Paenibacillus amylolyticus, *Paenibacillus campinasensis*, *Paenibacillus chondroitinus*, *Paenibacillus chungangensis*, *Paenibacillus doosanensis*, *Paenibacillus glucanolyticus*, *Paenibacillus humicus*, *Paenibacillus lactis*, *Paenibacillus lautus*, *Paenibacillus lentimorbus*, *Paenibacillus maceran*, *Paenibacillus macerans*-like, *Paenibacillus macquariensis*, *Paenibacillus motobuensis*, *Paenibacillus pabuli*, *Paenibacillus phoenicis*, *Paenibacillus polymyxa*, *Paenibacillus popilliae*, *Paenibacillus puldeungensis*, *Paenibacillus residui*, *Paenibacillus stellife*, *Paenibacillus thiaminolyticus*, *Paenibacillus validus*, and *Paenibacillus xylanisolvens*, or a combination thereof. In another example, the composition comprises one or both of dead non-disease species of *Paenibacillus* are dead *Paenibacillus alvei* and *Paenibacillus dentritiformis*, or a combination of both in combination with other *Paenibacillus*, or other inactivated cells or fragments of bacteria of the Family *Paenibacillace*.

[23] In one example of this method, the administering comprises feeding the worker bees, nurse bees, larvae and/or the queen bee an suitable amount of wafer of queen candy or sugar feed, wherein the amount administered per dose a vaccine, composition or formulation comprising between about 1.5×10^6 to about 1.5×10^{11} antigen units/gram of food, or from about 1.5×10^7 to about 1.5×10^{11} antigen units/gram of food, or from about 1.5×10^8 to about 1.5×10^{11} antigen units/gram of food, or from about 1.5×10^8 to about 1.5×10^{10} antigen units/gram of food, or from about 1.5×10^8 to about 1.5×10^9 antigen units/gram of food, or at least 1.5×10^7 antigen units/gram of food, or at least about 1.5×10^8 antigen units/gram of food, or at least about 1.5×10^9 antigen units/gram of food, or at least about 1.5×10^{10} antigen units/gram of food, of the least one dead non-disease species of *Paenibacillus* or fragments thereof.

[24] Further provided is a method for preparing an insect vaccine and/or composition and/or formulation comprising isolating from at least one, or at least two, or at least three, or at least four or more dead, non-disease causing bacterial species of a bacterial genus, whole cells or cell wall fragments from the least one dead, non-disease causing bacterial species of *Paenibaccilus sp.*. In one example, the method further comprises admixing the isolated antigen units with an insect food or carrier, such as a queen bee wafer or gel. In one example, the non-disease causing bacterial species is a species of the genus *Paenibaccilus, e.g., Paenibacillus alvei* or *Paenibacillus dentritiformis*, or a combination thereof. In another

example, the dead *Paenibaccilus* species is selected from the group consisting of *Paenibacillus alvei*, *Paenibacillus dentritiformis, Paenibacillus amylolyticus*, *Paenibacillus campinasensis*, *Paenibacillus chondroitinus*, *Paenibacillus chungangensis*, *Paenibacillus doosanensis*, *Paenibacillus glucanolyticus*, Paenibacillus humicus, *Paenibacillus lactis*, *Paenibacillus lautus*, *Paenibacillus lentimorbus*, *Paenibacillus maceran*, *Paenibacillus macerans*-like, *Paenibacillus macquariensis*, *Paenibacillus motobuensis*, *Paenibacillus pabuli*, *Paenibacillus phoenicis*, *Paenibacillus polymyxa*, *Paenibacillus popilliae*, *Paenibacillus puldeungensis*, *Paenibacillus residui*, *Paenibacillus stellife*, *Paenibacillus thiaminolyticus*, *Paenibacillus validus*, and *Paenibacillus xylanisolvens*, or a combination thereof. In another example, the dead *Paenibaccilus* species are *Paenibacillus alvei* and *Paenibacillus dentritiformis*.

[25] In one example, the whole cells or cell wall fragments of at least one, or at least two, or at least three, or at least four or more of dead, non-disease causing bacterial species of a bacterial genus per does is provided between about 1.5×10^6 to about 1.5×10^{11} antigen units/gram of food , or about 1.5×10^7 to about 1.5×10^{11} antigen units/gram of food, or from about 1.5×10^8 to about 1.5×10^{11} antigen units/gram of food, or from about 1.5×10^8 to about 1.5×10^{10} antigen units/gram of food, or from about 1.5×10^8 to about 1.5×10^9 antigen units/gram of food, or at least 1.5×10^7 antigen units/gram of food, or at least about 1.5×10^8 antigen units/gram of food, or at least about 1.5×10^9 antigen units/gram of food, or at least about 1.5×10^{10} antigen units/gram of food, of the dead non-disease species of *Paenibacillus* or fragments thereof.

[26] Also provide herein are the treatment and/or vaccine compositions prepared by the methods as described herein as well as the bee or an insect larvae or larvae population from a queen having been immunized by ingestion of the treatment and/or vaccine compositions as described herein. The compositions and/or formulations can be provided in a kit, comprising the composition as described herein and instructions for use.

[27] Other features, objects and advantages of the disclosure will be apparent from the detailed description which follows.

WHAT IS CLAIMED IS:

1. A composition comprising whole cells or cell wall fragments of at least one dead, non-disease causing bacterial species of a bacterial genus and a carrier.

2. The composition of claim 1, wherein the carrier is an insect food.

3. The composition of claim 1 or 2, wherein the non-disease causing bacterial species comprises the genus *Paenibaccillus*.

4. The composition of claim 1 or 2, wherein the dead, non-disease causing bacterial species is one or more of selected from the group consisting of *Paenibacillus alvei*, *Paenibacillus dentritiformis, Paenibacillus amylolyticus*, *Paenibacillus campinasensis*, *Paenibacillus chondroitinus*, *Paenibacillus chungangensis*, *Paenibacillus doosanensis*, *Paenibacillus glucanolyticus*, Paenibacillus humicus, *Paenibacillus lactis*, *Paenibacillus lautus*, *Paenibacillus lentimorbus*, *Paenibacillus maceran*, *Paenibacillus macerans*-like, *Paenibacillus macquariensis*, Paenibacillus motobuensis, *Paenibacillus pabuli*, *Paenibacillus phoenicis*, *Paenibacillus polymyxa*, Paenibacillus popilliae, *Paenibacillus puldeungensis*, *Paenibacillus residui*, *Paenibacillus stellife*, *Paenibacillus thiaminolyticus*, *Paenibacillus validus*, and *Paenibacillus xylanisolvens*, or a combination thereof.

5. The composition of claim 1or 2, wherein the composition comprises dead, non-disease causing bacterial species *Paenibacillus alvei* and *Paenibacillus dentritiformis*.

6. The composition of any of claims 1-5, wherein the composition comprises from about 1.5×10^7 to about 1.5×10^{11} antigen units of whole cells or cell wall fragments per gram of insect food or carrier.

7. Use of an effective amount of the composition of any of claims 1 to 6 in the manufacture of a medicament for vaccinating, treating or immunizing a bee queen or bee larvae against Foulbrood disease, wherein the medicament is to be administered to a bee selected from one or more of worker bees or nurse bees that feed the bee queen, bee larvae or the bee queen, thereby immunizing the queen bee or the bee larvae produced by the queen bee.

8. The use of claim 7, wherein the Foulbrood disease is caused by a species of *Paenibacillus.*

9. The use of claim 8, wherein the Foulbrood disease is American Foulbrood disease.

10. The use of any one of claims 7 to 9, wherein the composition comprises or consists essentially of one or both of *Paenibacillus alvei* or *Paenibacillus dentritiformis.*

11. The use of claim 10, wherein the Foulbrood disease is American Foulbrood disease and is caused by *P. larvae*.

12. The use of any one of claims 7 to 11, wherein the one or more of the queen bee, worker bees, nurse bees or the larvae are to be administered from about 1.5 x 10^7 to about 1.5 x 10^{11} antigen units of whole cells or cell wall fragments per dose.

13. The use of claim 12, wherein the one or more of the queen bee, worker bees, nurse bees or larvae are to be administered at least one, or at least two, or at least three, or at least four, or at least five, or at least six, or at least seven, or at least eight, or at least nine, or at least 10 dose(s) of from 1.5 x10^7 to about 1.5 x 10^{11} antigen units of whole cells or cell wall fragments of the dead, non-disease causing species of *Paenibacillus*.

14. Use of a composition comprising whole cells or cell wall fragments of at least one dead, non-disease species of *Paenibacillus* in the manufacture of a medicament for preventing or vaccinating against American foulbrood in a population of bees, optionally honeybees, wherein the composition is to be administered to a bee queen.

15. The use of claim 14, wherein the dead non-disease species of *Paenibacillus* are selected from one or more from the group consisting of *Paenibacillus alvei*, *Paenibacillus dentritiformis, Paenibacillus amylolyticus*, *Paenibacillus campinasensis*, *Paenibacillus chondroitinus*, *Paenibacillus chungangensis*, *Paenibacillus doosanensis*, *Paenibacillus glucanolyticus*, Paenibacillus humicus, *Paenibacillus lactis*, *Paenibacillus lautus*, *Paenibacillus lentimorbus*, *Paenibacillus maceran*, *Paenibacillus macerans*-like, *Paenibacillus macquariensis*, *Paenibacillus motobuensis*, *Paenibacillus pabuli*, *Paenibacillus phoenicis*, *Paenibacillus polymyxa*, *Paenibacillus popilliae*, *Paenibacillus puldeungensis*, *Paenibacillus residui*, *Paenibacillus stellife*, *Paenibacillus thiaminolyticus*, *Paenibacillus validus*, and *Paenibacillus xylanisolvens*, or a combination thereof.

16. The use of claim 14, wherein the dead non-disease species of *Paenibacillus* are dead *Paenibacillus alvei* or *Paenibacillus dentritiformis*, or a combination thereof.

17. The use of any one of claims 14 to 16, wherein the administration comprises feeding one or more of the queen bee, worker bees, nurse bees or larvae a suitable amount of queen feed comprising from about 1.5 x 10^7 to about 1.5 x 10^{11} antigen units per dose of at least one dead non-disease species of *Paenibacillus* whole cells or cell wall fragments thereof.

18. The use of claim 17, wherein the Foulbrood disease is American Foulbrood and is caused by *P. larvae*.

19. The use of any one of claims 14 to 18, wherein the composition comprises or consists essentially of one or both of *Paenibacillus alvei* or *Paenibacillus dentritiformis.*

20. The use of claim 21, wherein the Foulbrood disease is American Foulbrood disease.

21. The use of any one of claims 14 to 19, wherein the one or more of the queen bee, worker bees, nurse bees or the larvae are to be administered from about 1.5×10^7 to about 1.5×10^{11} antigen units of whole cells or cell wall fragments per dose.

22. The use of claim 21, wherein the one or more of the queen bee, worker bees, nurse bees or larvae are to be administered at least one, or at least two, or at least three, or at least four, or at least five, or at least six, or at least seven, or at least eight, or at least nine, or at least 10 dose(s) of from about 1.5×10^7 to about 1.5×10^{11} antigen units of whole cells or cell wall fragments.

23. A method for preparing an insect composition or vaccine comprising isolating whole cells or cell wall fragments from at least one dead, non-disease causing bacterial species of a bacterial *Paenibaccilus*.

24. The method of claim 23, further comprising admixing the isolated antigen units with an insect food.

25. The method of claim 24, wherein the insect food is selected from a queen bee wafer, a sugar eater, a spirulina supplement, queen candy in the shipping container, a queen cell, an insect supplement.

26. The method of claim 25, wherein the non-disease causing bacterial species is a species of the genus *Paenibaccilus,* optionally one or both of *Paenibacillus alvei* or *Paenibacillus dentritiformis*, or a combination thereof.

27. The method of claim 26, wherein the dead *Paenibaccilus* species is selected from one or more of the group consisting of *Paenibacillus alvei*, *Paenibacillus dentritiformis, Paenibacillus amylolyticus*, *Paenibacillus campinasensis*, *Paenibacillus chondroitinus*, *Paenibacillus chungangensis, Paenibacillus doosanensis, Paenibacillus glucanolyticus, Paenibacillus humicus, Paenibacillus lactis, Paenibacillus lautus, Paenibacillus lentimorbus, Paenibacillus maceran, Paenibacillus macerans-like, Paenibacillus macquariensis, Paenibacillus motobuensis, Paenibacillus pabuli, Paenibacillus phoenicis, Paenibacillus*

polymyxa, Paenibacillus popilliae, Paenibacillus puldeungensis, Paenibacillus residui, Paenibacillus stellife, Paenibacillus thiaminolyticus, *Paenibacillus validus*, and *Paenibacillus xylanisolvens*, or a combination thereof

28. The method of claim 27, wherein the dead *Paenibaccilus* species are *Paenibacillus alvei* and *Paenibacillus dentritiforms*.

29. The method of any one of claims 23 to 28, further comprising formulating the isolated whole cells or cell wall fragments to provide from about 1.5×10^7 to about 1.5×10^{11} antigen units per dose.

30. A composition prepared by a method of any one of claims 23 to 29.

31. A vaccine composition prepared by a method of any one of claims 23 to 29.

32. A kit comprising the composition of any one of claims 1-6, and instructions for use.

33. The composition of any of claims 1 to 6 for use in therapy.

34. A composition comprising whole cells or cell wall fragments of at least one dead, non-disease species of *Paenibacillus* for use in therapy.