

2018 MFRP Alliance Meeting

Workplanning - A Nationally Coordinated Effort

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Background

- Evolution of state contracts
 - 10K contract inspections
- Partnership Inspections
 - Inspection data for resources
- OIG Reports
 - 2000 and 2011
 - Findings
 - FDA Response



Contributing Factors

- Frequency mandates
 - State vs FDA
- Inventory
 - Valid?
 - Numbers?
 - Aligned?
- Contract requirements
 - Training
- IT Issues
 - eSAF, data exchange, secure access



Moving Forward...

while looking back

- Work Planning is an evolving process
 - FSMA, ER/RRT, priorities, emerging issues
- State and FDA are working collaboratively to improve the process.
- Projects
 - Data exchange
 - National Work Planning
 - National Sampling
- Identify areas for expansion





Mutual Reliance Work planning

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Albuquerque, NM January 2018



Mutual Reliance Premise and Goals

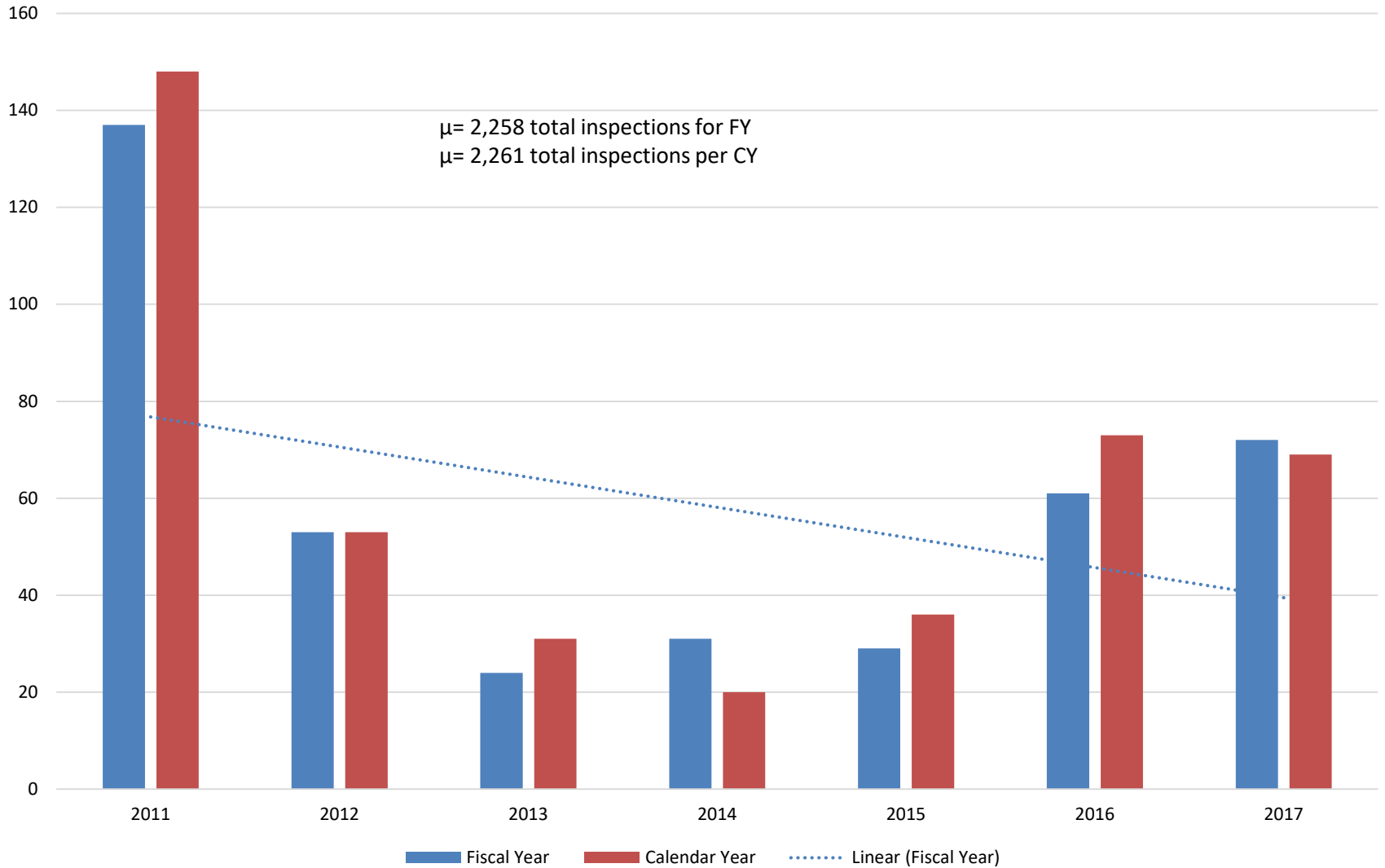
- By meeting program standards, state and federal regulatory programs can rely on each to more effectively and efficiently achieve compliance outcomes and protect public health.
- “One program, one mission”

Mutual Reliance Work planning

- Avoid duplicating inspectional work between agencies
 - Part of an Integrated Food Safety System (IFSS)
- Exchange work product to increase inspectional coverage

Metrics of Success

Slide from Joel Hustedt: Number of Firms With Independent Routine Inspections by both WDATCP and FDA in Same FY/CY



Why do we need Mutual Reliance Work planning?

- WI does not meet our targeted frequency, due to lack of trained staff and position authority to hire more staff
- Inventory of Manufactured Food Establishments ~3,500
 - DATCP MF Inspections per year (2015-2017): 1,200-1,949
 - 46% Overdue-Haven't been inspected since 2016 or before: we need the FDA to help us catch up

Mutual Reliance Work planning

- Prerequisites:
 - Access to un-redacted FDA reports
 - System to protect FDA reports from public requests for information
 - Best practices and quality assurance

Mutual Reliance in WI

- Ongoing practices formalized in a Mutual Reliance Pilot Project in FFY 2016
- Mutual Reliance Pilot activities are now formalized in a three-year MOU with FDA
- MRP now means “Mutual Reliance Practices”

MRP Work Planning

- Wisconsin DATCP counts FDA inspections of our shared inventory as its own.
- DATCP conducts 20 or so extra “MRP” unbilled contract inspections, which FDA counts as its own.
 - Initial inspection in a FSMA risk cycle

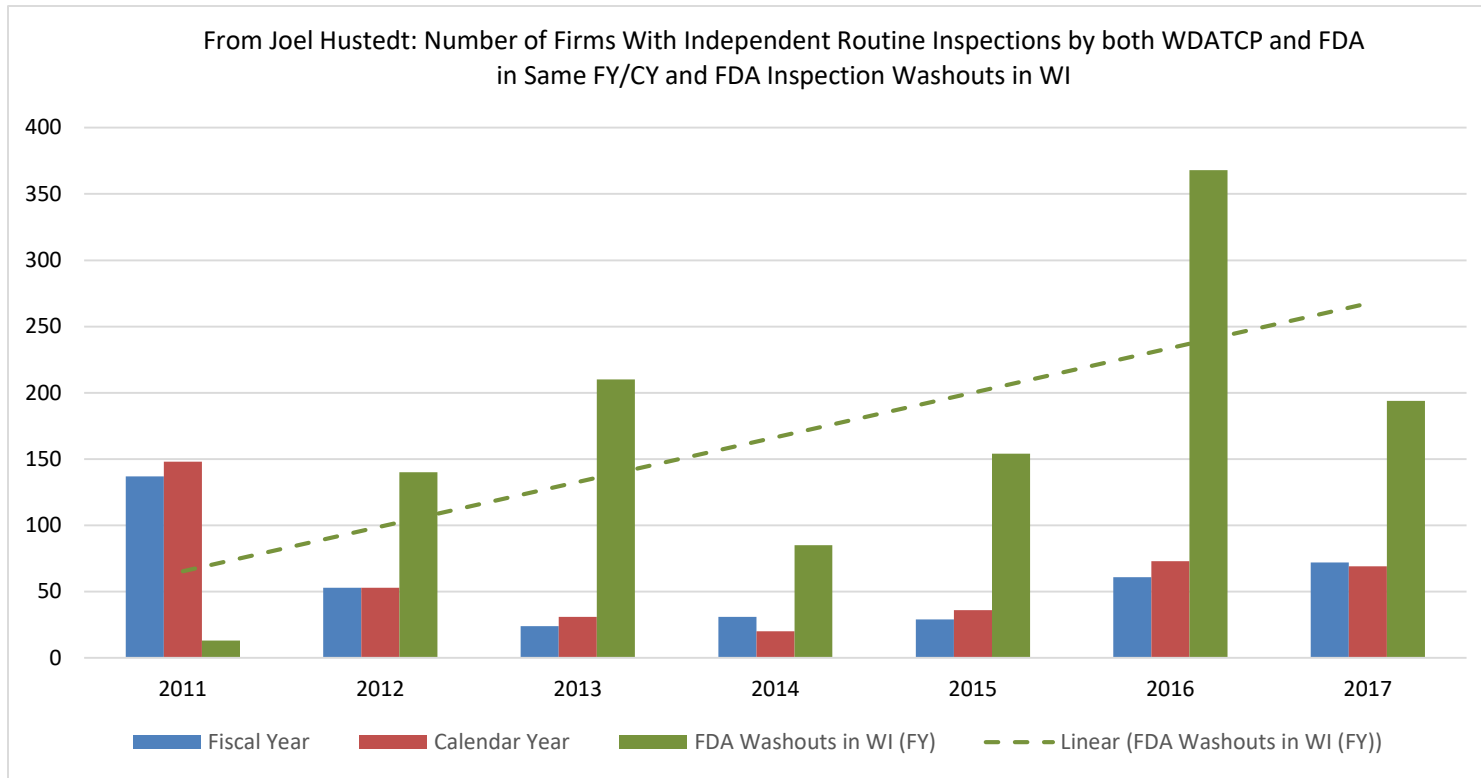
How Wisconsin Counts FDA inspections

- FDA Annual Work plan (~100 inspections) assigned to “FDA Inspector” each year.
 - Additional ad hoc inspections (100+) throughout the year.
 - WI Flexible, Risk-Based Work Planning
 - One month ahead of time

Mutual Reliance Challenges

- Majority of firms on HAF 1 Work plan for Wisconsin are not eligible for assignment to the FDA
 - Out of Business
 - Not required to be licensed by WI
 - Grade A Mandated
- Adjusting to ad hoc inspections not always possible; nor does it reduce duplication

Mutual Reliance Challenges



- FFY 2016: 92 of 569 inspections assigned to FDA
- FFY 2017: 179 of 536 inspections assigned to FDA
- FFY 2018: 98 of 338 inspections assigned to FDA

Challenges and Successes

- To increase inspectional coverage, it is necessary to agree that firms only need 1 regulatory inspection/year.
- Would mean that both agencies could focus on establishments that have not been inspected by either agency in more than 1 year.

Last inspection date?

- Half (49 of 101) FDA-assigned/planned inspections in FFY 2018 have not been inspected since 2016 or before (success!)
- Half (51 of 101) have been inspected by WDATCP in 2017, as recently as November 2017

Overdue establishments 30% more likely to need re-inspection

Last inspection date for all inspections including FDA Workplan

+ <12/17/2007	10
+ 2009	3
+ 2010	12
+ 2011	15
+ 2012	28
+ 2013	55
+ 2014	168
+ 2015	411
+ 2016	1035
+ 2017	2038
+ 2018	41
Grand Total	3816

Future MRP

- Improvements will come from agreement about when the establishment was last inspected; this will entail more “counting” of WI inspections
- MRP bring sustainable benefits, to both agencies and to the public
- Most tangible benefit to meeting MFRPS for inspection staff

Thank you!

Contact Information

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FDA Work Planning

Joann M. Givens

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U.S. FDA, Office of Regulatory Affairs

Albuquerque, NM January 31, 2018



FDA Work Planning



**Food
Strategic
Plans**



Resources



**Center
Priorities**



ORA Field



FDA Field Activities



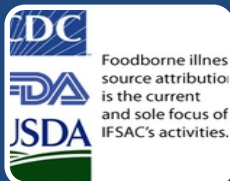
Inspections

- Domestic
- International



Sampling

- Product
- Environmental Sample
- FDA Laboratory Analysis



Unplanned

- Consumer Complaints
- Referrals from state and other federal agencies
- Foodborne Outbreaks



Miscellaneous Activities

- New Hire Training
- Programmatic Training

FDA Field Activities

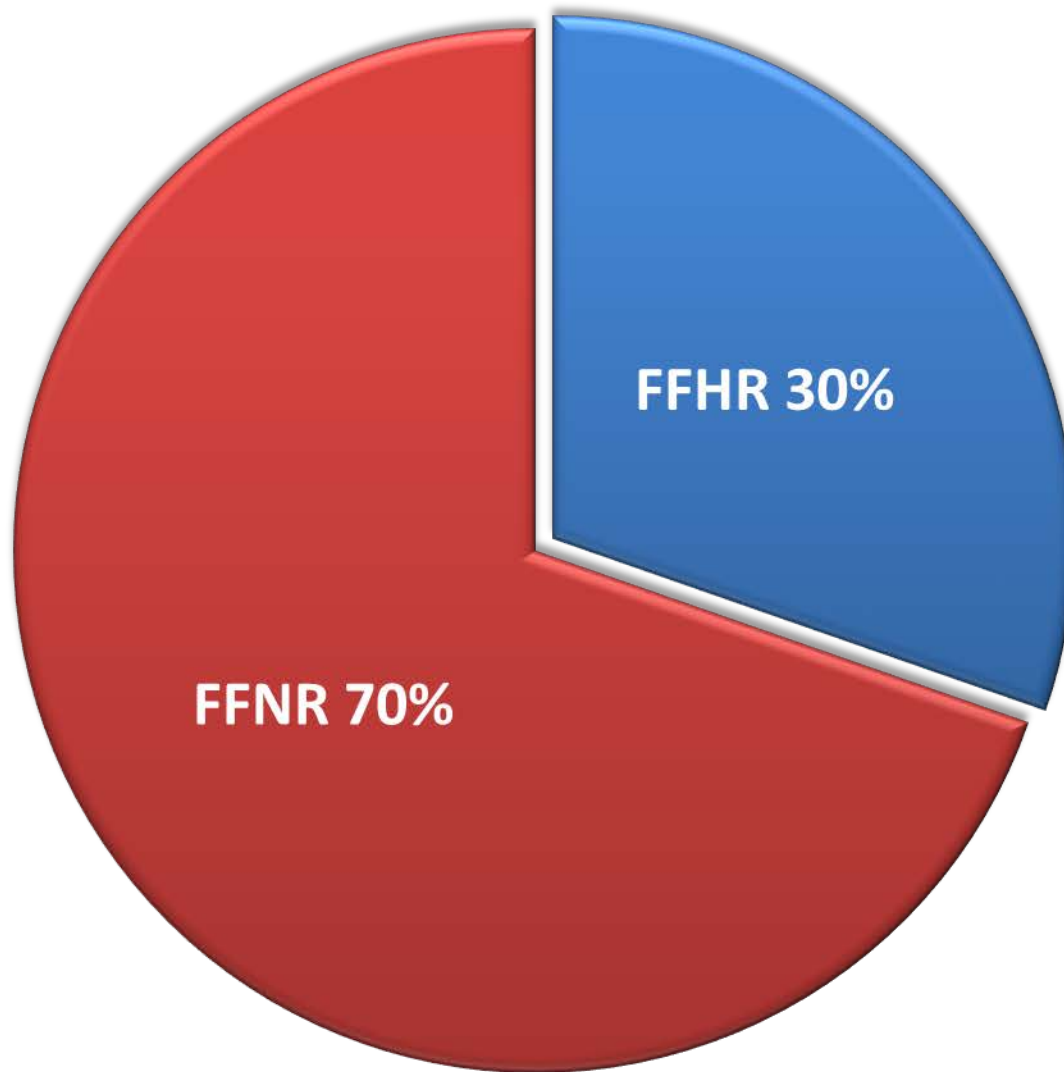
Let's Focus on Inspections:

- FSMA Inspection Resources
 - Mandated to inspect domestic **high-risk** facilities not less often than once every three years.
 - Mandated to inspect domestic **non-high-risk** facilities not less often than once every five years.
- **NEW** FSMA Rules: Preventive Controls- Human and Animal (CGMP), FSVP, Sprout Inspections
- Center assignments
 - Emerging issues
 - Compliance follow-up
 - Congressional requests

FDA Registered Firms (Domestic) by Facility Risk Category

n = 78,304

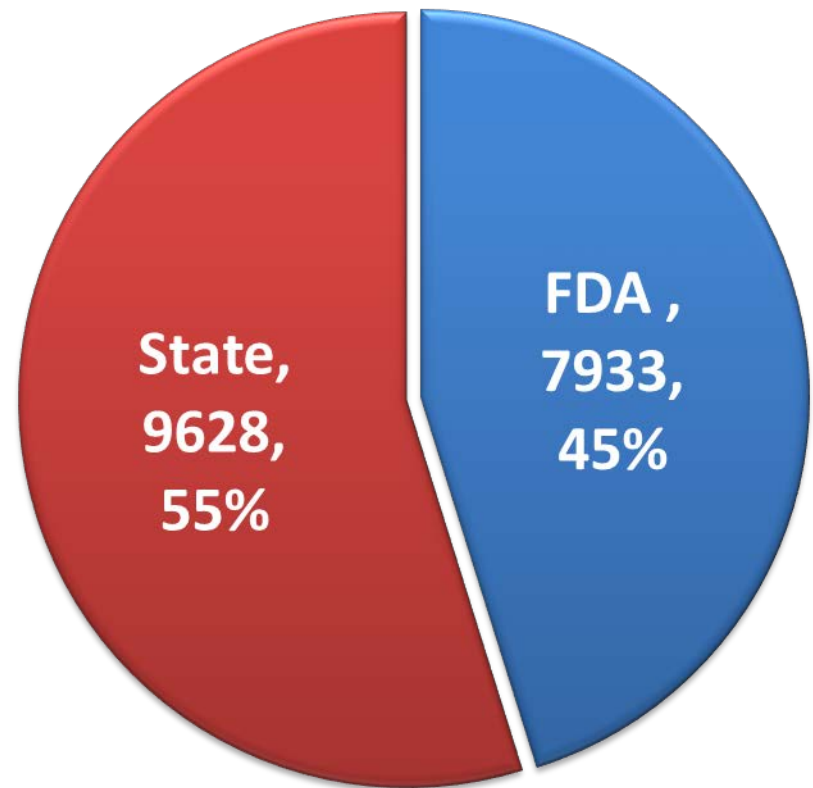
■ FFHR ■ FFNR



FSMA Inspection Resources

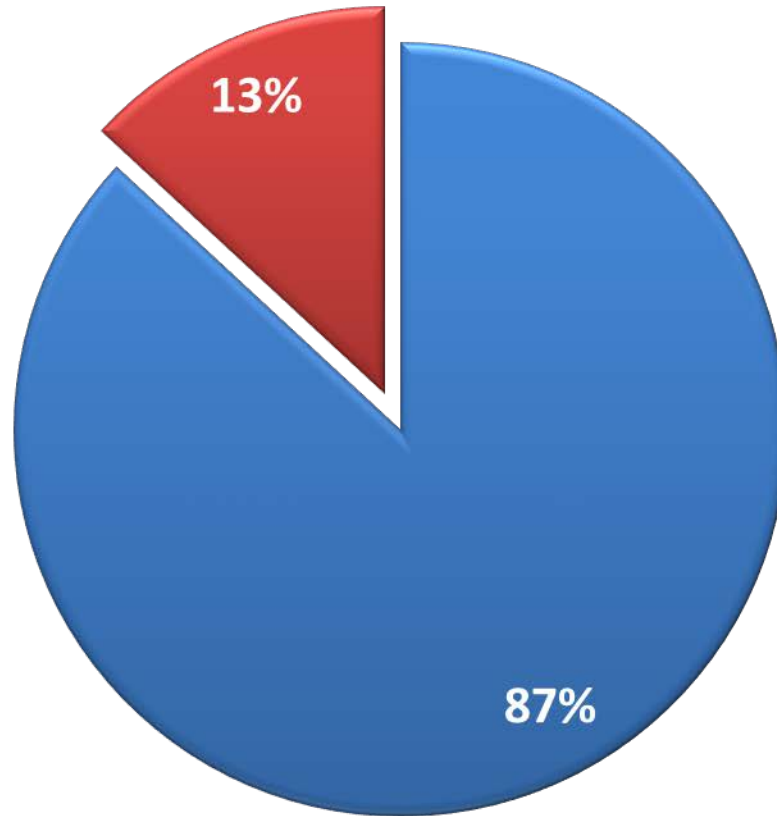
*Are we allocating resources –
FDA and state - to meet
inspection frequency
mandate?*

Establishment Inspections



Data Source: [FY2018 ORA – Field Activities](#) Budget –
FY16 Actuals, Unique Counts

FY2017 FSMA Inspection Frequency Mandates



■ FDA ■ State

Report in Brief

September 2017

Report No. OEI 02-14-00420

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL



Quotes from the report:

We recommend that FDA improve how it handles attempted inspections to ensure better use of resources.....

Shortened timeframes pose challenges for future non-high-risk cycles.

Room for Improvement

- Fragmented and outdated IT systems; data quality.
- Communicating FDA's national work plan for domestic operations.
- Minimizing duplication of work with states and other federal agencies.
- Coordination with state contracts to meet FSMA inspection frequency mandate, particularly for NHR facilities.

Take Home Message

The image features a word cloud of safety-related terms arranged in a staircase pattern from left to right. The words are: Efficiency, Accountability, Timeliness, Interactive, Dynamic, Preventive Controls, Work Planning, Complicated, Skill Sets, Inspection Frequency, and Mandate. The words are in various shades of green and brown.

Efficiency
Accountability
Timeliness
Interactive
Dynamic
Preventive Controls
Work Planning
Complicated
Skill Sets
Inspection Frequency
Mandate

Work Plan Before



Work Plan Success!



Work Plan 101
Meeting

References

- [FSMA Domestic Facility Risk Categorization \(FY 2012\)](#)
- [FY2018 ORA – Field Activities](#) Budget – FY16 Actuals, Unique Counts
- [OIG Challenges Remain in FDA’s Inspections of Domestic Food Facilities](#), September 2017
- [Field Management Directive 50](#) – State Correspondence, 5/2/2011

Contact Information

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