PRIA 3 Quarterly Stakeholder Meeting

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AGENDA

- Introductions
- Follow-up from previous Stakeholder Quarterly Meeting
- PRIA 3 Summary for FY'16 thru 5/31
- Renegotiation rates: FY'16 thru 5/31
- Analysis of high renegotiation rate in RD: FY'16 thru 5/31
- Context for Inert high renegotiation rate: FY'16 thru 5/31
- Late completions FY'16 thru 5/31
- Pending Non-PRIA Fast Tracks & Notifications
- Fees collected: FY'16 thru 5/31
- 2-day label approval: FY'16 thru 5/31
- electronic label reviews: FY'16 thru 5/31
- Electronic Submissions: FY'16 thru 5/31
- 45/90 Preliminary technical screen: FY'16 thru 5/31
- New AI error-only pilot
- Worker Protection Update
- Stakeholder issues

Follow-up from Feb. 24th Stakeholder Meeting

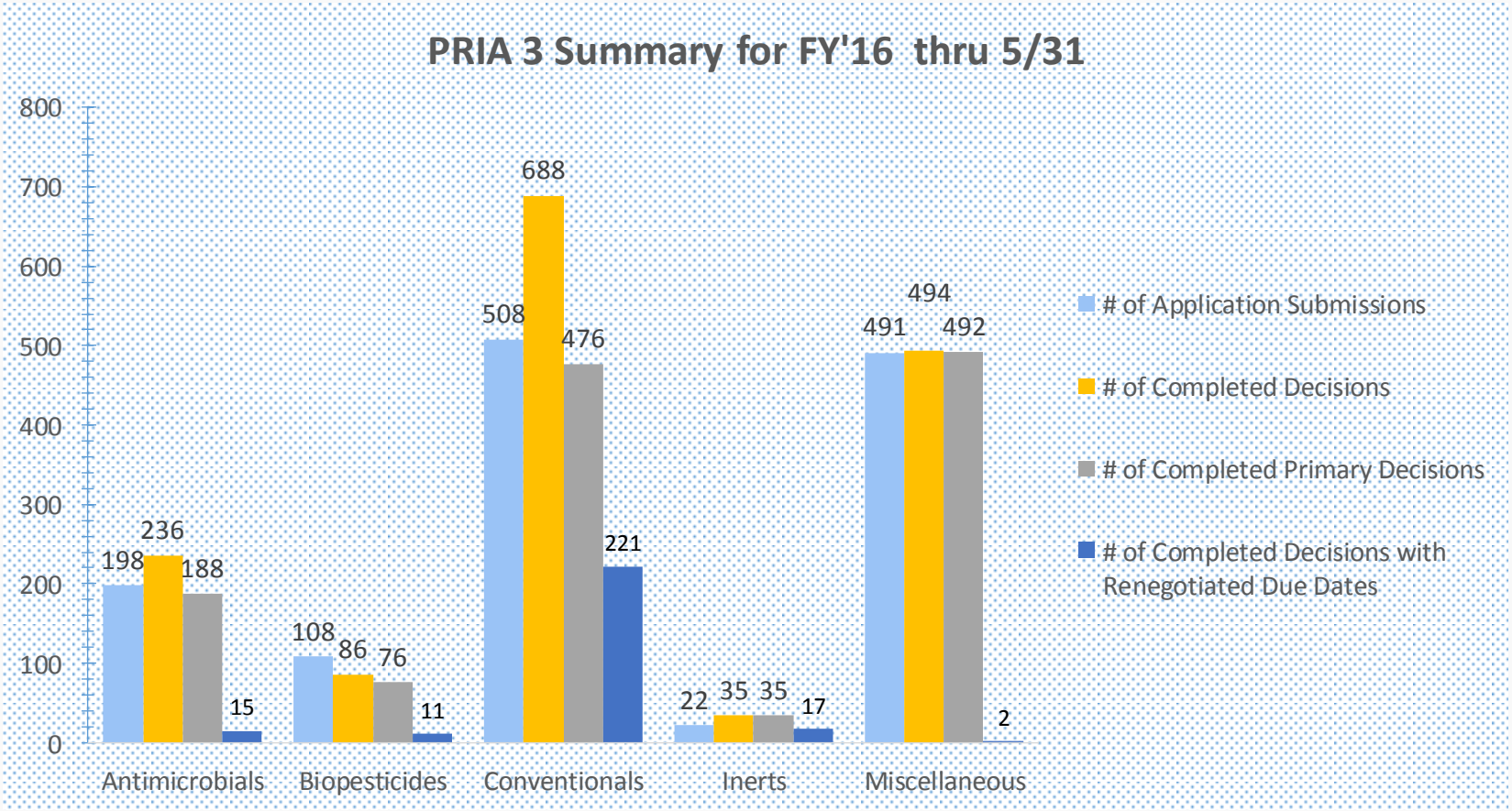
- Status of guidance for substantially similar submissions

  - an internal assessment of the substantially similar process in AD & RD indicated that development of guidance materials alone would not adequately address the problems;

  - the process is being revamped which should be completed this summer;

  - once new process is “up and running”, SOP & SEP will follow;

- Status of FRN on Notifications
  - Draft PRN on Notifications has been completed;
  - Currently in Division Director Review;
  - Next step will be to request a waiver from OMB review;


PRIA 3 Summary for FY'16 thru 5/31
800
700
600
500
400
300
200
100
0
198
236
188
15
108
86
76
11
508
688
476
221
22
35
35
17
491
494
492
2
Antimicrobials
Biopesticides
Conventionals
Inerts
Miscellaneous
# of Application Submissions
# of Completed Decisions
# of Completed Primary Decisions
# of Completed Decisions with Renegotiated Due Dates

Historical % of Completed PRIA Decisions with Renegotiated Due Dates

FY	Antimicrobials	Biopesticides	Conventionals	Misc.	Inerts
2009	68/342 = 19.9%	42/124 = 33.9%	193/1104 = 17.5%		
2010	108/310 = 34.8%	85/138 = 61.6%	277/1069 = 25.9%		
2011	85/346 = 24.6%	48/134 = 35.8%	236/1074 = 22.0%		
2012	86/333 = 25.8%	74/133 = 42.8%	235/1068 = 22.0%		
2013	73/329 = 22.2%	34/111 = 30.6%	205/1039 = 19.7%	0/562 = 0%	1/7 = 14.3%
2014	41/287 = 14.3%	30/129 = 23.2%	259/895 = 28.9%	1/575 = 0.2%	9/45 = 20%
2015	44/319 = 13.8%	28/154 = 18.2%	229/960 = 23.8%	2/622 = 0.3%	18/56 = 32.1%
2016 thru 5/31	15/236 = 6.4%	11/86 = 12.8%	221/688 = 32.1%	2/494 = 0.4%	17/35 = 48.6%

Analysis of High Renegotiation Rate in RD

- Of the 221 decisions renegotiated, 99 (45%) pertain to primary decisions and 122 (55%) pertain to secondary decisions; [When a primary decision due date is renegotiated, all secondary related decision due dates are also automatically changed accordingly.]

- Of the 99 primary decisions renegotiated:
  - 47% involved new use actions
  - 13% involved tolerance actions
  - 20% FT New Products
  - 4% NFT New Products
  - 16% amendments

Analysis of High Renegotiation Rate in RD – con't

- Notable drivers include:

  - resolution of cumulative risk impasse resulting in a large # of renegotiated new use actions being completed;

  - resolution of complicated meat & milk dietary risk cup issue involving a large # of PRIA actions across multiple categories including a significant # of new uses;

  - additional residue data required caused need for renegotiations;

  - non-target mitigation language (pollinators) on labels;

  - other unresolved label issues where companies requested renegotiated due date vs PRIA purgatory as due date approached;

Analysis of High Renegotiation Rate in RD – con't

- Areas for improvement
  - NOR & NOF published sooner;
  - Benefits documentation developed in more timely manner;
  - Communication of data deficiencies earlier;
  - Reduce back-n-forth in handling exclusive use/data comp issues;
  - Handling of registrant rebuttals in a more timely manner.

Context for High Inerts Renegotiation Rate

- Inerts first became a covered PRIA category under PRIA 3;
- Timeframes originally established based on best professional judgement;
- Inert productivity under PRIA 3 has increased:

  FY'13 – 43 clearances;

  FY'14 – 45 clearances;

  FY'15 – 56 clearances;

Inert Completion Performance under PRIA 3

PRIA Category	PRIA 3 Avg Completion Time (months)	PRIA 3 Timeframe (months)	Avg Difference (months)	Change in Timeframe under PRIA 4 (months)
I001	14.8	12	+2.8	+1
I002	11.5	10	+1.5	+1
I003	10.1	8	+2.1	+1
I004	6.1	8	-1.9	-2
I007	3.7	4	-0.3	No change
I008	5.3	5	+0.3	No change
I009	3.0	4	-1.0	No change

FY'16 thru 5/31: Number of Late PRIA Decisions

Type of decision	FY'16 Late Completions thru 5/31	FY'16 Rate of on-time Completions thru 5/31	FY'15 Rate of on-time Completions	FY'14 Rate of on-time Completions	FY'13 Rate of on-time Completions
Antimicrobial	2	99.2%	96%	78%	99%
Biopesticide	4	96.0%	98%	79%	98%
Conventional	6	99.1%	99%	78%	99%
Inert	2	94.3%	96%	91%	100%
Misc	2	99.6%	99%	99%	99%
Total	16	99.0%	98%	85%	99%

Pending Non-PRIA Fast-Track Amendments & Notifications as of 5/31

- As of 5/31/16 **AD** had 134 non-PRIA fast-track amendments pending, 17 of which were in backlog status (pending > 90 days); and 74 notifications were pending, 22 of which were in backlog status (pending > 30 days);

- As of 5/31/16 **BPPD** had 18 non-PRIA fast-track amendments pending, 1 of which was in backlog status; and 13 notifications were pending, 10 of which were in backlog status;

- As of 5/31/16 **RD** had 352 non-PRIA fast-track amendments pending, 80 of which were in backlog status; and 178 notifications were pending, 119 of which were in backlog status;

Fees Collected in FY16 thru 5/31

PRIA Fees: $13.8M

Maintenance Fees: $27.3M

FY'16 thru 5/31: Two-Day Label Review Approval Tracking Report Summary

Table 1: Completed Decisions Resulting in New or Amended Product Label Approvals

	Antimicrobial Decisions (A)	Conventional Decisions (R & M005)	Total
Completed Decisions	236	690	926
Completed PRIA 3 Decisions	235	689	924
PRIA 3 Decisions Involving Label Approvals	229	593	822

Table 2: Timing for Completion of PRIA 3 Label Reviews & Approvals

	Antimicrobial Label Reviews & Approvals (A)	Conventional Label Reviews & Approvals (R & M005)	Total
After the PRIA Due Date	1 (<1%)	3 (<1%)	4 (<1%)
On the PRIA Due Date	97 (42%)	141 (24%)	238 (29%)
Before the PRIA Due Date but after the Pre-decisional Determination due date	108 (47%)	250 (42%)	358 (43%)
On or before the Pre-decisional Determination Due Date	23 (10%)	199 (34%)	222 (27%)
Total	**229**	**593**	**822**

FY'16 thru 5/31: Electronic Label Reviews

- Tracking the use of electronic comparison software in conducting label reviews requires input from reviewers;

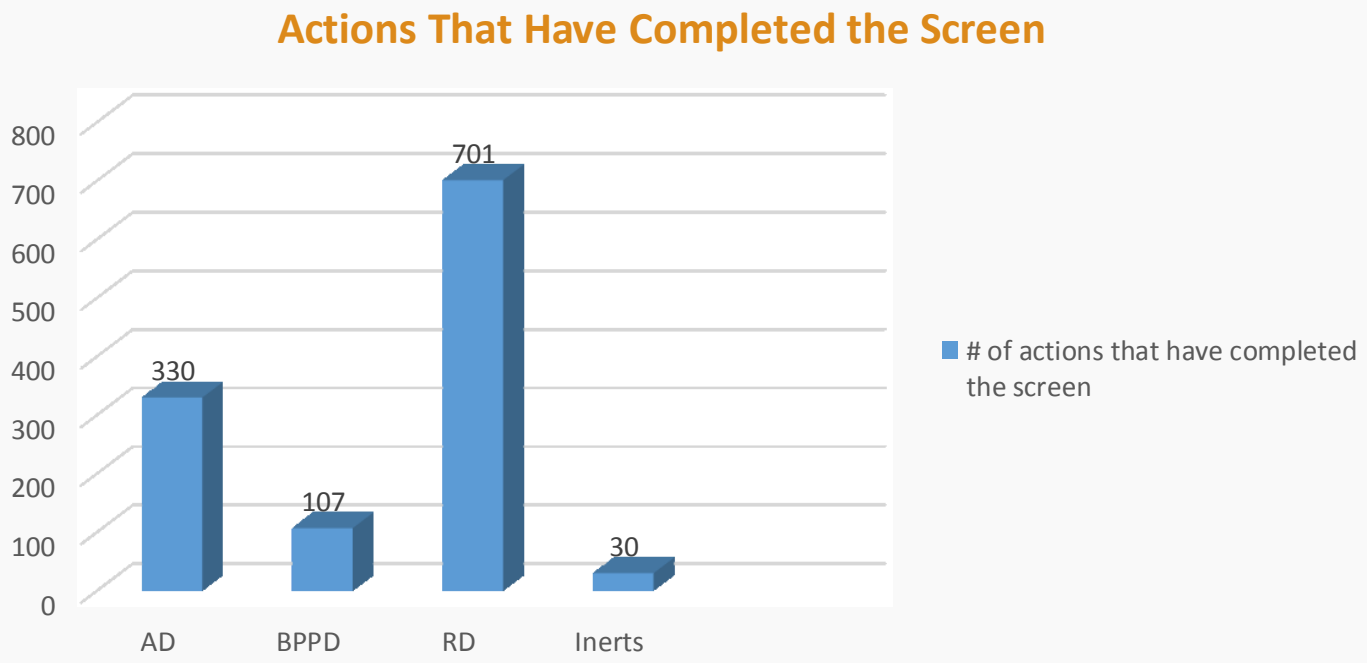
- The number of label reviews where the reviewers have not been providing the necessary input into the tracking system has been reduced but there is still room for improvement: RD – no input for 16% of completed label reviews, AD – no input for 9%, and BPPD no input for 30%;
- Lack of necessary input increases uncertainty;

- % of labels reviewed electronically in RD: 75% - 91%;
- % of labels reviewed electronically in AD: 82% - 92%;
- % of labels reviewed electronically in BPPD: 67% - 97%.

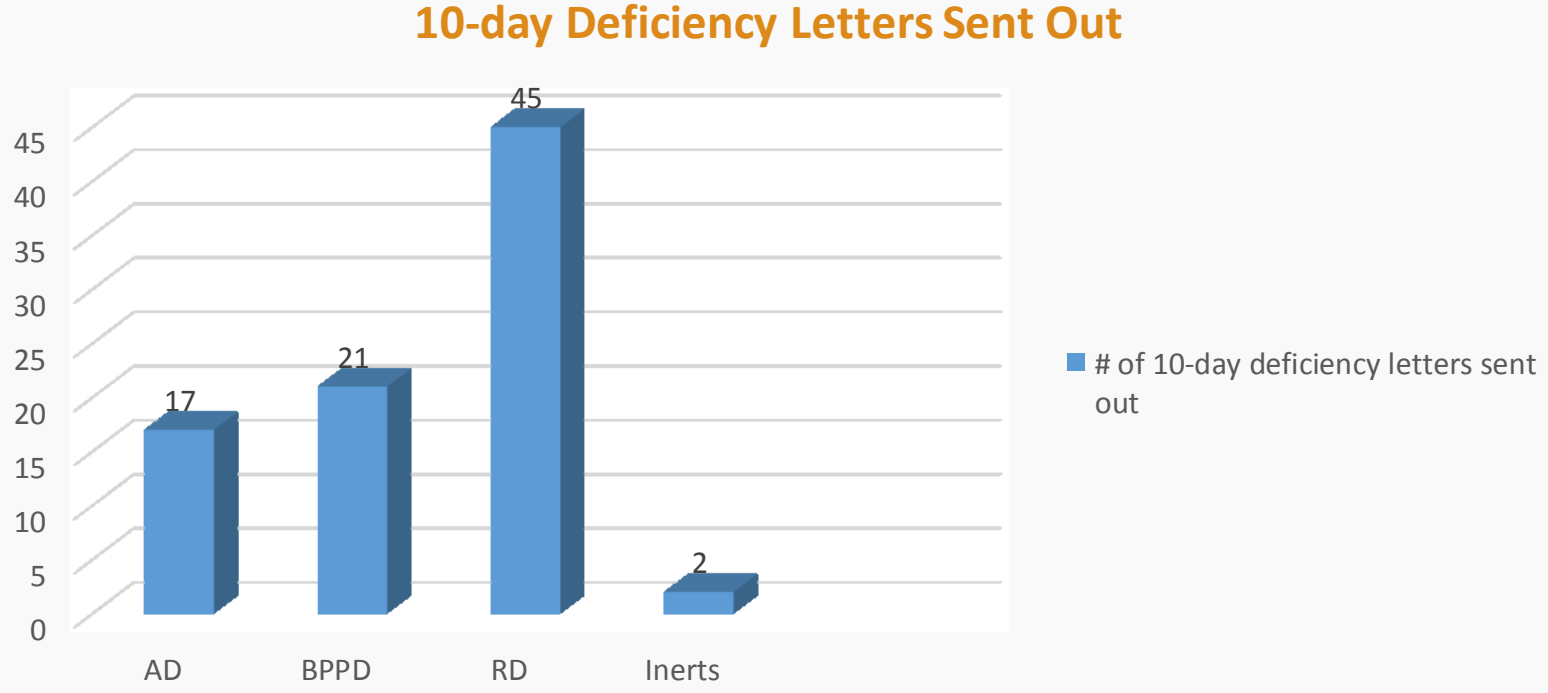
FY'16 thru 5/31: All Stakeholder Registration Submissions by Type of Product

Type of Product	Total # of Submissions	# Paper Submissions	# CD/DVD Submissions	# of Portal Submissions	% Paper Submission	% CD/DVD Submission	% Portal Submission
Conventional	6,197	4,467	165	1,565	72%	3%	25%
Antimicrobial	1,824	1,134	53	637	62%	3%	35%
Biopesticide	754	615	34	105	82%	4%	14%
total	**8,775**	**6,216**	**252**	**2,307**	**71%**	**3%**	**26%**

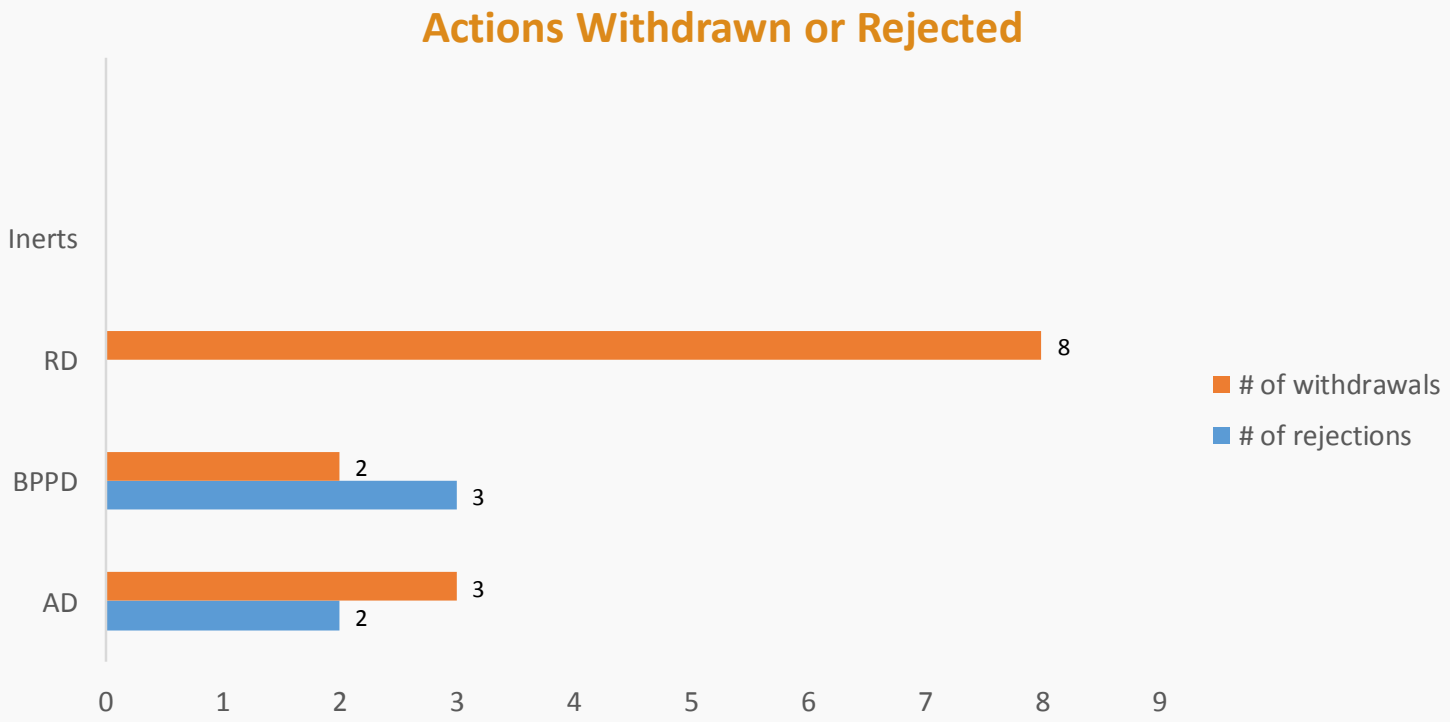
FY'16 thru 5/31: 45/90 Preliminary Technical Screen



FY'16 thru 5/31: 45/90 Preliminary Technical Screen *continued…*



FY'16 thru 5/31: 45/90 Preliminary Technical Screen *continued…*



FY'16 thru 5/31: Reasons for 45/90 Screen Rejections/Withdrawals

- ❑ Not substantially similar
- ❑ Data deficiencies/ Missing data
- ❑ Inadequate efficacy data to support claims
- ❑ Uncleared inerts/ missing inert data
- ❑ Inadequate acute toxicity data
- ❑ Data matrix/data comp issues
- ❑ Unregistered source for active ingredient
- ❑ Revised CSF significantly different from accepted CSF
- ❑ Bridging argument inadequate

New Active Ingredient Error-Correction Pilot

- Conducted to evaluate the need for an error correction step in the registration process where applicants are provided early access to risk assessments (RAs) to screen for errors;
- Currently, RAs only provided to applicants early if there is a risk issue that needs to be addressed;
- OPP conducted an error-only pilot involving 4 new AIs where all RAs were provided early to applicants;
- 2 weeks appears adequate as 3 out of 4 applicants reported back within that timeframe;
- 3 out of 4 reported no errors;
- 1 new AI reported 5 EFED issues and 27 HED issues;

New AI Error- Correction Pilot – con't

- 4 out of 5 EFED issues related to a late label change made to address risks. RA was not revised to reflect the revised use patterns in order to avoid further delays. EFED prepared an addendum to reflect these changes;

- HED's 27 comments included: 16 grammatical, 6 typographical and 5 related to label changes (reduced application rates);

- HED easily corrected the grammatical and typographical errors, but instead of revising the RA, in order to avoid delays they inserted a statement acknowledging the label changes.

- Error-corrections for the pilot chemicals required an average of 30 days to complete; correcting the RAs would have added more time;

Update on 2015 – 2016 Worker Protection Support Activities

- National Farmworker Training Program activities
- National Pesticide Information Center (NPIC)
- Migrant Clinicians Network – Preventing Pesticide Poisonings
- Pesticide Educational Resources Collaborative (UC Davis & OR State) – WPS materials projects
- Pesticide Safety Education Program

Stakeholder Issues

PRIA Points of Contact

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