Everyone in agriculture—from farmers, to agribusiness executives, to the professors who conduct agricultural research—says that decisions ranging from what to eat to settling international trade conflicts should be based on science.

“But developments in the past few weeks have raised questions about how much people should trust agricultural science and scientists.”

Outline of Today’s Talk

I. Policy Framework Governing Organic Food and Farming

II. USDA’s Commitment to Sound Science

III. Basis and Future Prospects for Value-Added Claims on Organic Products

IV. NGO and Private Sector Programs

V. Future Prospects for Nutrient Content Claims on Organic Brands

VI. The Case for USDA Policy Reform

Defining Characteristics of Federal Policy on Organic Production

- Organic farming **consistently delivers environmental benefits** rooted in soil health and the promotion of biodiversity, but...
- There are no consistent or meaningful differences in the nutritional quality or safety of organic versus conventionally raised food.

Are These Organic Food Policy Statements Consistent...

- … With **modern science** and USDA’s own data?
II. USDA Commitment to Sound Science

Are These Organic Food Policy Statements Consistent...

- ... With modern science and USDA’s own data?
- ... With federal agencies’ approach to value-added certification and label claims?

USDA Recognizes Changes...

Through the NOP, USDA has helped farmers and businesses create an industry that today encompasses over 17,000 organic businesses in the United States, and has grown to $31 billion in U.S. retail sales over 22 years, at an average growth rate of 16 percent. When viewed as a distinct category, organic ranks fourth in U.S.-based crop production at $59.8 billion.

Tom Vilsack
Secretary of Agriculture

II. USDA Commitment to Sound Science

U.S. DEPARTMENT OF AGRICULTURE
WASHINGTON, D.C., 20250

DEPARTMENTAL REGULATION

Subject: Scientific Integrity

Regulatory Impact Analysis

May 10, 2013

Office of the Chief Scientist

Promote a culture of scientific integrity. Science, and public trust in science, thrive in an environment that shields scientific data and analyses and their use in policy making from political interference or inappropriate influence.

... But Agencies Must Deal with the Tango Between Science and Policy

Congress Reacts

Law Passed

People NOT happy

Agency Collects Sound Science

Undermining Congressional Mandates in the Name of “Sound Science”

- July, 1996: Food Quality Protection Act (FQPA) passes unanimously in both Houses of Congress after 17 years of failed attempts.
- 1997–1998: Misleading ads (see left) and misinformation from industry lobbyists spread the rumor that EPA was about to cancel ALL uses of ALL organophosphate (OP) insecticides.
  
  So....
  
  Farmers “not happy”

Memo from V.P. Al Gore to Glickman and Browner on FQPA Implementation

April 8, 1998

MEMORANDUM FOR
SECRETARY DANIEL R. Glickman
ADMINISTRATOR CAROL M. Browner

Implementation of the FQPA’s stronger standards presents complex scientific and regulatory issues.

1. Regulatory decisions should be based on the best science and data that are available.
2. EPA should continue to seek peer review and public review of its methods and approaches for analyzing potential risk under the new law, particularly with respect to models, exposure scenarios, and use of scientific inferences. Use of default assumptions and exposure scenarios should be carefully considered and fully explained in the public record.
3. In evaluating whether or not to remove or reduce the presumptive tenfold safety factor for risks specific to children, EPA should recognize the discretion provided in the current law.
Hurry Up and Act So Delay Is Assured

MEMORANDUM FOR SECRETARY DANIEL R. Glickman
ADMINISTRATOR CAROL M. BROWNER

April 8, 1998

The V.P. gives the two agency heads 14 days to develop and implement a plan to, basically, slow the process down and amplify the voice of worried farmers (and the pesticide industry).

Another triumph for sound science, or capitulation to special interests?

But In Real Life, the Tango Can Get Fast and Heated ...

Congress Reacts
Law Passed

People NOT happy
Agency Collects Sound Science

... Because Issues are Complex ...

Congress Reacts
Law Passed

People NOT happy
Agency Collects Sound Science

... Because Biological Systems are Complex ...

Congress Reacts
Law Passed

People NOT happy
Agency Collects Sound Science

... Data Can Be Messy, and Actions Lead to Unintended Consequences ...

Congress Reacts
Law Passed

People NOT happy
Collects Science

Photo: Flickr user Brendan under CC BY 2.0

Photo: Flickr user Señor Hans under CC BY-NC-ND 2.0

Photo: Flickr user Señor Hans under CC BY-NC-ND 2.0

Photo: Flickr user Señor Hans under CC BY-NC-ND 2.0
III. Basis and Future Prospects for Value-Added Claims on Organic Products

A. Is Organic Food Always Better Than Conventional Food?

A farm or manufacturer can obtain and retain organic certification, while producing food that is no safer nor more nutritious than its conventional counterparts.

THIS REALITY IS THE BASIS FOR THE USDA/NOP POSITION REGARDING VALUE-ADDED BENEFITS

B. Key Distinction Between Generic and Brand Name Products

Label claims are made on specific products, not all products offered for sale by a company.
Claims Across Brand Name Products in a Category

Qualitative claims can be made – and justified – about specific branded products, that cannot be said about all products in the category.

C. Future of Value-Added Organic Label Claims

Statements regarding typical, value-added benefits stemming from organic certification can be made for some nutritional and food safety parameters grounded in organic production.

Some examples –

- Pesticide dietary risk,
- Antibiotics and animal hormones,
- Fatty acids in milk,
- GE food risks.

Value-Added Competition Across Organic Brands – An Emerging Challenge

- Truthful and valid statements can be made about some, but not all organic branded products in a category.
- As the diversity of organic brands grows, value-added competition across organic brands will intensify.
- Will competition push the circular firing squad into hyper-drive, or emulate the model pioneered by the German auto industry (honor quality at all price points)?

Proven Benefits of Organic Food and Farming Pesticide Risk Reduction

Reduction in pesticide dietary risks were carefully modeled, based on USDA “Pesticide Data Program” residue data.

Key findings:

- The average American is exposed to 10-13 pesticide residues per day, including 1-3 organophosphates.
- Organic production reduces average, overall dietary risk by 97%.

Antibiotic Resistance and Growth Hormone Benefits

No subtherapeutic use of antibiotics delivers important antibiotic-resistance-prevention benefits

No growth hormones assures that organic livestock do not add to risks to human health, whatever their magnitude.

Impacts on GMO Risks

Certified organic farming operations cannot:

- Plant GE crops,
- Use GE production inputs
- Use cloned animals.

So any problems stemming from this technology will be avoided. Plus, by promoting bio-diverse farming systems and use of locally adapted seed, organic farming serves as a hedge against conventional agriculture’s “all-in” strategy re GMO varieties.
D. Will Government Welcome or Resist Forthcoming Organic Label Claims?

- Will USDA continue their oft-repeated assertion that organic food offers no food safety or nutritional advantages?
- Will USDA and FDA attempt to block evidence-based organic value-added label claims?

What Will the Rules of the Road Be in Evaluating Organic Value-Added Claims?

What standards have the USDA, FDA, and EPA adhered to in approving other value-added claims, when setting policy, and in crafting messages to consumers?

How big must qualitative differences be to earn the government’s imprimatur via a seal or value-added claim on product labels?

Is the Organic Industry Ready for Value-Added Prime Time?

Several food safety and nutritional benefits flow from certified organic production and food manufacturing, sufficient to warrant a government-approved or sanctioned value-added claim.

Which organic companies and brands are likely to lead the way – and earn – the right to make a value-added claim that is sanctioned by a government agency?

IV. Standards, Criteria, Decision-Rules and Impacts of Existing Government-Sanctioned Label Programs

A. FDA Programs
   1. Single nutrient claims
   2. Health claims

B. USDA Programs
   1. Grass-fed
   2. Humanely Raised
   3. Never, Ever 3

C. EPA Programs
   1. “Reduced Risk” Registration Program

Sanctioned Nutritional Quality Claims

Governing statute – 1990 Nutrition Labeling and Education Act:

- Nutrient content claims (e.g., low fat; good source of fiber),
- Structure/function claims (calcium builds strong bones),
- Health claims (promotes heart health),
- Qualified health claims (may reduce the risk of certain birth defects in some populations).

Insights and Perspective from Other Seals and Claims

We will explore whether any value-added claims associated with organic production meet or exceed the requirements of existing programs, claims, and seals.
**Terms Allowed in Nutrient Claims**

“High”, “more”, “good source” – when a nutrient’s Recommended Daily Intake or Daily Reference Value is ~25% higher than other, competing brands.

“Low”, “light”, “reduced” – when a constituent generally linked to adverse health outcomes is ~25-50% lower than in other, competing brands.

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**Health- and Nutrition-Related (HRN) Claims**

- 43% of new products in 2010 contained at least one HRN claim.
- Newly introduced products contained 2.6 claims on average in 2010.
- In 2009, 12% ($73 billion) of all food-for-home purchases were products with claims.
- 8,098 HRN claims on new products in 2010.

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**Frequency of HRN Claims**

Top six types of claims in 2010:

- High vitamins and minerals – 12.2% of claims,
- No gluten – 10.8%,
- Low or no fat – 8.8%,
- Low or no calories – 7.8%,
- Low or no sugar/sweeteners added – 6.8%, and
- High fiber – 5.3%.

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**Trending Health and Nutrition Claims**

Newest claims since 2001:

- Gluten-free,
- High in antioxidants,
- Omega-3 fatty acid content (varied claims), and
- Non-GMO claims.

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**Benefits and Impacts Inherent in Nutrient Claims**

- Single nutrient or attribute – based on share of RDI, marginal differences across brands.
- Health claims – at least 25% higher level of a nutrient linked to an FDA health claim, or at least 25% lower level of a constituent in food linked to adverse health outcomes.
- In addition, other conditions must be met to qualify for specific health claims.

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**Process Verified Humanely Raised Perdue “Harvestland” Chicken**

- USDA verifies standards Perdue sets, based on National Chicken Council, industry-wide standards.
- Allows use of subtherapeutic antibiotics for growth promotion and disease prevention, and hormone use.
  - Codifies standard practices, so essentially no “value-added” impact.
  - Rated “Not meaningful” by Consumers Union’s Greenerchoices Food Safety & Sustainability Center.

http://www.greenerchoices.org/eco-labels/label.cfm?labelID=321
USDA Process Verified Labels: Grassfed Meat and Dairy

- 100% grass-based feed required, except for milk/calves, but USDA is lax in enforcement of compliance with 100% requirement.
- USDA allows animals that were grassfed at one point in their life, but then finished on grain in a feedlot, to bear the label.
- Feeds can include grain silage as long as grain is not mature.
- Label rated “Not meaningful” by Consumers Union.


USDA Process Verified: Never, Ever 3

Marketing claim approved in 2009 prohibits use of:

- Any and all antibiotics, but sick animals must be treated and removed from program (same as organic), except for ionophores as coccidiostats.
- No hormones may be administered.
- Allows no feeding of animal byproducts or proteins to, for example, prevent mad cow disease.
- Rated “Meaningful” by Consumers Union.

http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5066028

Impacts of USDA Process Verified Labels

- Individual companies have sought and received USDA “Process Verified” labels, composed of variable combinations of grass-fed, humanely raised, Never, Ever 3, the quality pork program, and others.
- Most of these livestock-system labels codify recommended industry “best practices.”
- All but “Never, Ever 3” rated “Not meaningful” by Consumers Union.
- At best, they discourage inhumane animal handling practices.

EPA Reduced Risk Pesticide Program

“The goal of the Reduced-Risk Pesticide Initiative […] is to encourage the development, registration and use of lower-risk pesticide products which would result in reduced risks to human health and the environment when compared to existing alternatives. The major incentive which EPA offers for these pesticides is expedited registration review.”


Criteria for Reduced Risk Designation

- Big benefit – average time from application to registration drops from 38 months to about 14 months for “reduced risk” pesticides.
- Multiple risks can qualify a pesticide as “reduced risk”.
- Generally must reduce at least one risk at least 35%.

Reduced Risk Criteria

To qualify for expedited registration, a newly proposed formulation must accomplish at least one of the following:

- At least a 35% reduction in application rate,
- 10-X or more reduction risk to mixers, loaders, applicators,
- 50% drop in risk of groundwater contamination,
- “Significant” reduction in eco-risk (birds, bees, fish, etc.).
“Reduced Risk” Registrations

- Peak years were 1999-2005 (total of 146, or 64%).
- Major beneficiaries include:
  - Glyphosate
  - Multiple IGRs
  - Spinosad
  - Strobilurins
  - Spinetoram
  - All nicotinyls:
    - Imidacloprid
    - Thiamethoxam
    - Clothianidin
    - Acetamiprid
    - Dinitrofuran.
   
“Reduced Risk” Nicotinyl Registrations?

In the case of the major neonicotinoids [imidacloprid (Admire), thiamethoxam (Cruiser), clothianidin (Gaucho), and acetamiprid (Assail)]:

- Markedly increased pollinator risks (neonicotinids among the most acutely toxic pesticides to bees, systemic action + persistence diversifies exposure pathways),
- Vastly increased reliance on systemic seed treatments, especially for high-priced GE seed.

Impacts of “Reduced Risk” Registration Program

In the case of glyphosate:
- In the short-run: reduced herbicide risks,
- Accelerated emergence and spread of resistant weeds,
- Increased reliance on herbicides and undermined integrated weed management, and
- In the long-run: significantly increasing herbicide use and risks.

Impacts of Government-Sanctioned, Programs, Claims and Seals

Differences in branded product A with a label claim or seal, versus similarly priced, competing brand B without the claim or seal:

- Nutrient content claims – usually 10% to 30% difference in concentrations, occasionally more, sometimes less, but overall, modest health impact.
- Health claims – at least 25% improvement in level of a food constituent linked to a known, health outcome.

Impacts of USDA and EPA Programs, Claims and Seals

Differences in branded product A with a label claim or seal, versus similarly priced, competing brand B without the claim or seal:

- USDA Process Verified – Mostly modest to no meaningful impacts on animal welfare or food safety and quality.
- EPA “Reduced Risk” Program – considerable to minor reductions in risk, some bad calls leading to increased risk, and major benefit to pesticide companies (~24 month quicker access to market) worth $10+ million per fast-track approval.

Known Impacts and Benefits of Organic Production Systems

- Pesticide dietary risk: about 95% reduction in risk.
- Antibiotics and animal hormones: 100% reduction of risks, plus promoting healthier livestock systems.
- GE agronomic and food safety risks: 100% avoidance, whatever they turn out to be.

But the USDA insists ...

- There are no consistent or meaningful differences in the nutritional quality or safety of organic versus conventionally raised food.
IV. NGO and Private Sector Programs

A. Scientific Certification Services “NutriClean” Program.

A. Whole Foods Market.

B. “Responsibly Grown” Sustainability Rating System.

A. Non-GMO Verified.

Private Seals Promising Pesticide Risk Reduction

Scientific Certification Services (SCS) International’s “NutriClean” certification program:

- In place since late 1980s,
- Millions of dollars spent by retailers (Fred Meyer, Raley’s, Whole Foods),
- Tested products meeting 0.01 ppm standard verified as “Pesticide Free”...

... But are they really?

Impacts of the “NutriClean” Program

“NutriClean” tested and verified produce generally has:

- About as many pesticide residues per sample as conventional,
- Average residue levels marginally below those in the same conventionally grown products ...

... Not surprising, since almost all “NutriClean” produce has been conventional.

Big Problem with the “NutriClean” Program

- “Pesticide free” only means free of pesticide residues over 0.01 ppm.
- Large percent of residues in any food product will be below 0.01 ppm.
- For high-risk pesticides, a 0.01 ppm residue level may not be safe.

Another Pesticide Risk Reduction Program – Whole Foods Market

- Designed to assure continuous reductions in risk – and their method will work because it is data-driven and based on latest and best risk assessment science.

Three Levels of Performance

- Launched as part of the “Produce and Floral Sustainability Rating Program” in 2014.
- Focus on pesticides known to impair neurological development and lower IQs.
- Three levels of ratings – “good,” “better,” “best” – with score compiled over several attributes, in addition to pesticide dietary risks.
• Known, prohibited risk-drivers will rarely, if ever, be in food sold at WFM stores – eliminating a big chunk of pesticide dietary risk in conventional food (around 2/3).
• Same rules apply to all imports, so risk reduction will be fair and universal, as opposed to the impact of most EPA actions.
• Added benefits for farmworkers abroad, and the birds and bees.

Benefits and Impacts of Non-GMO Labels

• On multi-ingredient processed foods not including any corn, soybeans, or canola — likely very small.
• For those processed foods including ingredients from corn, soybeans, or canola — usually, modest differences in GE content of the finished food product. Occasionally, significant reduction in GE content (e.g., soy hummus).
• As GE fruits and vegetables consumed in fresh forms reach the market — big impact (e.g., Bt-RR sweetcorn) to modest impact on intake of GE proteins (e.g. Artic apples).

Not Enough Science to Support Generic, Plant-Based Food Nutrient Claims

It is premature to seek any generic, across-all-organic-brands nutrient content claims for plant-based foods, but some brands probably can meet evidentiary thresholds.

BJN Meta-Analysis: Foundation for Future Nutrient Content Claims

Higher antioxidant and lower cadmium concentrations and lower incidence of pesticide residues in organically grown crops: a systematic literature review and meta-analyses

It is premature to seek any generic, across-all-organic-brands nutrient content claims for plant-based foods, but some brands probably can meet evidentiary thresholds.
Antioxidants over 17% higher in organic – average across 286 fruits and vegetables analyzed.

Baranski et al. 2014, British Journal of Nutrition

Options To Set Stage For Generic, Organic Nutrient Content Claims

- Modify OFPA and/or the NOP rule to provide for certification of systems known to reliably produce value-added benefits (e.g. tomato production systems with elevated lycopene or grape systems that boost resveratrol):
  - Initially, target human populations in need of functional foods,
  - Petition/review could be patterned on FDA health claim process.

Options To Set Stage For Generic, Organic Nutrient Content Claims

- Industry consortia work together to identify SOPs needed to reliably produce enhanced nutrient content and, when done and proven, seek health claim via FDA process:
  - Cascadian and Driscoll's – berries,
  - Stemilt and Zerkle
    Fruit on tree fruit,
  - Nature’s Path, Annie’s, and Clif Bar, focus on oat/wheat breeders and millers to elevate flavor, and vitamin and mineral content.

Three More Options To Seek Generic, Organic Nutrient Content Claims

1. TOC seeks industry, NIFA, or foundation money to contract with research teams to develop, test, refine, and document elevated nutrient content SOPs, and then pursues FDA health claim on behalf of industry consortium.
2. If adopted, allocate organic research and development funds to underwrite needed research, build industry consortia, and pursue health claims.
OTA-TOC lead effort to petition Foundation for Food and Agricultural Research (FFAR) to sponsor a competitive grant program focused on creating and vetting the potential to produce value-added, premium organic brands delivering clear, functional food benefits

- Target pregnant women, prevention of birth defects, lost IQ in children, and Pacific Rim nation health needs.

Some organic brands can and should seek nutrient content claims!!!

The single most “ready” organic food health claim is the vastly improved fatty acid profile in whole, organic milk and dairy products.

Smoothest path to the goal will be to limit the first, organic milk health claim petition to all-forage and pasture-raised and fed cows.

Organic Whole Milk Provides Best Heart Health Benefits, Study Says

Organic Milk May Have Healthier Ratio of Fatty Acids than Regular

Milk Nutritional Quality Study in *PLOS ONE*

Organic Production Enhances Milk Nutritional Quality by Shifting Fatty Acid Composition: A United States–Wide, 18-Month Study

Circulation/Reach: 431 million

Today Show, CBS, LA Times, NY Times, NPR, TIME Magazine.
Higher in omega-3, and lower in omega-6 fatty acids.

Photo: Flickr user Dana under CC BY-ND 2.0

Higher PUFA and omega-3 PUFA, CLA, α-tocopherol and iron, but lower iodine and selenium concentrations in organic milk: A Systematic Literature Review and Meta- and Redundancy Analyses

STATUS: Expected publication in summer 2015.

Higher PUFA and omega-3 PUFA, but lower myristic and palmitic acid, and copper concentrations in organic meat: A systematic literature review and meta-analysis

STATUS: Submitted, expected publication in mid- to late spring 2015.

• Analyzed 172 studies satisfactory for meta-analysis (vs. 11 studies in Dangour et al. 2009 and 37 studies in Smith-Spangler et al. 2012).
• High reliance on forage-based feeds in both conventional and organic systems reduces differences compared to U.S.
• December 2013 PLOS ONE organic milk paper was last one included in dataset.

Key Findings in Forthcoming BJN Dairy Product Meta-Analysis

Key Findings:

...based on weighted meta-analysis (conventional vs. organic), driven by high-forage diets:

✓ Total saturated fat ↓7%,
✓ Omega-3 ↑46%,
✓ Omega-6/Omega-3 ↑79%.
✓ Conjugated linoleic acid (CLA) ↑34%.
✓ Higher levels of α-tocopherol and iron.
Analyzed 67 studies published from 1992-2014 (63 peer-reviewed) (vs. 11 studies in Dangour et al. 2009).

Main findings using weighted meta-analysis (preferred method):

- Total fat 21%
- Total PUFA 23%
- Omega-3 47%
- Long-chain PUFAs 24%
- Thrombogenicity Index 35% (sum of saturated fatty acids divided by sum of PUFA levels).

Most comparison studies have been done in Europe or South America where both conventional and organic producers rely heavily on forage-based feeds.

Excellent 2014 study in *J. Dairy Science* by Brad Heins’s team (Univ. Minnesota) reported (for dairy steers; mean concentrations, conventional to organic):

- Total saturated fat 35.2 to 26.1
- Myristic (bad saturated) 4.1 to 3.3
- Omega-3 0.19 to 0.5
- Omega-6 2.5 to 0.68
- Omega-6/Omega-3 12.9 to 1.4!!!

Organic farming consistently delivers environmental benefits rooted in soil health and the promotion of biodiversity, but...

There are no consistent or meaningful differences in the nutritional quality or safety of organic versus conventionally raised food.

According to the USDA –

- ... With modern science and USDA’s own data?
- ... With federal agencies’ approach to value-added certification and label claims?

Policy changes clearly needed to avoid loss of confidence and credibility in all government value-added claims.

If such loss happens, there will be major economic consequences for U.S. Agriculture Inc., because credible, science-based and government-endorsed health and nutrition value-added claims are essential in accessing health-conscious, premium markets.

Without trust in USDA and FDA-sanctioned label claims, and agency regulatory actions, U.S. Agriculture Inc. could become the WalMart of the global food system, as European multinationals lock up value-added markets, along with their profits, jobs, and ability to drive innovation.

Mishandling of GE food testing, regulation, trade, and labeling challenges is already raising doubts and tarnishing our food system’s halo abroad.
Companies:
• Revisit SOPs to identify nutrition-related claim options.
• Do your science and testing homework.
• Track trends in quality in major, competing national brands to identify differences consistently >25%.
• Work with growers, breeders, researchers to develop nutrient-dense farming systems.
• Do not hesitate to push the envelope with government agencies – that is what the competition does far more often, and much more effectively.

Growers, retailers, activists:
• Push for change – and at a minimum, fairness – in the policy process, and daily with food $s.
• Pay closer attention to the science, and temper demands and expectations.
• Find a way to come together to support “value-added” innovations within the NOP rule and across organic brands.
• Encourage organic brands to develop value-added, functional foods that meet the special needs of vulnerable populations – consumer pull for value-added innovation is critical, and will move both markets and capital.

Organic food and farming leadership:
• Find ways to de-militarize the circular firing squad.
• A constructive step – gain widespread acceptance for organic brand, value-added differentiation and competition, following the German auto industry model.
• We are all stewards of the organic food and farming halo, and it is long-past time for the organic community to up its game in pursuit of this mission-critical priority.

1. The countries, companies, and industry players that most consistently create – and then abide by – sound science will incrementally prosper compared to those who place trust in PR and political clout.
2. Over the next 20 years, science-driven litigation and crisis-interventions will become far more important in driving change in government policy than they have been in the last 20 years.
3. The proven ability of organic farming to promote soil health and restore soil quality, will emerge as a powerful #2 reason people seek out organic food, and will also trigger long-overdue private investment in organic food industry, infrastructure, and R&D.

Thank You

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