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Attorneys for Plaintiff
Gabriel Rojas and the Proposed Class

FILED
OCT 01 2012
RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

E-filing

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

GABRIEL ROJAS, as an individual, and on behalf of all others similarly situated,	Civil No.: C 12 5099 JCS
Plaintiff,	**CLASS ACTION COMPLAINT FOR:**
vs.	1. Violations of Cal. Bus. & Prof. C. §§ 17200, *et seq.*
GENERAL MILLS, INC.,	2. Violations of Cal. Bus. & Prof. C. §§ 17500, *et seq.*
Defendant.	3. Violations of Cal. Civ. C. §§ 1750, *et seq.*;
	Jury Trial Requested

Plaintiff, GABRIEL ROJAS, by and through his undersigned counsel, and pursuant to all applicable *Federal Rules of Civil Procedure*, hereby files this Class Action Complaint, individually, and on behalf of all others similarly situated, and alleges against Defendant, GENERAL MILLS, INC. (collectively referred to herein as "GENERAL MILLS" or "Defendant"), as follows:

I. INTRODUCTION

1. Defendant has represented its Products as "100% NATURAL," when in fact, they are not because they contain Genetically Modified Organisms ("GMOs"). Defendant manufactures, markets, advertises, distributes and sells various granola bars and snack foods, including but not limited to its Nature Valley® Dark Chocolate Peanut Butter Crunchy Granola Bars and its Nature Valley® Oats and Honey Crunchy Granola Bars (the "Products") that misleadingly claim to be "100% NATURAL." The Products are not "100% NATURAL" because they contain GMO's in the form of corn and/or soy.

2. Defendant markets the Products as "100% NATURAL" on the Products' packaging. *See* **Exhibit 1**, attached hereto and incorporated herein, copy of the Nature Valley® Dark Chocolate Peanut Butter Crunchy Granola Bars packaging and labeling and copy of the Nature Valley® Oats and Honey Crunchy Granola Bars packaging and labeling.

3. Contrary to Defendant's representations, however, the Products use plants grown from GMOs. Notably, the Products contain Corn and Soy and/or Corn and Soy variations, among other ingredients, that are known to be derived from GMOs. Specifically, the Products contain the following ingredients consisting of GMOs:

a. Soy;

b. Yellow Corn Flour;

c. Soy Flour; and

d. Soy Lecithin.

4. Plaintiff contends that Defendant should cease labeling and advertising the Product as "100% NATURAL," because the presence of GMOs in the Product renders it not "100% NATURAL." Plaintiff expressly does not request that Defendant label the Product with a GMO disclosure; rather, Plaintiff only requests Defendant to remove the "100% NATURAL" labeling from its Product.

5. GMOs are plants that grow from seeds in which DNA splicing has been used to place genes from another source into a plant.

6. The Products pose a potential threat to consumers because medical research and scientific studies have yet to determine the long-term health effects of genetically engineered foods. Recent studies suggest that GMOs may in fact be harmful to a consumer's health. For example, an insecticidal toxin, known as BT toxin, is often inserted into the genetic code of an array of crops to enable the plant to produce its own insecticide. This insecticide is released when insects ingest it. Though BT toxin was supposed to be safe for humans (the digestion system in the human body was supposed to destroy it), more recent studies have shown that the human gut is actually not destroying it. Canadian researchers this year reported that the blood of ninety-three percent (93%) of pregnant women and eighty percent (80%) of their umbilical-cord blood samples contained a pesticide implanted in GMO corn by biotech company Monsanto, though digestion was supposed to remove it from the body.

7. The Products may also harbor allergens that are not typically associated with the listed ingredients. A person allergic to Brazil nuts, for example only, would be at risk of suffering an allergic reaction from consuming a Product that contained a GMO bioengineered to

contain DNA from Brazil nuts. The consumer would be unaware of the potential allergic reaction because the Product containing the GMO in no way warn of or even indicate its genetically modified condition because it claims to be "100% NATURAL.".

8. Plaintiff contends that Products containing GMOs are not "100% NATURAL" and that Defendant's advertising and labeling is deceptive and likely to mislead the public as a result. Plaintiff would not have purchased the Products if he had known that the Defendant could not support the claim that the Products are 100% NATURAL because they contain GMOs.

9. In fact, recently a study was published that noted the harmful effects of consuming GMOs. *See* **Exhibit 2**, attached hereto and incorporated herein, *Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize*. The study was published in the Food and Chemical Toxicology Journal. *Id.* The scientists who conducted the study concluded that rats fed a diet of genetically modified organisms got sicker faster than their counterparts eating food without GMOs. *Id.*

II. VENUE AND JURISDICTION

10. This Court has jurisdiction over the subject matter presented by this Complaint because it is a class action arising under 28 U.S.C. § 1332(d), which, under the Class Action Fairness Act of 2005 ("CAFA"), Pub. L. No. 109-2, 119 Stat. 4 (2005), which explicitly provides for the original jurisdiction of the Federal Courts of any class action in which any member of the plaintiff class is a citizen of a state different from any Defendant, and in which the matter in controversy exceeds in the aggregate the sum of $5,000,000.00, exclusive of interest and costs.

11. Plaintiff alleges that the total claims of the individual members of the Plaintiff Class in this action are in excess of $5,000,000.00 in the aggregate, exclusive of interest and costs, as required by 28 U.S.C. § 1332(d)(2), (5).

12. As set forth below, Plaintiff is a citizen of California, and GENERAL MILLS can be considered a citizen of Minnesota, where it is headquartered. Therefore, diversity of citizenship exists under CAFA, as required by 28 U.S.C. § 1332(d)(2)(A).

13. Furthermore, Plaintiff alleges on information and belief that more than two-thirds of all of the members of the proposed Plaintiff Class in the aggregate are citizens of a state other than California, where this action is originally being filed, and that the total number of members of the proposed Plaintiff Class is greater than 100, pursuant to 28 U.S.C. § 1332(d)(5)(B).

14. Venue in this judicial district is proper pursuant to 28 U.S.C. §1391(a) because, as set forth below, Defendant conducts business in, and may be found in, this district, and Plaintiff purchased the subject product of this action in this judicial district. The "Declaration of Benjamin M. Lopatin, Esq., Pursuant to Civil Code §1780(c) of the Consumer Legal Remedies Act, Civil Code §§1750 et seq." regarding venue under the California Consumer Legal Remedies Act ("CLRA") is submitted herewith and is incorporated herein by reference.

III. PARTIES

15. Plaintiff is an individual more than 18 years old, and is a citizen of California, who resides in the city and County of San Francisco. He respectfully requests a jury trial on damage claims. Plaintiff has purchased several of Defendant's products, including but not limited to: Nature Valley® Dark Chocolate Peanut Butter Crunchy Granola Bars and its Nature Valley® Oats and Honey Crunchy Granola Bars (the "Products") during the Class Period from

Safeway grocery stores, including two located at 350 Bay Street, San Francisco, California 94133 and 735 7th Avenue, San Francisco, California 94118.

16. In purchasing the Products, Plaintiff saw and relied on the labeling and advertising for it displayed on the packaging. He has been damaged by his purchase of the Product because the labeling and advertising for the Product was and is false and/or misleading under California law; therefore, the Product is worth less than what Plaintiff paid for it and/or Plaintiff did not receive what he reasonably intended to receive. The labeling and advertising for the Product relied upon by Plaintiff was prepared and/or approved by GENERAL MILLS and its agents, and was disseminated by GENERAL MILLS and its agents through labeling and advertising containing the misrepresentations alleged herein. The labeling and advertising for the Product was designed to encourage consumers to purchase the Product and reasonably misled the reasonable consumer, i.e. Plaintiff and the Class into purchasing the Product.

17. Defendant General Mills Company ("General Mills") is a Delaware licensed corporation with its principal place of business located in the State of Minnesota at One General Mills Blvd., Minneapolis, Minnesota 55426. General Mills lists with the Minnesota Secretary of State a Registered Agent designated as National Registered Agents, Inc., 1209 Orange Street, Wilmington, Delaware 19801. Therefore, General Mills can be considered a "citizen" of the State of Minnesota. Defendant General Mills also promoted and marketed the Product at issue in this jurisdiction and in this judicial district.

18. GENERAL MILLS is the owner, manufacturer and distributor of the Product, and is the company that created and/or authorized the false, misleading and deceptive labeling and advertising for the Product.

IV. FACTUAL ALLEGATIONS

19. All allegations herein are based on information and belief and/or are likely to have evidentiary support after reasonable opportunity for further investigation and discovery.

20. Plaintiff alleges that, at all times relevant herein, GENERAL MILLS and its subsidiaries, affiliates, and other related entities, as well as their respective employees, were the agents, servants and employees of GENERAL MILLS, and at all times relevant herein, each was acting within the purpose and scope of that agency and employment.

21. Plaintiff further alleges on information and belief that at all times relevant herein, the distributors and retailers who delivered and sold the Product, as well as their respective employees, also were GENERAL MILLS's agents, servants and employees, and at all times herein, each was acting within the purpose and scope of that agency and employment.

22. Additionally, Plaintiff alleges that, in committing the wrongful acts alleged herein, GENERAL MILLS, in concert with its subsidiaries, affiliates, and/or other related entities and their respective employees, planned, participated in and furthered a common scheme to induce members of the public to purchase the Product by means of false, misleading, deceptive and fraudulent representations, and that GENERAL MILLS participated in the making of such representations in that it disseminated those misrepresentations and/or caused them to be disseminated.

23. Whenever reference in this Complaint is made to any act by GENERAL MILLS or its subsidiaries, affiliates, distributors, retailers and other related entities, such allegation shall be deemed to mean that the principals, officers, directors, employees, agents, and/or representatives of GENERAL MILLS committed, knew of, performed, authorized, ratified

and/or directed that act or transaction on behalf of GENERAL MILLS while actively engaged in the scope of their duties.

24. Defendant manufactures, markets, advertises, distributes and sells various granola bars and snack foods, including the Products.

25. Defendant labels and continues to label the Products as "100% NATURAL." on the Products' packaging. *See* **Exhibit 1**. Defendant's claim is misleading, however, because Defendant's Products contain GMOs, ingredients that have been modified through biotechnology and are therefore not 100% NATURAL.

26. Contrary to Defendant's representations, however, the Products use plants grown from GMOs. Notably, the Products contain Corn and Soy and/or Corn and Soy variations, among other ingredients, that are known to be derived from GMOs. Specifically, the Products contain the following ingredients consisting of GMOs:

a. Soy;

b. Yellow Corn Flour;

c. Soy Flour; and

d. Soy Lecithin.

27. The GMOs at issue are plants grown from seeds in which DNA splicing has been used to place genes from another source into a plant. This gene splicing can be used to enable a certain crop to withstand a weed-killing pesticide, for example, or incorporate a bacterial toxin that can repel pests.

28. Simply put, GMOs are not natural.[1] Therefore, any product claiming to be "All Natural" or "100% Natural" is a false claim if the product contains GMOs, as is the case here.

29. Plaintiff would not have purchased the Product had he known it was not "100% NATURAL" because it contains GMOs.

30. Plaintiff contends that Defendant should cease labeling and advertising the Product as "100% NATURAL," because the presence of GMOs in the Product renders it not "100% NATURAL." Plaintiff expressly does not request that Defendant label the Product with a GMO disclosure; rather, Plaintiff only requests Defendant to remove the "100% NATURAL" labeling from its Product.

31. Calling the Product "100% NATURAL" is a misrepresentation of material fact and violates a consumer's democratic right to information and choice.

32. Most people consider the decision of what they put into their bodies to be tremendously important. People follow restricted diets for religious reasons (some observers of the Jewish faith keep Kosher, some observers of Muslim faith only eat Halal food, and some observers of Hindu faith refuse beef), for moral or personal reasons (many vegetarians and vegans restrict their diets for moral reasons), or because they physically cannot eat certain foods (those with celiac disease cannot eat wheat, those who are lactose intolerant cannot consume dairy products, and those with other food allergies face similar restrictions). In the latter scenario, eating the food in question could cause severe physical harm or death. In the first two scenarios, while the diets may be driven by personal choice rather than physical necessity, the

1. The FDA defines the term "natural" to mean merely that nothing artificial or synthetic (including colors regardless of source) is included in, or has been added to, the product that would not normally be there. 56 F.R. 60421-01 (1991).

beliefs behind the choices are often deeply held. If a Muslim eats soup that is labeled vegetarian but in fact contains pork, or if a vegetarian eats cereal that contains mouse parts, the mislabeling that led to the inadvertent consumption is likely to be extremely offensive.[2] Likewise, Defendant's covert inclusion of GMOs in its Product amounts to an unlawful affront to the health conscious consumers and the public at large.

V. CLASS ALEGATIONS

33. Plaintiff re-alleges and incorporates by reference the allegations set forth *supra* in this Complaint.

34. Plaintiff bring this class action pursuant Federal Rule of Civil Procedure 23, California Civil Code §1781 on behalf of herself and on behalf of all other persons similarly situated. The Class which Plaintiff seeks to represent are:

> **All persons residing in the State of California who purchased, for personal use and not for resale, Nature Valley granola bars containing soy, yellow corn flower, soy flower and/or soy lecithin, and were labeled "natural" and/or "all natural" and/or "100% natural" since September 28, 2008.**

35. Excluded from the Class are Defendant's officers, directors, and employees, and any individual who received remuneration from Defendant in connection with that individual's endorsement of the Products. Plaintiff reserves the right to amend the Class definition if further investigation and discovery indicates that the Class definition should be narrowed, expanded, or otherwise modified.

36. Defendant's practices and omissions were applied uniformly to all members of the Class, so that the questions of law and fact are common to all members of the Class. All

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2. Valery Federici. "Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws." *35 Brooklyn J. Int'l L. 51 5* at 528.

members of the putative Class were and are similarly affected by having purchased and used the Product for its intended and foreseeable purpose, and the relief sought herein is for the benefit of Plaintiff and members of the putative Class.

37. Plaintiff is informed and believes, and on that basis alleges, that the Plaintiff Class is so numerous that joinder of all members would be impractical. Based on the annual sales of the Product and the popularity of the Product, it is apparent that the number of consumers of the Product would at least be in the many thousands, thereby making joinder impossible.

38. Questions of law and fact common to the Plaintiff Class exist that predominate over questions affecting only individual members, including, *inter alia*:

43. Questions of law and fact common to the Plaintiff Class and any subclass exist that predominate over questions affecting only individual members, including, inter alia:

a. Whether Defendant's practices and representations related to the marketing, labeling and sales of the Product in California were unfair, deceptive and/or unlawful in any respect, thereby violating Cal. Bus. & Prof. Code §§ 17200 *et seq.*;

b. Whether Defendant's practices and representations related to the marketing, labeling and sales of the Product in California were unfair, deceptive and/or unlawful in any respect, thereby violating Cal. Bus. & Prof. Code §§ 17500 *et seq.*;

c. Whether Defendant violated Cal. Civ. Code §§ 1750 *et seq.* with its practices and representations related to the marketing, labeling and sales of the Product within California;

d. Whether Defendant failed to adequately warn of, and/or concealed the dangers and health risks associated with the Product; and

e. Whether Defendant's conduct as set forth above injured consumers and if so, the extent of the injury.

39. The claims asserted by Plaintiff in this action are typical of the claims of the members of the Plaintiff Class, as the claims arise from the same course of conduct by Defendant, and the relief sought is common.

40. Plaintiff will fairly and adequately represent and protect the interests of the members of the Plaintiff Class. Plaintiff have retained counsel competent and experienced in both consumer protection and class action litigation.

41. Certification of this class action is appropriate under Federal Rule of Civil Procedure 23 because the questions of law or fact common to the respective members of the Class predominate over questions of law or fact affecting only individual members. This predominance makes class litigation superior to any other method available for the fair and efficient adjudication of these claims.

42. Absent a class action, it would be highly unlikely that the representative Plaintiff or any other members of the Class would be able to protect its own interests because the cost of litigation through individual lawsuits might exceed expected recovery.

43. Certification is also appropriate because Defendant acted or refused to act on grounds generally applicable to the Class, thereby making appropriate final injunctive relief

with respect to the Class as a whole. Further, given the large number of consumers of the Products, allowing individual actions to proceed in lieu of a class action would run the risk of yielding inconsistent and conflicting adjudications. Certification of this class action is appropriate under Cal. Civ. Code §1781, Cal. Code of Civil Procedure §382 and Federal Rule of Civil Procedure 23 because the questions of law or fact common to the respective members of the Class and any subclass predominate over questions of law or fact affecting only individual members.

44. A class action is a fair and appropriate method for the adjudication of the controversy, in that it will permit a large number of claims to be resolved in a single forum simultaneously, efficiently, and without the unnecessary hardship that would result from the prosecution of numerous individual actions and the duplication of discovery, effort, expense and burden on the courts that such individual actions would engender.

45. The benefits of proceeding as a class action, including providing a method for obtaining redress for claims that would not be practical to pursue individually, outweigh any difficulties that might be argued with regard to the management of this class action.

VI. FIRST CAUSE OF ACTION:
VIOLATIONS OF CAL. BUS & PROF. CODE §§ 17200 *ET SEQ.*

44. Plaintiff re-alleges and incorporates by reference the allegations set forth *supra* in this Complaint.

45. This cause of action is brought on behalf of Plaintiff and members of the general public pursuant to Cal. Bus. & Prof. Code §§ 17200 *et seq.*, which provides that "unfair competition shall mean and include any unlawful, unfair or deceptive business act or practice and unfair, deceptive, untrue or misleading advertising and any act prohibited by Chapter I

(commencing with Section 17500) as Part 3 of Division 7 of the Business and Professions Code."

46. Defendant has violated the Act by engaging in the unfair and deceptive practices described above, which offend public policies and are immoral, unethical, unscrupulous and substantially injurious to consumers. Specifically, Defendant has represented that the Product is "100% NATURAL." Plaintiff contends that Defendant should cease labeling and advertising the Product as "100% NATURAL," because the presence of GMOs in the Product renders it not "100% NATURAL."

46. Plaintiff alleges that Defendant committed unfair business acts and/or practices, as set forth in detail above. The utility of Defendant's practices related to the deceptive labeling and advertising of the Product is negligible, if any, when weighed against the harm to the general public.

47. The harmful impact upon members of the general public who purchased and used the Product outweighs any reasons or justifications by Defendant for the deceptive labeling and advertising practices employed to sell the Product that misleadingly claims to be "100% NATURAL."

48. Defendant had an improper motive (profit before accurate marketing) in its practices related to the deceptive labeling and advertising of the Product, as set forth above.

49. The use of such unfair business acts and practices was and is under the sole control of Defendant, and was deceptively hidden from members of the general public in Defendant's marketing, advertising and labeling of the Product.

50. Defendant committed a deceptive act or practice by making the labeling and advertising representations set forth in detail above. These deceptive acts and practices had a capacity, tendency, and/or were likely to deceive or confuse reasonable consumers.

51. Defendant also committed an unlawful business practice by violating the FAL and CLRA as set forth in detail below. These violations serve as predicate violations of this prong of the UCL.

52. As a purchaser and consumer of Defendant's Product, and as a member of the general public in California who purchased and used the Product, Plaintiff is entitled to and does bring this class action seeking all available remedies under the UCL.

53. Defendant's labeling and advertising practices, as set forth above, were intended to promote the sale of the Product and constitute unfair, deceptive and/or unlawful business practices within the meaning of California Bus. & Prof. Code § 17200 *et seq.*

54. Pursuant to California Bus. & Prof. Code § 17203, Plaintiff, on behalf of himself and members of the general public, seeks an order of this Court requiring Defendant to restore to Plaintiff and other California purchasers of the Product all monies that may have been acquired by Defendant as a result of such unfair, deceptive and/or unlawful business acts or practices.

55. Plaintiff and California purchasers of the Product will be denied an effective and complete remedy in the absence of such an order.

56. As a result of Defendant's violations of the UCL, Plaintiff and California purchasers of the Product are entitled to restitution for out-of-pocket expenses and economic harm.

57. Pursuant to Civil Code § 3287(a), Plaintiff and California purchasers of the Product are further entitled to pre-judgment interest as a direct and proximate result of Defendant's wrongful conduct.

58. The amount on which interest is to be calculated is a sum certain and capable of calculation, and Plaintiff and California purchasers of the Product are entitled to interest in an amount according to proof.

VII. SECOND CAUSE OF ACTION: VIOLATIONS OF CAL. BUS. & PROF. CODE §§ 17500 *ET SEQ.*

59. Plaintiff re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs of this Complaint.

47. In violation of California Bus. & Prof. Code § 17500, Defendant disseminated, or caused to be disseminated, the deceptive Product labeling and advertising representations that misleadingly claim that the Product is "100% NATURAL." Plaintiff contends that Defendant should cease labeling and advertising the Product as "100% NATURAL," because the presence of GMOs in the Product renders it not "100% NATURAL."

60. Defendant's Product labeling and advertising representations are misleading because it cannot support its claim that the Product is "100% NATURAL."

61. Defendant's labeling and advertising representations for the Product are by their very nature unfair, deceptive and/or unlawful within the meaning of California Bus. & Prof. Code § 17500 et seq. The representations were likely to deceive reasonable consumers.

62. In making and disseminating the deceptive representations alleged herein, Defendant knew or should have known that the representations were misleading, and acted in violation of California's Bus. & Prof. Code §§17500 *et seq.*

63. As a direct and proximate result of Defendant's wrongful conduct, Plaintiff and California purchasers of the Product have suffered substantial monetary and non-monetary damage.

64. Pursuant to Bus. & Prof. Code § 17535, Plaintiff, on behalf of himself and other California purchasers of the Product, seeks an order of this Court requiring Defendant to restore to California purchasers of the Product all monies that may have been acquired by Defendant as a result of such unfair, deceptive and/or unlawful acts or practices.

65. As a result of Defendant's violations of the FAL, Plaintiff and California purchasers of the Product are entitled to restitution for out-of-pocket expenses and economic harm.

66. Pursuant to Civil Code § 3287(a), Plaintiff and California purchasers of the Product are further entitled to pre-judgment interest as a direct and proximate result of Defendant's wrongful conduct.

67. The amount on which interest is to be calculated is a sum certain and capable of calculation, and Plaintiff and California purchasers of the Product are entitled to interest in an amount according to proof.

VIII. THIRD CAUSE OF ACTION:
FOR VIOLATIONS OF CAL. CIV. CODE §§ 1750 *ET SEQ.*
(CLAIM FOR INJUNCTIVE RELIEF ONLY)

68. Plaintiff re-alleges and incorporates by reference the allegations set forth in the preceding paragraphs of this Complaint.

69. This cause of action is brought pursuant to Cal. Civ. Code §§ 1750 *et seq.*

70. Plaintiff and each California purchaser of the Product are "consumers" within the meaning of Civil Code §1761(d).

71. The purchases of the Product by Plaintiff and California purchasers of the Product were and are "transactions" within the meaning of Civil Code §1761(e).

72. Defendant has represented that the Product is "100% NATURAL." Plaintiff contends that Defendant labeled and advertised the Product as "100% NATURAL," when it is not because of the presence of GMOs in the Product, which renders it not "100% NATURAL," and which violated the CLRA in at least the following respects as set forth in detail above:

a. In violation of Civil Code §1770(a)(5), GENERAL MILLS represented that the Product has characteristics, ingredients, uses, and benefits which it does not have; and

b. In violation of Civil Code §1770(a)(7), GENERAL MILLS represented that the Product is of a particular standard, quality, or grade, which it is not.

c. In violation of Civil Code §1770(a)(9), GENERAL MILLS advertised the Product with an intent not to sell the Product as advertised;

d. In violation of Civil Code §1770(a)(14), GENERAL MILLS represented that the purchase of the Product confers or involves rights, remedies, or obligations which it does not have or involve, or which are prohibited by law; and

e. In violation of Civil Code §1770(a)(16), GENERAL MILLS represented that the subject of the sale of the Product has been supplied in accordance with a previous representation when it has not.

73. Plaintiff seeks and is entitled to injunctive, equitable relief in the form of an order requiring Defendant to make full restitution to California purchasers of the Product of all monies wrongfully obtained as a result of the conduct described above.

74. Plaintiff, by and through counsel, has notified Defendant in writing of the particular violations of Section 1770 of the CLRA, and demanded that it take certain corrective actions within the period prescribed by the CLRA for such demands.

75. In the event that Defendant fails to adequately respond to the demands for corrective action within the time prescribed by the CLRA, Plaintiff intends to amend this pleading to request statutory and actual damages, as well as punitive damages, interest and attorneys' fees as authorized by Section 1780(a) of the CLRA, along with this claim for injunctive relief.

76. Regardless of an award of damages upon the filing of an Amended Complaint, Plaintiff seeks and is entitled to, pursuant to Section 1780(a)(2) of the CLRA, an order for the equitable relief described above, as well as costs, attorney's fees and any other relief which the Court deems proper.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, GABRIEL ROJAS, individually, and on behalf of all others similarly situated, prays for relief pursuant to each cause of action set forth in this Complaint as follows:

1. For an order certifying that the action may be maintained as a class action, certifying Plaintiff as representative of the Class, and designating his attorneys Class counsel;

2. For an award of equitable relief as follows:

(a) Enjoining Defendant from making any claims for the Products found to violate the UCL, FAL, or CLRA as set forth above;

(b) Requiring Defendant to make full restitution of all monies wrongfully obtained as a result of the conduct described in this Complaint; and

(c) Requiring Defendant to disgorge all ill-gotten gains flowing from the conduct described in this Complaint.

3. For an award of attorney's fees pursuant to, *inter alia*, §1780(d) of the CLRA and Code of Civil Procedure §1021.5.

4. For actual damages in an amount to be determined at trial for the Fourth, Fifth and Sixth Causes of Action.

5. For punitive damages in an amount to be determined at trial for the Fifth Cause of Action.

6. For an award of costs and any other award the Court might deem appropriate; and

7. For pre- and post-judgment interest on any amounts awarded.

IX. DEMAND FOR JURY TRIAL

Plaintiff demands a jury trial on all issues so triable.

Respectfully Submitted,

Dated: September 27, 2012

By: /s/ Benjamin M. Lopatin
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Attorneys for Plaintiff
Gabriel Rojas and the Proposed Class

EXHIBIT

1

0.5g (3% DV), Trans Fat 0g, Cholesterol 0mg (0% DV), Sodium 160mg (7% DV), Total Carbohydrate 29g (10% DV), Dietary Fiber 2g (8% DV), Sugars 12g, Protein 4g, Iron (4% DV). Not a significant source of vitamin A, vitamin C and calcium. Percent Daily Values (DV) are based on a 2,000 calorie diet.
*16g of whole grain per serving. At least 48g recommended daily.
0 16000 26469 4
NATURE VALLEY
100% NATURAL
CRUNCHY
granola bars
Oats 'n Honey
16g of whole grain*
NET WT 1.5 OZ (42g)
Ingredients: Whole Grain Oats, Sugar, Canola Oil, Yellow Corn Flour, Honey, Soy Flour, Brown Sugar Syrup, Salt, Soy Lecithin, Baking Soda, Natural Flavor.
CONTAINS SOY; MAY CONTAIN PEANUT, ALMOND AND PECAN INGREDIENTS
DISTRIBUTED BY GENERAL MILLS SALES, INC., MINNEAPOLIS, MN 55440 USA
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NATURE VALLEY
granola bars
Oats 'n Honey
Take a bar with you wherever you go!
BOX TOPS EDUCATION
EXPIRES 6/1/15
NATURE VALLEY
100% NATURAL
CRUNCHY
granola bars
ENLARGED TO SHOW DETAIL
12 BARS
Oats 'n Honey
16g of whole grain*
6 - 1.5 OZ (42g) 2-BAR POUCHES NET WT 8.9 OZ (252g)
No matter where
the path
takes you...
Official natural granola bar of...
NATURE VALLEY
is there.
*16g of whole grain per serving.
Nutrition Facts
Serving Size 2 bars (42g)
Servings Per Container 6
Amount Per Serving 2 bars 1 bar
Calories 190 90
Calories from Fat 60 30
Total Fat 6g 9% 3g 5%
Saturated Fat 0.5g 3% 0g 0%
Trans Fat 0g 0g
Cholesterol 0mg 0% 0mg 0%
Sodium 160mg 7% 80mg 3%
Total Carbohydrate 29g 10% 15g 5%
Dietary Fiber 2g 8% 1g 4%
Sugars 12g 6g
Protein 4g 2g
Iron 4% 2%
Ingredients: Whole Grain Oats, Sugar, Canola Oil, Yellow Corn Flour, Honey, Soy Flour, Brown Sugar Syrup, Salt, Soy Lecithin, Baking Soda, Natural Flavor.
CONTAINS SOY; MAY CONTAIN PEANUT, ALMOND AND PECAN INGREDIENTS.
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Carbohydrate Choices: 2
3202646160
Quality Guarantee
NATURE VALLEY
granola bars


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Where do you
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on our favorite rafting trip
Mike – NY
a perfect snack out on the hiking trail
Sara – ID
NATURE VALLEY
CRUNCHY
Oats 'n Honey
Love to take them on camping trips with my friends
Earl – OK
Share your story on our Facebook page or tweet us!

Carbohydrate Choices: 2
Nutrition Facts Serving Size: 2 bars (42g), Amount Per Serving: Calories 190, Calories from Fat 70, Total Fat 8g (12% DV), Saturated Fat 1.5g (7% DV), Trans Fat 0g, Cholesterol 0mg (0% DV), Sodium 170mg (7% DV), Total Carbohydrate 27g (9% DV), Dietary Fiber 3g (10% DV), Sugars 12g, Protein 4g, Iron (4% DV). Not a significant source of vitamin A, vitamin C and calcium. Percent Daily Values (DV) are based on a 2,000 calorie diet.
0 16000 50706 7
02APR2013CD1425S
NATURE VALLEY
100% NATURAL
CRUNCHY
granola bars
190 CALORIES PER 2 BARS
Dark Chocolate Peanut Butter
NET WT 1.49 OZ (42g)
Ingredients: Whole Grain Oats, Sugar, Canola Oil, Dark Chocolate Chips (sugar, chocolate liquor, cocoa butter, soy lecithin, natural flavor, salt), Roasted Peanuts, Yellow Corn Flour, Soy Flour, Peanut Butter (peanuts, salt), Brown Sugar Syrup, Honey, Salt, Natural Flavor, Soy Lecithin, Baking Soda. CONTAINS PEANUT, SOY; MAY CONTAIN ALMOND AND PECAN INGREDIENTS.
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Nutrition Facts

Serving Size 2 bars (42g)
Servings Per Container 6

Amount Per Serving	2 bars	%DV*	1 bar	%DV*
Calories	190		100	
Calories from Fat	70		35	
Total Fat	8g	12%	4g	6%
Saturated Fat	1.5g	7%	0.5g	4%
Trans Fat	0g		0g	
Cholesterol	0mg	0%	0mg	0%
Sodium	170mg	7%	85mg	4%
Total Carbohydrate	27g	9%	14g	5%
Dietary Fiber	3g	10%	1g	5%
Sugars	12g		6g	
Protein	4g		2g	
Iron		4%		2%

Not a significant source of vitamin A, vitamin C and calcium.

*Percent Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

	Calories	2,000	2,500
Total Fat	Less Than	65g	80g
Sat Fat	Less Than	20g	25g
Cholesterol	Less Than	300mg	300mg
Sodium	Less Than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Ingredients: Whole Grain Oats, Sugar, Canola Oil, Dark Chocolate Chips (sugar, chocolate liquor, cocoa butter, soy lecithin, natural flavor, salt), **Roasted Peanuts, Yellow Corn Flour, Soy Flour, Peanut Butter** (peanuts, salt), **Brown Sugar Syrup, Honey, Salt, Natural Flavor, Soy Lecithin, Baking Soda.**

CONTAINS PEANUT, SOY; MAY CONTAIN ALMOND AND PECAN INGREDIENTS.

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EXHIBIT

2

Food and Chemical Toxicology xxx (2012) xxx–xxx

Contents lists available at SciVerse ScienceDirect

Food and Chemical Toxicology

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journal homepage: www.elsevier.com/locate/foodchemtox

Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize

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ARTICLE INFO

Article history:
Received 11 April 2012
Accepted 2 August 2012
Available online xxxx

Keywords:
GMO
Roundup
NK603
Rat
Glyphosate-based herbicides
Endocrine disrupting effects

ABSTRACT

The health effects of a Roundup-tolerant genetically modified maize (from 11% in the diet), cultivated with or without Roundup, and Roundup alone (from 0.1 ppb in water), were studied 2 years in rats. In females, all treated groups died 2–3 times more than controls, and more rapidly. This difference was visible in 3 male groups fed GMOs. All results were hormone and sex dependent, and the pathological profiles were comparable. Females developed large mammary tumors almost always more often than and before controls, the pituitary was the second most disabled organ; the sex hormonal balance was modified by GMO and Roundup treatments. In treated males, liver congestions and necrosis were 2.5–5.5 times higher. This pathology was confirmed by optic and transmission electron microscopy. Marked and severe kidney nephropathies were also generally 1.3–2.3 greater. Males presented 4 times more large palpable tumors than controls which occurred up to 600 days earlier. Biochemistry data confirmed very significant kidney chronic deficiencies; for all treatments and both sexes, 76% of the altered parameters were kidney related. These results can be explained by the non linear endocrine-disrupting effects of Roundup, but also by the overexpression of the transgene in the GMO and its metabolic consequences.

1. Introduction

There is an ongoing international debate as to the necessary length of mammalian toxicity studies in relation to the consumption of genetically modified (GM) plants including regular metabolic analyses (Séralini et al., 2011). Currently, no regulatory authority requests mandatory chronic animal feeding studies to be performed for edible GMOs and formulated pesticides. However, several studies consisting of 90 day rat feeding trials have been conducted by the biotech industry. These investigations mostly concern GM soy and maize that are rendered either herbicide tolerant (to Roundup (R) in 80% of cases), or engineered to produce a modified *Bt* toxin insecticide, or both. As a result these GM crops contain new pesticide residues for which new maximal residual levels (MRL) have been established in some countries.

If the petitioners conclude in general that there is no major change in genetically modified organism (GMO) subchronic toxicity studies (Domingo and Giné Bordonaba, 2011; Hammond et al., 2004, 2006a,b), significant disturbances have been found and may be interpreted differently (Séralini et al., 2009; Spiroux de Vendômois et al., 2010). Detailed analyses have revealed alterations in kidney and liver functions that may be the signs of early chronic diet intoxication, possibly explained at least in part by pesticide residues in the GM feed (Séralini et al., 2007; Spiroux de Vendômois et al., 2009). Indeed, it has been demonstrated that R concentrations in the range of 10^3 times below the MRL induced endocrine disturbances in human cells (Gasnier et al., 2009) and toxic effects thereafter (Benachour and Seralini, 2009), including *in vivo* (Romano et al., 2012). After several months of consumption of an R-tolerant soy, the liver and pancreas of mice were affected, as highlighted by disturbances in sub-nuclear structure (Malatesta et al., 2008a, 2002a,b). Furthermore, this toxic effect was reproduced by the application of R herbicide directly to hepatocytes in culture (Malatesta et al., 2008b).

Abbreviations: GM, genetically modified; R, Roundup; MRL, maximal residual levels; GMO, genetically modified organism; OECD, Organization for Economic Co-operation and Development; GT, glutamyl-transferase; PCA, principal component analysis; PLS, partial least-squares; OPLS, orthogonal partial least-squares; NIPALS, Nonlinear Iterative Partial Least Squares; OPLS-DA, Orthogonal Partial Least Squares Discriminant Analysis; G, glycogen; L, lipid droplet; N, nucleus; R, rough endoplasmic reticulum (on microscopy pictures only); U, urinary; UEx, excreted in urine during 24 h; APPT, Activated Partial Thromboplastin Time; MCV, Mean Corpuscular Volume; PT, Prothrombine Time; RBC, Red Blood Cells; ALT, alanine aminotransferase; MCHC, Mean Corpuscular Hemoglobin Concentration; A/G, Albumin/Globulin ratio; WBC, White Blood Cells; AST, aspartate aminotransferase.

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0278-6915/$ - see front matter
http://dx.doi.org/10.1016/j.fct.2012.08.005

Since then, long-term and multi-generational animal feeding trials have been performed with some possibly providing evidence of safety, while others conclude on the necessity of further investigations because of metabolic modifications (**Snell et al., 2011**). However, none of these studies have included a detailed follow-up of the animals with up to 11 blood and urine samples over 2 years, and none has investigated the NK603 R-tolerant maize.

Furthermore, toxicity evaluation of herbicides is generally performed on mammalian physiology through the long-term study of only their active principle, rather than the formulation used in agriculture, as was the case for glyphosate (**Williams et al., 2000**), the active herbicide constituent of R. It is important to note that glyphosate is only able to efficiently penetrate target plant organisms with the help of adjuvants present in the various commercially used R formulations (**Cox, 2004**). When R residues are found in tap water, food or feed, they arise from the total herbicide formulation, which is the most commonly used mixture in agriculture; indeed many authors in the field have strongly emphasized the necessity of studying the potential toxic effects of total chemical mixtures rather than single components (**Cox and Surgan, 2006; Mesnage et al., 2010; Monosson, 2005**). Even adjuvants and not only glyphosate or other active ingredients are found in ground water (**Krogh et al., 2002**), and thus an exposure to the diluted whole formulation is more representative of an environmental pollution than the exposure to glyphosate alone in order to study health effects.

With a view to address this lack of information, we have performed a 2 year detailed rat feeding study. The actual guideline 408 of the Organization for Economic Co-operation and Development (OECD) was followed by some manufacturers for GMOs even if it was not designed for that purpose. We have explored more parameters and more frequently than recommended in this standard (**Table 1**) in a long-term experiment. This allowed us to follow in details potential health effects and their possible origins due to the direct or indirect consequences of the genetic modification itself in GMOs, or due to the formulated herbicide mixture used on GMOs (and not glyphosate alone), or both. Because of recent reviews on GMOs (**Domingo and Giné Bordonaba, 2011; Snell et al., 2011**) we had no reason to settle at first for a carcinogenesis protocol using 50 rats per group. However we have prolonged the biochemical and hematological measurements or disease status recommended in combined chronic studies using 10 rats per group (up to 12 months in OECD 453). This remains the highest number of rats regularly measured in a standard GMO diet study. We have tested also for the first time 3 doses (rather than two in the usual 90 day long protocols) of the R-tolerant NK603 GM maize alone, the GM maize treated with R, and R alone at very low environmentally relevant doses starting below the range of levels permitted by regulatory authorities in drinking water and in GM feed.

2. Materials and methods

2.1. Ethics

The experimental protocol was conducted in accordance with the regulations of our ethics in an animal care unit authorized by the French Ministries of Agriculture and Research (Agreement Number A35-288-1). Animal experiments were performed according to ethical guidelines of animal experimentations (CEE 86/609 regulation). Concerning field studies of plant species, no specific permits were required, nor for the locations/activities. The maize grown (MON-00603-6 commonly named NK603) was authorized for unconfined release into the environment and use as a livestock feed by the Canadian Food Inspection Agency (Decision Document 2002-35). We confirm that the location is not privately-owned or protected in any way and that the field studies did not involve endangered or protected species. The GM maize was authorized for import into the European Union (CE 258/97 regulation).

2.2. Plants, diets and chemicals

The varieties of maize used in this study were the R-tolerant NK603 (Monsanto Corp., USA), and its nearest isogenic non-transgenic control. These two types of maize were grown under similar normal conditions, in the same location, spaced at a sufficient distance to avoid cross-contamination. The genetic nature, as well as the purity of the GM seeds and harvested material, was confirmed by qPCR analysis of DNA samples. One field of NK603 was treated with R at 3 L ha^{-1} (WeatherMAX, 540 g/L of glyphosate, EPA Reg. 524-537), and another field of NK603 was not treated with R. Corns were harvested when the moisture content was less than 30% and were dried at a temperature below 30 °C. From these three cultivations of

Table 1
Protocol used and comparison to existing assessment, and to non-mandatory regulatory tests.

Treatments and analyses	In this work	**Hammond et al., 2004**	Regulatory tests
Treatments + controls	GMO NK603, GMO NK603 + Roundup, Roundup, and closest isogenic maize	GMO NK603 + Roundup, closest isogenic maize, and six other maize lines non substantially equivalent	GMOs or chemicals (in standard diet or water)
Doses by treatment	3	2	At least 3
Duration in months	24 (chronic)	3 (subchronic: 13 weeks)	3
Animals measured/group/sex	10/10 SD rats (200 rats measured)	10/20 SD rats (200 rats measured/total 400)	At least 10 rodents
Animals by cage (same sex)	1–2	1	1 or more
Monitoring/week	2	1	1 or more
Feed and water consumptions	Measured	For feed only	At least feed
Organs and tissues studied			For high dose and controls
Histology/animal	34	17/36	At least 30
Organs weighted	10	7	At least 8
Electronic microscopy	Yes	No	No
Behavioral studies (times)	2	1 (no protocol given)	1
Ophtalmology (times)	2	0	2
Number of blood samples/ animal	11, each month (0–3) then every 3 months	2, weeks 4 and 13	1, at the end
Blood parameters	31 (11 times for most)	31 (2 times)	At least 25 (at least 2 times)
Plasma sex steroids	Testosterone, estradiol	No	No, except if endocrine effects suspected
Liver tissue parameters	6	0	0
Number of urine samples	11	2	Optional, last week
Urine parameters studied	16	18	7 if performed
Microbiology in feces or urine	Yes	Yes	No
Roundup residues in tissues	Studied	Not studied	Not mandatory
Transgene in tissues	Studied	Not studied	Not studied

The protocol used in this work was compared to the regulatory assessment of NK603 maize by the company (**Hammond et al., 2004**), and to non mandatory regulatory *in vivo* tests for GMOs, or mandatory for chemicals (OECD 408). Most relevant results are shown in this paper.

maize, laboratory rat chow was made based on the standard diet A04 (Safe, France). The dry rat feed was made to contain 11, 22 or 33% of GM maize, cultivated either with or without R, or 33% of the non-transgenic control line. The concentrations of the transgene were confirmed in the three doses of each diet by qPCR. All feed formulations consisted in balanced diets, chemically measured as substantially equivalent except for the transgene, with no contaminating pesticides over standard limits. All secondary metabolites cannot be known and measured in the composition. However we have measured isoflavones and phenolic acids including ferulic acid by standard HPLC-UV. All reagents used were of analytical grade. The herbicide diluted in the drinking water was the commercial formulation of R (GT Plus, 450 g/L of glyphosate, approval 2020448, Monsanto, Belgium). Herbicides levels were assessed by glyphosate measurements in the different dilutions by mass spectrometry.

2.3. Animals and treatments

Virgin albino Sprague-Dawley rats at 5 weeks of age were obtained from Harlan (Gannat, France). All animals were kept in polycarbonate cages (820 cm^2, Genestil, France) with two animals of the same sex per cage. The litter (Toplit classic, Safe, France) was replaced twice weekly. The animals were maintained at 22 ± 3 °C under controlled humidity (45–65%) and air purity with a 12 h-light/dark cycle, with free access to food and water. The location of each cage within the experimental room was regularly moved. This 2 year life-long experiment was conducted in a GPL environment according to OECD guidelines. After 20 days of acclimatization, 100 male and 100 female animals were randomly assigned on a weight basis into 10 equivalent groups. For each sex, one control group had access to plain water and standard diet from the closest isogenic non-transgenic maize control; six groups were fed with 11, 22 and 33% of GM NK603 maize either treated or not with R. The final three groups were fed with the control diet and had access to water supplemented with respectively 1.1×10^{-8}% of R (0.1 ppb of R or 50 ng/L of glyphosate, the contaminating level of some regular tap waters), 0.09% of R (400 mg/kg, US MRL of glyphosate in some GM feed) and 0.5% of R (2.25 g/L, half of the minimal agricultural working dilution). This was changed weekly. Twice weekly monitoring allowed careful observation and palpation of animals, recording of clinical signs, measurement of any tumors that may arise, food and water consumption, and individual body weights.

2.4. Biochemical analyses

Blood samples were collected from the tail vein of each rat under short isoflurane anesthesia before treatment and after 1, 2, 3, 6, 9, 12, 15, 18, 21 and 24 months: 11 measurements were obtained for each animal alive at 2-years. It was first demonstrated that anesthesia did not impact animal health. Two aliquots of plasma and serum were prepared and stored at −80° C. Then 31 parameters were assessed (**Table 1**) according to standard methods including hematology and coagulation parameters, albumin, globulin, total protein concentration, creatinine, urea, calcium, sodium, potassium, chloride, inorganic phosphorus, triglycerides, glucose, total cholesterol, alanine aminotransferase, aspartate aminotransferase, gamma glutamyl-transferase (GT), estradiol, testosterone. In addition, at months 12 and 24 the C-reactive protein was assayed. Urine samples were collected similarly 11 times, over 24 h in individual metabolic cages, and 16 parameters were quantified including creatinine, phosphorus, potassium, chloride, sodium, calcium, pH and clairance. Liver samples at the end made it possible to perform assays of CYP1A1, 1A2, 3A4, 2C9 activities in S9 fractions, with glutathione S- transferase and gamma-GT.

2.5. Anatomopathology

Animals were sacrificed during the course of the study only if necessary because of suffering according to ethical rules (such as 25% body weight loss, tumors over 25% body weight, hemorrhagic bleeding, or prostration), and at the end of the study by exsanguination under isoflurane anesthesia. In each case, the following organs were collected: brain, colon, heart, kidneys, liver, lungs, ovaries, spleen, testes, adrenals, epididymis, prostate, thymus, uterus, aorta, bladder, bone, duodenum, esophagus, eyes, ileum, jejunum, lymph nodes, lymphoreticular system, mammary glands, pancreas, parathyroid glands, Peyer's patches, pituitary, salivary glands, sciatic nerve, skin, spinal cord, stomach, thyroid and trachea. The first 14 organs (at least 10 per animal depending on the sex, **Table 1**) were weighted, plus any tumor that arose. The first nine organs were divided into two parts and one half was immediately frozen in liquid nitrogen/carbonic ice. The remaining parts including other organs were rinsed in PBS and stored in 4% formalin before anatomopathological study. These samples were used for further paraffin-embedding, slides and HES histological staining. For transmission electron microscopy, kidneys, livers and tumors were cut into 1 mm^3 fragments. Samples were fixed in pre-chilled 2% paraformaldehyde/2.5% glutaraldehyde in 0.1 M PBS pH 7.4 at 4 °C for 3 h and processed as previously described (**Malatesta et al., 2002a**).

2.6. Statistical analysis

Biochemical data were treated by multivariate analysis with the SIMCA-P (V12) software (UMETRICS AB Umea, Sweden). The use of chemometrics tools, for example, principal component analysis (PCA), partial least-squares to latent structures (PLS), and orthogonal PLS (OPLS), are robust methods for modeling, analyzing and interpreting complex chemical and biological data. OPLS is a recent modification of the PLS method. PLS is a regression method used in order to find the relationship between two data tables referred to as X and Y. PLS regression (**Eriksson et al., 2006b**) analysis consists in calculating by means of successive iterations, linear combinations of the measured X-variables (predictor variables). These linear combinations of X-variables give PLS components (score vectors t). A PLS component can be thought of as a new variable – a latent variable – reflecting the information in the original X-variables that is of relevance for modeling and predicting the response Y-variable by means of the maximization of the square of covariance (Max $cov^2(X,Y)$). The number of components is determined by cross validation. SIMCA software uses the Nonlinear Iterative Partial Least Squares algorithm (NIPALS) for the PLS regression. Orthogonal Partial Least Squares Discriminant Analysis (OPLS-DA) was used in this study (**Weljie et al., 2011; Wiklund et al., 2008**). The purpose of Discriminant Analysis is to find a model that separates groups of observations on the basis of their X variables. The X matrix consists of the biochemical data. The Y matrix contains dummy variables which describe the group membership of each observation. Binary variables are used in order to encode a group identity. Discriminant analysis finds a discriminant plan in which the projected observations are well separated according to each group. The objective of OPLS is to divide the systematic variation in the X-block into two model parts, one linearly related to Y (in the case of a discriminant analysis, the group membership), and the other one unrelated (orthogonal) to Y. Components related to Y are called predictive, and those unrelated to Y are called orthogonal. This partitioning of the X data results in improved model transparency and interpretability (**Eriksson et al., 2006a**). Prior to analysis, variables were mean-centered and unit variance scaled.

3. Results

3.1. Mortality

Control male animals survived on average 624 ± 21 days, whilst females lived for 701 ± 20, during the experiment, plus in each case 5 weeks of age at the beginning and 3 weeks of stabilization period. After mean survival time had elapsed, any deaths that occurred were considered to be largely due to aging. Before this period, 30% control males (three in total) and 20% females (only two) died spontaneously, while up to 50% males and 70% females died in some groups on diets containing the GM maize (**Fig. 1**). However, the rate of mortality was not proportional to the treatment dose, reaching a threshold at the lowest (11%) or intermediate (22%) amounts of GM maize in the equilibrated diet, with or without the R application on the plant. It is noteworthy that the first two male rats that died in both GM treated groups had to be euthanized due to kidney Wilm's tumors that were over 25% of body weight. This was at approximately a year before the first control animal died. The first female death occurred in the 22% GM maize feeding group and resulted from a mammary fibroadenoma 246 days before the first control. The maximum difference in males was 5 times more deaths occurring during the 17th month in the group consuming 11% GM maize, and in females 6 times greater mortality during the 21st month on the 22% GM maize diet with and without R. In the female cohorts, there were 2–3 times more deaths in all treated groups compared to controls by the end of the experiment and earlier in general. Females were more sensitive to the presence of R in drinking water than males, as evidenced by a shorter lifespan. The general causes of death represented in histogram format (**Fig. 1**) are linked mostly to large mammary tumors in females, and other organic problems in males.

3.2. Anatomopathological observations

All rats were carefully monitored for behavior, appearance, palpable tumors, infections, during the experiment, and at least 10 organs per animal were weighted and up to 34 analyzed post mortem, at the macroscopic and/or microscopic levels (**Table 1**).

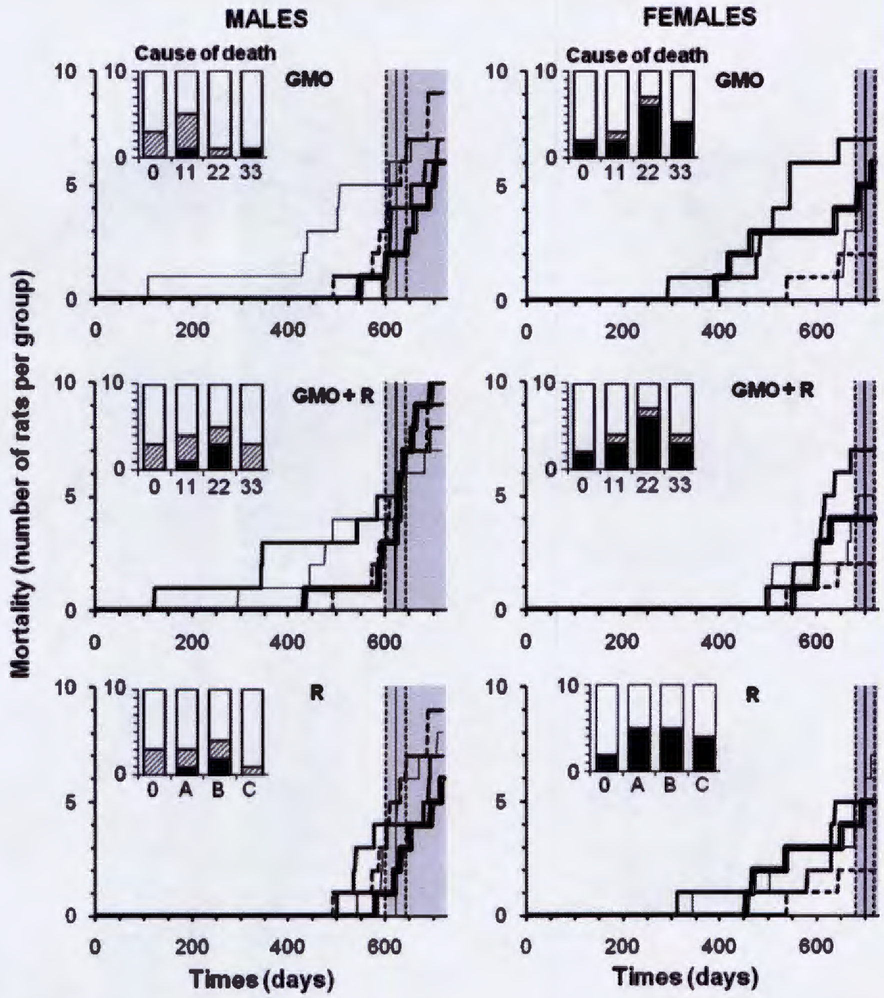

Fig. 1. Mortality of rats fed GMO treated or not with Roundup, and effects of Roundup alone. Rats were fed with NK603 GM maize (with or without application of Roundup) at three different doses (11, 22, 33% in their diet: thin, medium and bold lines, respectively) compared to the substantially equivalent closest isogenic non-GM maize (control, dotted line). Roundup was administrated in drinking water at 3 increasing doses, same symbols (environmental (A), MRL in agricultural GMOs (B) and half of minimal agricultural levels (C), see Section 2). Lifespan during the experiment for the control group is represented by the vertical bar ± SEM (grey area). In bar histograms, the causes of mortality before the grey area are detailed in comparison to the controls (0). In black are represented the necessary euthanasia because of suffering in accordance with ethical rules (tumors over 25% body weight, more than 25% weight loss, hemorrhagic bleeding, etc.); and in hatched areas, spontaneous mortality.

All data cannot be shown in one report, and the most relevant are described here. There was no rejection by the animals of the diet with or without GMOs, nor any major difference in the body weight.

The largest palpable growths (above a diameter of 17.5 mm in females and 20 mm in males) were found to be in 95% of cases non-regressive tumors, and were not infectious nodules. These growths progressively increased in size and number, but not proportionally to the treatment dose over the course of the experiment (Fig. 2). As in the case of rates of mortality, this suggests that a threshold in effect was reached at the lowest doses. They were rarely equal but almost always more frequent than in controls for all treated groups, often 2–3 times more in both sexes. Tumors began to reach a large size on average 94 days before in treated females, and up to 600 days earlier in 2 male groups eating the GM maize (11 and 22% with or without R).

In female animals, the largest tumors were in total 5 times more frequent than in males after 2 years, with 93% being mammary tumors. Adenomas, fibroadenomas and carcinomas were deleterious to health due to a very large size, rather than the grade of the tumor itself. Large tumor size caused impediments to either breathing or nutrition and digestion because of their thoracic or abdominal location and also resulted in hemorrhaging. In addition, one metastatic ovarian cystadenocarcinoma and two skin tumors were identified. Metastases were observed in only 2 cases; one in a group fed with 11% GM maize, and another in the highest dose of R treatment group.

Up to 14 months, no animals in the control groups showed any signs of tumors whilst 10–30% of treated females per group developed tumors, with the exception of one group (33% GMO + R). By the beginning of the 24th month, 50–80% of female animals had developed tumors in all treated groups, with up to 3 tumors per animal, whereas only 30% of controls were affected. The R treatment groups showed the greatest rates of tumor incidence with 80% of animals affected with up to 3 tumors for one female, in each group. A summary of all mammary tumors at the end of the experiment, independent of the size, is presented in Table 2. The same trend was observed in the groups receiving R in their drinking water; all females except one (with metastatic ovarian carcinoma) presented, in addition mammary hypertrophies and in some cases hyperplasia with atypia (Table 2).

The second most affected organ in females was the pituitary gland, in general around 2 times more than in controls for most treatments (Table 2). At this level again, adenomas and/or hyper-

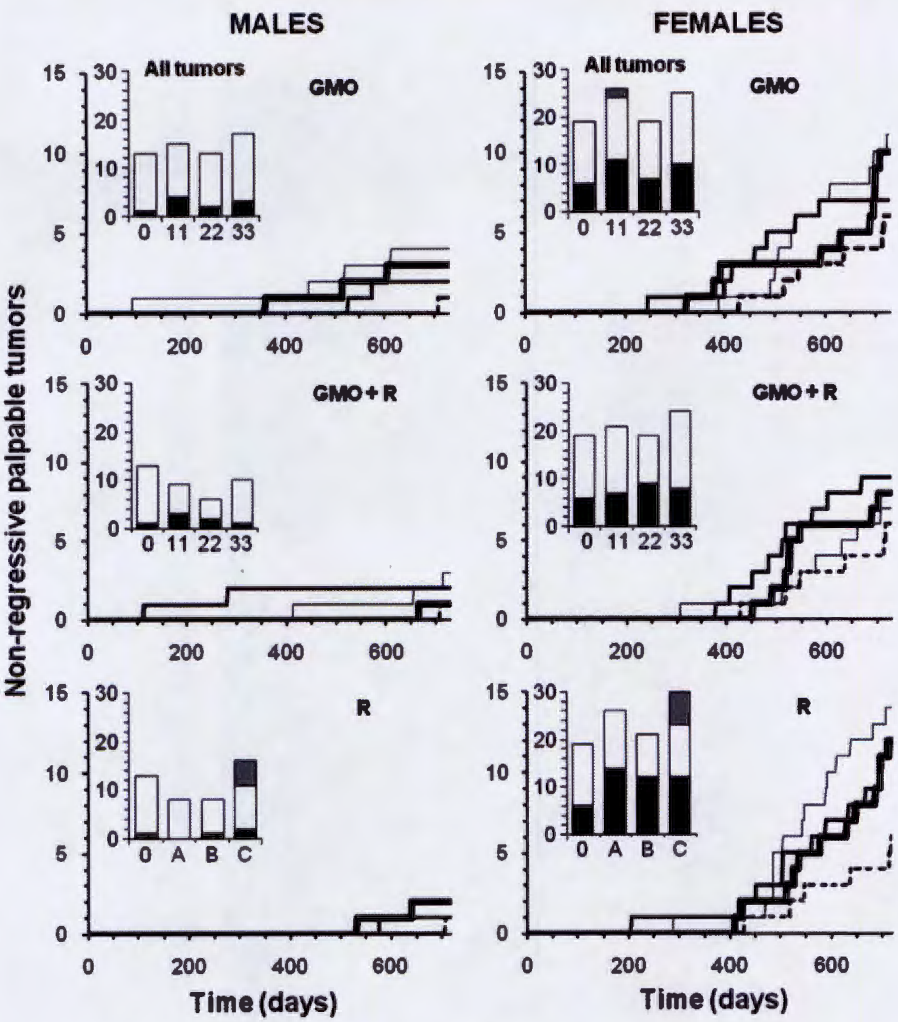

Fig. 2. Largest non-regressive tumors in rats fed GMO treated or not by Roundup, and effects of Roundup alone. The symbols of curves and treatments are explained in the caption of Fig. 1. The largest tumors were palpable during the experiment and numbered from 20 mm in diameter for males and 17.5 mm for females. Above this size, 95% of growths were non-regressive tumors. Summary of all tumors are shown in the bar histograms: black, non regressive largest tumors; white, small internal tumors; grey, metastases.

Table 2
Summary of the most frequent anatomical pathologies observed.

Organs and associated pathologies	Controls	GMO 11%	GMO 22%	GMO 33%	GMO 11% + R	GMO 22% + R	GMO 33% + R	R (A)	R (B)	R (C)
Males, in liver	2 (2)	5 (4)	11 (7)	8 (6)	5 (4)	7 (4)	6 (5)	11 (5)	9 (7)	6 (5)
In hepatodigestive tract	6 (5)	10 (6)	13 (7)	9 (6)	9 (6)	13 (6)	11 (7)	23 (9)	16 (8)	9 (5)
Kidneys, CPN	3 (3)	4 (4)	5 (5)	7 (7)	5 (5)	4 (4)	4 (4)	6 (6)	5 (5)	3 (3)
Females, mammary tumors	8 (5)	15 (7)	10 (7)	15 (8)	10 (6)	11 (7)	13 (9)	20 (9)	16 (10)	12 (9)
In mammary glands	10 (5)	22 (8)	10 (7)	16 (8)	17 (8)	16 (8)	15 (9)	26 (10)	20 (10)	18 (9)
Pituitary	9 (6)	23 (9)	20 (8)	8 (5)	19 (9)	9 (4)	19 (7)	22 (8)	16 (7)	13 (7)

After the number of pathological abnormalities, the number of rats reached is indicated in parentheses. In male animals pathological signs are liver congestions, macroscopic spots and microscopic necrotic foci. Hepatodigestive pathological signs concern the liver, stomach and small intestine (duodenum, ileum or jejunum). Only marked or severe chronic progressive nephropathies (CPN) are listed, excluding two nephroblastomas in groups consuming GMO 11% and GMO 22% + Roundup. In females, mammary fibroadenomas and adenocarcinomas are the major tumors detected; galactoceles and hyperplasias with atypia are also found and added in mammary glands pathological signs. Pituitary dysfunctions include adenomas, hyperplasias and hypertrophies. For details of the various treatment groups see Fig. 1.

plasias and hypertrophies were noticed. For all R treatment groups, 70–80% of animals presented 1.4–2.4 times more abnormalities than controls in this gland.

The big palpable tumors in males (in kidney, and mostly skin) were by the end of the experimental period on average twice as frequent as in controls, in which one skin fibroma appeared during the 23rd month. At the end of the experiment, internal non-palpable tumors were added, and their sums were lower in males than in females. They were not really different from controls, although slightly above in females (Histograms Fig. 2).

The most affected organs in males were the liver, together with the hepatodigestive tract and kidneys (Table 2 and Fig. 3). Hepatic congestions, macroscopic and microscopic necrotic foci were 2.5–5.5 times more frequent in all treatments than in control groups. Gamma GT hepatic activity was increased in particular for GMO + R groups (up to 5.4 times), this being probably due to a liver disorder.

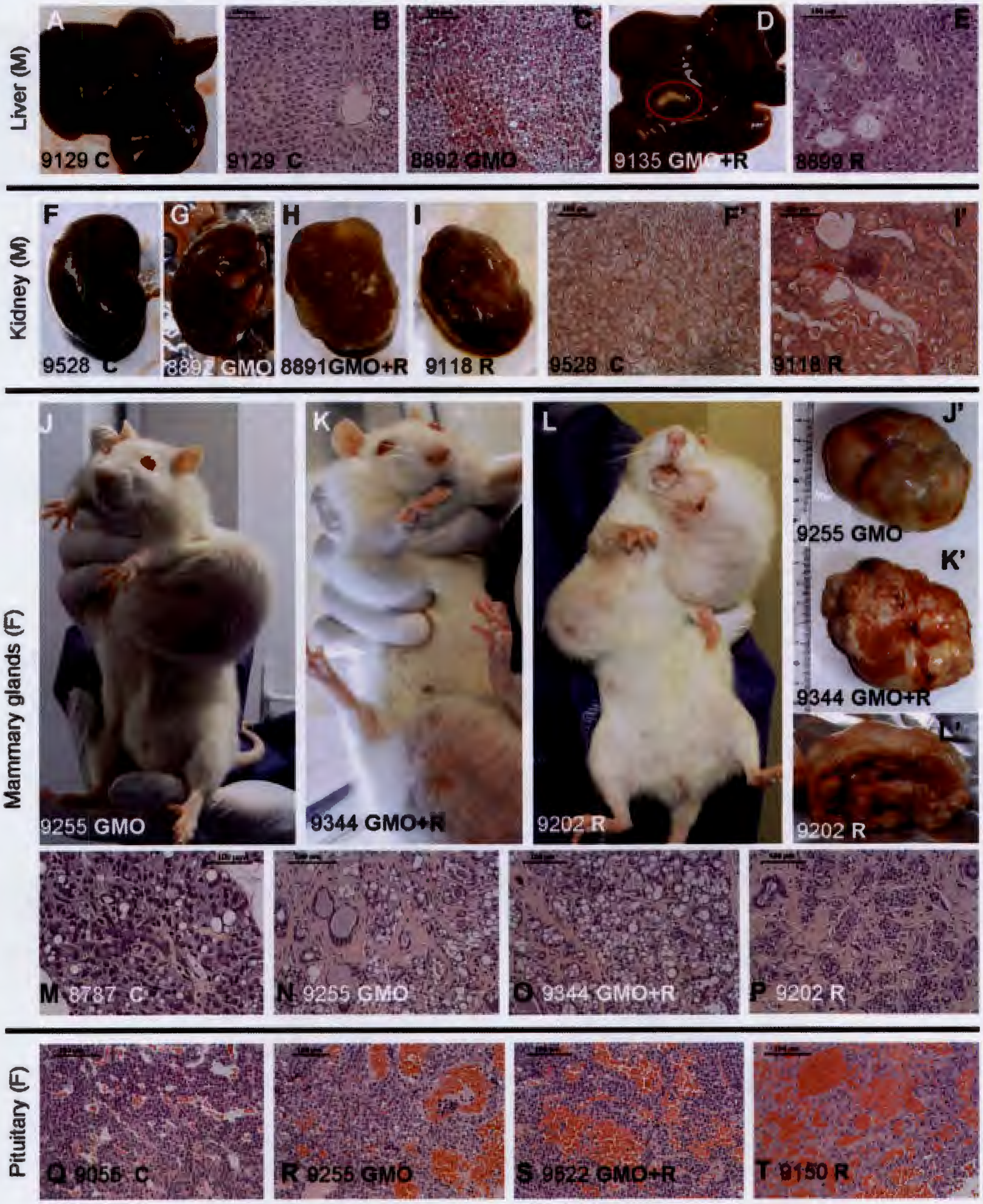

Fig. 3. Anatomopathological observations in rats fed GMO treated or not by Roundup, and effects of Roundup alone. Macroscopic and microscopic photographs show male livers (A–E) and left kidneys (F–I'), female mammary glands (J–P) and pituitaries (Q–T), according to Table 2. The number of each animal and its treatment is specified. Macroscopic pale spots (D) and microscopic necrotic foci in liver (C clear-cell focus, E basophilic focus with atypia), and marked or severe chronic progressive nephropathies, are illustrated. In females, mammary tumors (J,J',N adenocarcinoma and K,K',L,L',O,P fibroadenomas) and pituitary adenomas (R–T) are shown and compared to controls (C after the rat number).

In addition, cytochrome activities also generally increased in the presence of R (in drinking water or GM diet) according to the dose up to 5.7 times at the highest dose. Transmission electron microscopic observations of liver samples confirmed changes for all treated groups in relation to glycogen dispersion or appearance in lakes, increase of residual bodies and enlargement of cristae in mitochondria (Fig. 4). The GM maize fed groups either with or without R application (in plants) showed a reduced transcription in mRNA and rRNA because of higher heterochromatin content, and decreased nucleolar dense fibrillar components. In the GMO + R group (at the highest dose) the smooth endoplasmic reticulum was drastically increased and nucleoli decreased in size,

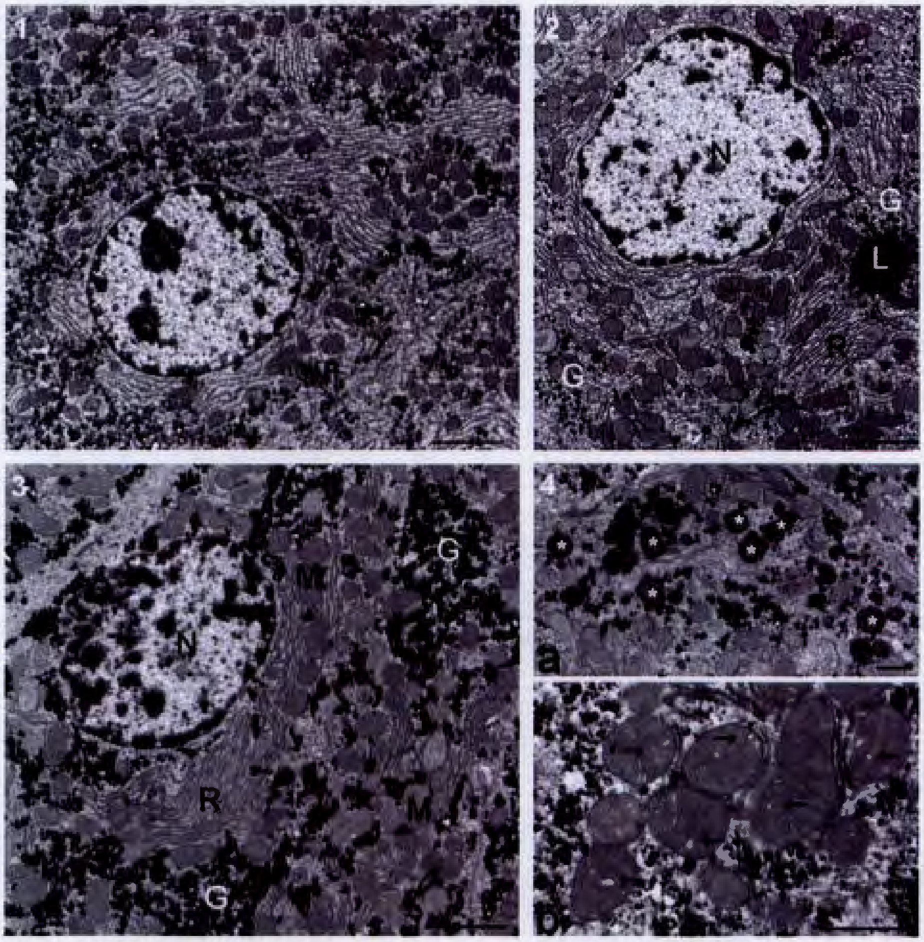

Fig. 4. Ultrastructure of hepatocytes in male rats from groups presenting the greatest degree of liver pathology. (1) Typical control rat hepatocyte (Bar 2 μm except in 4). (2) Effects with Roundup at the lowest dose. Glycogen (G) is dispersed in the cytoplasm. L, lipid droplet; N, nucleus; R rough endoplasmic reticulum. (3) Hepatocytes of animal fed GM maize (GMO) at 22% of total diet. Large lakes of glycogen occur in the cytoplasm. M, mitochondria. (4) Details of treatment effects with 22% dietary GMO (Bar 1 μm). (a) Cluster of residual bodies (asterisks). (b) Mitochondria show many enlarged cristae (arrows).

becoming more compact. For R treatment alone similar trends were observed, with a partial resumption of nucleolar activity at the highest dose.

Degenerating kidneys with turgid inflammatory areas demonstrate the increased incidence of marked and severe chronic progressive nephropathies, which were up to 2-fold higher in the 33% GM maize or lowest dose R treatment groups (**Table 2** and **Fig. 3**).

3.3. Biochemical analyses

For the different corns and diets, the study of the standard chemical composition revealed no particular difference; this is why they were classified as substantially equivalent, except for transgene DNA quantification. For instance, there was no difference between total isoflavones. In addition, other specific compounds not always requested for substantial equivalence establishment were assayed. Among phenolic acids, the only consistent and significant ($p < 0.01$) results concerned ferulic acid that was decreased in both GM and GM + R diets by 16–30% in comparison to the control diet (889 ± 107, 735 ± 89 respectively vs control 1057 ± 127 mg/kg) and caffeic acid by 21–53% (17.5 ± 2.1, 10.3 ± 1.3 vs control 22.1 ± 2.6 mg/kg).

For biochemical measurements in rats, statistical analysis was performed on the results obtained from samples taken at the 15th month time point, as this was the last sampling time when most animals were still alive (in treated groups 90% males, 94% females, and 100% controls). OPLS-DA 2-class models were built between each treated group per sex and controls. Only models with an explained variance $R^2(Y) \geqslant 80\%$, and a cross-validated predictive ability $Q^2(Y) \geqslant 60\%$, were used for selection of the discriminant variables (**Fig. 5A**), when their regression coefficients were significant at 99% confidence level. Thus, in treated females, kidney failures appeared at the biochemical level (82% of the total disrupted parameters). Ions (Na, Cl) or urea increased in urine. Accordingly, the same ions decreased in serum (**Fig. 5B**) as did the levels of P, K and Ca. Creatinine or clairance decreased in urine for all treatment groups in comparison to female controls (**Table 3**). In GM maize treated males (with or without R), 87% of discriminant variables were kidney related, but the disrupted profiles were less obvious because of advanced chronic nephropathies and deaths. In summary, for all treatments and both sexes, 76% of the discriminant variables versus controls were kidney related.

Moreover, in females (**Table 3**) the androgen/estrogen balance in serum was modified by GM maize and R treatments (at least 95% confidence level, **Fig. 5B**), and for male animals at the highest R-treatment dose, levels of estrogens were more than doubled.

4. Discussion

This report describes the first life-long rodent (rat) feeding study investigating possible toxic effects rising from an R-tolerant

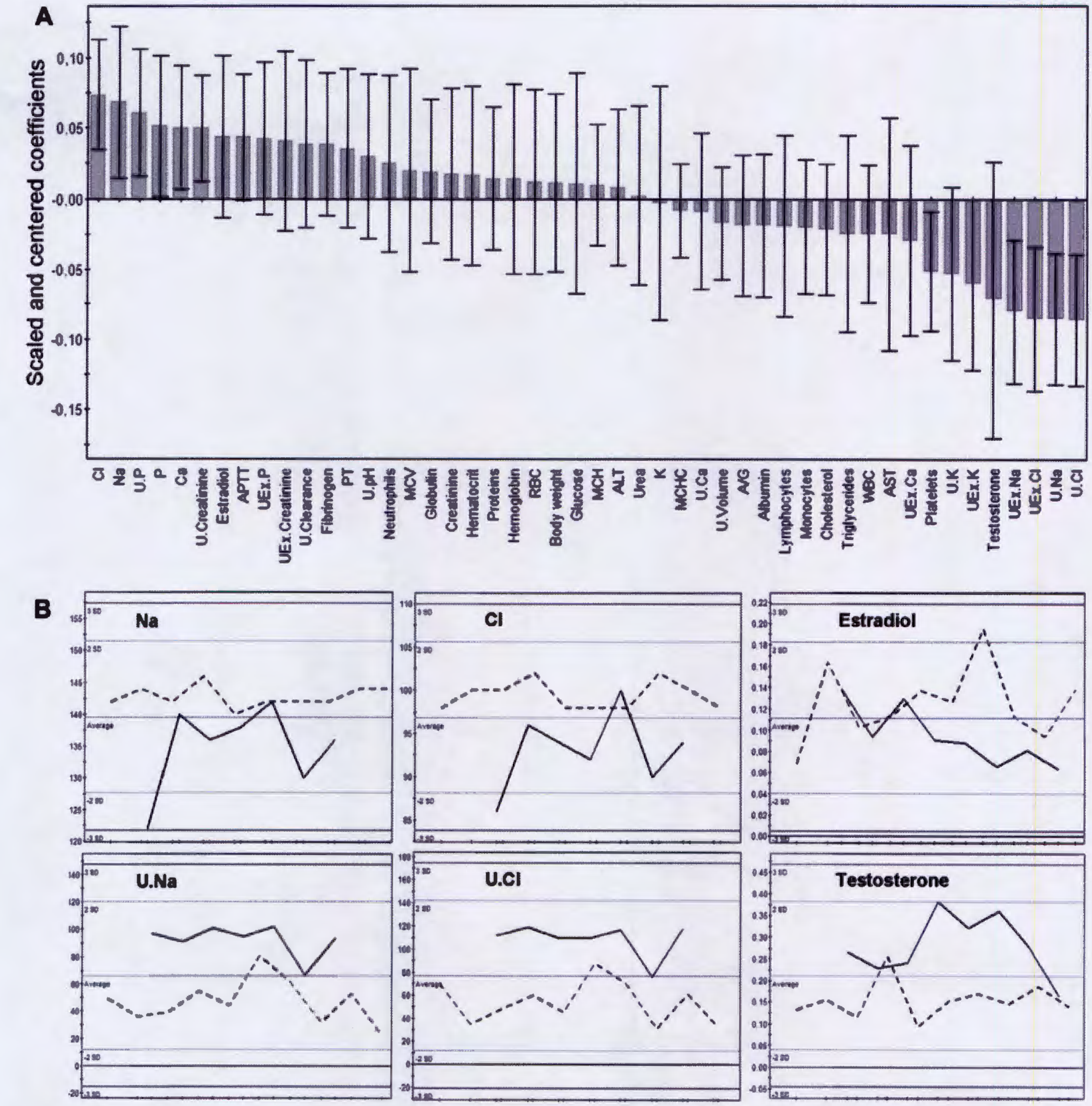

Fig. 5. Orthogonal Partial Least Squares-Discriminant Analysis (OPLS-DA) for biochemical data (females fed 33% GMO versus controls). (A) OPLS-DA regression coefficients for predictive component, with jack-knifed confidence intervals at 99% confidence level, indicate discriminant parameters versus controls at month 15 (Abbreviations: U Urinary, UEx Excreted in urine during 24 h, APPT Activated Partial Thromboplastin Time, MCV Mean Corpuscular Volume, PT Prothrombine Time, RBC Red Blood Cells, ALT ALanine aminoTransferase, MCHC Mean Corpuscular Hemoglobin Concentration, A/G Albumin/Globulin ratio, WBC White Blood Cells, AST aspartate aminotransferase). (B) In this case, detailed examples of significant discriminant variables distribution between females fed 33% GMO (bold line) and controls (dotted line). On *x* axis: animals; on *y* axis: serum or urine biochemical values for Na, Cl, estradiol, testosterone. Profiles evidence kidney ion leakages and sex hormonal imbalance versus controls.

GM maize (NK603) and a complete commercial formulation of R-herbicide.

Our data show that, as is often the case for hormonal diseases, most observed effects in this study were not proportional to the dose of the treatment (GM maize with and without R application; R alone), non-monotonic and with a threshold effect (Vandenberg et al., 2012). Similar degrees of pathological symptoms were noticed in this study to occur from the lowest to the highest doses suggesting a threshold effect. This corresponds to levels likely to arise from consumption or environmental exposure, such as either 11% GM maize in food, or 50 ng/L of glyphosate in R-formulation as can be found in some contaminated drinking tap waters, and which fall within authorized limits.

The lifespan of the control group of animals corresponded to the mean rat lifespan, but as is frequently the case with most mammals including humans (WHO, 2012), males on average died before females, except for some female treatment groups. All treatments in both sexes enhanced large tumor incidence by 2–3-fold in com-

Table 3
Percentage variation of parameters indicating kidney failures of female animals.

Discriminant variables		GMO 11% + R	GMO 22% + R	GMO 33% + R	GMO 11%	GMO 22%	GMO 33%	R (A)	R (B)	R (C)
Urinary decrease	Clairance	−4	−11	−20	**−20**	**−20**	−19	**−20**	**−24**	**−40**
	Creatinine	−5	**−32**	**−37**	−19	−37	**−36**	−43	−23	−1
	Creatinine ex	−5	−11	**−19**	−18	**−17**	−21	**−21**	**−22**	**−39**
Urinary increase	Urea	12	**18**	15	15	12	−1	0	13	**32**
	Na	25	33	30	52	−2	**95**	**62**	65	**91**
	Na ex	24	50	68	50	24	**125**	**108**	51	7
	Cl	14	35	28	46	5	**101**	**67**	56	**94**
	Cl ex	20	63	70	51	31	**138**	**121**	48	13
Serum decrease	Na	2	1	1	−1	**−4**	−6	−7	**0**	−3
	Cl	−1	−2	−2	−5	−7	**−6**	**−8**	−1	−4
	P	−6	−11	−13	−17	**−18**	**−20**	**−32**	−9	−13
	K	**4**	5	10	2	−4	**0**	−4	8	**−5**
	Ca	**4**	3	3	**2**	−2	**−5**	−6	3	**−6**
Gonads	Estradiol	8	−1	2	5	−2	−25	−26	**−73**	39
	Testosterone	5	−9	27	**56**	17	81	**97**	**−72**	10

OPLS-DA was performed on 48 variables at month 15. Here we showed mean differences (%) of variables (discriminant at 99% confidence level, in bold character) indicating kidney parameters of female animals, together with sex hormones. Male kidney pathologies are already illustrated in Table 2.

parison to our controls but also for the number of mammary tumors in comparison to the same Harlan Sprague Dawley strain (Brix et al., 2005), and overall around 3-fold in comparison to the largest study with 1329 Sprague Dawley female rats (Chandra et al., 1992). In our study the tumors also developed considerably faster than the controls, even though the majority of tumors were observed after 18 months. The first large detectable tumors occurred at 4 and 7 months into the study in males and females respectively, underlining the inadequacy of the standard 90 day feeding trials for evaluating GM crop and food toxicity (Séralini et al., 2011).

Suffering inducing euthanasia and deaths corresponded mostly in females to the development of large mammary tumors. These appeared to be clearly related to the various treatments when compared to the control groups. These tumors are generally known to be mostly estrogen-dependent (Harvell et al., 2000). We observed a strikingly marked induction of mammary tumors by R alone, a major formulated pesticide, even at the very lowest dose administered. R has been shown to disrupt aromatase which synthesizes estrogens (Richard et al., 2005), but to also interfere with estrogen and androgen receptors in cells (Gasnier et al., 2009). In addition, R appears to be a sex endocrine disruptor *in vivo*, also in males (Romano et al., 2010). Sex steroids are also modified in treated rats. These hormone-dependent phenomena are confirmed by enhanced pituitary dysfunction in treated females. An estrogen modified feedback mechanism may act at this level (Popovics et al., 2011; Walf and Frye, 2010). The similar pathological profiles provoked by the GM maize containing R residues may thus be explained at least by R residues themselves, knowing that the medium dose of the R treatment corresponds to acceptable levels of this pesticide residues in GMOs.

Interestingly, in the groups of animals fed with the NK603 without R application, similar effects with respect to enhanced tumor incidence and mortality rates were observed. A possible explanation for this finding is the production of specific compound(s) in the GM feed that are either directly toxic and/or cause the inhibition of pathways that in turn generate chronic toxic effects. This is despite the fact that the variety of GM maize used is this study was judged by industry and regulators as being substantially equivalent to the corresponding non-GM closest isogenic line. As the total chemical composition of the GM maize cannot be measured in details, the use of substantial equivalence is insufficient to highlight potential unknown toxins and therefore cannot replace long-term animal feeding trials for GMOs. A cause of the effects of the effects could be that the NK603 GM maize used in this study is engineered to overexpress a modified version of the *Agrobacterium tumefaciens* 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) (Hammond et al., 2004) allowing the R tolerance. The modified EPSPS is not inhibited by glyphosate by contrast to the wild enzyme. This enzyme is known to drive the first step of aromatic amino acid biosynthesis in the plant shikimate pathway; in addition estrogenic isoflavones and their glycosides are also products of this pathway (Duke et al., 2003). They were not disturbed in our study. By contrast, the levels of caffeic and ferulic acids in the GM diets, which are also secondary metabolites from this pathway, but not always measured in regulatory tests, are significantly reduced. This may lower their protective effects against carcinogenesis and even mammalian tumors (Kuenzig et al., 1984; Baskaran et al., 2010). Moreover, these phenolic acids and in particular ferulic acid may modulate estrogen receptors or the estrogenic pathway in mammalian cells (Chang et al., 2006). This does not exclude the action of other unknown metabolites. This explanation also corresponds to the fact that the observed effects of NK603 and R are not additive and reached a threshold. This implies that both the NK603 maize and R may cause hormonal disturbances in the same biochemical and physiological pathway.

As expected, mammary tumors in males occurred far less frequently than in females. Death in male rats was mostly due to the development of severe hepatorenal insufficiencies, confirming the first signs of toxicity observed in 90 day feeding trials with NK603 maize (Spiroux de Vendômois et al., 2009). In females, kidney ion leakages were evidenced at the biochemical levels at month 15, when severe nephropathies were evidenced in dead male animals afterwards, at the anatomopathological level. Early signs of toxicity at month 3 in kidney and liver were also observed for 19 edible GM crops containing pesticide residues (Séralini et al., 2011). As a matter of fact, only elderly male rats are sensitive to chronic progressive nephropathies (Hard and Khan, 2004). The disturbed kidney parameters may have been induced by the reduction of phenolic acids in our study, since caffeic and ferulic acids are beneficial in the kidney as they prevent oxidative stress (Srinivasan et al., 2005; U Rehman and Sultana, 2011). Accordingly, we previously demonstrated that plant extracts containing ferulic and caffeic acids were able to promote detoxification of embryonic kidney cells after R contamination (Gasnier et al., 2011). It is thus possible that NK603 consumption by reducing these compounds may well provoke an early aging of kidney physiology in this study, like R by oxidative stress.

Disturbances that we found to occur in the male liver are characteristic of a chronic intoxication, confirmed by alterations in biochemical liver and kidney function parameters. The observation that liver function in female animals is less affected may be due to their physiology being better adapted to estrogen metabolism. Furthermore, liver enzymes have been clearly demonstrated as sex-specific in their expression patterns, including in a 90-day rat feeding trial of NK603 maize (Spiroux de Vendômois et al., 2009). However, in a long-term study, evidence of early liver aging was observed in female mice fed with R-tolerant GM soy (Malatesta et al., 2008a). In the present investigation, deeper analysis at an ultrastructural level revealed evidence of impediments in transcription and other defects in cell nuclear structure that were comparable in both sexes, and dose-dependent in hepatocytes in all treatments. This is consistent with the well-documented toxic effect of very low dilutions of R on apoptosis, mitochondrial function, and cell membrane degradation inducing necrosis of hepatocytes, and other cell lines (Benachour and Seralini, 2009; Benachour et al., 2007; Gasnier et al., 2010; Peixoto, 2005).

The disruptions of at least the estrogen-related pathways and/or enhancement of oxidative stress by all treatments need further investigations. This can be addressed through the application of transcriptomic, proteomic and metabolomic methods to analyze the molecular profiles of kidneys and livers, as well as the GM NK603 maize (Jiao et al., 2010; Zhou et al., 2009; Zolla et al., 2008). Other possible causes of observed pathogenic effects may be due to disturbed gene expression resulting from the transgene insertional, general mutagenic or metabolic effects (Latham et al., 2006; Wilson et al., 2006) as has been shown for MON810 GM maize (Rosati et al., 2008). A consequent disruption of general metabolism in the GMO cannot be excluded, which could lead, for example, to the production of other potentially active compounds such as miRNAs (Zhang et al., 2012) or leukotoxin diols (Markaverich et al., 2005).

In conclusion, it was previously known that glyphosate consumption in water above authorized limits may provoke hepatic and kidney failures (EPA). The results of the study presented here clearly demonstrate that lower levels of complete agricultural glyphosate herbicide formulations, at concentrations well below officially set safety limits, induce severe hormone-dependent mammary, hepatic and kidney disturbances. Similarly, disruption of biosynthetic pathways that may result from overexpression of the EPSPS transgene in the GM NK603 maize can give rise to comparable pathologies that may be linked to abnormal or unbalanced phenolic acids metabolites, or related compounds. Other mutagenic and metabolic effects of the edible GMO cannot be excluded. This will be the subject of future studies, including transgene and glyphosate presence in rat tissues. Reproductive and multigenerational studies will also provide novel insights into these problems. This study represents the first detailed documentation of long-term deleterious effects arising from the consumption of a GM R-tolerant maize and of R, the most used herbicide worldwide.

Altogether, the significant biochemical disturbances and physiological failures documented in this work confirm the pathological effects of these GMO and R treatments in both sexes, with different amplitudes. We propose that agricultural edible GMOs and formulated pesticides must be evaluated very carefully by long term studies to measure their potential toxic effects.

Conflict of Interest

The authors declare that there are no conflicts of interest.

Acknowledgments

We thank Michael Antoniou for English assistance and constructive comments on the manuscript, as well as Herrade Hemmerdinger for proofreading. We gratefully acknowledge the Association CERES, the Foundation "Charles Leopold Mayer pour le Progrès de l'Homme", the French Ministry of Research, and CRIIGEN for their major support.

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